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Original contribution

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

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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.

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