

ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS
Providing industry views on single patient use medical devices

December 7, 1999

BY FACSIMILE

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Center for Devices and Radiological Health
Food and Drug Administration
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Re: Further Evidence of Increased Patient Risk with Reprocessed Used Single-Use Medical Devices

Dear Dr. Feigal:

ADDM is a trade association of original device manufacturers dedicated to protecting patient safety through proper regulation of single use device reprocessing. In a November 22, 1999 letter, ADDM summarized sixteen studies already on file at FDA and supplied the FDA with new evidence of increased patient risk with reprocessed used single-use medical devices. The purpose of this letter is to further supply the FDA with published evidence of the existence of valid scientific data that confirms the physical, microbiological, and functional performance failures associated with reprocessed used single-use medical devices. Three published literature reports on the dangers of reprocessing used single use devices are enclosed.

The first article entitled "Parental Report of Pediatric Tracheostomy Care," draws a correlation between the increased incidence of pneumonia in pediatric patients and the reuse of tracheostomy tubes, which are devices labeled as "single-use only." Tracheostomy tube reuse was reported by 55% of the 60 participants. Approximately 60 percent of the pediatric patients on whom reprocessed tracheostomy tubes were used developed pneumonia within the previous year, compared to only 25 percent of pediatric patients on whom new tracheostomy tubes were used in the same time period. Other potential variables such as patient age, diagnosis, method of tube cleaning, and frequency of tube change showed no correlation to increased incidence of pneumonia, leaving tracheotomy tube reuse as the only predictor of pneumonia. The author's conclusion questions the safety of reusing these single-use devices.

The article entitled "Iatrogenic Central Retinal Artery Embolization: A Complication of Cardiac Catheterization," reports that a 57-year old man experienced a

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sudden loss of vision in one eye during a cardiac catheterization for coronary angiography after a heart attack. The loss of vision was due to a reprocessed catheter, the tip of which fragmented and lodged in the patient's central retinal artery on the optic nerve head of the patient's right eye, leaving that eye with only light perception vision. At the end of a six-month follow-up, the patient's right eye vision remained only perception and nasal projection of light. The catheter fragmentation was attributed to the reautoclaving process and the reuse of the single-use device. The authors recommend compliance with manufacturers' single use label to prevent complications such as this.

The third article, "A Pseudo-Outbreak of *Aureobasidium* Lower Respiratory Tract Infections Caused by Reuse of 'Single-Use' Stopcocks During Bronchoscopy," highlights a very important public health issue associated with reprocessing used single-use devices: antibiotic resistance. The report reveals that reprocessed stopcocks labeled "single-use only" led to a pseudo-outbreak in which nine patients were misdiagnosed as being infected with *Aureobasidium*, a genus of the fungus known as "black yeast." Had this erroneous diagnosis involved a different organism, these patients would have likely received unnecessary antibiotic treatment for their "infections." This article demonstrates the potential that reprocessed single use devices may be serious contributors to the growing problem of antibiotic resistance in the U.S.

This sample of reported incidents further indicates the need for the FDA to recognize the important patient safety issues associated with reprocessing used single-use devices, and fully enforce the Food, Drug and Cosmetic Act, including the requirements for premarket submissions.

Sincerely,



Josephine M. Torrente

JMT/dmb

cc: Stephen Brobeck
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Iatrogenic Central Retinal Artery Embolization: A Complication of Cardiac Catheterization

DIETRICH HALLERMANN, MD, AND GURINDER SINGH, MD

A 57-year-old man with a myocardial infarction was subjected to cardiac catheterization as a follow-up study for his heart problem. The catheter, made for one time use only, was reautoclaved and used sometime before catheterizing this man. A small fragment of this catheter dislodged while guiding the parent catheter into coronary vessels with a metallic guide-wire. The fragment traveled getting lodged in the central retinal artery of the right eye leaving the eye with only light perception vision. The catheter fragment could be seen in the central retinal artery at the optic nerve head.

The investigative and therapeutic procedures like cardiac and carotid catheterization and external carotid therapeutic embolisation, etc, have great advantages in the management of patients and are routine procedures. But simultaneously, these procedures have potential risks of serious complications. Ocular complications like central retinal artery occlusion or embolization during cardiac catheterization,¹ as a complication of external carotid therapeutic embolization² and during carotid angiography^{3,4} are well documented. Like most of the other patients, one man developed sudden loss of vision in his right eye because of central retinal artery embolization caused by a catheter fragment. To the best of our knowledge, central retinal artery embolization by cardiac catheter fragment has never been reported. This needs discussion because necessary precautions must be observed in the future to prevent such a dreadful complication.

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Report of a Case

A 57-year-old man was brought to the University Eye Clinic with sudden loss of vision in his right eye that had developed the day before. He was subjected to cardiac catheterization for coronary angiography for a follow-up study of his myocardial infarction that he suffered three months earlier. The catheter was introduced through the right cubital vein and was being guided up into the coronary vessels when he noticed loss of vision in his right eye. That procedure was stopped there only. Three hours after the episode the attending physician recorded vision of light perception in right eye and full vision (1.0) in the left eye. Next day he was brought to us.

The patient was seen by us about 20 hours after the episode. He had vision of light perception only with nasal projection of light with eccentric-seeking in the involved eye. The pupil was mid-dilated, reacting normally in consensual light but very sluggishly to direct light. On ophthalmoscopic examination, a green crystalline foreign-body was seen within the central retinal artery on the optic nerve head (Fig 1). Retinal arteries were constricted with mild venous engorgement. Nasal disc margin was slightly blurred with filling up of the disc-cup and showing mild papilledema. The fundus background was paler than the left fundus but there was not much of retinal edema to present a picture of a fully developed cherry-red spot. Anterior segment, ocular media, and intraocular pressure (IOP B/E 14 mm Hg) were normal. The left eye did not show anything significant except for the absence of consensual light reflex.

Vasodilators and eyeball massage were not helpful in dislodging the foreign-body into the branch artery. Mild retinal edema remained for about two months after which it started regressing. Six months later the fundus looked normal (as in the left eye). Even after six months fol-



Figure 1 Cardiac catheter fragment occluding the central retinal artery at its point of bifurcation on the optic nerve head (arrow pointing to catheter fragment).

low-up the vision in the right eye remained only perception and nasal projection of light. The foreign-body was still on the optic nerve head within the central retinal artery though the venous congestion had regressed and the arteriovenous ratio was normal.

Discussion

Central retinal artery embolism usually is consequent to dislodging the atheromata of carotid arteries, post-rheumatic vegetations, myxomas, or following iatrogenic or self-inflicted trauma by intravenous injections of drugs and chemicals.³ Air and dye entering the circulation during angiographic techniques are other potent causes.¹ Recently, a case has been seen with branch artery occlusion as a complication of selective external carotid embolization done in a case of juvenile nasopharyngeal angiofibroma.² In the present case, the green crystalline embolus seen in the central retinal artery was a piece of cardiac catheter that broke from the catheter and lodged in the right central retinal artery. This, to our knowledge, happens to be the first of such a complication of cardiac catheterization.

The retrospective analysis revealed that it is a common practice with cardiology units of most hospitals to reautoclave the plastic cardiac catheters and reuse one catheter on five to six patients before discarding. According to the manufacturers, every catheter is to be used only once. But, because of the cost involved, large number of cardiology units do not adhere to

these instructions and reuse the catheters on many patients after reautoclaving. In the present case also the cardiac catheter was reautoclaved against the instructions and it is presumed that this made the catheter friable leading to this unusual and dreadful complication. This fragmentation might have been further enhanced because of the metallic guide-wire used to guide the tip of the catheter into the specific artery. It is suggested that cardiology units should comply with the manufacturer's instructions and not take the risks of complications like the one that developed in our case. Also, the quality of the material used for these delicate instruments should be improved.

The patient was seen about 20 hours after the episode of sudden loss of vision. Had the patient been diagnosed earlier with central retinal artery embolus the early active treatment like paracentesis, vasodilators, or eyeball massage might have helped to move the embolus further into the branch artery. Some useful vision may then have been saved. On clinical assessment, the artery obstruction was not total, postischemic retinal edema was not severe enough to produce a full bloom cherry-red spot and residual light perception showed that the retina was getting partial or minimal blood supply. (Retinal angiography was denied by the patient because of the previous investigation leading to this complication.) Beginning vasodilators and eye massage 20 hours after the obstruction was already too late to think of regaining useful vision and also the irregular shape of the catheter fragment made it stick at the branching of the central retinal artery. Considering the optic nerve head diameter as 1.5 mm the size of the catheter fragment was about 0.16 mm (Fig 2) and this big embolus with sharp

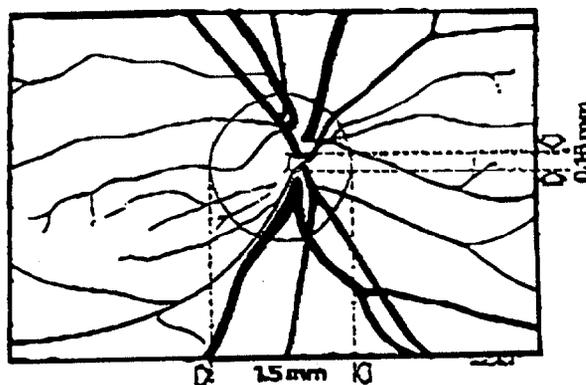


Figure 2 Taking the average diameter of the optic nerve head as 1.5 mm the width of catheter fragment is about 0.16 mm.

irregular edges could not be expected to move further into the branch retinal artery. Minimal residual blood supply left the retina with vision of light perception and nasal projection.

Anatomical predisposition of the right common carotid artery to get cardiac emboli was reason for this fragment to travel into the right arterial circulation. It is very unusual for such a foreign-body to travel all the way up into the ophthalmic artery and then ultimately get lodged in a terminal part of the central retinal artery.

Comment

To conclude, it is strongly recommended or suggested that though potential, yet dreadful, risk factors must be considered seriously before subjecting the patients to investigative procedures like cardiac catheterizations especially

when these are done for follow-up studies only. Also, due care should be taken both by physicians and surgeons and also the manufacturers in selecting the quality of materials used in different instruments.

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The opinions expressed herein are those of the authors and are not official opinions of the Department of the Navy.

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In Reply.—Wilson and McClatchey raise important questions that deserve careful analysis. Because it has been shown that esotropes with a high accommodative convergence/accommodation ratio or a nonaccommodative convergence excess do require larger amounts of surgery than other esotropes,¹ we intentionally excluded such patients from our study. We only included acquired esotropes in whom the near deviation and distance deviation were approximately equal. We are surprised that Wilson and McClatchey believe that this group of esotropes requires a larger amount of surgery for a given deviation than congenital esotropes. All of the popular strabismus textbooks and journal articles we are aware of do not recommend a different surgical formula for congenital esotropes than for decompensated accommodative esotropes in whom the near deviation equals the distance deviation. We therefore thought it was appropriate to combine these two patient groups in our study. Nevertheless, because of the questions raised by Wilson and McClatchey, we reanalyzed our data separating congenital esotropes from acquired esotropes. For the 15 congenital esotropes in our study the response to surgery had a significant inverse correlation with axial length ($r = -.502, P < .05$). For the 21 acquired esotropes in our study the response to surgery did not correlate significantly with axial length ($r = -.381, P < .10$). We were concerned that because all of our acquired esotropes were beyond the age of rapid ocular growth, and, consequently, there was a much narrower range of axial lengths in these patients than in the congenital esotropes, that the number of patients would be too small to establish significance for what appeared to be a "trend," although there were more patients in this group than in the congenital esotropia group. Because our data collection is ongoing, we chose to further analyze patients with acquired esotropia by including the additional 14 patients we have now studied who met all the criteria of our original study. In these 35 patients the correlation of response to surgery with axial length was significant ($r = -.371, P < .05$).

Of greater importance is the suggestion by Wilson and McClatchey that the correlation we found between axial length and response may have really been a reflection of the fact that patients with smaller eyes tend to have larger deviations (congenital esotropes), and, according to Mims, larger deviations have a greater response to surgery than smaller deviations. To address this question it is important to determine the partial correlation coefficient for response to surgery with axial length, adjusting for deviation. This statistical text will reveal how response correlates with axial length if the influence of any variation in deviation is eliminated. For 36 patients in our original study, the partial correlation coefficient of axial length and response, adjusting for deviation was still significant ($r = -.3890, P < .02$).

Our study confirms theoretical calculations that axial length should be important in determining the response to strabismus surgery. Although Mims and others have found a bimodal dose-response curve, to our knowledge there is no

satisfactory theory as to why it should be so. We believe our data suggest that the bimodal response found in strabismus surgery for esotropia may reflect the fact that larger deviations occur in patients with smaller eyes, and, because of the smaller axial length in patients with large deviations, the response to the same amount of surgery is greater.

Finally, although we did calculate response in degrees per millimeter, we did not actually generate a dose-response curve in this study, not did we extrapolate to zero, as Wilson and McClatchey suggested. Although it is clinically easier to measure patients using prism diopter notation (because that is how our prisms are calibrated), we believe that the use of degrees for calculations more accurately describes the deviation of an eye and its change in position after surgery.

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Retinal Artery Embolism Following Cardiac Catheterization

To the Editor.—In the March 1989 issue of the ARCHIVES, Pe'er et al¹ reported various fundus findings secondary to retinal emboli 1 day following cardiac valve surgery in 10 of 81 patients. They did not mention the number of eyes involved. Even then, this alarmingly high number (12%) suggests the need for more extensive preoperative and postoperative ocular workup to prevent and treat these complications that will go undetected otherwise. This study reveals the fact that retinal emboli following cardiac surgery are underdiagnosed, underreported, or both.

Although since the late 1970s only one report² addressing the subject of perioperative retinal emboli after open heart surgery has been published, cases of retinal emboli following cardiac catheterization³ and therapeutic external carotid embolization⁴ have been reported in the 1980s. My colleague and I reported a case of central retinal artery embolization by cardiac catheter fragment.³ Our patient, a 57-year-old man, underwent cardiac catheterization for coronary angiography as a follow-up study of his myocardial infarction. The fragmentation of the tip of the catheter was related to the reautoclaving and reusing of the disposable catheter against the manufacturer's instructions, and to the metallic guidewire used to guide the catheter into the specific artery. The visual acuity in the involved eye was reduced to light perception after embolism.

I recommend that potential ocular risk factors must be considered and discussed with the patients before subjecting them to cardiac or cardiovascular procedures.

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PHOTOCOPIED FROM THE ARCHIVES OF OPHTHALMOLOGY

Parental Report of Pediatric Tracheostomy Care

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ABSTRACT. Bahng SC, VanHala S, Nelson VS, Hurvitz EA, Roloff DW, Grady EA, Lewis CC. Parental report of pediatric tracheostomy care. *Arch Phys Med Rehabil* 1998;79:1367-1369.

Objective: There are little data on the actual care given pediatric tracheostomy patients in their homes. Information on the use of supplies and on techniques and frequency of care is valuable for a better understanding of the needs of this population.

Design: Questionnaires were distributed by mail or at clinic visits from May 1995 to June 1996 to a convenience sample of tracheostomized patients at the University of Michigan Pediatric Physical Medicine and Rehabilitation clinic.

Setting: Tertiary care clinic.

Results: Clean technique for suctioning was reported by 96.7% of subjects and the rest reported sterile technique. Fifty percent of subjects reported reusing suction catheters. Cleaning solutions used to clean suction catheters for reuse varied. Tracheostomy tube reuse was reported by 55% of subjects. Sixty percent of those who reused tracheostomy tubes had had pneumonia within the previous year, whereas only 25% of those who never reused the tracheostomy tube had pneumonia in the same time period.

Conclusions: Suctioning frequency, suction catheter, and tracheostomy tube reuse and cleaning methods are variables that warrant further investigation of safety and efficacy.

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MANY PEDIATRIC PATIENTS require a long-term tracheostomy for airway access, mechanical ventilation or both.¹ Home care is a reasonable goal for most children with a tracheostomy. Studies have shown that home tracheostomy care, in conjunction with proper parental training, equipment, follow-up visits, and home nursing care, can be as safe as hospital care and, in most cases, more beneficial to the child's growth and development.¹⁻³ Home care for respiratory technology-assisted patients has also been shown to be more cost effective than institutional care.⁴ Although home tracheostomy care has been evaluated for safety and cost effectiveness, and the literature describes and evaluates the proper training and preparation of parents,⁵ an extensive search of the literature

found no studies describing the actual methods and supplies used in the home. Such information would contribute to a better understanding of the needs of this population, providing recommendations in the training of home caregivers and helping to increase cost effectiveness. We asked parents of pediatric patients with tracheostomies to report use of supplies, techniques, and frequency of tracheostomy care in the home, and the incidence of pneumonia within the past year.

METHODS

Questionnaires were distributed by mail or at clinic visits from May 1995 to June 1996 to a convenience sample of children with tracheostomies followed at the University of Michigan Pediatric Physical Medicine and Rehabilitation Clinic. Of 90 questionnaires distributed, 60 were returned—an overall return rate of 67%. Patients ranged in age from 9 months to 28 years, with a median age of 7.5 years; 35% of the sample was male. Length of time for which the patient had a tracheostomy ranged from 1 to 15 years, with a median of 4 years ($\bar{x} = 4.8$ yrs). Diagnoses of the patients were: neuromuscular problems, 63%; lung disease, 18%; congenital central hypoventilation syndrome and VACTERL syndrome, 12%; and airway problems, 7%. Lung disease category is comprised of patients with congenital diaphragmatic hernia, bronchopulmonary dysplasia, lymphangiectasia, or multiple congenital anomalies. In the neuromuscular category were patients with spinal cord injury, neuromuscular disease, cerebral palsy, dwarfism, myelodysplasia, brain tumor, stroke, traumatic brain injury, and neurofibromatosis. Eighty percent (48 of 60) of the patients used a ventilator. This study sample is reflective of patients followed in our clinic. Data collected in this study depended on parental report since no verification of the responses through charts or supplies was made. The questionnaire respondent is referred to as a "subject," whereas the recipient of care is referred to as "patient." (The home caregiver and questionnaire respondent was usually a parent, but in a few cases a patient who was old enough to complete a questionnaire was also the respondent.)

Frequency calculation and univariate analysis was performed using Epi Info 6.04.⁶ Multiple regression analysis using STATA 4.0⁷ was performed to identify which variables played a role in recurrent infections.

RESULTS

General descriptive data. Of patients who used a ventilator, 10 used a bilevel positive airway pressure machine and 38 used a volume ventilator. Hours of ventilator use ranged from 1 to 24 hours, with 16 patients using the ventilator 24 hours a day. Forty-five percent (27 of 60) of the patients were reported to have had pneumonia within the past year, with 12 subjects reporting one episode, 7 subjects reporting two episodes, 3 subjects reporting three episodes, and 2 subjects reporting four episodes. Three subjects did not indicate the number of pneumonias. Inner cannulas were used by 26 of 60 (26.7%) patients. Thirteen (21.7%) used a cuffed tracheostomy tube; 12 of the 13 used an air cuff and one subject used a foam cuff.

Suctioning. Suctioning was performed once every hour by 13.6% (8), once every 1 to 4 hours by 40.7% (24), once every 4

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to 8 hours by 20.4% (12), and less frequently than once every 8 hours by 25.4% (15). Use of clean technique when suctioning was reported by 58 (96.7%), and only 2 (3.3%) reported using sterile technique. Clean gloves were used by 43 (71.7%) of the subjects, sterile gloves were used by 10 (16.7%), and 7 (11.7%) reported using no gloves. No association was found between glove usage and reported pneumonia.

Fifty percent of the subjects reported reusing suction catheters and the others reported using sterile catheters. Of those who reported reusing suction catheters (30), 80% (24) cleaned their catheters with vinegar, 17% (5) used water, and 13% (1) used another solution. No statistically significant association was found between the use of sterile or reused suction catheters and reported pneumonia within the past year. Number of catheters used per month is shown in table 1. The median number of catheters used per month was 60; the mean was 108.

Tracheostomy care. Brand A (Shiley^c) tracheostomy tubes were used by 28 (46.7%) patients, brand B (Bivona^d) by 19 (31.7%), and brand C (Portax^e) by 13 (21.7%). Fifty-five percent (33 of 60) reported reusing the tracheostomy tube and the rest reported never reusing the tracheostomy tube. Reuse of the tracheostomy tube was correlated with a higher incidence of pneumonia. Approximately 60% (20 of 33) of those who reused the tracheostomy tube reported pneumonia within the past year, whereas only 25% (7 of 27) of those who never reused reported pneumonia. Age, type of tracheostomy tube, diagnosis, and frequency of tube change were tested along with tube reuse using logistic regression. Among these variables, reuse of the tracheostomy tube was the only predictor of pneumonia. The odds ratio for tube reuse with pneumonia as an outcome was 5.6 (confidence interval 1.2 to 26; $p = .03$). The R^2 value was .12.

Frequency of tracheostomy tube change is presented in table 2. Frequency of tube change correlated with the patient's age, with older patients tending to change less frequently. Seventy-two percent (31 out of 43) of patients younger than 13 years reported changing the tube weekly to twice monthly, whereas 24% (4 out of 17) of older patients reported changing at this frequency. Seventy percent (12 out of 17) of older patients and only 23% (10 of 43) of younger patients changed the tube monthly or less frequently than every month. Those who changed the tube more frequently were more likely to reuse the tracheostomy tube. Sixty-six percent of those who changed weekly to twice monthly reused, whereas only 9% of those who changed monthly to less than every month reused their tubes. Reuse of the tracheostomy tube correlated with a higher incidence of pneumonia, whereas the frequency of tube change and age did not.

Of those who reused their tracheostomy tubes (33 subjects), 40.6% (13) used hydrogen peroxide to disinfect the tube, 21.9% (7) used soap and water, 12.5% (4) used vinegar, and 25% (8) used a combination of solutions (hydrogen peroxide, vinegar,

Table 2: Frequency of Tracheostomy Tube Changes

Frequency	Patients (no.)
2/day	1
1/day	2
1/week	27
2/month	8
1/month	19
<1/month	3

and soap and water). No association between pneumonia and the method of disinfecting the tracheostomy tube was found.

DISCUSSION

Suctioning

A comparison of clean versus sterile tracheostomy care technique and levels of pulmonary infection in the hospital setting has shown that clean technique does not lead to more infections.⁶ Many parents are taught to use clean technique in the home because sterile technique is not only too cumbersome and costly, but also rarely is strictly carried out. The majority of respondents in our study (58 out of 60) reported using clean technique, consistent with the current trend.

A physician survey on the care of children with tracheostomy found that approximately 50% (31 out of 64) of physicians recommended suctioning on an "as needed" basis, whereas 35% (23 out of 64) recommended suctioning at least hourly.⁷ In our sample, 13.6% suctioned hourly. It would be valuable to know whether suctioning frequency is "as needed" or at physician direction, especially considering the potential harmful side effects of endotracheal suctioning.⁸

The Centers for Disease Control (CDC) recommend that a sterile catheter be used for each series of suctionings of patients in the hospital. The CDC has made no recommendations for patients in the home care setting, however, where the risk of acquiring multiple antibiotic-resistant organisms is lower.⁹ Fifty percent of our study sample used sterile catheters and the others reused suction catheters. No association was found between sterile versus reused suction catheters and reported pneumonia.

A study by Shabino and coworkers¹⁰ tested the effectiveness of a three-step disinfecting process involving hydrogen peroxide, 100°C soapy water, and 100°C rinse water. This study found the three-step method of disinfecting the suction catheter to be effective under laboratory conditions but did not investigate the matter of defining a practical and cost effective method for home caregivers.

Our study showed vinegar to be the most common (24 out of 30) solution for cleaning the suction catheter for reuse. Although no previous studies have tested the effectiveness of vinegar to disinfect suction catheters, our study indicated that reused suction catheters cleaned with vinegar were not associated with a higher incidence of pneumonia when compared with sterile catheters. Current literature does not address the effectiveness of the cleaning methods used in the home setting or offer guidelines for reuse of the suction catheter. It is evident that further research needs to be done in this area to evaluate and improve the methods used by home caregivers.

Tracheostomy Care

Very little research has addressed the frequency of tracheostomy tube changes or offered guidelines for reusing tracheostomy tubes. The guidelines for tube changes that do exist are contradictory.¹¹ In our sample, age of the patient was strongly

Table 1: Suction Catheters Used Per Month

Catheters (no.)	Patients (no.)
2-10	4
11-25	4
30-35	15
40-50	3
60	4
90-100	6
105-155	5
168-200	4
200-299	3
300 plus	5

correlated with the frequency of tube change. Age of the patient affects the size of the tube, and smaller tubes may necessitate more frequent changes to prevent plugging. Although younger patients changed tubes more frequently and reused tubes more than older patients, age was no predictor of pneumonia.

Reuse of the tracheostomy tube in our sample was found to correlate with a higher incidence of pneumonia. Other factors, such as method of disinfecting the tube, frequency of tube change, patient age, diagnosis, and type of tube, were not predictors of pneumonia. The R^2 value of .12 indicates that the regression equation only predicts about 12% of the variability. Although this is not very high, it is significant enough to be of clinical concern. Another aspect of tracheostomy care that needs to be evaluated is the method of cleaning and disinfecting the tracheostomy tube. Little exists in the current literature regarding this matter. Subjects in our sample reported using hydrogen peroxide, vinegar, soap and water, or a combination of solutions. The results of our study strongly suggest the need for evaluating the safety of reusing the tracheostomy tube in the home.

CONCLUSION

This was a study of reported home management of tracheostomy care in children. Descriptive data of home care were obtained regarding suctioning, tracheostomy care, supplies, and cleaning and disinfecting practices. Correlations of various factors with pneumonia were made. Reuse of the tracheostomy tube was the only statistically significant predictor of pneumonia. Research is needed to evaluate the safety of home care practices that may improve the health of children with tracheostomies as well as increase the cost effectiveness of their home health care.

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Suppliers

- Epidemiology Program Office, Centers for Disease Control, Atlanta, GA.
- Stata Corporation, 702 University Drive East, College Station, TX 77840.
- Mallinkrodt Medical Inc., Critical Care Division, 675 McDonnell Boulevard, PO Box 5840, St. Louis, MO 63134.
- Bivona Medical Technologies, 5700 West 23rd Avenue, Gary, IN 46406.
- SIMS Portex, Inc., 10 Bowman Drive, PO Box 0724, Keene, NH 03431.

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A Pseudo-Outbreak Of *Aureobasidium* Lower Respiratory Tract Infections Caused By Reuse Of "Single Use" Stopcocks During Bronchoscopy

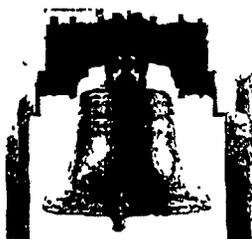
STEPHEN J WILSON, RICHARD J EVERTS, KATHRYN B KIRKLAND, and DANIEL J SEXTON, Duke Univ Med Ctr, Durham, NC, and Palmerstown North Hosp, Palmerstown N., New Zealand

BACKGROUND: Reuse of medical devices labeled for single use has become increasingly widespread as hospitals try to save money. **OBJECTIVE:** To investigate, control, and report, an apparent outbreak of lower respiratory infections due to *Aureobasidium* spp. **DESIGN:** Hospital-based outbreak investigation. **SETTING:** University-affiliated hospital. **PATIENTS:** Ten bronchoalveolar lavage (BAL) fluid cultures from nine patients grew *Aureobasidium* between June and August 1998; whereas, respiratory specimens from only two patients grew *Aureobasidium* during the preceding six years. **RESULTS:** No patient was judged to have true infection due to *Aureobasidium* either before or after bronchoscopy. Nine of the 10 bronchoscopies that yielded *Aureobasidium* were performed in the outpatient bronchoscopy suite. The aureobasidium isolates were not associated with any one bronchoscope. Observation of bronchoscopy procedure revealed that plastic stopcocks labeled for single use were repeatedly reused on different patients during BAL. There was no record of how many times each stopcock was being reused. After each use the stopcocks were placed in an automated disinfection machine designed for bronchoscopes. Culture of the stopcocks after they had been "disinfected" yielded a heavy growth of *Aureobasidium*, while cultures of samples from the automated disinfection machine were negative. Reuse of the stopcocks was halted, and during the following six-month period, *Aureobasidium* spp. were not isolated from any BAL specimen. **CONCLUSIONS:** Reuse of medical equipment designed for single use is potentially hazardous, especially if no quality control system is in place to monitor sterility and function after reprocessing.



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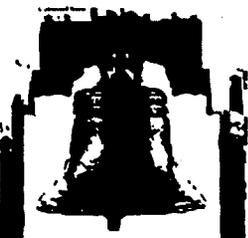
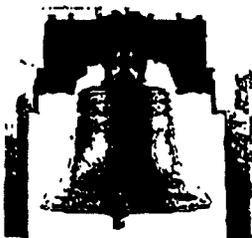
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