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Guidelines for Reprocessing Non-Lumened, Heat-Sensitive ENT Endoscopes

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Additional information is available at the end of the chapter

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Abstract

Endoscopes have become an indispensable instrument in the ENT department, but their use has introduced potential health risks such as the infection transmission.

Numerous guidelines have been issued for both digestive and respiratory endoscopes, while to date specific references to ENT endoscopes do not exist. The diagnostic ENT endoscope does not generally have an operative channel, it is shorter, thinner and has a much more frequent usage. As a consequence the guidelines for digestive or respiratory endoscopes are not always functional for the ENT department.

This paper proposes: 1. to standardize the correct way to carry out the disinfection procedure of heat-sensitive non-lumened ENT endoscopes, 2. to guarantee the disinfection within a limited time frame, appropriate for an ENT out-patients department.

In the initial phase the critical areas encountered in ENT endoscopy were determined. This was followed by a research of the literature in order to identify existing guidelines for the reprocessing of endoscopes with a view to establishing a common disinfection procedure of non-lumened ENT endoscopes. Finally, the new methods of disinfection, developed specifically for the reprocessing of ENT endoscopes were examined and discussed.

Keywords: Heat-sensitive ENT endoscopes, Cleaning, Disinfection

1. Introduction

The introduction of the endoscopes into clinical practice has certainly improved the diagnosis and treatment of numerous pathologies, but has also brought the risk of transmission of infections.

In the Literature, [1] the incidence of infection appears to be 1 per every 1,800,000 endoscopic procedures performed (0.000056%).

Considering the high number of endoscopic procedures performed daily worldwide, the endoscopy-related infections are those most often associated with the medical device.

In nearly all of the infections transmitted, the problem is a defect in the cleaning and disinfection procedures, [2, 3, 4] in particular during

- the pre-washing step (12%),
- the washing/disinfection step (73%),
- drying and storage (12%).

Flexible endoscopes are heat-sensitive and therefore cannot be sterilised in an autoclave, but must be disinfected. [5]

In otorhinolaryngology, unlike digestive and respiratory endoscopy, to date, no specific guidelines yet exist. ENT diagnostic endoscopes do not have the operating channel, their size is smaller and their use is more frequent, including in outpatient situations.

Then, the guidelines used in digestive and respiratory endoscopy are not always functional in the ENT department, since they do not consider the dynamism and intensity of the work carried out there.

2. Objectives

This document proposes to

1. standardise the correct method of disinfection procedures for heat-sensitive, non-channelled ENT endoscopes,
2. reduce the risk of transmitting infections,
3. increase operator safety,
4. guarantee disinfection in fast times.

3. Methods

In the initial phase, we identified the main critical procedures within ENT endoscopy departments. Next, we researched the literature to find all the guidelines on reprocessing endoscopes.

Lastly, we discussed the new disinfection methods designed specifically for the reprocessing of ENT endoscopes.

In order to form a basis for the guidelines for the reprocessing of flexible ENT endoscopes, the working group decided to conduct a survey among the Italian ENT departments with the objective to gather information regarding the methodologies actually employed for the disinfection of heat-sensitive, non-lumened endoscopes. Two hundred and seventy two questionnaires were sent out to the ENT departments. The questionnaire was divided into six sections: the first dealt with general information, sections 2 to 5 considered the four principle reprocessing methods of flexible ENT endoscopes (automated, manual immersion, wipes and sheaths). The last section considered the storage of the endoscopes.

The information requested referred to the way the endoscope was reprocessed by each participant and an evaluation of the method in relation to the needs of the department.

4. Survey findings

The following general considerations emerged from the study:

- The average number of endoscopic visits per day was around 10 and the majority of the doctors referred to difficulties in performing more examinations due to the limited number of instruments and the time necessary for reprocessing.
- Reference to guidelines is made in just above 30% of cases, they are not always the same and generally refer to gastroendoscopes/bronchoscopes (Figure 1).

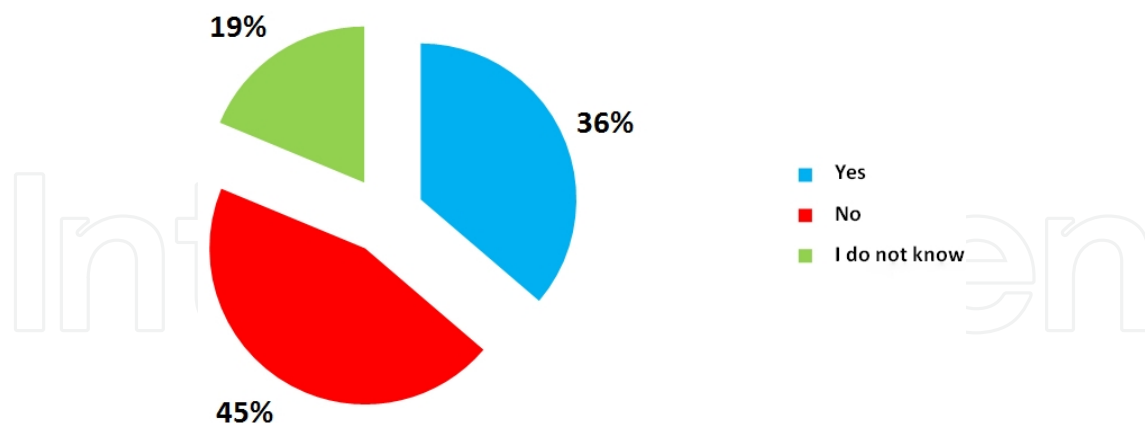


Figure 1. Dear Authors, Please add caption

- *Manual immersion is the principle method (about 70% of cases) for the disinfection of ENT endoscopes (Figure 2), followed by the sheath, which in 50% of cases is used in conjunction with other methods. The automated endoscope reprocessor (AER) is present in about 20% of the departments, but in over 60% of cases is used in conjunction with other systems, evidence maybe of the difficulties of habitual usage.*

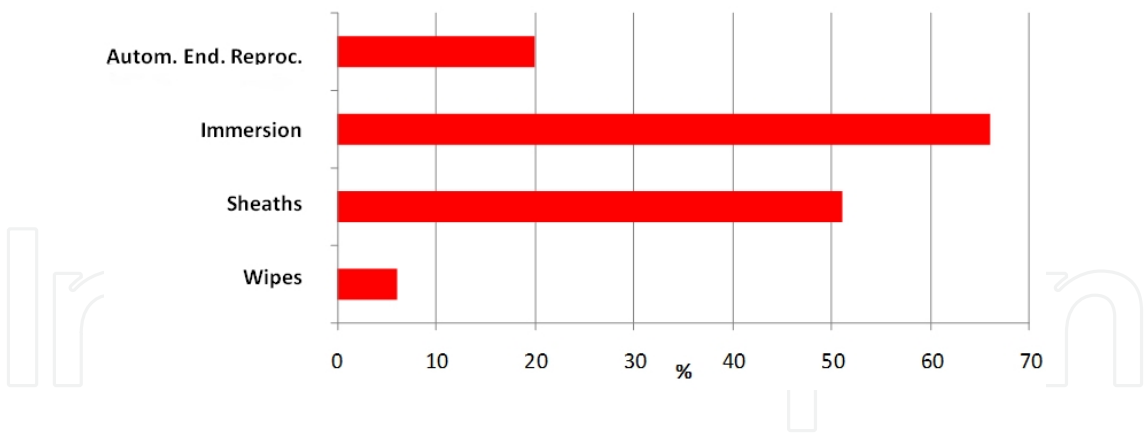


Figure 2. Dear Authors, Please add caption

a. Immersion

- Immersion is the most utilized method, both as a sole method and as a method used in conjunction with others. A basin or tray is mostly utilized for the immersion of the instrument.
- The leak test is performed in about 80% of cases.
- The enzymatic detergent is mostly used in the pre-cleaning step (about 50% of cases), while simple soap and water in about 20%. The time taken for pre-cleaning is normally less than 5 minutes, but can exceed 15.
- At least in 42% of cases the same detergent is re-used. It must be remembered that the detergent does not have any biocidal activity and so it is plausible that microbes can survive in the solution. As a consequence, a new solution should be used on each occasion.
- A wide variety of disinfectants are used for the disinfection step, mainly peracetic acid based, but also glutaraldehyde and orthophthalaldehyde are used (Figure 3).

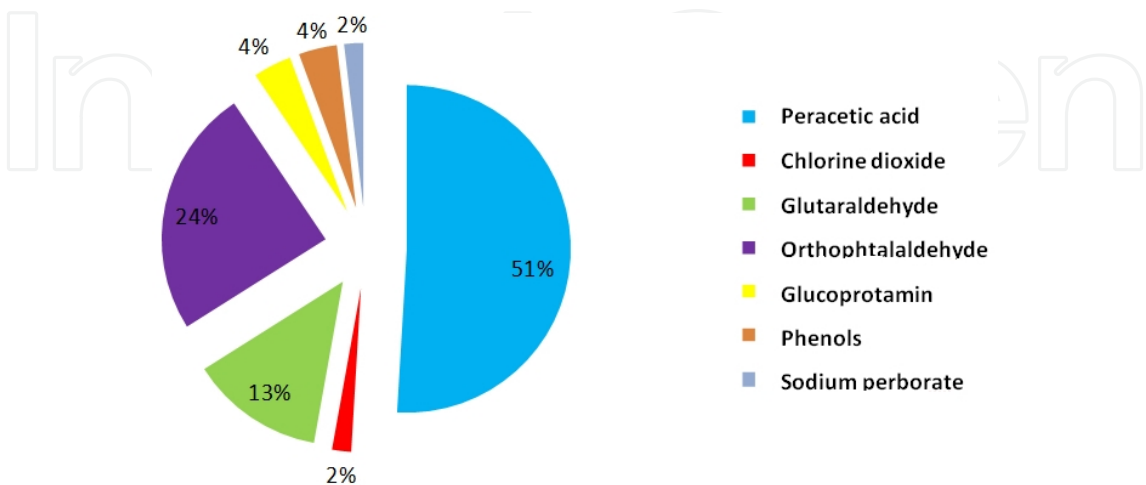


Figure 3. Dear Authors, Please add caption

- From an analysis of the disinfectants used, it was noted that not all the products have been tested according to current European norms (EN 14885) and that different contact times have been indicated for the same product. *It is therefore important to underline that even if the disinfectants have the same molecular base, the formulations may be different and consequently the way in which they are used can be different.*
- The majority of disinfectants are multi-use which makes it difficult to implement a traceability system.
- For 75% of cases, the rinse step is performed by using tap water and is completed in less than 5 minutes.
- *The use of a traceability system is practically impossible with a re-usable disinfectant, but 95% of the respondents would appreciate a registration system.*
- In the evaluation of the method employed, *the respondents highlighted the problems of traceability and personal protective equipment.*
- The sheath is used in more than 30% of cases after disinfection, mainly for patients with a perceived risk of infection.
- Microbiological controls of the instrument are performed in less than 20% of cases.

b. Sheaths

- About 30% of ENT departments use exclusively the sheath. *It is mainly used in conjunction with other reprocessing methods, primarily for cases where the instrument must be used on patients with a recognized risk of infection.*
- Respondents expressed a critical evaluation regarding:
 1. the less than optimal adherence of the sheath,
 2. possible damage to the instrument, particularly during removal (50% of respondents),
 3. possible tearing of the sheath (17% of cases),
 4. reduced image quality (70% of respondents),
 5. patient discomfort, particularly children.
- The main reason for using the sheath is for better instrument turnaround (Figure 4), which can mean less expenditure for instruments. Avoiding cross-contamination and chemical products and practical usage are other important motivations.
- The overall evaluation is positive, but some *perplexity remains, particularly regarding traceability and the cost/benefit relationship* (from the sample the average cost of the sheath is around €10, but it can cost up to €25).
- The literature regarding the use of the sheath is limited, but where it exists, it is clearly indicated that the instrument needs to be cleaned and disinfected with ethanol after the sheath is removed in order to be equivalent with high-level disinfection. From the replies this occurs in only 2% of cases.

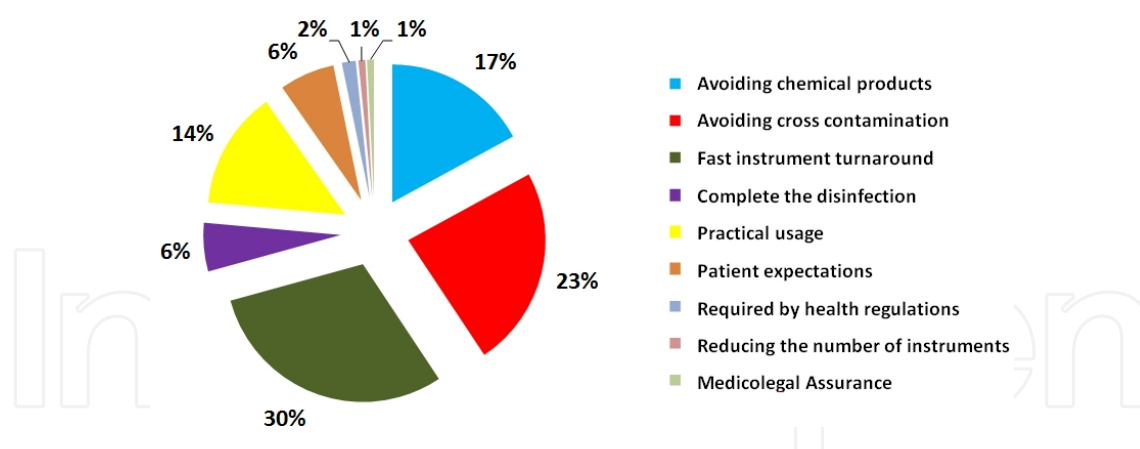


Figure 4. Dear Authors, Please add caption

- Microbiological controls are performed in 17% of cases and leak tests in 82%.

c. Automated endoscope reprocessors (AERs)

- In most cases, they are used in conjunction with sheaths (more than 50% of cases).
- In more than 33% of cases, the AER is not located in the department but in a central sterilization centre, affecting instrument rotation times.
- Cycle times vary between 20 and 30 minutes, which when added to the time for transporting endoscopes (when the endoscope is reprocessed outside the department) means that *the rotation time is about 1 hour in 70% of cases*.
- Pre-cleaning is mainly performed with an enzymatic detergent (75% of cases), but soap and water or only water are also used.
- The automatic reprocessors use mainly chemical disinfectants, notably single-use peracetic acid.
- The AERs can contain up to four instruments per cycle and in 75% of cases, both flexible and rigid scopes at the same time.
- Rinsing is normally performed while the instrument is automatically dried in only 50% of cases.
- The majority of AERs provide a confirmation print out for validation purposes, but the print outs are not always filed in a special record book.
- Microbiological controls are performed in 50% of cases, normally on a monthly basis and leak tests are nearly always performed.

d. Wipes

- They are used by less than 10% of respondents probably due to their recent introduction.
- The leak test is performed less often compared to other systems (60% of cases).

- The overall evaluation is favourable, both regarding the practicality and the traceability.
- For patients with a known risk of infection, normally the sheath is also used.

e. Storage

There are diversified methods of storing the instrument between one visit and another (Figure 5).

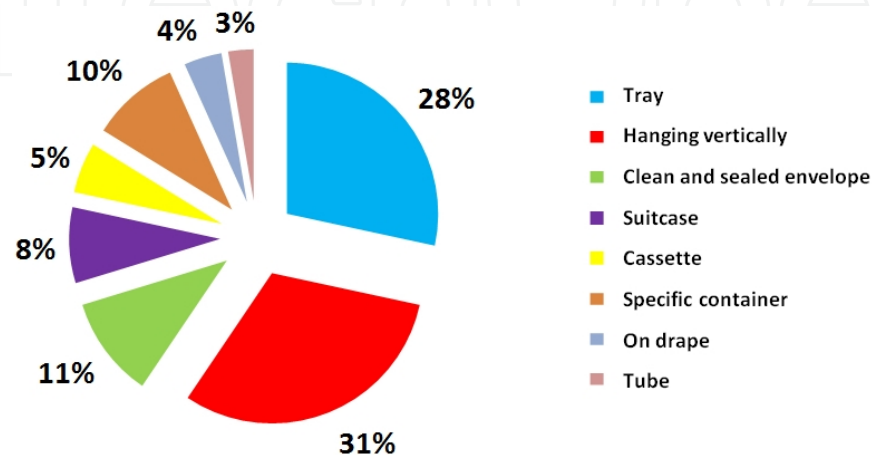


Figure 5. Dear Authors, Please add caption

It is worth noting that about 10% of respondents store the instrument in its case, which actually represents one of the main sources of contamination.

From the answers, it can be seen that over 50% of respondents believe the instrument can be contaminated during storage, but, despite this risk, the disinfection cycle is performed in only 33% of cases on instruments being taken out of storage.

5. Principle problems related to endoscope reprocessing

Schematically, the problems most frequently encountered with endoscope reprocessing are associated with [6]:

- environment,
- organization of endoscopic activity,
- personnel.

Problems associated with the environment:

1. the room or the disinfection area is not equipped with an extractor hood despite the use of certain disinfectants where it is specified,
2. the presence of a sharp smell due to the disinfectant solution,

3. insufficient space in relation to the volume of activity,
4. no distinct separation between dirty and clean work surfaces,
5. environmental cleaning can be of poor quality.

Problems associated with the organization of endoscopic activity:

1. excessive volumes of activity in relation to staff allocation and equipments available.
2. unplanned endoscopic examinations affect the organization of the programmed work.

Problems associated to personnel:

1. Insufficient number of nurses,
2. the personnel are not aware of the reprocessing procedures or, when they are available, they are not known or shared,
3. respect of safety precautions by the operators is not optimal,
4. specific training of the personnel involved is not always performed.

6. Principles of hygiene in the endoscopic procedures [7, 8]

Abiding to the basic principles of hygiene represents the foundation for the control of risks of infection associated with endoscopic procedures.

These basic principles must be applied to

- equipment and medical devices,
- environmental surfaces,
- health operator behaviour.

The equipment and medical devices are the principle vehicles for cross-infections in that they are continually contaminated by microbes originating from assistance to patients.

They must be carefully cleaned and subjected to a process of high-level disinfection (or sterilization in the case of devices which can be placed in the autoclave) according to the indications of the manufacturer.

The environmental surfaces are likewise a vehicle for cross-infections in that they are continuously contaminated not only by environmental microbes but also by those originating from assistance to patients. The objective of the cleaning and disinfection of the surfaces is to ensure a low-level bacterial count and interrupt the risk of transmission of pathogens. *Sanitization should be performed with water and detergent.*

Disinfection should be performed preferably with chlorine-based disinfectants to ensure the destruction of the more resistant microbes.

The area where the disinfection of the endoscope takes place should be distinct from where the endoscopic examination is performed. A separate and specific room is “highly preferable”; but in the reality of the ENT department, unlike others such as gastroenterology, it is possible that the reprocessing of the endoscope is carried out in the same room as the patient’s examination. It is necessary therefore *to highlight the need to ensure a clear division between contaminated areas (where the used instruments are placed) and clean areas (from where the reprocessed instruments are picked up)* so that the used instruments are completely separate from the reprocessed ones, avoiding risks of cross-contamination.

The *wash basins* should be of adequate dimension to allow the complete immersion of the instruments, without causing damage, preferably in steel (ceramic basins can be the cause of damage due to knocks to the terminal part of the instrument).

The necessity or not to install an extractor hood should be evaluated in function of the room and the equipment installed. It is absolutely necessary and essential if chemical products are used in open containers. Automatic systems which incorporate a device for the handling of vapours do not necessarily require the hood.

Where the room is not naturally ventilated, an *air ventilation system* needs to be installed (supply and extraction) in order to reduce to a minimum the exposition of everybody to the potentially harmful vapours (e.g. glutaraldehyde). In Italy, the limit of 10 air changes per hour is considered acceptable.

Operator behaviour is critical for the prevention of cross-infections. *Fundamentally, the principle that all patients are potential carriers of infections should be considered.*

Standard precautions

- should be applied by all health operators for all patients who receive assistance, irrespective of the diagnosis or the presumed state of infection,
- have the objective protecting health personnel and patients,
- should be based on the following healthcare practices:
 1. washing of hands and use of gloves,
 2. use of face masks, eye protection, smocks.

Written procedures should be present in all working environments with clear indications of each stage of the process.

Personnel must be taught to apply the “standard precautions” published periodically by the C.D.C. (Control Diseases Center of Atlanta) for infection control and should know:

- the procedure for cleaning and disinfecting each device,
- the conduct to follow in case of an alarm or malfunctioning of equipment,
- the biological and chemical risks which can be incurred during the disinfection procedure and how they should be encountered.

The responsibility of the disinfection procedure for endoscopes is attributed both to the nursing staff and to the doctor using the instrument. [5]:

- *the nurse and healthcare operator* are responsible for performing decontamination, pre-cleaning and disinfection of the equipment,
- *the head nurse of the operating unit* is responsible for verifying that the procedure is carried out correctly,
- *the doctor* using the instrument must visibly check that the instrument has been reprocessed before performing the examination,
- *the head consultant of the operating unit* is responsible for overseeing organizational aspects.

Endoscopes are very delicate instruments and therefore should be handled only by trained operators authorized to use and disinfect them.

The ENT operating unit together with the infection control unit should organize courses to train how to use and disinfect the endoscopes correctly and should keep an up to date list of all authorized personnel.

7. Risk of infection in endoscopy

The sources of infection are represented by infected or colonized patients [9] and by environment [10], in particular, the water used to rinse the endoscopes. Where possible, rinsing in sterile water is recommended. Differently, rinsing in high-quality drinking water is also acceptable using a bacteria-retentive filtering system (0.2 μ).

An observational study [11] conducted at 26 hospitals in the United States revealed that the endoscopes and bronchoscopes can be improperly disinfected due to inappropriate disinfectant solution, lack of control of the disinfectant's concentration, failure to clean all the parts of the endoscope and failure to measure manual disinfection times.

The *degree of risk* is classified as

- low when there is contact with healthy skin,
- intermediate when there is contact with the mucous membranes or superficially damaged skin,
- high for penetration into tissue or sterile cavities or into the vascular system.

The degree of risk determines the reprocessing level of the instrument used: *the risk of infection of the ENT endoscopes* (entering into contact with mucous membranes or damaged skin) *is intermediate and the high-level disinfection is then required.* [12, 7, 8]

High-level disinfection presumes the inactivation of all the bacteria, mycobacteria, fungi and viruses, but not necessarily of all bacterial spores. In ENT this is sufficient to have a guarantee regarding the transmission of pathogenic microorganisms for both the doctor and the patient.

7.1. High-level disinfection of endoscopes: traditional and emerging methods [13– 14]

We have categorized disinfection systems into two types:

1. *Traditional:*

- *Immersion:* the operator manually performs all the steps of the disinfection,
- *Automatic:* the disinfection is handled automatically without manual intervention,

2. *Emerging,* methods designed specifically for the ENT department:

3. *Complete reprocessing using wipes,*

4. *Immersion systems electronically controlled by a microprocessor:* part of the process is handled by the operator and part occurs automatically,

5. *Sterile protective sheaths:* constitute a protective barrier of the endoscope and not a system of disinfection.

The steps to reprocess endoscopes common to all traditional disinfection systems are described in Table 1. We must first emphasize the following points:

1. *reprocess the endoscope immediately after use* to prevent the formation of encrustations and consequent damage to the instrument.
2. *the entire endoscope must be cleaned and disinfected:* to be avoided are the wall tubes fitted in cui only the insertion tube of the instrument is placed, preventing contact between the control head and the disinfectant.

After analysing the reference literature, the authors suggest the following recommendations divided according to the type of disinfection system (Table 2).

In the following, we provide in detail the main considerations and evaluations for each system presented.

8. Traditional systems

1. Manual disinfection system by immersion

The manual procedure is relatively inexpensive but has the following disadvantages:

- errors or forgetfulness,
- lack of traceability,
- risk of contact between operators and contaminated material,
- damage to the instruments,
- disinfection times of at least 20 minutes.

2. Automatic disinfection systems

While until very recently only automatic systems for gastroscopies and bronchoscopies were available, today several companies realized washer-endoscopes for non-channelled ENT endoscopes.

The automatic systems can

- automatically cleanse, disinfect and dry,
- perform only the disinfection step.

These systems are composed of

- a tub for the disinfectant and one for the cleaning solution,
- a basin with a cover for the positioning of the endoscope. Washer-disinfector-endoscopes normally can reprocess several endoscopes simultaneously,
- a panel for setting the washing cycle (in general, the time and the temperature of the washing and disinfection sequences).

The disinfectant is transferred from the tub to the basin containing the endoscope and remains here for the time indicated on the technical sheet. This is followed by rinsing and the endoscope is ready for re-use.

In order to reduce the risk of contaminations, the washer-disinfector-endoscopes are usually equipped with thermal auto-disinfection systems.

It is advisable to position washer-disinfector in well-ventilated areas separated from those in which occurs the endoscopic examination.

When buying a washer-disinfector-endoscope, one should pay attention to the following aspects:

- automatic loading of cleanser and disinfectant,
- capacity to reprocess more than one endoscope simultaneously,
- programmability,
- the possibility of performing a complete cycle of cleansing, disinfection and rinsing,
- cycle time,
- the type of disinfectants for which the system is certified and their cost per cycle,
- the possibility of performing auto-disinfection/auto-sterilization,
- the presence of visual and sound alarms,
- required space,
- registration of procedures performed, an aspect strongly advised today because of medical-legal lawsuits. In general, the data that is recorded and/or printed are
 - identification number of the instrument;

- details of the operator;
- operating parameters relating to procedures;
- date and time of the procedure.

The automatic procedures therefore

- standardizes the process, reducing the possibility of errors,
- allows the immersion of the entire endoscope,
- makes it possible to “track” the procedures by printing a receipt after every disinfection cycle,
- reduces the risk of contact between operators or environment and contaminated instruments,
- reduces the risk of damage to endoscopes.

The main disadvantages are

- the cost of equipment and maintenance expenses; *some companies have product-specific washer-disinfector-endoscopes for ENT, smaller and less expensive* (Figure 6),



Figure 6. Dear Authors, Please add caption

- the possibility of recontamination of the endoscopes by the same washer-disinfector,
- time required for the disinfection process (in general at least 20 minutes).

9. Emerging systems

9.1. Manual disinfection system with wipes

The disinfection system by means of wipes is a manual sporicidal disinfection treatment of semi-critical, non-channelled and heat-sensitive endoscopes.

The active ingredient used is chlorine dioxide (ClO_2), patented under the name “Tristel”.

The Tristel Wipe System consists of a wipe for the pre-disinfection cleaning step, a wipe for the disinfection process and one for the post-disinfection rinsing step. The mechanical wiping action increases the efficacy of the cleaning and disinfection. The wipes are single-use and thus permit tracking of the procedures.

Treatment time is only 2–3 minutes allowing a notable reduction in disinfection times compared with other disinfectants in immersion methods. The Tristel Wipe System was in fact designed for the rapid turnaround of the ENT endoscope.

In addition, the wipes are non-toxic and non-irritating, thus allowing manual wiping technique not possible with the other traditional high-level disinfectants.

This simple system, however, is manual and can lead to different results between the various operators: accurate training is necessary to ensure that all operators are capable of optimal performance.

9.2. Immersion disinfection system electronically controlled by a micro-processor

This is a high-level disinfection system of the endoscopes by immersion controlled electronically. *The time necessary for disinfection is 5 minutes*, but the overall treatment time depends on the cleaning and rinsing method used, respectively, before and at the end of disinfection.

The system (Figure 7) consists of a base unit with a cover in which the instrument is placed, after cleaning, and to which is added the high-level disinfectant, ClO_2 -based [15, 16].



Figure 7. Dear Authors, Please add caption

At the end of the disinfection cycle, the disinfectant is automatically emptied out in the sink and the instrument is rinsed manually.

At the end of the treatment, the base unit can be used as an aseptic container for short-term storage and/or for transport of the endoscope. The base unit and the cover are made of polycarbonate resin and can tolerate up to 30 autoclave cycles.

The micro-processor records every disinfection cycle and the recorded data can be downloaded on to the PC and archived, making it possible *to track the entire process*.

Placing the instrument in the empty unit and removing it only when the disinfectant is emptied out *avoids any skin contact with the disinfectant*.

Furthermore, the system is easily transportable because no connection to the electrical network is necessary; the only installation requirement is its positioning close to a sink in order to empty out the used disinfectant.

The immersion system with electronic control, by means of the micro-processor, ensures adequate contact time with the disinfectant and potentially damaging chemical overexposure, in addition to the ability to track the entire procedure.

9.3. Sterile protective sheaths

This is an endoscope encasing system that can represent an alternative to the high-level disinfection of endoscopes (Figure 8).



Figure 8. Dear Authors, Please add caption

Various studies [17, 18] have demonstrated *the necessity to clean the entire endoscope with an enzymatic cleanser, followed by a disinfectant with 70% ethanol, immediately after the removal of the sheath*, in order to guarantee the equivalent of a high-level disinfection. In fact, it was seen that small viruses are capable of penetrating the sheath.

From our investigation conducted at ENT departments in Italy in 2010, we have seen that the practice of cleaning and disinfecting is done in only 2% of cases after removal of the encasing.

The advantage of this system is *the speed*.

The *disadvantages* are represented by:

- an increase of the diameter of the endoscope with the subsequent discomfort for the patient,
- the possibility of contamination of the control head unprotected,
- the risk of breakage of the sheath during the exam [19],
- the possibility of damage to the endoscope when removing the sheath,
- vision is not optimal,
- costs: endoscopes of various brands moreover require specific sheaths and their cost ranges from 8 to 25 euros.

To remember:

- The choice of disinfection systems should be made in agreement between the head of the operating unit, the hospital pharmacy, the hospital infection control committee and the indications of the endoscope manufacturer.
- Endoscopes which cannot be fully immersed should be substituted.
- Instruments should be reprocessed immediately after use because if allowed to dry for a long period, the residues can become encrusted and even damage the instrument.
- If the endoscope is immersed for too long a period, the outer casing and the seals can be damaged.
- The endoscopic examination should be avoided for patients with suspected Creutzfeldt-Jakob disease (prions are resistant to all forms of conventional sterilization). When the endoscope is considered really necessary, a dedicated endoscope should be used, maybe single-use, or else an instrument which is reaching the end of its life cycle. After use, the endoscope must be put in quarantine until definitive confirmation of the pathology.

10. Disinfection of endoscopes contaminated by HVB, HVC, HIV or mycobacterium [20, 21]

At the time of writing, there have been no reports of the transmission of viruses by means of bronchoscopes, while cases of the transmission of HBV and HBC by means of gastroendoscopes inadequately reprocessed have been reported.

The majority of viruses, including HVB, HVC and HIV, are quickly neutralized with disinfection solutions. The major risks of virus transmission reside in the unsuccessful removal of

biological residues during the manual pre-clean, which allows the virus to avoid contact with the disinfectant.

Mycobacterium are responsible for an elevated percentage of contamination incidents referred to in the literature. All cases of tuberculosis have been attributed to the failed observance of infection control procedures.

Although some authors have sustained the need for longer disinfection times for endoscopes after use in patients affected by mycobacterium, this strategy is not required if infection control guidelines are carefully followed. Numerous studies have, for example, demonstrated that immersion for 20 minutes in a basic 2% solution of glutaraldehyde at 20°C, after an adequate pre-clean, significantly reduces the bacterial count of *M. Tuberculosis*.

11. Disinfection of endoscopes contaminated by prions [22– 23]

Prions are responsible for transmissible spongiform encephalopathy (TSE), capable of provoking degenerative diseases to the central nervous system in animals and man.

The most frequent disease from prions is Creutzfeldt Jakob Disease (CJD); other forms include variant Creutzfeldt Jakob Disease (vCJD), Gertsmann Straussler Scheinker syndrome (GSS), Fatal Familial (FFI), insomnia and Kuru.

Prions are resistant to common disinfectant substances. The tissues at high risk of infection include the brain, the dura mater, the spinal cord and the eyes, while tissues at low risk include cerebrospinal fluid, liver, lymph nodes, kidneys, lungs and spleen.

There have been no indications of cases of CJD attributable to devices contaminated with blood. Recognized cases of CJD as iatrogenic have been attributed to contaminated medical devices such as cerebral electrodes, cerebral neurosurgical instruments, dura mater grafts, corneal grafts, gonadotropins and human growth hormones.

From an analysis of the literature, it can be deduced that endoscopes (apart from those used in neurosurgery) are devices which do not normally come into contact with tissues at risk of TSE and consequently, even when used during diagnostic procedures on high-risk patients, standard reprocessing protocols are adequate.

The primary and principle preventive measure, however, in the case of high-risk patients, is to limit endoscopic examinations exclusively to when necessary. If the examination is effectively necessary, it is advisable to designate one endoscope for such patients also for the future.

In the case of an endoscopic examination which envisages contact with high and low risk tissues in a probably or certainly infected patient, the WHO guidelines indicate special treatments (sodium hydroxide, sodium hypochlorite, phenol, sterilization in autoclave) which are not compatible with endoscopes.

Seeing that the most common disinfectants used for endoscopes are not efficacious and considering the high cost of the instrument, some authors suggest covering the endoscope with a plastic sheath as a partial protection which can be eliminated after use as a special waste.

The ENT endoscopic procedures can, however, be managed without any special precautions due to the fact that the tissues with which there is contact are not considered infectious. For these patients, the standard protocols of pre-cleaning and high-level disinfection are adequate.

12. Biological controls

The monitoring infections resulting from endoscopic procedures cannot be an indicator of the efficacy of disinfection since infections are rarely linked to the execution of the endoscopic exam performed.

Moreover, the culture methods currently in use have not been rigorously validated, with the danger of underestimating or overestimating results, consequently causing potential harm to patients and health facilities. [24]

In the absence of adequate scientific evidence, the APIC (Association for Professionals in Infection Control and Epidemiology) and the CDC (Centres for Disease Control and Prevention) do not recommend routine microbiological tests and advise them *only in cases of epidemics*.

13. Tracking systems [5]

In every endoscopy unit, it is desirable to have a registration system in which the following information would need to be recorded for each procedure:

- examination number,
- patient generality,
- doctors and nurses generality,
- type of procedures,
- time,
- endoscope identification number,
- type of disinfection carried out.

The nursing coordinator of the unit should maintain

- documentation relating to installation, testing and maintenance of the washer-disinfector-endoscope machines (up to 5 years following the end of service),
- user's manuals for all the equipment,

- registration of biological controls carried out on the washer-disinfector-endoscope machines and on the endoscopes (at least 5 years),
- a copy of the print-out issued by the washer-disinfector-endoscopes, certifying the disinfection cycle (at least 5 years).

14. Disinfectants for the reprocessing of heat-sensitive, non-lumened ENT endoscopes

The survey findings indicated that peracetic acid and orthophthalaldehyde are the high-level disinfectants most commonly used for endoscopes. Chlorine dioxide is a disinfectant which is being increasingly used over the past few years.

Often, it is possible to find different disinfection solutions used for the same type of endoscope in the same hospital, and the use of a disinfectant as opposed to another is dependent on the operating unit.

Before examining the principle disinfectants, it is necessary to consider the following points regarding choice and usage [25, 26]:

1. Disinfectants must be registered at the Health Ministry and the technical bulletin should clearly indicate
 - how to use,
 - concentrations,
 - contact times,
 - temperature,
 - pH.
2. Choose the disinfectant which is compatible with the endoscope in accordance with the indications of the instrument manufacturer.
3. The choice of solutions should be made in agreement with the pharmacy, health management and the heads of the operating units involved.
4. The disinfectants in use must be managed and stored in such a way as to avoid contamination (for example, containers handled with dirty hands and gloves, partial closure of packaging, etc).
5. When the disinfectant is re-usable, it is necessary
 - to test the minimum effective concentration (MEC) at the beginning of the day. Results should be documented and the solution discarded when inferior to MEC,

- discard the disinfection solution at the end of the indicated usage period irrespective of the MEC. In cases where the disinfectant is added to AERs, the determination of the expiry date should be based on the original preparation date.

Monographs of the most commonly used disinfectant solutions are reported below *according to the information supplied by the manufacturers and the data from scientific literature.*

14.1. Glutaraldehyde (e.g. Cidex, Asep, Glutaster basica, Sporex) [27, 28]

Active ingredient

Glutaraldehyde or glutaric aldehyde in aqueous solution has a colourless or verging on yellow clear appearance and a pungent odour. The most common usage is a 2% *alkaline* solution.

Characteristics

Glutaraldehyde is mainly commercialized in an acid form which is stable for long periods when stored in cool conditions and in tightly closed container (up to 5 years).

Before use, glutaraldehyde must be “activated” by adding a buffer and surfactant in order to obtain a pH of 7.5–8.5. The activator (e.g. bicarbonate) is supplied separately and is used to obtain a working solution *stable for 14 days*. This period of validity refers to the activated solution in its original bottle, while the period of reusability should be considered in function of the concentration level, generally not less than 1.5% (the concentration diminishes in time and in function of the number of disinfections).

Mode of action

Glutaraldehyde is also defined as glutaric dialdehyde because it is endowed with two aldehydic groups (CHO), positioned at the extremes of the molecule, which are the real source of biocidal action; they are directly involved in the alkylation of sulphide, carboxylic, amino and hydroxyl groups of the proteins of the microorganism, causing an irreversible alteration of the protein synthesis and the nucleic acids.

Glutaraldehyde is not deactivated significantly by organic material even though its presence renders the disinfection less effective due to the fixative capability of glutaraldehyde, which creates a protective covering that prevents the destruction of the microbial cells. It is recognized in fact that glutaraldehyde is not efficacious against biofilm.

Spectrum of activity

The spectrum of activity of glutaraldehyde is almost complete but the contact times vary notably according to conditions, e.g. a 2% solution in laboratory has been demonstrated to be active in

- 1–2 minutes against bacteria in vegetative form (e.g. *Staphylococcus aureus*, including the penicillin, *Pseudomonas aeruginosa*, *Escherichia coli*),
- 5–10 minutes against viruses (e.g. *Poliovirus* Type 1, *Coxsackie B1*, *ECHO 6*, *Rotavirus*, *HAV*, *HBV*, *HCV*, *HTLV-III/LAV*),

- 10 minutes against yeasts, fungi and moulds (e.g. *Trichophyton interdigitalis*, *Microsporum gypseum*, *Candida albicans*, *Aspergillus niger*),
- 20 minutes against *Mycobacterium tuberculosis* whereas the activity is slower against other types of mycobacterium (at least 60 minutes) due to the lipidic component in the cellular wall which makes them almost impermeable. The contact time can be reduced by using a 3–4% solution and/or increasing the temperature to 25°C,
- 3 hours against spores. Concentrations less than 2% do not offer guarantees of being sporicidal, even with an increase in the contact time.

Material compatibility

Glutaraldehyde is not corrosive to metals and does not present particular problems for rubber, plastic, glass and optical fibres. It is necessary, however, to take precautions:

- objects in carbon steel should not remain in contact with the solution for more than 24 hours.
- it is necessary to avoid contact between different metals during immersion (danger of causing an electrolytic reaction, capable of corroding instruments).

Toxicity/precautions

Glutaraldehyde is a toxic, irritant and sensitizing substance and can cause, in the case of inadequate rinsing, rhinoconjunctivitis, asthma, diarrhoea and abdominal cramp.

The main risk of glutaraldehyde toxicity is run by the staff who have to handle it, because:

- frequent contact with the skin can cause dermatitis and a persistent yellow or brown colouring of the skin,
- contact with the eyes can cause reddening of the conjunctiva or grievous damage to the cornea.
- irritation to the conjunctiva with burning, lachrymation and reddening,
- damage to the respiratory system with bronchitis, dyspnoea, bronchial asthma,
- damage to the central nervous system with headache, depression,
- ingestion can cause from moderate to marked irritation to the mouth, throat, oesophagus and stomach, pains in the chest and abdomen, nausea, vomiting, diarrhoea, dizziness, drowsiness, shock.

The product did not result to be carcinogenic, for inhalation, on laboratory animals after continued exposure.

The literature reports TLV/TVA¹ values from 0.2 to 0.05 ppm.

For these reasons *the use of glutaraldehyde must*

¹ Threshold limit value-time weighted average: average concentration of a chemical agent weighted on an exposure level of 8 hours and for 40 hours per week, to which operators may be exposed without adverse effects for their health being apparent.

1. *Envisage the use of adequate personal protective equipment:*
 - protective eyewear,
 - authorized ventilators with filters for organic vapours, only in the presence of elevated vapours,
 - protective smock,
 - butyl or nitrile gloves or a double pair of latex gloves.
2. *Envisage use in a ventilated environment, in closed containers and in the presence of adequate extraction systems.*
3. *Envisage staff training for correct usage and relative information regarding toxicity.*

In the case of exposure, the first aid measures depend on the affected site:

- Contact with eyes: wash with plenty of water for at least 10 minutes. Remove contact lenses if possible to do easily. Visit the optician.
- Skin contact: remove contaminated clothes and wash with soap and water the affected parts of the skin. Consult a doctor if irritation persists.
- Ingestion: the product can cause ulceration and inflammation of the upper digestive system; it is preferable, therefore, not to cause vomiting but to resort to a cautious gastric lavage.
- Inhalation: transfer the person to a ventilated area. Artificial respiration may be necessary.

The use of glutaraldehyde as a high-level disinfectant is in constant decline, not particularly for reasons of efficacy, but rather for reasons linked to staff health and safety issues. It is worth noting that this chemical solution can no longer be used in British hospitals.

Disposal

The starting concentration of glutaraldehyde (2%) is possibly harmful. The concentration level, however, diminishes progressively due to re-use, evaporation and progressive dilutions.

According to Italian legislation, which has adopted European norms, disposal of the exhausted solution to sink is permitted, considering the high levels of dilution by water used daily for patient care. The sink must, however, be in a well-ventilated environment and disposal should be followed by running water to accelerate the discharge. Attention must be taken disposing large quantities directly into the sewers due to possible damage to the purification system through the inhibition of bacterial activity.

Indications for use

2% glutaraldehyde is indicated for the high-level disinfection of endoscopes and semi-critical medical devices with a contact time of not less than 20 minutes at a temperature of 20°C or more.

A contact time of 1 hour is advisable for bronchoscopes due to the slower mycobacterial activity. A satisfactory sporicidal activity is achieved after 3 hours.

After studying glutaraldehyde residues in plastic and rubber, after immersion in 2% glutaraldehyde, it was concluded that a 2 minute rinse is sufficient to significantly reduce the quantity of the active ingredient absorbed in the exposed material, with the exception of natural rubbers for which a prolonged soak and rinse is recommended.

14.2. Orthophthalaldehyde (e.g. Cidex OPA, Opaster) [29– 30]

Active ingredient

An aromatic dialdehyde in commerce for a few years also in Italy, generally used at a concentration of 0.55% in an aqueous solution, with a lowly accentuated odour and blue colour. It is stable at 15–30°C for 2 years.

Characteristics

Unlike glutaraldehyde, orthophthalaldehyde (OPA) is ready to use and does not require activation. Once opened, the unused solution can be stored in the original bottle for up to 2 months while the solution poured into the disinfection tray can be used for no more than 14 days, providing that the concentration level is superior to the MEC (at least 0.3%) indicated by special test stripes. After 14 days the product must be disposed, even if the concentration is still superior to the MEC.

Mode of action

In the case of bacteria, OPA provokes the formation of crossed bonds between the cytoplasmic membrane lipoproteins with a subsequent cementation effect on the external layer of the cell and limitation of the exchanges. The periplasmic enzymes are also deactivated with consequent rapid death of the cell.

In the case of fungi and yeasts, the main interaction site is the chitin, principle component of the cellular wall, as well as the superficial enzymes present in the cellular membrane. As with glutaraldehyde, OPA is not effective against biofilm.

Spectrum of activity

OPA is capable of performing a rapid disinfection action in just 5 minutes at room temperature (20°C) on the majority of tested microorganisms, with the exception of spores for which higher concentrations and contact times (1% for 10–12 hours or 0.55% for 24 hours) are required.

Specifically, in laboratory, it is effective in:

- 5 minutes against bacteria in vegetative form (e.g. *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *Enterococcus*, *Escherichia coli*).
- 5 minutes against viruses (*Adenovirus*, *Coxsackie virus*, *Citomegalovirus*, *Herpes simplex*, *HIV-1*, *Human Coronavirus*, *Influenza Type A*, *Poliovirus*, *Rhinovirus*),
- 5 minutes against yeasts, fungi and moulds (*Candida albicans*, *Aspergillus niger* and *Trichophyton mentagrophytes*),
- 5 minutes against *Mycobacterium bovis*, *M. avium*, *M. terrae*, *M. smegmatis*,

- 10 hours against the spores *Clostridium difficile* and *Bacillus subtilis*.

Material compatibility

OPA has proved to be compatible with a wide range of materials commonly used in the production of re-usable medical devices (metal, plastic, elastomers and adhesives) and, in many cases, it was found to be less aggressive than glutaraldehyde. Endoscopic instruments have undergone tests and are considered to be compatible with the solution. For prolonged contact times (greater than 15 minutes), the substrates with which it comes into contact can be subjected to permanent discolouring.

Toxicity/precautions

OPA is a molecule less volatile than glutaraldehyde and its toxicity, considering the same target organs, is of minor relevance.

Exposure to OPA has different effects according to the type of contact:

- Ingestion can cause irritation to the pharynx, esophagus and stomach with nausea, vomiting and diarrhoea.
- Skin contact can cause temporary blotches and slight irritations mainly after prolonged exposure. Such symptoms usually disappear when exposure is terminated.
- Eye contact can cause marks, excessive lachrymation and conjunctivitis.
- Inhalation: OPA is not considered volatile and is not thought to carry risks for inhalation during normal use. Exposure to spray or particulate can provoke, however, bland irritation to respiratory tracts with coughing and sneezing.

This product does not result to be mutagenic, embryotoxic or teratogenic in humans. Its components are not considered carcinogenic.

Occupational exposure limits have not, however, been established.

As with glutaraldehyde, the use of OPA also must

1. *Envisage the use of adequate personal protective equipment:*
 - protective eyewear,
 - authorized ventilators with filters for organic vapours, only in the presence elevated vapour concentrations,
 - protective smock,
 - butyl or nitrile gloves or a double pair of latex gloves.
2. *Envisage use in a ventilated environment and in closed containers* (if these requisites are satisfied, extraction systems are not necessary).
3. *Envisage staff training for correct usage and relative information regarding toxicity.*

In case of exposure, the same first aid measures for glutaraldehyde are valid:

- Eye contact: wash with plenty of water for at least 10 minutes. Remove contact lenses if possible to do easily. Visit the optician.
- Skin contact: remove contaminated clothes and wash the affected parts with soap and water. Consult a doctor if irritation persists.
- Ingestion: the product can cause ulceration and inflammation of the upper digestive system if ingested; it is preferable, therefore, not to cause vomiting but to resort to a cautious gastric lavage.
- Inhalation: transfer the person to a ventilated area. Artificial respiration may be necessary.

Disposal

According to Italian legislation, as with glutaraldehyde, disposal of the exhausted solution to sink is permitted, taking into account the high levels of dilution by water used daily for patient care. The sink must, however, be in a well-ventilated environment and disposal should be followed by running water to accelerate the discharge. The disposal of large quantities directly into the sewers can, however, cause damage to the purification system through the inhibition of bacterial activity.

Indications for use

0.55% OPA is indicated for the high-level disinfection of endoscopes and semi-critical medical devices with a contact time of at least 5 minutes at a temperature of 25°C in an AER and 12 minutes at 20°C in a manual immersion system.

Rinsing for at least 1 minute with copious water is sufficient to remove all traces of the disinfectant.

14.3. Peracetic acid (e.g. Nu Cidex, Steris, Persafe, Gigasept, Adaspor, Oxydrox, Perax liquid, Steradrox, Anioxide, SP3) [31, 32]

Active ingredient

Peracetic acid solutions are colourless or slightly yellow aqueous solutions, with a pungent odour and pH of around 6, containing a mixture of hydrogen peroxide and acetic acid.

The peracetic acid solutions commonly used in the medical field are:

- diluted working solution from concentrates,
- working solutions prepared by automatic systems which control all variables (dilution, temperature, contact times and pH),
- prepared to a defined concentration (0.35%).

Characteristics

Peracetic acid is an unstable compound and therefore it is necessary to store the concentrated solutions in bottles, preferably in a cool environment. *The working solutions should be prepared*

and are valid from 1 hour to 12 days depending on the type of dilution, on the pre-cleaning procedure and on the minimum recommended concentration.

Mode of action

It has not been defined definitively; the activity seems to be linked to the strong oxidizing power both at the cellular membrane level of the microorganism (interruption of the chemiosmotic function) and inside the microbial cell (irreversible damage to the essential enzymatic system).

Being an oxidant, peracetic acid cleans and de-scales eventual deposits of the material.

Spectrum of activity

Peracetic acid is characterized by a rapid disinfection activity. A 0.35% solution in laboratory was seen to be effective in 10 minutes at room temperature against the following microorganisms:

- Bacteria in vegetative form (e.g. *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Enterococcus*, *Escherichia coli*).
- Viruses such as HCV, HIV, HBV, *Coronavirus*.
- Yeasts, fungi and moulds (*Candida albicans*, *Aspergillus niger*).
- Mycobacterium such as *Mycobacterium tuberculosis*, *M. avium*, *M. terrae*, *M. smegmatis*.
- Spores of *Clostridium sporogenes*, *Bacillus subtilis*, *Bacillus cereus*.

Material compatibility

The activated solution demonstrates good compatibility with materials commonly present in medical devices, particularly endoscopes and AERs. It can cause discolouring of the insertion tube.

Toxicity/precautions

The concentrated solutions (>0.35%) and the peracetic acid vapours in contact with the skin and the mucous membranes can cause irritation, sometimes even severe; for this reason, it is necessary to rinse carefully all disinfected medical devices and wear appropriate personal protective equipment during handling:

- mask for acid vapours in case of emergency,
- protective gloves (neoprene or heavy rubber),
- protective eyewear,
- complete protective clothing.

The 0.15% commercial solutions are neither corrosive nor irritants (only slightly for the eyes).

The literature indicates TLV/TVA² values of 10 ppm.

In case of exposure, the following are required:

- Eye contact: wash with plenty of water for at least 10 minutes. Remove contact lens if possible to do easily. Visit the optician.
- Skin contact: remove contaminated clothes and wash with soap and water the affected parts of the skin. Consult a doctor if irritation persists.
- Ingestion: the product can cause ulceration and inflammation of the upper digestive system if ingested; it is preferable, therefore, not to cause vomiting but to resort to a cautious gastric lavage.
- Inhalation: transfer the person to a ventilated area. Artificial respiration may be necessary.

Disposal

Peracetic acid is not harmful and does not pollute the environment because it breaks down into acetic acid, water and oxygen.

Indications for use

Cartridges containing 35% peracetic acid inserted into a specific AER obtain, in controlled conditions, a 0.2% solution and operate at around 55°C with a contact time of 12 minutes. This does not seem to be a particularly suitable system for flexible endoscope reprocessing due to the cost of each cycle.

The stabilized and buffered 0.35% solution has, according to studies, the same indications, being effective in 5 minutes against bacteria, fungi, virus and mycobacterium and 10 minutes against spores. It should be prepared as a working solution and is stable for 24 hours. It can be used for up to 20 cycles or up to a concentration of not less than 2500 ppm.

Even though the solution contains anti-corrosion inhibitors, it is not recommended for use in AERs which contain aluminium or copper. Tests have demonstrated variations in the plating of rigid endoscopes which contain such metals.

The technical bulletin for the 0.15% stabilized solution indicates a contact time of 10–15 minutes for high-level disinfection and 30 minutes for sporicidal action. This solution must also be activated and disposed of every 24 hours.

As confirmed by the study carried out among the ENT departments, there are a variety of products marketed under the name of peracetic acid. The usage and the contact times vary according to the product and consequently it is necessary, to carefully follow the instructions supplied by the manufacturer, as well as verifying the compatibility of the product with the instruments which need to be disinfected.

14.4. Chlorine dioxide (e.g. ClO₂ Tristel) [26, 35, 36]

Active ingredient

A molecule composed of one atom of chlorine and two atoms of oxygen (ClO₂). The biocidal power of ClO₂ has long been recognized for use in different industrial applications and for the

2 Threshold limit value-time weighted average: average concentration of a chemical agent weighted on an exposure level of 8 hours and for 40 hours per week, to which operators may be exposed without adverse effects for their health being apparent.

disinfection of drinking water. The particular characteristic of this disinfectant is its broad spectrum of activity in rapid contact times at low levels of concentration. Its oxidizing capacity is the equivalent of 2.5 times that of chlorine. It can be used in manual systems, electronically controlled manual systems and also automatic systems.

Characteristics

ClO₂ is an unstable gas, it cannot be transported and therefore *must be generated at the moment of use*. The patented Tristel method envisages generation by means of mixing a sodium chlorite solution with a mixture of organic acids, prevalently citric acid. The almost instantaneous reaction between the two precursors produces chlorous acid, which in turn dissociates to release a ClO₂ gas in solution for immediate use at a level of concentration suitable for the sporicidal disinfection of semi-critical medical devices. The concentration of ClO₂ (read by spectrophotometry immediately at the end of the activation time) in the wipes system is 175–225 ppm (approximately 0.02%) while the diluted liquid format for immersion is 50–60 ppm (0.005–0.006%).

Mode of action

ClO₂ reacts almost instantaneously with all types of microorganisms, creating an electron transfer to form a breach in the surface from which all vital constituents pour out of the microorganism with consequent destruction by lysis. The particular means of microbial destruction prevents bacteria, fungi and viruses developing resistance to the molecule and creating mutant strains.

Spectrum of activity

The ClO₂ activity in its different formulations has been tested microbiologically in laboratories according to the European norms EN 14885 to demonstrate its effectiveness.

It is effective in 30 seconds in the ready-to-use format and in 5 minutes in the diluted liquid format for immersion on the following microorganisms:

- Spores (e.g. *Bacillus subtilis* and *Clostridium difficile*),
- Mycobacterium (e.g. *M. tuberculosis*, *M. avium* e *M. terrae*),
- Viruses (e.g. HBV, HCV, HIV, Poliovirus Type 1, Adenovirus, Orthopoxvirus),
- Fungi (e.g. *Candida albicans*, *Aspergillus niger*),
- Bacteria (e.g. *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Enterococcus*).

Material compatibility

Instrument integrity is guaranteed when used with single-use ClO₂, providing the instructions are followed: *no damage has ever been noted from using the wipes system, neither after extensive laboratory testing nor after a decade of use in the field.*

Toxicity/precautions

The safety for people using ClO₂ has been confirmed by toxicological studies performed on both humans and animals. The results demonstrated that at the concentrations used there are no reactions or contraindications. It is however recommended to use gloves during handling.

Disposal

The solution of ClO₂ decomposes into a simple saline solution and consequently has no negative impact on the environment and does not entail additional disposal costs.

Indications for use

ClO₂ is indicated for the high-level disinfection of endoscopes and semi-critical medical devices. The formulation used in the wipes system is ready to use with a contact time of 30 seconds, while the diluted liquid formulation has a contact time of 5 minutes.

There is only one dilution with water at room temperature and pH adjustment is unnecessary.

14.5. Glucoprotamin (e.g. Sekusept Plus, Sekumatic) [36]

Active ingredient

Glucoprotamin is a substance with a wide spectrum of activity obtained from the reaction of glutamic acid and coco alkyl propylene diamine. Both precursors are natural compositions and therefore highly biodegradable.

Characteristics

A clear aqueous solution, yellow in colour, not volatile, which must be diluted in water from 1–4% without the necessity of additional activators. It is usable in both manual and automatic systems.

The solution is valid for 14 days.

Mode of action

Glucoprotamin operates by disrupting the cell membrane, by inhibiting the activity of the principle enzymes and denaturing the cell proteins.

Spectrum of activity

Glucoprotamin has a wide spectrum of activity against bacteria (including mycobacterium), yeast and fungi, enveloped viruses and partially effective against non-enveloped viruses. It acts specifically on the following microorganisms:

- Bacteria (tested on *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus*, *Micrococcus luteus*, *Enterococcus hirae*, *Gemella morbillorum*, *Corynebacterium* spp.),
- Mycobacterium (tested on *M. tuberculosis*, *M. avium* and *M. terrae*),
- Viruses (tested on HIV, HBV, HCV),
- Yeasts (tested on *Candida albicans*).

The contact time for bacteria is 5 minutes and 15 minutes for yeasts.

Material compatibility

The product has been tested and approved for use on Olympus and Storz endoscopes, Rusch anesthesia materials and Martin instruments.

Toxicity/precautions

Health risks: eye irritation.

The literature indicates TLV/TVA³ values of 500 ppm.

Respiratory tract protection: none, in normal usage conditions.

Hand protection: wear protective gloves in nitrilic or butylic rubber.

Eye protection: wear protective eyewear.

Skin protection: none, in normal usage conditions.

In case of exposure, the following first-aid measures should be adopted:

- Eye contact: wash with plenty of water for at least 10 minutes. Remove contact lens if possible to do easily. Visit the optician.
- Skin contact: remove contaminated clothes and wash with soap and water the affected parts of the skin. Consult a doctor if the irritation persists.
- Ingestion: the product can cause ulceration and inflammation of the upper digestive system if ingested; it is preferable, therefore, not to cause vomiting but to resort to a cautious gastric lavage.
- Inhalation: transfer the person to a ventilated area. Artificial respiration may be necessary.

Disposal

The discharge of the product into the water network is damaging to microflora, microfauna and aquatic organisms for a brief period.

According to Italian legislation, disposal of the exhausted solution to sink is permitted, considering the high levels of dilution by water used daily for patient care. The sink must, however, be in a well-ventilated environment and disposal should be followed by running water to accelerate the discharge.

Indications for use

Glucoprotamin is indicated for the high-level disinfection and simultaneous deteration of flexible endoscopes, anaesthesia materials and semi-critical medical devices.

³ Threshold limit value-time weighted average: average concentration of a chemical agent weighted on an exposure level of 8 hours and for 40 hours per week, to which operators may be exposed without adverse effects for their health being apparent.

Glucoprotamin has been taken into consideration because its usage in some ENT departments was found in the survey findings. Evaluation studies of its microbial efficacy currently available indicate a wider spectrum of activity than intermediate disinfectants, but its efficacy against spores, a fundamental requisite for a high-level disinfectant, is not documented. Further research is necessary in order to confirm its use for the reprocessing of endoscopes.

15. Conclusions

15.1. General norms

1. Every patient should be considered a potential source of infection and consequently, each examination and all reprocessing procedures must be performed with the same accuracy.
2. The responsibility of the disinfection process is attributed to the nursing staff and the doctor using the instrument.
3. The choice of disinfection systems should be made in agreement between the head of the operating unit, the hospital pharmacy and the hospital infection control committee.
4. Staff should wear personal protective equipment during the endoscopic procedure and in the various phases of reprocessing of the instrument.
5. Contaminated and clean areas should be distinctly divided.
6. Disinfection should be performed by adequately trained staff, whose competence is periodically checked.
7. Periodic microbiological controls are not advisable as an indicator of the disinfection process. In case of suspected contamination, endoscope, tap water and instruments used in the disinfection process should be microbiologically tested.
8. When there is a suspected or ascertained case of infection, consult the hospital infection control committee.

15.2. Reprocessing steps

1. After the endoscopic exam, a leak test and a visual check of the integrity of the instrument should be performed before reprocessing.
2. Endoscopes which cannot be completely immersed should be substituted.
3. Before using the pre-clean or disinfection solution, consult the technical bulletin and the safety data sheet: concentration levels, temperature, contact time should be respected in order to achieve an effective disinfection.
4. The thorough cleaning of the instrument (immediately after use) with a detergent solution in order to remove soil and organic material is fundamental for a successful disinfection.

5. The disinfectant should be registered with the Health Ministry and the registration includes the indication of how to use, the concentrations, contact time, temperature and pH.
6. In the case of the disinfectant being reusable, it is necessary to:
 - Test the MEC of the disinfectant at the beginning of each working day. The results should be documented and the solution should be disposed if the concentration is below the minimum required.
 - Dispose of the disinfection liquid at the end of the period indicated for use without taking into account the MEC.
7. Rinse the endoscope according to indications and dry before storing. The humidity increases the risk of infections.
8. Keep a register of the endoscope usage and of the management and disinfection of eventual AERs.

15.3. Disinfection systems

The ideal disinfection system should allow

- standardization of the process, to reduce the possibility of error,
- rapid turnaround of endoscopes,
- reduction of risks of operator contamination,
- reduction of risks of damage to endoscopes.

Advantages and disadvantages of the various disinfection systems are indicated so that everyone can choose the one most adaptable to their local situation (human and economic resources, available space, volume of activity, number of endoscopes).

1. Manual immersion systems do not require big investments but have the following disadvantages:
 - risks of errors or forgetfulness,
 - inadequate “traceability”,
 - risk of operator contamination,
 - risk of environmental contamination,
 - damage to endoscopes,
 - disinfection times of at least 20 minutes.
2. AERs:
 - standardized process which avoids errors or forgetfulness,

- allows “traceability” of the process,
- reduces possible operator contact with contaminated instruments,
- reduces the possibility of environmental contamination,
- reduces risk of damage to endoscopes.

Possible disadvantages:

- equipment and maintenance costs,
- adequate space for installation of equipment (often at a distance from the endoscopic room with consequent loss of time due to transport and the increased risk of damage to the instrument during transport),
- time required for the disinfection process (normally at least 20 minutes). Added to transport times, the endoscope may not be available before 1 hour.

Some manufacturers produce AERs specifically for ENT endoscopes, smaller than those used for gastroenterology, easier to locate and at lower cost.

3. The wipes system using ClO₂

- allows a rapid rotation of the instrument (less than 5 minutes),
- allows traceability because the wipes are single use.

Although easy to use, the system is manual and therefore requires careful and continuous staff training to ensure that the procedure is performed correctly.

4. Manual immersion system with microprocessor:

- guarantees the contact time and avoids over exposure to chemistry which can potentially damage the instrument,
- allows traceability,
- has lower purchase and maintenance costs compared to AERs.

The pre-clean step and the rinse step are both manual and therefore require care.

5. Sterile protective sheaths:

allow a rapid rotation of the instrument, but the correct usage envisages cleaning and disinfection after sheath removal.

Disadvantages include

- possible discomfort for the patient,
- optical part of the endoscope not protected against contamination,
- possible rupture of the sheath during patient visit,
- possible damage to the endoscope when removing the sheath,

- hampered visuals,
- cost.

The choice of the disinfection system is made in consultation with the Director of the Unit, the Pharmacy Service and the Infection Control Task.

The nursing staff as well as the doctor using the endoscope are responsible for the disinfection process and must be adequately trained.

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