The safety of reused endotracheal tubes sterilized according to Centers for Disease Control and Prevention guidelines

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Abstract

Study Objective: To investigate safety issues associated with the reuse of sterilized endotracheal tubes (ETTs).

Design: Prospective, randomized study.

Setting: Laboratory in vivo testing.

Intervention: Staphylococcus aureus, Escherichia coli, and Pseudomonas aeruginosa were inoculated onto ETT cuffs. Following inoculation, ETTs were sterilized with either ethylene oxide or glutaraldehyde. Cuffs were then swabbed and cultured for 24 hours. To examine changes in the physical integrities of sterilized ETT cuffs, ETTs were sterilized with ethylene oxide gas once, twice, or three times (the E1, E2, and E3 groups, respectively). Alternatively, ETTs were soaked in glutaraldehyde for 150, 300, 450, or 600 minutes (the G1, G2, G3, and G4 groups, respectively).

Measurements: Endotracheal tube cuffs were considered nonsterile if a visible colony of test organisms was cultured, and sterile if no colony was cultured. Changes in the physical integrity of sterilized ETT cuffs were determined by measuring changes in intracuff pressure or tensile strength.

Main Results: No growth of bacteria was observed in sterilized tubes. Endotracheal tube cuffs of the E1 and E2 groups showed almost the same physical integrity as those of the control group, whereas E3 group cuffs were softer than those of the untreated controls. Endotracheal tube cuffs...
of the G1 and G2 groups were harder than untreated controls; than of those of the G3 and G4 groups were similar to the controls. **Conclusions:** Endotracheal tubes can be reused sterilized safely. The physical integrity of ETT cuffs may be compromised by glutaraldehyde or ethylene oxide sterilization treatments. © 2007 Elsevier Inc. All rights reserved.

### 1. Introduction

The reprocessing and reuse of single-use devices (SUDs) is gaining popularity as a result of the escalating costs of health care. Reports have advocated the cost merits and the safety of reprocessing SUDs [1,2]. Furthermore, a survey revealed that approximately 20% to 30% of hospitals in the United States reprocess SUDs [3]. Recently, a Food and Drug Administration (FDA) policy statement entitled “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals” was released to regulate the reprocessing of SUDs by third parties and hospitals [4]. The FDA decided that it would not recommend the nonreuse of SUDs and strongly recommended that reprocessed SUDs meet the original manufacturers’ quality assurance standards and safety criteria. Endotracheal tubes (ETTs) were listed by the FDA among their enforcement priorities as an SUD type known to be reprocessed [5]. Endotracheal tubes are items of anesthesia and respiratory equipment and are classified as semicritical items in the “Guidelines for Disinfection and Sterilization in Healthcare Facilities” published by the Centers for Disease Control and Prevention (CDC) [6]. The reuse of semicritical items requires a high-level disinfection and sterilization.

There are three basic safety concerns regarding the reuse of medical devices: [7] their sterility, their mechanical integrity, and the safety of performing the sterilization.

The safety of sterilized ETTs and the effects of sterilization on ETT physical integrity according to the CDC guidelines have yet to be determined.

### 2. Materials and methods

This study was approved by the Seoul National University Hospital’s institutional review board.

#### 2.1. Sterility of devices

##### 2.1.1. Test organisms

The following test organisms were grown in nutrition broth at 37°C overnight to a concentration of approximately $10^8$ colony-forming units per milliliter: *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 25922), and *Pseudomonas aeruginosa* (ATCC 27853).

#### 2.1.2. Endotracheal tube preparation

In a laminar flow hood, wearing a mask, a sterile gown, and gloves, the experimenters removed an ETT with an inner diameter of 7.0 mm (Hi-Lo; Mallinckrodt Inc, St. Louis, MO; ethylene oxide (EO)–processed) from its sterile package. Ninety such ETTs were prepared on a sterile bench using sterile techniques.

#### 2.1.3. Inoculation and sterilization

Thirty ETTs were immersed in each inoculum to the cuff level for one minute and then incubated for 30 minutes at 37°C to facilitate microorganism adhesion [8]. After this inoculation process, all ETTs were rinsed with warm water for three minutes, brushed thoroughly, and wiped with a sterile gauze. Endotracheal tubes treated with each inoculum were then sterilized using EO gas (EO group, n = 10) or were submerged in 2% alkaline glutaraldehyde (GA) solution (CIDEX PLUS, Johnson and Johnson Medical, New Brunswick, NJ) for 30 minutes at 20°C to 25°C (GA group, n = 10), and 10 ETTs treated with each inoculum were prepared without the disinfection process and served as a positive control group. After sterilization, all ETTs were swabbed using a sterile technique and incubated for 24 hours at 37°C. Results were considered nonsterile if a visible colony was observed and sterile in the absence of such a colony.

#### 2.2. Physical integrities of the devices

Sixty-four 7.0-mm inner diameter ETTs (Hi-Lo; EO-processed) were used for testing. Nonreprocessed ETTs (n = 8) served as controls. Five ETTs were used to measure intracuff pressure and three, for tensile strength measurements.

##### 2.2.1. Reprocessing

Twenty-four new ETTs were sterilized using a 12% EO: 88% chlorofluorocarbon mix at 55°C for 120 minutes and 11 hours of aeration at 55°C. Endotracheal tubes were sterilized with EO gas once (E1 group, n = 8), twice (E2 group, n = 8), or three times (E3 group, n = 8). In each group, 5 ETTs were prepared for intracuff pressure measurements and three ETTs for tensile strength measurements.

Thirty-two new ETTs were sterilized with 2% alkaline GA solution (CIDEX PLUS). Eight ETTs were submerged in GA solution for 150 minutes at 20°C to 25°C, assuming that each ETT was exposed to 5 simulations of sterilization (G1 group, n = 8); 300 minutes, assuming that each ETT was exposed to
10 simulations of sterilization (G2 group, n = 8); 450 minutes, assuming that each ETT was exposed to 15 simulations of sterilization (G3 group, n = 8); and 600 minutes, assuming that each ETT was exposed to 20 simulations of sterilization (G4 group, n = 8). In each group, 5 ETTs were prepared for intracuff pressure measurements and three ETTs for tensile strength measurements.

2.2.2. Measurement of intracuff pressures
After the ETT cuff had been completely deflated, an ordinary air-filled pressure transducer was connected to the pressure channel of an operating room monitor, set to zero, and to the pilot balloon/cuff inflation line of the ETT via a stopcock. A 10-mL syringe was inserted onto the other port of the same stopcock, which allowed air to be added to or removed from the cuff. Finally, a male plug was placed in the remaining port of the pressure transducer to seal the system. One-millimeter volumes of air were introduced into the cuff incrementally via the three-way stopcock until the pressure reached 40 mmHg.

2.2.3. Measurement of tensile strength
Tube tensile strengths were measured using a universal tensile strength testing machine (N500; Shimadzu Corporation, Kyoto, Japan). Rectangular specimens (80 mm long, 10 mm wide, and one mm thick) were prepared. All specimens were uniaxially loaded at a gauge length of 27 mm and stretched at a crosshead speed of 60 mm/min at room temperature. The test was repeated three times for each, and means were recorded.

2.2.4. Statistical analysis
Endotracheal tube volume-pressure curves were integrated for each group (E1, E2, and E3, and G1, G2, G3, and G4). Measured areas were compared with untreated controls using the Mann-Whitney test. Differences were considered to be statistically significant when the probability of a type α error was less than 5%.

3. Results

3.1. Sterility of devices
No S. aureus, E. coli, or P. aeruginosa colonies were observed in the EO or GA groups, whereas visible colonies were observed for nonsterilized control groups.

3.2. Physical integrities of devices
3.2.1. Intracuff pressure
In EO-treated groups, the pressure-volume curve skewed left slightly (P > 0.05), but as the number of EO treatments increased, pressure-volume curves skewed to the right (Fig. 1A), and the E3 group skewed significantly to the right compared with the control group (P < 0.05). In the GA-treated groups, the pressure-volume curves of the G1 and G2 groups skewed to the left compared with the untreated controls (P < 0.05). G3 group pressure-volume curves showed almost the same features as the G4 group. As the exposure time of ETTs to GA increased, pressure-volume curves gradually skewed right. The pressure-volume curve of the G4 group overlapped that of the control group (P > 0.05; Fig. 1B).

3.2.2. Tensile strength
Fig. 2A shows the EO treatment effects on tensile strength and stretch. After EO treatment, ETT cuff tensile strengths
decreased, and elongations increased. As the number of EO treatments increased, tensile strength continuously decreased. The tensile strengths of the E2 and control groups showed maximum tensile strengths, and the E3 group showed minimum tensile strength. The tensile strength and elongation values of the GA-treated groups are shown in Fig 2B. Tensile strengths and elongations were highest for the G1 group. As ETT exposure time to GA increased, tensile strength decreased. The tensile strength of the G4 group was the same as that of the control group.

4. Discussion

Our results suggest that the sterilization methods described in the CDC guidelines may prevent cross-infection but that ETT cuff physical characteristics may change markedly after GA or EO sterilization.

The reprocessing of ETTS has rarely been raised as an issue in developed countries because single-use ETTS are inexpensive. Rather, researchers in developed countries have focused on reprocessing expensive equipment such as endoscopes. However, many physicians in developing countries reprocess ETTS on a daily basis to reduce costs. Moreover, it is not known how many times an ETT can be reprocessed while retaining the cuff’s original physical characteristics.

In this study, we adopted the GA and EO gas sterilization method as described by the CDC [6]. Polyethylene tubes and catheters can be sterilized by low-temperature sterilization methods, such as EO hydrogen peroxide gas plasma, or by chemical disinfectants. Although hydrogen peroxide gas plasma is superior to EO because it is safer for health care workers and leaves no toxic residues, it requires packing with synthetic material and special packing trays. In contrast, EO gas can penetrate medical packagings and many plastics, which is why EO gas sterilization is the most commonly adopted means by original equipment manufacturers when they process SUDs. Moreover, the GA sterilization method has long been regarded as an inexpensive and safe method that is compatible with the materials used [9]. In addition, this method is the most commonly used high-level disinfectant method for medical equipment, especially for anesthesia and respiratory equipment [10].

Brown et al [11] demonstrated that disinfection and sterilization can affect the tensile strengths of various materials used in medical devices, and our results show that the repeated use of GA and EO can affect the tensile strengths and compliances of ETT cuffs. The E1 group and the nonreprocessed controls had almost the same physical characteristics. As the number of EO treatments increased, the ETT cuffs became soft (Figs. 1A and 2A), and the E3 group showed minimal tensile strength among the EO treated groups. Moreover, when ETTS were sterilized with EO gas more than three times, cuffs became soft and allowed peritracheal air leakage.

Although our results suggest that GA sterilization can be used 20 times in terms of compliance, special attention should be given to the compliance of the G1 group (Figs. 1B and 2B). Endotracheal tubes cuffs began to stiffen after
5 sterilizations, and this resulted in greater pressure increases than for the nonreprocessed control group. Submerging ETTs in GA for 150 minutes (G1 group, 5 sterilization simulations) hardened ETT cuffs, and as submersion times increased, cuffs softened. After submerging ETTs in GA for 600 minutes (G4 group, 20 sterilization simulations), cuff compliance approached that of the nonreprocessed controls. Maximum tensile strengths were obtained for the G1 group. Moreover, as exposure time to GA increased, tensile strengths decreased. The tensile strength of the G4 group was the same as that of the nonreprocessed control group.

Some limitations of the present study should be mentioned. The procedure used was artificial, that is, it would have been better if we had simulated the real situation and investigated ETT sterility and compliance in the operating room. However, to ensure that ETT cuffs were actually infected, we deliberately contaminated them with microorganisms. Perhaps organisms other than the test organisms should have been studied. Although GA and EO gas cannot effectively sterilize prions [12], they can sterilize mycobacteria and viruses with the same efficiencies as bacteria [13].

Our findings suggest that ETTs can be sterilized effectively. Physical integrity was altered by GA sterilization after 5 sterilization simulations, and EO sterilization caused little compliance change after two reprocessings. Therefore, a tagging system indicating the number of reprocessings with EO or GA is needed to prevent air leakage or airway injury after reprocessing ETTs.

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References