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Editorial

The reuse of anesthesia breathing systems: another difference of opinion and practice between the United States and Europe

Every day at our California hospital, 100 surgical cases are performed requiring anesthesia, such that every year, more than 21,000 plastic breathing circuit tubes are thrown away. Visiting faculty from Europe are dismayed by this single-use waste, especially as reuse of the anesthesia breathing system is common in several European countries [1-3]. In these countries, a breathing filter is placed between the patient and the breathing system at the Y-piece to prevent cross-contamination and cross-infection. This filter is discarded after one use, but the breathing system is reused and discarded only at the end of the day or even after several days. The intent is to minimize waste and acquisition costs of breathing systems.

Why is there a difference in practice between the United States and Europe?

1. The role of regulatory agencies in the United States

In the U.S. the use of breathing filters remains controversial because of the potential risk of cross-contamination and cross-infection. In their “Guidelines for Preventing Health-Care Associated Pneumonia, 2003,” the Centers for Disease Control and Prevention (CDC) provide no recommendation for “placing a bacterial filter in the breathing system or patient circuit of anesthesia equipment” and regard this as an “unresolved issue” [4]. However, these CDC guidelines also mandate that “between uses on different patients” ... “reusable components of the breathing system or patient circuit (eg, endotracheal tube or face mask; inspiratory and expiratory breathing tubing; y-piece; reservoir bag; humidifier; and tubing)” be cleaned and that these items be sterilized or subject “to high-level liquid chemical disinfection or pasteurization in accordance with the device manufacturers’ instructions for their reprocessing.”

Based on current federal laws in the U.S. if a device labeled in the packaging as single-use is to be considered for reuse, it must undergo reprocessing and be certified as safe as when it was originally shipped by the manufacturer. Reuse of disposable single-use items shifts all liability from the manufacturer to the practitioner in the operating room (OR). Because the Food and Drug Administration’s policy for medical devices is that valid scientific evidence is needed to ensure safety, manufacturers would need to perform expensive prospective studies to prove the safety of their breathing circuits (used with a filter) before being able to market the circuits as multiple-use.

The Joint Commission on Accreditation of Healthcare Organizations requires “Reuse of equipment designated by the manufacturer as disposable in a manner that is consistent with regulatory and professional standards” [5].

According to guidelines for proper infection control techniques (last updated in 1999), the American Society of Anesthesiologists does not support the reuse of breathing systems. However, the references cited to support their concerns refer to CDC guidelines from the mid-1990s [6]. At our hospital, infection prevention policy prohibits the reuse of breathing systems without providing a specific rationale.

Because the clinical efficacy of single-use filters used multiple times has not been proven by a controlled study to eliminate the risk of cross-infection, it is assumed in the U.S. that patients could be harmed by this practice. Because of these concerns, it is said that it would be unethical to change the practice of the use of the filters for economical and environmental reasons [7,8]. Ideally, the clinical safety of breathing filters and reuse of the breathing systems would need to be evaluated by comparing the incidence of postoperative respiratory tract infections with the incidence associated with the standard practice of using a sterile system for every patient [9]. Other noninfectious risks associated with breathing filters

include barotrauma and pneumothorax caused by obstruction of the filter, air leak, inefficient ventilation, and disconnection of the breathing system [8].

2. The British approach

In contrast to U.S. practice, the British have a “presumption of innocence” for reuse of breathing circuits. Until 2001, in the U.K. it was common practice to reuse anesthesia circuits for several patients, without a filter. However, in 2002, an agreement was reached between the Association of Anaesthetists of Great Britain and Ireland, the health authorities, and medical device manufacturers [2]. Breathing systems in the U.K. now have new filter products with licenses for multiple uses up to one week, if a new filter is placed at the Y-piece of the system for each patient. In addition, it is recommended that the breathing system be inspected regularly and the circuit be exchanged if visibly soiled or after use in a patient with a highly infectious disease [10].

The scope of the U.K. policy seems to be unique; in other European countries, regulations affecting anesthesia breathing systems are less specific. For example, in Spain and France, the use of single-use anesthesia circuits is a recommendation and not legally required. Each European country seems to have its own specific requirements toward the use of a new breathing filter for each patient.

3. Rationale for the British policy

Airway devices designed to preserve heat and moisture (to prevent hypothermia and airway desiccation) are known as heat and moisture exchangers (HMEs). Breathing filters that also prevent the inhalation of microorganisms are usually referred to as HME filters (HME-F). Laboratory studies show that breathing filters have a microbial penetration value, defined as the number of microbes passing through the filter per 10 million microbes, as low as 1.2 for bacteria and 89 for viruses, which corresponds to a filtration efficiency of 99.9999 and 99.9991%, respectively [11]. The filtration performance of pleated hydrophobic membrane filters is greater than that of electrostatic filters. In addition, pleated hydrophobic filters prevent liquid contamination of breathing systems [12]. Another positive feature of a breathing filter is its capability of retaining airborne latex particles [13].

A recent study of the practice of reusing anesthesia breathing systems and changing the breathing filter in between cases in the OR did not find an increased incidence of postoperative pneumonia (using the German hospital infection surveillance system KISS) [1]. These German researchers also examined the magnitude of cost savings by reusing breathing systems. Material and labor costs between different practices (change of the anesthesia breathing

circuits after each patient versus the use of a hydrophobic HME-F with daily or weekly change of the circuit) were compared. The authors found total cost savings of approximately *\$12 per general anesthetic.

4. Economics at our hospital

We performed a similar cost-identification analysis to quantify the annual cost difference for the year 2005 between the (current) practice of replacing the breathing circuit (\$7.20 for 21,137 cases = \$152,186 USD) after each case, and a new breathing filter (price quote \$2.50) for each patient with breathing circuit reuse for several patients and replaced only at the end of the day. For this analysis we assumed the breathing circuit would also be replaced in 10% of cases because it was visibly soiled after the previous case, or with a patient with special infectious disease status (eg, tuberculosis, HIV, variant Creutzfeldt-Jakob disease, avian influenza A, severe acute respiratory syndrome). With breathing system reuse, 9,568 circuits would have been needed such that purchasing costs for breathing circuits would have been \$68,890. The purchasing costs for breathing filters would have been $21,137 \times \$2.50$, or \$52,843. With the reuse of breathing circuits, the total purchasing costs for breathing circuits and filters would have been \$121,733. Our findings confirmed the results of a similar study that showed savings of up to \$50,000 per year in a facility with about 60 general anesthetics per day [14]. Nevertheless, estimated cost savings can differ widely depending on the manufacturer, type, and quality of breathing filter used, and the purchase agreement. For example, pleated paper hydrophobic breathing filters may be more expensive than electrostatic felted polypropylene filters. Under such circumstances the cost of the former may exceed the cost of a disposable circle breathing system.

5. Conclusion

In a previous study [15], we clearly showed that all the breathing filters that we studied in healthy patients undergoing general anesthesia retained moisture. But we found significant performance differences between the different filters. In only one type did the moisture output correspond with ISO specifications. We concluded that in vivo performance of breathing filters may not correspond to the manufacturer’s specifications. Further work needs to be done to establish appropriate standards indicating the kind of filter used, the efficiency of filters, the filtrate they capture, and the duration of effective filtration.

We fully understand that using a filter in an anesthetic system does not protect the anesthesiologist against litigation in the event of sequential transmission of pathogens. Also, we

should always remember that if a risk of patient-to-patient infection is perceived, we are duty bound to change the circuit between patients.

Why do Americans and Europeans who share the same scientific information arrive at a totally different standard of practice in reuse of breathing systems in the OR? Is it cultural differences, or is it medicolegal concerns (more so in the U.S.) that explain the difference of attitude toward this practice? Cultural differences can be changed with education. The medicolegal concerns could be negotiated with the suppliers. As concern for the environment continues to grow worldwide, perhaps there is an opportunity to reduce landfill waste of plastic breathing hoses. We call for a renewed discussion of this topic among U.S. manufacturers, physicians, and regulatory bodies to ascertain if the reuse of current anesthesia breathing systems is safe when breathing filters are used once and then replaced between cases.

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