Original article

Safety of wet-primed cardiopulmonary bypass circuits during extended standby

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Objectives To determine the period of sterility safety in wet-primed cardiopulmonary bypass (CPB) circuits under normal conditions during prolonged standby.

Methods Experimental CPB circuits were assembled under routine clinical conditions. The sterility of 9 pre-assembled CPB circuits was studied for a period of 168 hours. Three circuits were assembled and stored uncovered in the operating room and six circuits were assembled and stored in the perfusionist room. Priming solution was added and continuously recirculated in the experimental CPB circuits. Fifty milliliters of circulating fluid was collected at the sampling port under aseptic conditions to test for microbial growth after 0, 24, 48, 72, 96, 120, 144 and 168 hours.

Results The microbiology of all samples from both groups was negative throughout the study period with the exception of the occurrence of Bacillus species in two samples from the equipment in the perfusion room at 96 hours. However, that was considered to be contamination because further samples after 96 hours were all negative.

Conclusions The sterility of wet-primed CPB circuits can be maintained for up to 168 hours. The strategy of having primed circuits available could be a benefit in emergency situations without extra expense. **Chiang Mai Medical Journal 2020;59(2):61-4.**

Keywords: cardiopulmonary bypass circuit, sterility

Introduction

The immediate establishment of cardiopulmonary bypass (CPB) is a critical step in emergency and/or salvage cardiac surgery. Delayed conversion to CPB is associated with poor surgical outcomes (1). In normal circumstances CPB circuit preparation takes between 10-20 minutes, including assembling, priming, and debubbling. Therefore, a standby pre-assembled CPB circuit could be highly beneficial during the unofficial hours periods as it could shorten the time of routine surgical processes. The use of pre-assembled CPB circuits can help get critical patients on CPB more rapidly and reducing the risk of multi-organ injury from prolonged cardiovascular decompensation.

Normally, a CPB circuit is essential for the safety of the patient during off-pump coronary artery bypass procedures. A pre-assembled CPB circuit is discarded after an operation. Previous studies have reported that wet-primed CPB circuits can be used for 2-7 days without risk of microbial contamination (1-5). However, most of those studies tested the sterility of assembled CPB circuits which were placed outside the operating room (OR). There have been few studies of equipment which was stored in an OR or nearby area. This paucity of evidence might cause surgeons to be reluctant to use pre-assembled CPB circuits. In order to evaluate the safety of using pre-assembled CPB circuits, this study examined sterility of

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units under normal environmental conditions in an OR and a perfusionist room.

Objectives

To determine sterility safety periods in wet-primed CPB circuits under normal conditions during extended standby.

Methods

The experimental CPB circuits were composed of hollow fiber with a hard shell reservoir (Dideco Compactflo EVO, Sorin), a bubble trap (D730 Microtrap, Sorin) and a custom heart lung tubing pack (JSM heart lung pack) as shown in Figure 1. All CPB circuits were assembled using aseptic techniques after performing hand hygiene procedures including alcohol hand rubbing under routine clinical conditions. The closed-reservoir CPB circuits were primed with 2,000 mL of Acetate Ringer's Solution. The sterility of the 9 pre-assembled CPB circuits was studied for a period of 168 hours. Three of the circuits were assembled and stored uncovered in one corner of an OR which was used for routine cardiac surgery. The temperature of the OR ranged from 18-25 °C. The other six circuits were assembled and stored in the perfusionist room with the room temperature controlled at 26 °C by an air conditioner. All 9 assembled CPB circuits were left unattended and uncovered throughout the study period.

The priming solution was continuously recirculated in the experimental CPB circuits. Fifty milliliters of the circulating fluid were collected at the sampling port under aseptic conditions to test for microbial growth after 0, 24, 48, 72, 96, 120, 144, and 168 hours. The samples were transported to the laboratory using the in a sterilized container and were processed within 2 hours. The membrane filter method was used to identify any microbial growth. The test fluid was processed using the following steps. The sampling fluid was first filtered through a cellulose membrane (0.45 µm pores) and the material retained by the filter was cultured on a blood agar plate. The samples

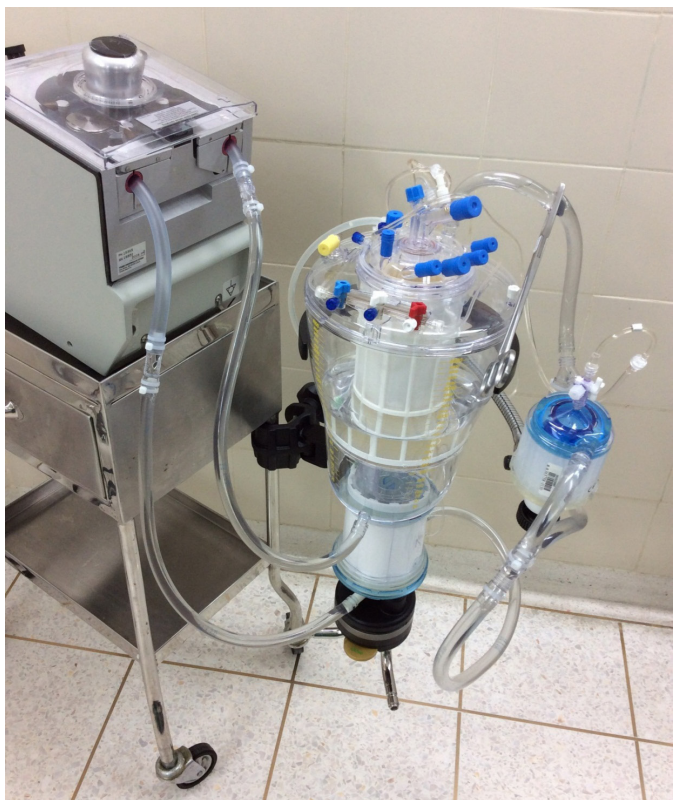

Figure 1. CPB circuits: hollow fiber with a hard shell reservoir (1), a bubble trap (2) and the custom heart lung tubing pack.

Table 1. Microbial growth results (n=9)

	Duration (hours)							
Storage	**0**	**24**	**48**	**72**	**96**	**120**	**144**	**168**
Operating room (n=3)	0	0	0	0	0	0	0	0
Perfusionist room (n=6)	0	0	0	0	2	0	0	0
					Bacillus spp.			

were incubated at 37 ºC . The entire procedure was performed in a sterile room and on a bench with laminar airflow. The culture medium was examined for microbial growth after 48 hours. Spores, bacillus species and mixed cultures of indigenous skin flora were predefined as contaminants in the study protocol (6).

Results

The microbiology of all samples from both groups was negative at every time period with the exception of the occurrence of Bacillus species in two samples from the equipment held in the perfusionist room after 96 hours. However, those cases were considered to be contamination because further samples after 96 hours were all negative.

Discussion

This study demonstrated that the wet-primed CPB circuits were still sterile up to 168 hours both inside and outside the clinical practice environment (OR). This period is similar to findings of by Young et al. (1) who reported that either primed or unprimed, sterility could be maintained in CPB circuits for at least seven days. Witschi et al. (3) examined the sterility of CPB circuits under actual clinical conditions with circulating intratube fluid and within the operation area and found that 72 hours was safe with no changes in endotoxin levels. Additionally, Tagaya et al. (5) reported that unattended circuits could remain in a sterile state for up to 6 days in a clinical setting because no bacteria contamination was noted over 6 days under normal clinical conditions. The microbial growth that was observed in two samples in this study clearly falls under the predefined definition of procedure contamination.

Incorporating the findings of the present study into actual practice could increase confidence in the use of wet-primed CPB circuits, e.g., it would be possible to prime and leave a circuit during weekends (2-3 days), ready for use in an emergency case. If it were not used for an emergency over the weekend, the circuit could be used in an elective case on the subsequent working day. This strategy would mean that the $700 USD per wet-primed circuit was not wasted, and that the circuit was available for emergency cases.

There are some limitations to this study. We only used microbiology results; the finding would have been enhanced if we had included endotoxin levels as well. All samples were ex-vivo. The in-vivo response of patients remains unknown. Further study should be considered regarding inflammatory, hematologic and neuro-hormonal responses.

Conclusions

The sterility of wet-primed CPB circuits in the OR can be maintained for up to 168 hours. The strategy of having primed circuits available could be beneficial in emergency situations without creating extra expense.

Conflicts of Interest

The authors have no financial conflicts to disclose.

Acknowledgements

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ความปลอดภัยของการใช้ชุดสายยางไหลเวียนนอกร่างกายที่ใส่สารละลายขยายเวลาพร้อมใช้งาน

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วัตถุประสงค์ การวิจัยนี้มีเป้าหมายเพื่อศึกษาระยะเวลาที่ปลอดภัยในการใช้ชุดสายยางไหลเวียนโลหิตนอกร่างกายที่ใส่สารละลายในภาวะปกติขยายเวลาพร้อมใช้งาน

วิธีการ เป็นการศึกษาแบบทดลองชุดสายยางไหลเวียนโลหิตนอกร่างกายที่ได้รับการติดตั้งตามปกติพร้อมใช้งาน ศึกษาความปลอดเชื้อของสารละลายที่บรรจุอยู่ในชุดสายยางจำนวน 9 ชุดในช่วงระยะเวลา 168 ชั่วโมง โดยนำชุดสายยางไหลเวียนโลหิตนอกร่างกายแบบพร้อมใช้งาน จำนวน 3 ชุดตั้งในห้องผ่าตัดโดยไม่คลุมผ้า และชุดสายยางไหลเวียนโลหิตนอกร่างกายแบบพร้อมใช้งาน จำนวน 6 ชุด ตั้งในห้องเก็บอุปกรณ์ และทำการเก็บตัวอย่างสารละลายในชุดสายยางจำนวน 50 ซีซี เพื่อส่งตรวจเพาะเชื้อเมื่อเวลาผ่านไป 0, 24, 48, 72, 96, 120, 144 และ 168 ชั่วโมง

ผลการศึกษา ผลการตรวจเพาะเชื้อของสารละลายตัวอย่างทั้ง 2 กลุ่มเป็นลบในทุกช่วงระยะเวลาที่ทำการส่งตรวจ ยกเว้นสารละลายตัวอย่างในชุดสายยางไหลเวียนโลหิตนอกร่างกายแบบพร้อมใช้ที่วางไว้ในห้องเก็บอุปกรณ์เมื่อครบ 96 ชั่งโมง ซึ่งพบการเจริญเติบโตของเชื้อ *Bacillus* spp.

สรุป สภาพปลอดเชื้อของชุดสายยางไหลเวียนโลหิตนอกร่างกายที่ใส่สารละลายแบบพร้อมใช้สามารถคงอยู่ได้นาน 168 ชั่วโมง ดังนั้นชุดสายยางไหลเวียนโลหิตนอกร่างกายที่ใส่สารละลายสามารถเตรียมไว้ใช้ในกรณีฉุกเฉินเร่งด่วน โดยไม่มีค่าใช้จ่ายเพิ่มเติม **เชียงใหม่เวชสาร 2563;59(2):61-4.**

คำสำคัญ: ชุดสายยางไหลเวียนโลหิตนอกร่างกาย สภาพปลอดเชื้อ