EFFICACY OF THE ISO-GARD HIGH EFFICIENCY PARTICULATE AIRBORNE [HEPA] LIGHT BREATHING FILTER IN PREVENTING CROSS CONTAMINATION THROUGH ANESTHESIA BREATHING CIRCUITS

Sahar El-Karadawy and Ghada Fahmy Helaly
Departments of Anesthesia and Microbiology Medical Research Institute, Alexandria University, Egypt.

ABSTRACT

Background: *Respiratory infections are among the most important causes of nosocomial infection in the postoperative period and are associated with prolonged hospitalization and increased costs. Respiratory pathogens can be transmitted through breathing circuits used to provide anesthesia, therefore, appropriate decontamination of respiratory equipment is essential to provide better patient care .The use of appropriate single-use filters to isolate the anesthetic circuit for each patient in order to maintain sterility and to prevent cross infection, may appear prudent for patient safety and cost containment.*

Objectives: *As the efficacy and effectiveness of bacterial filters for breathing circuits or anesthesia ventilators to prevent cross infections have not been fully investigated in the clinical setting. Therefore the purpose of this study was to evaluate, in the usual clinical anesthesia setting, the bacterial filtration efficacy of an anesthesia-breathing filter.*

Methods: *A new sterile Iso-Gard High Efficiency Particulate Airborne (HEPA) light breathing filter was aseptically connected to the Y-piece of a sterile disposable clear anesthesia breathing circuit before the induction of general anesthesia. At the end of anesthesia, the breathing filter was removed from the Y-piece. Both sides of the breathing filter (patient and circuit) were sampled for bacterial culture, immediately plated on three growth media: Chocolate, Blood and MacConkey agar, incubated at 37°C for 24 - 48 hours. Bacterial identification was conducted using standard microbiological procedures.*

Results/Conclusion: *Bacterial cultures were negative on both sides of the filter membrane of 43/50 filters studied. Cultures were positive on the patient side of five filters. In one of those nearly the same bacteria were found on both the circuit side and the patient side of the filter. Cultures were positive on circuit side of two filters. Therefore these data indicate a clinical effectiveness of 98 % (confidence interval, CI 95%, 94.12-101.88 %), and an in vivo filtration efficacy of 80 % (C.I. 95 %, 74.57-85.43 %). Thus this study concluded that; using a sterile Iso-Gard HEPA light breathing filter for every patient while reusing the anesthesia breathing circuit would result in a cross contamination rate of the breathing circuit in two every one hundred cases.*

Key words: *Nosocomial infection, bacterial filters, anesthesia breathing circuits*

Abbreviations:

Iso-Gard [HEPA] light breathing filter*: Iso-Gard High Efficiency Particulate Airborne (HEPA) light breathing filter*

INTRODUCTION

Respiratory infections are among the most important causes of nosocomial infection in the postoperative period and are associated with prolonged hospitalization and increased costs. Contaminated anesthesia breathing circuits have been responsible for nosocomial upper respiratory tract and pulmonary infections in patients undergoing general anesthesia. [1-6] Airway instrumentation bypass' the upper respiratory tract defenses and interferes with the normal function of mucociliary clearing system. So respiratory pathogens can be transmitted directly into lower respiratory tract through breathing circuits used to provide anesthesia, Indeed, microorganisms have been isolated in almost every part of the anesthesia breathing circuits [7,8]. Thus the current recommendations of the Centers for Disease Control (CDC), the Canadian Laboratory Center for Disease Control (LCDC, Health Protection Branch, Health Canada) and the American Society of Anesthesiologists (ASA) state that sterile anesthesia breathing material should be used for every patient[9,10] .

Because of increasing concerns about cost containment in health care, some single-use devices, including disposable anesthesia breathing systems, could be reused for several patients before they are submitted to a high-level disinfections procedure [9,10]. Lysoformin 3000 is used routinely nowadays for disinfection of anesthetic machine and circuits. Hundred gram solution of lysoformin contains 7.5 g glyoxal, 9.5 g didecyl- dimethylammonium-chloride. It controls bacterial, fungus and virus infections[11]. But this appropriate disinfection procedure may be unpractical if it is used between each patient because of time and cost consuming.

The use of appropriate single-use filters to isolate the anesthetic circuit for each patient in order to maintain sterility and to prevent cross infection appears prudent for patient safety and cost containment. It has been suggested to place the breathing filter between the Y-piece of the anesthesia breathing circuit and the proximal end of the endotracheal tube [12, 13]. Iso-Gard High Efficiency Particulate Airborne (HEPA) light breathing filter is among heat and moisture exchange filters that has ideal hygroscopic properties, excellent bacterial filtration efficiency > 99.9999 % reported from a laboratory study [14]. But laboratory studies must be interpreted with caution and high filtration efficacy reported must be confirmed in clinical setting before any recommendation on the wide spread use of breathing filter can be made

Therefore the purpose of this study was to evaluate, in the usual clinical anesthesia setting, the bacterial filtration efficacy of Iso-Gard (HEPA) light breathing filter.

SUBJECTS AND METHODS

The study was conducted in the operating room of Medical Research Institute hospital-Alexandria University. After disinfection of anesthetic circuits with lysoformin 3000 or the use of new sterile circuits, all daytime cases were scheduled to general anesthesia included in the study. For each case, a new sterile Iso-Gard HEPA light breathing filter (Louis Gibeck, Sweden) was aseptically connected to the Y-piece of a sterile disposable clear anesthesia breathing circuit of 22 mm diameter before the induction of general anesthesia. Thereafter, no attempt of any kind was made to guide or alter the management of anesthesia which was conducted in the usual manner by the same anesthesiologist. The airway was managed either with an endotracheal tube or a laryngeal mask airway. The ventilation was controlled and the fresh gas flow was maintained at 6-7 litter during surgery. Data on length and type of surgery, presence of macroscopic secretions in the filter and presence of bronchospasm or cough were collected for each patient. At the end of anesthesia, the breathing filter was removed from the Y-piece. Both sides of the breathing filter (patient and circuit) were sampled for bacterial culture using the following procedure. First, the outside of the proximal connector (circuit side) of the breathing filter was disinfected with an alcohol wipe. The inside of the connector was then swabbed avoiding any contact with the filter membrane. Second, the outside of the connector of the endotracheal tube (patient side) was also disinfected with an alcohol wipe and its inside was swabbed, again avoiding any contact with the filter membrane. Both swabs were immediately plated on three growth media: Chocolate, Blood and Mac-Conkey agar. Chocolate and Blood plates were incubated at 37°C in 5% CO2 atmosphere for 48 hours. For Mac-Conkey agar plates, they were incubated at 37°C in an aerobic atmosphere for 24-48 hours. Bacterial identification was conducted using standard microbiological procedures. After the results of bacterial growth were known, filters were classified into four groups according to the side of bacterial growth. In group A, bacterial growth was negative on both sides of the filter (circuit and patient sides). In group B, bacterial growth was only positive on the patient side. In group C, bacterial growth was only positive on the circuit side. Finally, in group D, bacterial growth was present on both sides of the filter.

Data analysis:

Continuous parametric data are presented as mean. Bacterial passage through the filter membrane was considered positive

when the same microorganism was isolated on both sides of the breathing filter. The clinical effectiveness of a breathing filter to prevent contamination of the anesthesia breathing circuit was calculated using the ratio of bacterial passage through the filter membrane to the total number of filters studied. ***Clinical effectiveness = 1- [no. bacterial passage / total no. filters studied] X 100.*** The in vivo filtration efficacy of the breathing filter tested was calculated using the ratio of bacterial passage through the filter membrane to the number of breathing filters submitted to a definite bacterial challenge (positive bacterial growth on the patient side of the filter) ***Filtration efficacy in vitro = 1-[no. bacterial passage/ no. challenged filters] X 100***. These data are presented as percentages with 95% CI.

RESULTS

Fifty anesthesia breathing filters were studied over 20 week's period. Type of surgery, the mean duration of anesthesia and the number of patients undergoing these different surgical procedures included in the current study were demonstrated in Table1. After the results of bacterial growth were known, filters were classified into four groups according to the side of bacterial growth. In group A (n=43 filters), bacterial growth was negative on both sides of the filter (circuit and patient sides). In group B (n = 4 filters), bacterial growth was positive on the patient side and negative on the circuit side. In group C (n = 2 filters), bacterial growth was positive on the circuit side and negative on the patient side. Finally, in group D (n =1 filter), bacterial growth was present on both the circuit and patient sides. Bacterial species isolated in groups B, C and D were reported in Tables 2 and 3.

According to the definition mentioned above, positive bacterial passage through the filter membrane occurred in the last filter only. It was used during a general surgery case lasting 150min. The airway was managed with an endotracheal tube. No coughing or bronchospasm occurred and no secretion was observed in the endotracheal tube in this case. Therefore the positive bacterial passage through the membrane of one out of 50 breathing filters tested represents a clinical effectiveness = 1- [1/50] X 100 = 98 % (C.I. 95 % = 94.12 - 101.88 %). Taking into account only the filters that were submitted to a documented bacterial challenge (groups B and D); the *in vivo* filtration efficacy of the breathing filter was = 1- [1/5] X 100 = 80 % (C.I. 95% = 74.57-85.43 %).

DISCUSSION

It has been clearly demonstrated in the operating room that all parts of an anesthesia breathing circuit may become contaminated by bacterial and viral pathogens. Medical devices used for any respiratory intervention by their nature, carry a risk of cross-patient-infection because these devices bypass normal host defense barriers. Breathing filters are designed to prevent the passage of microorganisms and to decrease the contamination rate of the anesthesia and respiratory care equipments[15,16].

This study showed that, the sterile Iso-Gard HEPA light breathing filter did not completely prevent contamination of the breathing circuit. The clinical effectiveness of that filter was 98 % (C.I. 95 % =94.12-101.88 %). Two cases every one hundred cases would be at risk of bacterial contamination when a sterile Iso-Gard HEPA light breathing filter was using through anesthesia breathing circuit. But it should be stressed that this figure does not represent the risk of acquiring a bacterial respiratory tract infection. This risk is most likely lower since the presence of bacteria in the breathing circuit does not mean that the next patient using the same breathing circuit will become contaminated or developed a respiratory tract infection [5, 17]. The risk of acquiring a respiratory tract infection from a contaminated anesthesia breathing circuit is determined by the bacterial load and the host defense mechanisms. Besides, it can be expected that the breathing filter will have some efficacy for downstream protection of the patient from contaminated breathing circuit therefore reducing further the bacterial load [17].

Table 1 Type of surgery, the number of patients, the mean duration of anesthesia/min and grouping of bacterial filters used in these different surgical procedures according to bacterial growth.

Type of surgery	No. of patients	Duration of anesthesia	Group
Cholecystectomy	8	58.125(45-75)	
Mastectomy	8	83.75 (60-120)	
Breast biopsy	6	40 (30-60)	
Thyroidectomy	3	90 (70-120)	**A**
Hernioraphy	10	50 (45-90)	
Appendicectomy	5	58 (50-60)	
Splenectomy	3	90 (70-120)	
Gastrectomy	1	150	
Colectomy	1	120	
Debridment of the diabetic foot	1	30	**B**
Lymphoma (Cervical lymph node biopsy)	1	180	
Breast biopsy	1	30	**C**
Varecocele	1	30	
Gastrectomy	1	150	**D**

Table 2 Bacterial species isolated from both sides of the bacterial filters.

Bacterial Species	Patient side No.	%	Circuit side No.	%
Pseudomonas aeroginosa	1	2	1	2
Pseudomonas cepacia	1	2	1	2
Klebsiella pneumoniae	1	2	1	2
β-hemolytic streptococci	1	2	0	0
Streptococcus pyogenes	2	4	0	0
Brahamella catarrhalis	2	4	0	0
Mixed oropharyngeal flora	2	4	0	0
Staphylococcus epidermidis	0	0	2	4
Staphylococcus aureus	2	4	0	0
Diphtheroids	1	2	0	0

Table 3 Bacterial identification in the studied groups.

	Filters Patient side	Circuit side	No.	%
Group A	**Negative**	**Negative**	**43**	
			86	
Group B	**Positive**	**Negative**	**4**	**8**
Case 1	*Staphylococcus aureus, Diphtheroids.*	…….	1	2
Case 2	*Staphylococcus aureus Brahamella catarrhali*	…….	1	2
Case 3	*Streptococcus pyogenes, Mixed oropharyngeal flora.*	…….	1	2
Case 4	*Streptococcus pyogenes, Brahamella catarrhalis.*	…….	1	2
Group C	**Negative**	**Positive**	**2**	
			4	
Case 1	…….	*Staphylococcus epidermidis.*	1	
Case 2	…….	*Staphylococcus epidermidis.*	2	
			1	
			2	
Group D	**Positive**	**Positive**	**1**	
			2	
Case 1	*Pseudomonas aeroginosa.*	*Pseudomonas aeroginosa.*		
	Pseudomonas cepacia.	*Pseudomonas cepacia.*		
	Klebsiella pneumoniae.	*Klebsiell pneumoniae.*		
	β-hemolytic streptococci.			

In the present study, most of the filters were not contaminated on the patient side (group A and C, n = 45). Thus, the definitive challenge was limited to filters which had bacterial growth on the patient side (group B and D, n=5). This low rate of bacterial challenge may be expected, and demonstrated in several previous studies. Since most surgical procedures were elective; in healthy patients whose trachea should have a low rate of bacterial colonization. [18] *Luttropp et al* [19] studied 55 bacterial filters of three different types (Pall Ultipor BB 50®, Gibeck Humid- Vent ® and Pharma BACT-HME®) placed between the y- piece and the endotracheal tube during low flow anesthesia. At the end of anesthesia both sides of the filters were sampled. They found no positive bacterial culture on the patient side of the filters (100% effectiveness). *Callery et al*[20] reported two cases of bacterial contamination among 96 breathing circuits protected by breathing filters. Filters in group C (n=2) were contaminated on the circuit side only. These filters grew mostly skin flora and these are probably the result of external contamination during the manipulations associated with mask ventilation and tracheal intubation. This illustrates that some anesthesia breathing circuits will get contaminated during the normal course of anesthesia, making the

sterilization or disinfection to a high degree reusable breathing circuits between patients very important. Filters in group B (n = 4) were positive on the patient side only and grew either skin or pharyngeal flora. In this group, the anesthesia breathing circuits were effectively protected from contamination. Filter in group D (n = 1) had bacterial growth on both sides. It grew nearly the same genera on both sides; this represents positive contamination of the breathing circuit from the patient respiretory tract through a deficient filter membrane. This means, bacterial passage through a deficient filter membrane, which may have occurred because of the limited efficacy of the filtration media or because of a defect in the filter membrane. External contamination with the same bacteria on both sides of the filter is also possible. The possibility of contamination of the breathing circuit from the patient respiretory tract through a deficient filter membrane was reported in previous studies. *Nielsen et al*[21] in a study conducted by them for two commercially available bacterial filters to be used as part of the mechanical ventilation unit during anesthesia were tested for hygienic criteria, recommended that the use of bacterial filters during mechanical ventilation reduces the probability of bacterial contamination, but does not make sterilization of the tubes and ventilation circuit unnecessary. Manangan *et al.* [22] mentioned in their study that a postal survey of 120 US hospitals was conducted to assess the current use of filters in anesthetic breathing systems and consultant anesthetists' opinion of their value; 66.3% believed filters were worthwhile whereas only 35.9% thought they were cost effective. In a study carried out by *Vezina et al.* [23] including 2001 bacterial filters (DAR Barrierbac S® breathing filter), they found that bacterial cultures were negative on both sides of the filter membrane of 92% of the studied. Cultures were positive on the patient side of 5% of the filters studied. In two of those, the same bacteria were found on both the circuit side and the patient side of the filter. They concluded that the practice of using a sterile DAR Barrierbac S breathing filter for every patient while reusing the anesthesia breathing circuit would result in a cross contamination rate of the breathing circuit lower than once every 250 cases. Laboratory studies [24, 25] have reported filtration efficacy exceeding 99.99% for anesthetic breathing filters. But the clinical effectiveness of anesthetic filter in the current study and in previous clinical studies differed from there laboratory results. his could be explained by that first the conditions encountered in the clinical anesthetic setting where the filters are submitted to moisture, secretions, cough, bidirectional airflow and pressure changes differ from the laboratory settings. Second, in laboratory studies, the performance of anesthesia breathing filters is usually reported as the titer reduction value and the bacterial removal efficiency. Although such data are useful to compare the perormance of different filters, they are insufficient to assess the performance of filters in clinical anesthesia practice.

In conclusion, the practice of using Iso-Gard (HEPA) light filter for every patient while reusing the anesthesia breathing circuit resulted in bacterial contamination of the breathing circuit in two every one hundred cases. Further studied are recommended to investigate other anesthetic filters with different construction or filtration material which may perform differently also to investigate the efficacy of breathing filter in prevention of viral, fungal and mycobacterial contamination.

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