South African survey on disinfection techniques for the flexible nasopharyngoscope


Abstract
This random survey was to determine the flexible nasopharyngoscope disinfection practice employed by South African otolaryngologists and to establish whether a breach in the disinfection process exists. The study also aimed to identify organisms most likely to be transmitted via endoscopy and to propose a protocol for the disinfection of the flexible nasopharyngoscope.

A questionnaire regarding disinfection techniques used for the flexible nasopharyngoscope was sent to 90 otolaryngologists in South Africa. All provinces were equally represented in the survey.

Forty-five otolaryngologists out of a total of 90 participated in the study. Many of the otolaryngologists had no access to a flexible nasopharyngoscope and were therefore not included in the study. Fewer than 50 per cent of the 45 surgeons washed the instrument with soap/detergent and water after use. Only 42 per cent of surgeons used a FDA-approved disinfectant, 52 per cent of which immersed the scope for a shorter period than the recommended contact time. Of the 58 per cent using non-FDA-approved products, 33 per cent used only a 70 per cent Isopropyl alcohol wipe, without immersion of the scope in disinfectant solution. The remaining 25 per cent used non-FDA-approved disinfectants either by wiping or limited immersion of the scope. Of the 45 surgeons, 49 per cent used a different method of disinfection for high-risk patients.

Strict guidelines have been proposed for the disinfection of this semi-critical device by the Association of Professionals for Infection Control (APIC) and the Centers for Disease Control (CDC). These guidelines are currently not being followed by many South African otolaryngologists. There is therefore a real risk of transmitting infectious diseases, especially tuberculosis, via endoscopy.

Key words: Disinfection; Endoscopes; Tuberculosis

Introduction
An increasing number of Otorhinolaryngologists use the flexible nasopharyngoscope in the consulting room. Its use has become so routine that a risk exists for a breach in the disinfection technique, in particular in a busy ENT service. Disinfection of the instrument varies in terms of immersion techniques, while others make use of an automated endoscope reprocessor (AER) or simply an alcohol swab.

The flexible scope is classified as a semi-critical device since it comes into contact with mucous membranes in the nasal passages, nasopharynx, oropharynx and the larynx. High-level disinfection with an FDA-approved high-level disinfectant solution for a recommended exposure time, is required for all semi-critical devices.

Some microorganisms are easily killed by simply using soap and water, while others are very hard to kill even with disinfectant solutions. If the contact time or dilution of the disinfectant solution is incorrect, there is a real risk of transmitting infectious diseases from one patient to the next. South Africa is burdened by one of the worst tuberculosis epidemics in the world, with an estimated incidence in the year 2000 of 528 cases per 100 000 population. This disease rate is more than sixty times higher than in developed countries. It is estimated that 60 per cent of tuberculosis cases in South Africa are also human immunodeficiency virus (HIV) positive. According to World Health Organization statistics for the year ended 2001, there are an estimated five million South Africans living with HIV. Adherence to strict disinfection protocols is therefore essential.

Materials and methods
A random, anonymous survey of the disinfection protocols used by South African otolaryngologists...
was done. The surgeons were chosen at random. There are currently 173 private ENT surgeons in South Africa. Questionnaires were sent to 90 surgeons and 45 completed their questionnaires. Many of the 90 surgeons were disqualified from the study because they had no access to a flexible nasopharyngoscope. All provinces and major centres in the country were well represented. The survey was mainly based on city hospitals for there are no full-time otolaryngologists in the rural areas. Patients from the rural areas were referred to the city hospitals.

A questionnaire, which consisted of structured questions, was sent via telefax to determine the following: the number of times the scope was used per day, washing of the instrument after use, immersion or wiping of the scope with a disinfectant solution, duration of immersion, the method of drying and storage of the scope. The otolaryngologists were also asked whether there was any change in protocol for high risk patients, e.g. those with HIV or tuberculosis. The data obtained from the 45 completed questionnaires was analyzed to determine the average number of times the flexible nasopharyngoscope was used per day and to determine what percentage of surgeons failed to adhere to the recommended disinfection protocols.

Results

Forty-five completed questionnaires were returned. On average the scope was used five times per day with values ranging between one and 16 times per day.

Cleaning of the instrument

Eighteen (40 per cent) of the surgeons cleaned the scope with soap/detergent and water. The remainder used either an alcohol swab to wipe the instrument or placed it directly into the disinfectant solution.

Disinfection protocols

Only 42 per cent of ENT surgeons immersed the scope in a FDA-approved high-level disinfectant solution (mostly >2.4 per cent glutaraldehyde products), but 52 per cent of these surgeons soaked the instrument for less than the approved contact time of 20 minutes. The duration of immersion of the scope varied from 30 seconds to one hour for all disinfectants used (FDA and non-FDA approved substances) with a mean of 19 minutes.

Twenty-five per cent (11/45) of surgeons used non-FDA approved high-level disinfectants (hypochlorite solutions, quaternary ammonium compounds and alcohols). Thirty-three per cent of surgeons used only a 70 per cent isopropyl alcohol swab to disinfect the scope. None of the surgeons used an automated endoscope reprocessor.

High-risk patients

Forty-nine per cent of surgeons (22/45) adapted their disinfection protocol for high-risk patients (known/ suspected HIV positive; Hepatitis B; tuberculosis). The scope would either be soaked (if only wiped before) in disinfectant solution or immersed for a longer period of time.

Storage of flexible scope

Scopes were stored in the original casing in 47 per cent (21/45) at the end of the day. Eight per cent of surgeons soak the instrument in a disinfectant solution overnight. The remaining surgeons hang the instrument vertically to air-dry.

Discussion

Fibre-optic endoscopy is used to diagnose disease previously difficult to assess by indirect methods. The field continues to grow and flexible scopes are used by gastroenterologists, urologists, cardiologists, respiratory physicians and otolaryngologists. New problems have arisen with the routine use of the instrument in the busy out-patient and consulting room settings.

A number of cases of flexible endoscope-related transmission have been reported. Mycobacteria have been most frequently implicated. Transmission of Mycobacterium tuberculosis by flexible bronchoscopy was reported by two centres in 1997.\(^6\) The time intervals between scoping infected and non-infected patients were two and 17 days respectively. There were multiple breakdowns in the disinfection procedures, including inadequate cleaning, insufficient immersion in glutaraldehyde and incorrect drying of the scope. Numerous other reports of transmission during endoscopy (flexible bronchoscopy) have been documented.\(^7\)

Colonies of organisms form biofilms when bacteria attach to a surface. These biofilms interfere with disinfection and are difficult to break down especially when located on the internal channels of endoscopes.\(^8\) Mechanical cleaning is important to remove such biofilms. Mechanical cleaning reduces the level of microbial contamination and removes foreign material from the scope prior to the disinfection process. Foreign material can interfere with the disinfection process in two ways: A chemical reaction can occur between the organic material and the disinfectant, and it may protect microorganisms by forming a physical barrier.\(^8\) Mechanical cleaning is thus essential prior to disinfection.

Simply using soap and water easily kills some organisms, while others are very hard to kill, even with disinfectants. The lipid or medium-sized viruses (Herpes simplex, Hepatitis B, HIV) are most easily killed, followed by the vegetative bacteria, fungi, non-lipid and small viruses. Mycobacteria and bacterial spores are most resistant to disinfection. Bacterial spores are inactivated only by employing sterilization methods.\(^1,9\)

Because the flexible scope comes into direct contact with mucous membranes, the flexible nasopharyngoscope is classified as a semi-critical device.\(^1,9\) High-level disinfection, and not sterilization, is therefore necessary to kill all microorganisms.\(^9\) For high-level disinfection, a
FDA-approved disinfectant solution should be used with the recommended FDA-approved contact time. The contact time for glutaraldehyde products can vary from 20 to 90 minutes depending on the concentration, active ingredients and temperature of disinfectant used. Some 3.4 per cent glutaraldehyde solutions require a contact time of 20 minutes at 25°C for high-level disinfection, whereas the 2.5 per cent solution requires a contact time of 90 minutes at 25°C. It is therefore essential to be aware of the type, concentration and optimal temperature of the solution. Glutaraldehyde solutions are only sporicidal once they are ‘activated’ (made alkaline with sodium bicarbonate) to a pH of 7.5–8.5. This process reduces their shelf-life to 14 days. Although glutaraldehyde concentrations of >2 per cent kill vegetative bacteria in less than two minutes, data suggests that 20 minutes at room temperature is the minimum exposure time needed to reliably kill organisms resistant to disinfectants, such as M. tuberculosis. Glutaraldehyde solutions are non-corrosive and do not damage the plastic, rubber or lenses of the flexible scope, but exposure can lead to dermatitis, irritation of mucous membranes and pulmonary symptoms. The scope should therefore be adequately rinsed with water before insertion into the nose to prevent mucosal irritation. Healthcare workers need to be protected from the glutaraldehyde vapours by working in well-ventilated rooms, using tight-fitting lids on immersion baths, and using gloves and goggles.

Because glutaraldehyde solutions have numerous side-effects, some centres are now using 0.55 per cent ortho-phthalaldehyde. It is non-irritating to the eyes and nasal passages and does not require activation or exposure monitoring. It also has only a 12-minute high-level disinfectant claim.

Many surgeons in our survey were under the false impression that ‘Cidex’ was one product, namely glutaraldehyde, and that they were therefore correctly disinfecting their flexible scopes. There are, however, four different ‘Cidex’ products on the market. They are all FDA-approved but their concentrations differ and therefore immersion times differ. Cidex®OPA is 0.55 per cent ortho-phthalaldehyde, whereas all the other products range from 2.4–3.4 per cent glutaraldehyde solutions with contact times ranging from 20 to 90 minutes.

Products that are not FDA-cleared and contraindicated for disinfection of the flexible nasopharyngoscope include the following: alcohols, iodophors, hypochlorite solutions, quaternary ammonium compounds and phenolics. The use of these products should be discouraged because of lack of proven efficacy against all microorganisms and incompatibility with the flexible scope materials.

In our survey, 33 per cent of otolaryngologists used only a 70 per cent isopropyl alcohol wipe to disinfect the scope. A study done by Banfield and Hinton revealed that 23 per cent of ENT outpatient departments in the United Kingdom also used this method.

Alcohol damages the rubber of the scope and can cause damage to the shellac mounting of the lens. Because the alcohol evaporates rapidly, exposure time is very limited. Smith noted that 95 per cent ethanol killed the tubercle bacilli in sputum or water suspension within 15 seconds. A contact time of more than 10 seconds is necessary to kill vegetative organisms. The exact time required for 70 per cent isopropanol is unknown, but mucin-loop tests which have been designed for the purpose of producing long survival times, have demonstrated a period of five minutes for complete destruction of the bacilli. The investigators have however cautioned that this time cannot be extrapolated to surgical material.

It is important to dry the flexible scope in order to prevent microbial growth or transmission in a moist environment. Rinsing all channels with 70 per cent alcohol and hanging the scope vertically facilitates drying.

Endoscopes should not be stored in a way that can lead to recontamination of the instrument. Flexible nasopharyngoscopes must not be stored in foam-lined cases because the foam lining is impossible to clean should it become contaminated.

Our study revealed that some otolaryngologists adapt their disinfection techniques for high-risk patients. This practice is indefensible, as many patients have subclinical HIV, tuberculosis and Hepatitis B, and all patients should be considered to be harbouring occult disease. Furthermore, if correct disinfection techniques are routinely employed, there should be no need to adapt the protocol for high-risk patients.

The APIC have released definite guidelines for infection prevention and control in flexible endoscopy. The flexible nasopharyngoscope is a semicritical device and should be disinfected in exactly the same way as the flexible bronchoscope.

The APIC guidelines suggest a five-step process for the disinfection of this instrument:

1. Mechanical cleaning of all surfaces;
2. Immersion in FDA-approved high-level disinfectant with adherence to stipulated immersion times;
3. Rinse flexible scope, preferably with sterile water;
4. Rinse all channels with alcohol before air-drying;
5. Store instrument in a way to prevent recontamination.

Conclusion

This study has demonstrated a serious breach in disinfection protocols of flexible nasopharyngoscopes by South African otolaryngologists, similar to that reported by Banfield and Hinton in the United Kingdom. Particularly in a country with a very high prevalence of HIV and tuberculosis, it is essential to safeguard our patients against these transmissible infections by stringently adhering to,
and enforcing, the APIC guidelines. Flexible endoscopes that cannot withstand the processes described in the APIC guidelines because of age, design, or damage should not be used.

References

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Dr D. E. Lubbe takes responsibility for the integrity of the content of the paper.
Competing interests: None declared