Original Article

Sterility of Previously Assembled Cardiopulmonary Bypass Circuits

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Keywords: cardiopulmonary bypass, cardiopulmonary bypass circuit, microbial contamination, extracorporeal circuit, priming

ABSTRACT

The sterility of previously assembled cardiopulmonary bypass circuits was investigated for 17 extracorporeal circuits. The closed circuits were assembled using aseptic technique and remained in the operating room until the time of use. The mean time from point of setup to point of priming for the 17 randomly chosen circuits was 21.47 hours, with a range of 13.50 to 60.50 hours. Circuits were primed with three liters of sterile Plasma-Lyte A Injection, circulated for 5 minutes and tested for microbial contamination by withdrawing one liter of the priming solution through an Addi-Chek Quality Control System. The Addi-Chek canister, which contains a 0.45 μm cellulose membrane filter, was then filled with tryptic soy broth and incubated for 14 days. All were found to be free of microbial contamination as indicated by no growth in culture.

The results of this investigation demonstrate that the sterility of the extracorporeal circuit, pre-assembled in advance of actual priming, can be maintained over an extended interval when standard aseptic technique is used. This allows the utilization of a pre-assembled circuit for emergency cardiopulmonary bypass support.

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INTRODUCTION

The initiation of immediate cardiopulmonary bypass in emergency situations is life-saving. However, before emergency cardiopulmonary bypass can begin, the perfusionist must aseptically assemble, prime, and debubble the extracorporeal circuit as quickly as possible. The availability of a previously assembled, sterile extracorporeal circuit in these instances can save 15 - 30 critical minutes. The purpose of this investigation was to determine whether an extracorporeal circuit could be aseptically assembled prior to use and sterility maintained over an extended interval without contamination.

Although a number of investigations (1,2) of the causes of infection in open heart surgery patients have considered cardiopulmonary bypass apparatus, only one report examined the sterility of assembled extracorporeal circuits. Chorak (3) et al examined the sterility of 26 extracorporeal circuits assembled 24 - 96 hours prior to priming by culture of 3 ml of prime solution in the Bactec NR 660 nonradiometric system. Twenty-five of 26 circuits were found to be sterile; a *Corynebacterium* species, which was considered to be insignificant, grew in the culture of one circuit. Chorak et al concluded from their study that the use of previously assembled extracorporeal circuits did not pose an increased risk of postoperative infection to patients undergoing cardiac surgery.

It was the intention of the present investigation to culture a much larger volume of prime solution, as a more rigorous test of sterility, and to utilize a culture method that could be performed without complex laboratory instrumentation.

MATERIALS AND METHODS

The extracorporeal circuit consisted of a Bentley Univox-IC oxygenator[a] with integrated cardiotomy and venous reservoirs, a Bio-Medicus model BP-80 blood pump[b], a Bentley Duraflow II arterial filter[a], and Bentley Bypass -70 tubing[a]. A large portion of the circuit was preassembled in a Bentley Custompac tubing pack[a] with 14 connections required to complete the set-up, including pressure monitoring and accessory lines.

The extracorporeal setups were assembled and the remaining 14 connections made aseptically with all vent and priming ports remaining capped. The heart/lung machine was covered with a clean OR sheet and remained in the operating room until the next open heart surgery case. At the time of the surgery, the vent caps were removed and the system was flushed with carbon dioxide via a 0.3 micron Bentley Gas Line Filter[a] for 4-5 minutes at a flow rate of 6 liters per minute via a stopcock on the arterial filter. The heater-cooler was connected to the oxygenator heat exchanger and circulated. The circuit was then primed with 3

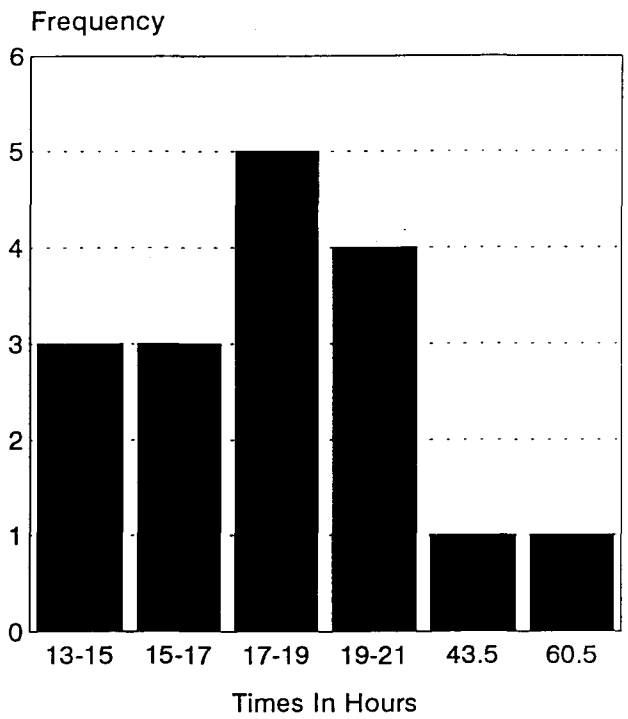
a Bentley Division, Baxter Healthcare Corp., Irvine, CA 92714

b BioMedicus, Eden Prairie, MN 55344

TABLE 1
Elapsed times in hours from setup to priming
(N = 17)

SAMPLE	ELAPSED TIME
1	19.75
2	14.25
3	17.25
4	19.25
5	60.50
6	18.50
7	14.50
8	19.25
9	18.75
10	18.50
11	43.50
12	16.25
13	16.75
14	19.50
15	13.50
16	18.50
17	16.50
MEAN	21.47
S.D.	12.03

Figure 1
Elapsed times from setup to priming



liters of Plasma-Lyte A Injection[c] with recirculation through both reservoirs, the arterial filter, and the oxygenator at a flow of one liter per minute for 5 minutes.

After recirculation, an Addi-Chek Quality Control System[d] was connected to a 1/4 inch accessory line splitting from the oxygenator outflow tubing. One liter of the priming solution was pumped through the 0.45 μm cellulose filter in the Addi-Chek canister at a flow rate of 400 ml/min. The effluent was then discarded and the primed extracorporeal circuit used for perfusion during cardiac surgery. The Addi-Chek canister outflow was recapped aseptically, the vent cap opened, and 100 ml of tryptic soy broth added from a single use container through the inflow port. The vent was then recapped and the inflow port clamped as well. The canister was incubated at 35°C for 14 days according to manufacturer directions. Turbidity of the tryptic soy broth, at any time during the incubation period would indicate microbial contamination and would be considered a positive result.

A total of 17 extracorporeal circuits were tested using this procedure.

RESULTS

Seventeen extracorporeal circuit set-ups were tested for microbial contamination using the Addi-Chek Quality Control System. Elapsed time from set-up of the circuit to priming ranged from 13.50 to 60.50 hours with a mean time of 21.47 hours. The individual times for the 17 samples are presented in Table 1 and Figure 1. For a sample to be considered positive, the tryptic soy broth must have appeared turbid at some point during the 14 day incubation interval.

All of the 17 samples were interpreted as negative due to the absence of turbidity in the broth cultures. The estimate for the non-sterility rate is therefore 0, and 95% upper confidence limit with N = 17 is 0.16.

DISCUSSION

The Millipore Addi-Chek Quality Control System was chosen for this investigation because of its simplicity and its capacity to rapidly test large volumes of intravenous fluids for evidence of microbial contamination. The Addi-Chek System is primarily marketed as a quality control system for pharmacists to determine the microbial quality of intravenous solutions and admixtures. The system employs membrane filtration sterility testing. The membrane filtration method utilizes a 0.45 μm cellulose membrane filter in a closed, sterile, disposable canister, and is accepted by the FDA and pharmacopeias in the United States and abroad as a valid means of sterility testing. In a 5 year study published in 1985(4), no bacterium or fungus was found to pass through a 0.45 μm-rated-pore-diameter membrane filter. We feel that Addi-Chek Quality Control System is ideally suited for sterility testing of assembled extracorporeal circuits for the following reasons. First, the canister connects easily to the extracorporeal circuit by inserting the sterile inflow port into any 1/4 inch interior diameter tubing. Second, the canister requires no advance preparation because it is completely assembled within the packaging. Third, the canister is able to handle a flow rate of at least 400 ml/min which allows for the sampling of a sizable quantity of prime solution within a reasonable period of time. Fourth, no expensive instrumentation is required to monitor microbial growth in the broth culture.

This investigation examined one liter samples of prime solution for evidence of microbial contamination from a previously assembled extracorporeal circuit and documented maintenance of sterility up to 60.50 hours post-assembly. A prior study (3) utilized a 3 ml sample of prime solution processed in the Bactec NR 660 nonradiometric system to monitor microbial growth in broth culture. Because of the expense of this instrumentation, this method may not be as widely available as needed.

The results of our investigation provide further evidence that extracorporeal circuits can be assembled for approximately 2.5 days in advance of cardiovascular surgery with minimal risk of contamination of the setup. The ability to pre-assemble an extracorporeal circuit in advance of emergency cardiac surgery, such as might occur during evenings, nights, and weekends, affords the opportunity for the perfusionist to complete the assembly of the circuit with maximum attention to aseptic technique. This study demonstrates that sterility of pre-assembled circuits can be maintained over time following utilization of standard aseptic techniques during assembly. This protocol for the culture of large volumes of prime solution can be utilized by staff at other institutions to monitor and validate sterility of assembled extracorporeal circuits.

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c Baxter Healthcare Corp., Deerfield, IL 60015
d Millipore, Bedford, MA 01730