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JOURNAL OF HOSPITAL INFECTION 2008

RM-20003-C1 Rev. 1

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Journal of Hospital Infection (2008) 68, 101–107

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REVIEW

Reassessment of the risk of healthcare-acquired infection during rigid laryngoscopy

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Available online 15 January 2008

KEYWORDS
Rigid laryngoscopy;
Infection control;
Nosocomial infections;
Sheath technologies;
Spaulding; Sterilisation

Summary Inadequate reprocessing of rigid laryngoscopes has been linked to nosocomial outbreaks with associated morbidity and mortality. Last year an outbreak of *Pseudomonas aeruginosa* in a neonatal intensive care unit was responsible for multiple infections and colonisations, and at least two infant deaths. An investigation of this outbreak identified contaminated rigid laryngoscopes as its source, demonstrating that inadequate reprocessing of rigid laryngoscopes remains a current public health concern. This article revisits and reassesses the risk of healthcare-acquired infection during rigid laryngoscopy and establishes the minimum reprocessing requirements for blades and handles of rigid laryngoscopes. Several potential risk factors for microbial transmission are identified and discussed, including the publication of inconsistent reprocessing guidelines for rigid laryngoscopes. Concern about guidelines that recommend low-level or intermediate-level disinfection of rigid laryngoscopes is expressed. The use of a sterile disposable sheath to cover the rigid laryngoscope and minimise the risk of contamination is also discussed. Regardless of whether a sheath is used during the procedure, thorough cleaning followed by high-level disinfection and drying of the instrument is recommended to prevent microbial transmission.

Introduction

The blades and handles of rigid laryngoscopes have been documented to be contaminated with blood, body fluids, and potentially pathogenic micro-organisms during clinical use.[1–15] Nosocomial outbreaks with associated morbidity and

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doi:10.1016/j.jhin.2007.11.004

mortality caused by inadequate reprocessing of rigid laryngoscopes have also been documented.[9–15] Last year an outbreak of *Pseudomonas aeruginosa* in a neonatal intensive care unit (NICU) was identified.[13,14] Fifteen of 22 premature infants were infected or colonised with the outbreak strain of *P. aeruginosa*, at least two of whom reportedly died. Improper reprocessing of rigid laryngoscopes was identified as the cause of this outbreak.[13–15] In part as a response to this outbreak, the California Department of Health Services issued a safety notice that discussed inadequate reprocessing of rigid laryngoscopes and other types of reusable medical instruments as a significant risk factor for disease transmission.[15] This recent outbreak of *P. aeruginosa* and safety notice demonstrate that inadequate reprocessing of rigid laryngoscopes remains a current public health concern.

This review revisits and reassesses the risk of healthcare-acquired infection (HAI) during rigid laryngoscopy and establishes the minimum reprocessing requirements for blades and handles of rigid laryngoscopes.

Methods

A thorough study of the medical literature was performed, including a review of: (a) several reports that linked disease transmission, HAIs and outbreaks to the ineffective reprocessing of rigid laryngoscopes; (b) guidelines for reprocessing blades and handles of rigid laryngoscopes; (c) surveys and studies that report current practices for reprocessing rigid laryngoscopes; and (d) the labelling and reprocessing instructions provided by different manufacturers of rigid laryngoscopes. This study also aimed to determine whether the use of a sterile disposable barrier or sheath to cover the rigid laryngoscope has been demonstrated to reduce markedly the risk of disease transmission during rigid laryngoscopy.

Results

Several potential risk factors for disease transmission associated with the reprocessing of rigid laryngoscopes were identified and are presented in Table I. Firstly, no consensus statement or endorsed guideline for reprocessing the rigid laryngoscope's blade and handle has been published. Secondly, published guidelines for reprocessing the blades and handles of rigid laryngoscopes are available, but several are incomplete, inconsistent, or inadequate.[1,2,15–26] Thirdly, the reprocessing instructions provided by different manufacturers of rigid laryngoscopes are also inconsistent and vary in detail, scope and content from one manufacturer to another.[27–30] Fourthly, rigid laryngoscopes are classified as Class 1 devices exempt from the Food and Drug Administration's (FDA) premarket notification (510[k]) requirements. Based on the findings of this review, it is not surprising that practices for reprocessing rigid laryngoscopes in the clinical setting were found to be inconsistent and in some instances to vary significantly from one healthcare facility to another, as well as within the same facility.[5–7,31,32] Variations in reprocessing practices can pose an increased risk of ineffective reprocessing, inconsistent standards of patient care, and microbial transmission.[33,34] No studies were identified that demonstrate a significant reduction in the risk of HAI attributed to the use of a sterile disposable protective sheath to cover the rigid laryngoscope during the procedure.

Table I Potential risk factors for microbial transmission associated with the reprocessing of rigid laryngoscopes

- The lack of a published consensus statement or endorsed guideline for reprocessing rigid laryngoscopes.
- The publication of incomplete, inconsistent and inadequate reprocessing guidelines, some of which recommend low-level disinfection of rigid laryngoscopes after each use.[1,2,15–26]
- Reprocessing instructions provided by different manufacturers of rigid laryngoscopes that vary in detail, scope, and content.[27–30]
- The classification of rigid laryngoscopes as Class 1 devices exempt from the Food and Drug Administration's premarket notification requirements.
- Inconsistent reprocessing practices for rigid laryngoscopes that may vary significantly from one healthcare facility to another, as well as within the same facility.[5–7,31,32]

Discussion

A rigid or flexible endoscope may be used to treat several patients in one day. If inadequately reprocessed after each use, these instruments can infect a significant number of patients with disease in a relatively short period of time.[33,34] Nosocomial outbreaks caused by inadequate reprocessing of the blades of rigid laryngoscopes have been reported.[9–15] Although the rigid laryngoscope's handle has not been directly linked to HAI, reports of its contamination with blood and other potentially infectious materials suggest its potential, like the

blade, as a vector for microbial transmission.[1,2] In addition to occult (i.e. not visible) blood, rigid laryngoscopes have been reported to be contaminated with, among other potentially pathogenic microorganisms, *Streptococcus* spp., *Staphylococcus* spp. including meticillin-resistant *S. aureus* (MRSA), *Serratia marcescens* and *P. aeruginosa*.[1–13] Most outbreaks linked to inadequate reprocessing of rigid laryngoscopes are similar in cause and outcome, involve transmission of Gram-negative bacilli – namely, *S. marcescens* and/or *P. aeruginosa* – and usually affect immunocompromised patients such as premature infants in NICUs.[9,10,13–15] The aim of this discussion is to highlight the risk of HAI associated with improper reprocessing of rigid laryngoscopes.

A consensus statement for reprocessing rigid laryngoscopes

Professional organisations have published consensus statements for reprocessing flexible gastrointestinal endoscopes and bronchoscopes.[35–40] In general, these guidelines are consistent (except with regard to endoscope drying[33]) and provide step-by-step reprocessing instructions. A published consensus statement for reprocessing the rigid laryngoscope's blade and handle, however, has not been published.[41] This oversight can contribute to confusion and raise questions about the minimum requirements for reprocessing rigid laryngoscopes, posing the potential for an increased risk of HAI (Table I). The development and publication of a consensus statement for reprocessing rigid laryngoscopes is encouraged to minimise confusion and reduce the risk of HAI. A detailed step-by-step set of instructions for reprocessing rigid (and flexible) laryngoscopes was developed by this article's author and has been published.[42,43]

Inconsistent reprocessing guidelines

Some guidelines for reprocessing rigid laryngoscopes have been published, but their recommendations may be incomplete, inconsistent, or inadequate, posing the potential for an increased risk of HAI (Table I).[21,24,26] (Concerns about the potential for an increased risk of HAI as a result of inconsistent guidelines for reprocessing both GI endoscopes and bronchoscopes have been published.[33,40]) Guidelines published by the American Association of Nurse Anesthetists (AANA), among other organisations, classify the rigid laryngoscope's blade and handle as semi-critical instruments for which high-level disinfection (or sterilisation) is recommended.[1,2,16,24,25] Although recommending high-level disinfection (or sterilisation) of the rigid laryngoscope's blade, however, a different guideline classifies the handle as non-critical for which it recommends low-level disinfection (e.g. washing using soap and water). (Ironically, this guideline references as the rationale for its low-level disinfection instruction a study that recommends at least high-level disinfection of the handle).[1,21] The rigid laryngoscope's handle is not isolated from the patient and directly attaches to the blade, both functioning together as one instrument. The blade typically becomes contaminated via direct contact with the patient's mucous membranes, while the handle, similar to a dental handpiece, is more likely to become contaminated via indirect (than direct) contact. The rigid laryngoscope's handle may become contaminated through indirect contact during folding of a contaminated blade onto the handle after endotracheal intubation, or during improper handling of the handle with soiled hands or gloves during or after rigid laryngoscopy. Connection of a low-level disinfected handle to a high-level disinfected (or sterilised) blade lowers the level of disinfection of the blade, causing it to be low-level disinfected, which for semi-critical devices is contraindicated and poses an increased risk of HAI.[15,16,22,24,25,42,43]

Inconsistent manufacturer reprocessing instructions

The reprocessing instructions provided by different manufacturers of rigid laryngoscopes were found during this review to vary in detail, scope and content from one manufacturer to another.[27–30] Some manufacturers recommend low-level or intermediate-level disinfection of rigid laryngoscopes, whereas others recommend high-level disinfection or sterilisation to prevent microbial transmission.[27–30] Adding to the confusion about the minimum requirements for reprocessing rigid laryngoscopes, these inconsistencies in manufacturers' instructions can result in variations in clinical practices and ineffective reprocessing, posing an increased risk of HAI (Table I).[24,33]

Variations in reprocessing practices

Having identified inconsistencies in published guidelines and manufacturers' instructions for reprocessing rigid laryngoscopes, it is not surprising that practices for reprocessing the blades and handles of rigid laryngoscopes are also inconsistent and vary significantly from one healthcare facility to another, posing the potential for an increased risk

of HAI (Table I).[4–8,11–13,31,32] Some medical facilities steam sterilise the blades of rigid laryngoscopes after each use, while others may only clean them using detergent (no disinfection or sterilisation).[5] Moreover, many healthcare facilities do not have on file written policies and procedures for reprocessing either the handle or the blade.[4,5,7] In addition to varying from one healthcare facility to another, reprocessing practices for rigid laryngoscopes may vary significantly within the same facility.[4–8,31,32] A medical facility's central processing department, for example, may steam sterilise laryngoscope blades, while its operating room or respiratory departments may instead only wash the blades with detergent (no disinfection or sterilisation). Variations in clinical practices are problematic and can result in ineffective reprocessing, inconsistent standards of patient care, disease transmission, and HAI.[33]

Class 1 devices

Virtually all types of semi-critical instruments are Class 2 devices requiring their manufacturers to satisfy all of the FDA's 510(k) requirements, because of the inherent risk of microbial transmission associated with their use. In general, the reprocessing instructions of reusable Class 2 devices are critically reviewed by the FDA to ensure adequacy, completeness, and, to some degree, consistency from one manufacturer to another. Rigid laryngoscopes, however, are Class 1 devices exempt from the FDA's premarket notification requirements. As a consequence, their reprocessing instructions may not necessarily be reviewed by the FDA prior to their sale in the U.S., which might explain, in part, why the reprocessing instructions provided by different manufacturers of rigid laryngoscopes, like some of the published guidelines for the reprocessing of their handles and blades, are incomplete, inadequate, and inconsistent. The extent to which the classification of rigid laryngoscopes as Class 1 devices may pose an increased risk for microbial transmission is unclear (Table I).

Is the risk of healthcare-acquired infection associated with rigid laryngoscopes underestimated?

While uncommon, healthcare-acquired outbreaks with associated morbidity and mortality caused by inadequate reprocessing of contaminated rigid laryngoscopes have been published.[9–15] Whether microbial transmission due to inadequate reprocessing of a rigid laryngoscope occurs more frequently than reported, but is 'masked' and often not identified, is unclear. Endoscopy-related infections are rare, often difficult to identify, and usually present themselves as outbreaks, rather than as isolated infections.[44] Several factors that may contribute to underestimating the risk of HAI associated with inadequately reprocessed rigid laryngoscopes include a dearth of well-designed studies that prospectively monitor patients for HAIs following the procedure; the long incubation periods associated with infections caused by some types of pathogens that may be encounted during rigid laryngoscopy; and HAIs that may be transient and quickly resolve themselves, or that may be subclinical or asymptomatic.[44]

Sterile disposable sheaths

FDA-cleared sterile disposable sheaths may be used to cover instruments and minimise the risk of contamination during the procedure.[5,45–50] Concerns have been expressed, however, that these sheaths might sometimes provide a false level of protection and safety.[5,18,24,45–47] Not only might the sheath be defective, or break or tear during the procedure, but there is also concern that the rigid laryngoscope could become contaminated by soiled hands or gloves either before or after removal of the sheath.[18,45–50] While there is no doubt that rigid laryngoscopes (and other types of semi-critical instruments) require reprocessing after the sheath's removal, the degree, extent or level of reprocessing required to prevent microbial transmission is controversial.[18,24,45] Some guidelines and reports recommend intermediate-level disinfection of the rigid laryngoscope after removal of the sheath, provided the effectiveness of the sheath has been adequately demonstrated.[18,45,49] This recommendation is inconsistent with Spaulding's medical-device classification scheme, however (which requires high-level disinfection or sterilization of semi-critical devices).[24,25,43] Furthermore, it cannot be known for sure whether the sheath broke during the procedure or the instrument was contaminated during placement or removal of the sheath.

Unlike high-level disinfection and sterilisation, intermediate-level (and low-level) disinfection cannot assure destruction of every type of clinically relevant micro-organism associated with disease in the healthcare setting, such as the spore-former *Clostridium difficile* and other potentially infectious agents including *Mycobacterium tuberculosis* and both hepatitis B (HBV) and C (HCV) viruses.[16,22,24,25,43,45,51,52] Some guidelines recommend wiping the instrument with 70% isopropyl alcohol after removal of the sheath;[18,29,45,49] however, this practice may not provide the requisite

contact time to achieve intermediate-level disinfection, defined to completely destroy *M. tuberculosis* and all less-resistant infectious agents including HCV.[22,25,43,51,52] Studies suggest that complete immersion of the instrument in, as opposed to wiping it with, 70% isopropyl alcohol for ≥5 min may be necessary to achieve intermediate-level disinfection.[51,52] In addition, guidelines require that only FDA-cleared high-level disinfectants or sterilants be used to reprocess semi-critical instruments.[22,52] The use of 70% isopropyl alcohol to disinfect a rigid laryngoscope would, therefore, be contraindicated, because not only would it pose an increased infection risk, but also there are no marketed solutions of 70% isopropyl alcohol cleared by the FDA as a high-level disinfectant or sterilant.

For these reasons, high-level disinfection (or sterilization) of the rigid laryngoscope's blade and handle is recommended after each use, regardless of whether a sheath is used.[1,2,4,16,24,25,43,53] This recommendation, which may warrant revision if new data become available demonstrating the safety and effectiveness of sheathed technologies, is in accordance with the recommendations of the American Institute of Ultrasound in Medicine, which requires high-level disinfection (or sterilisation) of endocavitary ultrasound probes after removal of the sheath;[48] the Association for Professionals in Infection Control and Epidemiology, which recommends high-level disinfection of vaginal probes used in sonographic scanning after removal of the sheath;[50] and Centers for Disease Control and Prevention guidelines, which recommend the cleaning and heat sterilisation, or high-level disinfection, of barrier-protected semi-critical instruments.[53] Only if the instrument cannot 'tolerate' these rigorous procedures would the use of an FDA-cleared sheath be necessary, followed after its removal by cleaning and intermediate-level disinfection.[18,24,32,53]

Conclusion

Although HAIs linked to inadequate reprocessing of rigid laryngoscopes are infrequently reported, a recent outbreak in a NICU caused by inadequate reprocessing of rigid laryngoscopes indicates that disease transmission during rigid laryngoscopy remains a current concern.[9–13] Guidelines that provide

Table II Eight myths about rigid laryngoscope reprocessing

Myth 1.	The reprocessing of rigid laryngoscopes is not critical to the prevention of disease transmission. Fact: Contaminated rigid laryngoscopes have recently been identified as the source of an outbreak of *P. aeruginosa*, demonstrating that inadequate reprocessing of rigid laryngoscopes remains a current public health concern.[13–15]
Myth 2.	Intermediate-level disinfection of a rigid laryngoscope is safe and effective. Fact: Intermediate-level disinfection cannot ensure destruction of all relevant infectious agents such as *C. difficile* and therefore is contraindicated for semi-critical instruments including rigid laryngoscopes.
Myth 3.	Wiping an instrument's surfaces with 70% isopropyl alcohol achieves intermediate-level disinfection. Fact: This practice does not necessarily achieve intermediate-level disinfection. Complete immersion of an instrument in 70% alcohol for ≥5 min may be necessary to achieve intermediate-level disinfection.[51,52] (Solutions of 70% isopropyl alcohol cannot be used to achieve high-level disinfection.)
Myth 4.	Rigid laryngoscopes covered by a sheath do not require reprocessing after use. Fact: The blade and handle of a rigid laryngoscope require high-level disinfection (or sterilisation) after each use, regardless of whether a sheath is used (refer to main article).
Myth 5.	A limited number of rigid laryngoscope blades and handles in inventory does not pose an infection risk. Fact: An inadequate number of rigid laryngoscopes in inventory can interfere with the meticulous reprocessing of their blades and handles and increase the risk of HAI.
Myth 6.	Rigid laryngoscopes are Class 2 devices subject to FDA premarket notification requirements. Fact: Rigid laryngoscopes are Class 1 devices exempt from FDA 510(k) requirements.
Myth 7.	Guidelines for reprocessing rigid laryngoscopes are all the same. Fact: Not true. Whereas one organisation may recommend low-level disinfection of rigid laryngoscopes, another organisation may require instead that it be high-level disinfected (or sterilised) after each use.[21,24,26]
Myth 8.	Reprocessing instructions provided by different manufacturers of rigid laryngoscopes are all the same. Fact: Reprocessing instructions provided by different manufacturers of rigid laryngoscopes vary in the detail, scope and content from one manufacturer to another.[27–30]

HAI, healthcare-acquired infection; FDA, Food and Drug Administration.

consistent and evidence-based recommendations are important to minimise confusion and prevent disease transmission. Nevertheless, this review found that published guidelines, manufacturers' instructions, and clinical practices for reprocessing rigid laryngoscopes may be inconsistent, inadequate and incomplete, causing confusion about the minimum reprocessing requirements for their blades and handles and the potential for an increased risk of HAI (Table I). Rigid laryngoscopes are classified as semicritical devices, and studies demonstrating that the use of a disposable sheath reduces the risk of HAI during rigid laryngoscopy are lacking. Publication of a consensus statement that recommends cleaning followed by high-level disinfection (at a minimum) and drying of the blades and handles of rigid laryngoscopes, therefore, is recommended, regardless of whether a disposable protective sheath is used.[1,2,4,16,24,25,43,53] (The use of a sheath to further minimise the risk of contamination may well be advantageous.[53]) Table II provides eight 'myths' and 'facts' that dispel misconceptions about the reprocessing of rigid laryngoscopes. In particular, concern about guidelines that recommend low-level or intermediate-level disinfection (instead of high-level disinfection or sterilization) of the rigid laryngoscope's blade or handle is expressed (see 'myth 2', Table II). Caution is also advised regarding wiping the rigid laryngoscope's blade or handle with 70% alcohol after removal of a sheath (see 'myth 3', Table II), because not only does it not achieve high-level disinfection, but this practice may not necessarily achieve intermediate-level disinfection. The reclassification of rigid laryngoscopes as Class 2 devices by the FDA is recommended (see 'myth 6', Table II). Finally, readers are encouraged to review additional recommendations that were previously published to prevent HAI during rigid and flexible laryngoscopy, bronchoscopy and gastrointestinal endoscopy that were previously published.[24,33,40,42,43,54,55]

Conflict of interest statement

The author is employed by Custom Ultrasonics, Inc., a manufacturer of flexible endoscopic reprocessing equipment and he is not financially associated with the reprocessing of rigid laryngoscopes.

Funding sources

Custom Ultrasonics, Inc. was the sole funding source for the research and writing of this review.

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