Is automatic disinfection between each endoscopy mandatory ?

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Introduction

Endoscopy is a minimally invasive diagnostic and therapeutic procedure, which actually plays an essential role in the management of gastrointestinal disorders. Although its benefits far outweigh the complications, which may arise, case-reports and surveys performed over the last 25 years have confirmed that endoscopic procedures do occasionally cause cross-infection (1,2). The emergence of HIV infection, and more recently of hepatitis C virus (HCV) infection has highlighted the potential for disease transmission if suitable precautionary measures are not generally applied in digestive endoscopy practice. The risk for transmitting infections via these procedures depends essentially on three factors ; exposure of the endoscopes to microorganisms, cleaning and disinfection procedures. Contaminated equipment may cause infection in several ways : 1) by transmission of pathogenic organisms from patient-to-patient (e.g. *Salmonella* sp., *Clostridium difficile*, hepatitis B, HCV ...) ; 2) transmission of infection such as hepatitis B, HIV or HCV from patients to staff by needle-stick injury ; or 3) by the introduction of contaminating (opportunistic) organisms from the environment (e.g. *Pseudomonas aeruginosa* or some atypical mycobacteria (*M. chelonei, M. fortuitum*) from irrigating solutions, automatic washing devices ...) which may colonize endoscopic and ancillary equipment during cleaning, disinfection, rinsing procedures or on storage. Colonization of the endoscopes or auxiliary materials may subsequently cause focal sepsis or septicemia, depending on the inoculum size and intrinsic virulence characteristics of the microorganisms as well as on its resistance to the disinfection procedures applied. The susceptibility of the hosts also plays an important role and severe infections such as cholangitis, pancreatic sepsis and septicemia for examples are more likely to occur following endoscopic retrograde cholangio-pancreatography (ERCP) in immunocompromised patients (3,4). In an exhaustive meta-analysis reviewing 265 selected articles related to transmission of infection by gastrointestinal endoscopy between 1966 and 1992, Spach *et al.* (2) reported 281 infections caused by various microorganisms, the clinical spectrum of which ranged from asymptomatic colonization to death. The most common causative agents of infection were *Salmonella* species and *Ps. aeruginosa*. Despite the exhaustiveness of the authors in reviewing all the published literature data, one can easily assume that there is considerable underreporting, especially for some infections with longer incubation periods such as hepatitis B or C which may not be related to an earlier endoscopy, and also because most endoscopies are carried out in outpatient settings, often without having the possibility of following-up patients in the community.

Notwithstanding these considerations, the major reasons for transmission found in the studies reported were improper cleaning and/or disinfection techniques, the lack of standard guidelines or the failure to adhere to these. Other reasons for transmission of infection included the inability to decontaminate endoscopes, despite the use of standard disinfection techniques, because of their complex channel and valve systems or because of the contamination of the endoscopes by automatic washers.

Decontamination of endoscopes : basic principles

From the early 80's onwards until nowadays, several individual national endoscopy groups or international working parties have issued strict guidelines concerning the cleaning and disinfection practices of endoscopes in order to minimize the risk of infection following endoscopy (5-11). Basically, all these different guidelines are very similar from each other. In our country, similar recommendations have lately been issued by the Conseil Supérieur d'Hygiène (CSH) (7).

Thorough manual mechanical cleaning with water and a detergent immediately after endoscopy is one of the main requirement for the processing of all types of endoscopes and constitutes a prerequisite to subsequent disinfection or sterilization whatever the method used (2,7,8,10,11). The aim of this procedure is to remove many of the organisms as well as the blood and proteinaceaous secretions that may protect them and also prevent the penetration of disinfectant in the internal channels. Cleaning should thus include the external surface of the scope and its extremities, as well as meticulous flushing/brushing of all internal channels, valves and pistons. Mechanical cleaning is of paramount important in the decontamination process of the endoscopes since it has been shown to reduce the number of residual contaminating organisms to levels which are unlikely to cause infection (12,13). The second step

consists in rinsing and flushing all channels of the scope with tap or filtered water prior to disinfection in order to expel small organic particles, which could eventually lead to blockage. The disinfection step, which follows, is aimed to eliminate the risk of cross-infection by vegetative bacteria and viruses. Among the various chemical disinfectants that have been recommended, 2% activated glutaraldehyde is still considered as the preferred disinfectant product for this purpose in most countries (14,15). Numerous laboratory studies have shown that 2% glutaraldehyde was effective against most bacteria (including *Ps. aeruginosa, Salmonella* sp, *H. pylori* ...) fungi and viruses (including HIV, HBV, HCV, HAV, poliovirus or other enteroviruses ...) and could completely kill or reduce the infectious titers by 3 to 5 $\log_{10}$ (99.9% to 99.999% of the initial inoculum) in less than 5 minutes at room temperature (16-21).

Several public health and scientific authorities including the British Society for Gastroenterology and the Belgian CSH felt therefore that exposure of gastroscopes and colonoscopes to 2% glutaraldehyde for 10 minutes (between patient's sessions) at 20°C (room temperature) after thorough cleaning should be adequate (7,9).

However, the exposure time to the disinfectant may not only depend on its spectrum, potency and biocidal activity, but it may also vary according to the infection risk which may relate both to the procedure performed (e.g. insertion of the instrument through a contaminated site or in a normally sterile cavity), the immune status of the host (e.g. neutropenia, organ grafts, immunocompromised patients ...) or the knowledge or suspicion of a potentially transmittable disease in a patient (e.g. carrier of HBV, HIV infected patient ...). In such situations as well as at the end of the session higher-disinfection levels may be required and the disinfectant contact times of the scopes have to be extended up to 30 minutes.

Due to constant dilution of disinfectant by wet instruments, disinfectants should be changed regularly. Although the maximum shelf life of 2% glutaraldehyde is 14 days, several studies have indicated that its concentration rapidly declined to 1% or less after 20 cycles because of dilution with detergent (22,23). Thus, usage pattern and frequency seems more important than time in assessing when to renew the disinfectants.

Following disinfection, the instruments have to be rinsed both internally and externally preferably with sterile water, or if not feasible by tap water followed with an alcohol rinse, in order to remove all traces of disinfectants. The rinse water should not be reused after a decontamination cycle in order to avoid the transfer of disinfectant residues to the endoscopes, which may toxic for the patient or the endoscopy staff.

Finally, the endoscopes should be dried when not immediately reused by insufflating forced air through the channels. Thorough drying by aspiration of 70% alcohol through the channel is particularly important at the end of the session before storage in order to reduce the risk of subsequent microbial proliferation.

Accessories (e.g. water bottles, suction valves, biopsy forceps, dilators, guidewires ...) require the same attention to detail as the endoscope itself. These devices should be sterile whether reusable or not. They should be treated as high-risk items (i.e. items penetrating the mucous membranes or entering a sterile cavity) and cleaned and sterilized by autoclaving in the sterile services department. Immersion in glutaraldehyde may be required for heat-labile items, but ethylene oxide treatment is to be preferred to immersion in glutaraldehyde if available. Single-use items may be used when they cannot be cleaned of all foreign matter, or if they are cost-effective (24,25). A report of the BSG Working Party on the reuse of endoscopic accessories has recently been published (26).

Effectiveness of endoscope disinfection practices for preventing transmission of infection

As mentioned earlier, most of our knowledge concerning the effectiveness of the various disinfectants (selection of disinfectant, dilution-use, exposure time needed) for endoscope disinfection has been gained from empirical use or from laboratory experiments in which endoscopes were artificially contaminated with various concentrations of appropriate organisms (e.g. *Ps. aeruginosa, Ps. cepacia, H. pylori*, several viruses including HIV and HCV). Such tests have been widely used to evaluate the efficiency of manual or automated cleaning and disinfection procedures (17,18,19,20,21,27), or to compare the efficacy of different automated machines between each others (13,28) but they are rather artificial, and the contamination is usually easily removed (reduction of 10^5 or 10^6 organisms) whatever the cleaning/disinfection process used (manual or automatic). However, these tests have problems in reproducibility, are difficult to standardize and may thus not reflect the conditions observed in real practice (difference in infectious inoculum size, possible variations in contamination levels at different sites of the endoscopes, presence of organic secretions which may neutralize the disinfectant, ...).

More importantly, several authors did recently conduct prospective studies on endoscopes and on biopsy forceps to look for the presence of HCV or of *H. pylori* and to assess the efficacy of the usual disinfection procedures in eliminating these organisms (29-35). These studies showed that HCV RNA (29-33) or *H. pylori* DNA (34-36) were occasionally found especially in the operating channel of the scopes or on biopsy forceps using PCR testing immediately after gastroscopy, thereby confirming the existence of a small but yet definite risk for nosocomial transmission of these organisms through endoscopy. Nevertheless, the reassuring finding from all these studies was that the application of the conventional guidelines for cleaning

and disinfection proved in all cases effective in eliminating viable contaminating organisms found on the endoscopes whatever the disinfection procedure used (i.e. manual vs automated) (cf. infra).

Conversely, in most cases of nosocomial infections associated with gastrointestinal endoscopy (1,2) including the very rare documented cases of hepatitis C transmission (37), contamination was usually attributed to an inadequate procedure during the disinfection of the endoscopes or its accessories (reuse of the same biopsy forceps or polypectomy snares for different patients, inadequate mechanical cleaning or brushing, insufficient exposure time to disinfectant ...).

Automated disinfection of endoscopes

Since many years automated endoscope washer/disinfectors have been introduced on the market (13,28,38,39,40). Several machines of different design are available. Some of them are only designed for disinfection and complete irrigation of all channels, while others ensure a complete treatment cycle including washing, disinfection, rinsing and drying of the endoscopes. It is important to stress that these automated machines do not negate the need for manual cleaning of the insertion tube, suction/biopsy channel, instrument tips, and valve recesses prior to endoscope processing. Automated machines also differ among each other by the disinfection process : first generation machines use 2% alkaline glutaraldehyde at room temperature whereas the most recent automated disinfection machines combine chemical and thermic treatment by using glutaraldehyde, combination of several aldehydes or peracetic acid heated at 50 or 55°. These processes usually ensure a superior and more rapid bactericidal activity.

Based on the most salient literature data (7,9,12,38) the advantages of automated endoscope washers over manual disinfection can be summarized as follows :

— They offer a more reliable and reproducible decontamination procedure than manual processing (especially a better monitoring of the exposure time to disinfectant).

— They are more convenient for endoscopy staff and reduce the workload (especially in endoscopy units where patient throughput is high).

— They considerably reduce the likelihood of eye, skin or respiratory exposure to glutaraldehyde or other toxic, irritant and sensitizing disinfectants.

— Automated systems are prone for quality control (visual/audible signals to denote the end of a cycle or register a fault, stop of cycle in case of problem, visual cycle counter useful for indicating when the disinfectant or rinsing water requires changing, for planning preventive maintenance, hard data records of the decontamination cycles ...)

Although automated machines have many advantages, some problems remain as for example :

— Although automated machines have been shown to be more effective than manual disinfection for endoscope decontamination in microbiologic laboratory tests using endoscopes artificially seeded with defined concenctrations and types of microorganisms (27,38), clinical studies have failed to demonstrate such superiority. In one prospective randomized trial comparing manual and automated endoscope disinfection methods (50), 18% of 60 endoscopes were still contaminated after disinfection, but no significant differences in contamination rates were observed between automated and manually disinfected endoscopes.

— Manual mechanical cleaning (i.e. brushing and flushing of all accessible channels) is still required before automated processing.

— Regular maintenance is required to ensure that strainers and filters, pipeworks and tanks are free of debris, which may reduce the flow of fluid entering the immersion tray and irrigating the channels.

— There is a possibility of recontamination during the rinsing stage of the process, from the machine itself or from the water supply used for rinsing. Several infections or pseudo-infections mainly due to *Ps. aeruginosa*, other Gram-negative bacteria or some atypical mycobacteria have been reported due to design faults in some washing machines. As a consequence, the water used for final rinse should be of suitable quality (bacteria-free filtered water) and automated machines should be fitted with water treatment systems (water softeners, bacteriological filters, UV light, heat treatment ...) in order to prevent contamination with microorganisms and the formation of biofilm or limestone deposits.

— The use of automated machines may increase the vapor levels of glutaraldehyde in the atmosphere as disinfectant-laden air is displaced from the immersion tanks and storage reservoirs when fluids are pumped within the machine (need for exhaust ventilation or filter systems).

— Excessive dilution of the disinfectant leading to reduction in potency may occur after 20 or more cycles because of dilution with the detergent cleansing solution or rinse waste (13,22,23).

— The level of glutaraldehyde in rinsing water may progressively increase if the rinse water is reused (41). This may transfer toxic residues to the endoscope and cause irritation of the patient's mucosa (41,42). To reduce this problem, the rinse water should be changed after every cycle and the endoscope should be dried thoroughly before use.

— Limitation by the manufacturers of the type of endoscope that can be processed and selection of disinfectants that are compatible for use with some automated machines.

— The investment costs which should include not only the initial purchase costs, but also the costs per cycle taking into account the cost of the disinfectant products recommended by the manufacturer as well as the maintenance costs of the automated machine (water

treatment systems, maintenance of immersion tanks, reservoirs and pipeworks, periodical decontamination of the internal components ...)

Adherence to the recommended strategies for disinfection of endoscopes : the gaps between basic principles and actual practice

Several studies addressed the level of adherence to recommended guidelines for cleaning and disinfection of gastrointestinal endoscopes (43-48). In one survey performed in the late 1980's in 74 European endoscopy centres, 30% of the centres inadequately disinfected the endoscope after procedures in patients with upper gastrointestinal bleeding and unknown HIV or HBV status (43). For routine procedures in patients with unknown HIV or HBV status, 70% and 100% of centers did not adequately disinfect instruments after ERCP and upper endoscopy, respectively. Similar surveys performed in Australia and in the US reported that about only half the hospitals both cleaned and disinfected endoscopes satisfactorily (44,45). Directly observed errors included failure to time the period of disinfection, failure to flush and clean all channels, failure to immerse the endoscope, and use of inappropriate chemicals that are not considered as appropriate for endoscope disinfection. In another US study (46), the investigators showed that 78% of 26 centres surveyed failed to sterilize biopsy forceps, and they isolated at least 100 000 colonies of bacteria from 24% of the cultures taken from the internal channels of 71 endoscopes.

Additional and more recent studies have confirmed the lack of uniform compliance with recommended guidelines (47-49). For example, an audit of manual procedures for cleaning and disinfection of endoscopes performed in 1995 in 47 healthcare centres in the southwest of France revealed that all stages of the disinfection were respected in about 70% of cases (48). While disinfection between endoscopy sessions was carried out in 95% of all observations, cleaning was performed in only two-third of all cases. Notable improvement to be made mainly concerned : lumen irrigation/flushing of channels (performed in 80% of cases), respect of immersion time (44% immersed less than 10 minutes), sterilization of accessories (performed in less than 60% of cases) and respect of universal precautions concerning both patients and staff (precautions for patients with presumed infection, adequate protection of personnel (gloves, mask, goggles).

Need for quality control of endoscope disinfection practices and for infection control surveillance programs

An inquiry on the methods of surveillance and quality controls tests on the efficacy of endoscopy disinfection procedures was carried out by the GDEPIH/GOSPIZ (Belgian scientific society of hospital hygiene) in 1994 (47). Anonymous questionnaires were sent to infection control nurses or practitioners of the 208 acute Belgian hospitals. There were 112 nonvalidated answers (= 54% of respondents). At least some type of surveillance was said to be performed by 73% of the respondents. However, in most cases this seemed to be limited only to punctual investigations of suspected cases of nosocomial infections (in 54% of hospitals) or to periodic routine culture of endoscopes (in 40% of the hospitals).

Less than one third of all respondents reported having detected at least one case of bacterial contamination associated or not with nosocomial infection by culture of the endoscopes after disinfection within the past 5 years.

Only 5% of the hospital centres had a permanent infection control surveillance program. Also very distressing and emphasizing the need of improving quality control programs and of implementing audits was the observation that only 22% of the 112 respondents reported having written guidelines on cleaning and disinfection procedures of the endoscopes in their hospital endoscopy unit.

Conclusions

With the expected increase in the number of invasive endoscopic procedures and a greater awareness on patient and processing safety, it is highly expectable that more reliance will be placed in the future on automated systems for flexible gastrointestinal heat-labile endoscopes. Although their superiority over manual procedures for disinfection of endoscopes has not been (and will probably never) proven in the clinic, they probably increase patient safety by ensuring a more reliable and more reproducible decontamination procedure than manual processing. Another significant advantage of these devices over manual endoscope reprocessing is that they improve the protection of personnel by minimizing the risk of personal exposure to the liquid disinfectant and its vapors. Automated machines may also be convenient to endoscopy staff, particularly in endoscopy units with a high throughput of patients, because they decrease the workload.

Endoscopy staff should however be aware of the limitations and associated problems. In particular it should be well realized that the use of an automated machine does not negate the importance of manual cleaning/brushing, which remains an essential prerequisite of all forms of cleaning and disinfection (manual or automated). Owing to the number of different automated machines available on the market and the pitfalls associated with some of these, it is of utmost importance that independent evaluation and test report should be performed on site before considering the purchase of any machine.

Beyond the debate of the "pro" and "cons" of automated machines or of manual disinfection, it appears essential to stress again that the risk of noso-

comial infection transmitted through endoscopy can virtually be eliminated by strictly adhering to the recommended basic principles of endoscope cleaning and disinfection practice.

Whatever the disinfection procedure applied, it is of utmost importance to implement training of all endoscopy staff to all the different aspects of the endoscope disinfection practice.

In order to evaluate the gaps existing between recommended guidelines and the actual practice quality assurance programs and audits of endoscope cleaning-disinfection practices should be set up jointly by national endoscopy and hospital hygiene societies. Such actions would allow to determine the state-of-the-art and to suggest what measures should be taken to prevent infections in endoscopy.

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CONTRA : M. Etienne

Introduction

In medicine as in any other professional activity regulated by some working rules, the replacement of a well established practice by new "norms" must at least meets one essential criteria : the new technique must have proved its superiority over the old one. This principle is fundamental and important as soon as we want to impose this new working procedure to a large number of people (i.e. the gastroenterologists) whose practice is far from being standard (private offices, medical centers, majors hospitals). Nevertheless, concerning disinfection of flexible endoscopes, it is necessary to note that the so-called "automatic" methods have not shown any sort of bacteriological superiority over the proven manual procedures, as long as some basic rules are respected (cfr. infra). Moreover, there is no real "quality standards" for such disinfection equipments as each machine has its own characteristics which can be rather different from an internal bacteriological control standpoint.

The question about the validity of our current practice is far more important than this fake debate (manual vs. automated disinfection). No one has any doubt or will contest the fact that proper disinfection is a "must". But the legitimate question is to know whether or not the current methods are appropriate and how to improve them, if necessary. Even if many studies highlight — fortunately ! — the bacteriological efficacy of several washing machines (1), you can find many arguments in the literature pointing out that the scrupulous respect of the strict rules of manual disinfection is perfectly appropriate. For example, in 1995, Rey *et al.* (2) proved that proper cleaning/washing effectively eliminated viral particles from the endoscopes contaminated with the virus of hepatitis C (HCV). The study of Gaudin *et al.* (3) has recently fully confirmed these initials works : whereas RNA of HCV was indeed present in the biopsy channel in 80% of the cases after endoscopy and biopsies among infected patients, it has never been found after complete disinfection.

Therefore, it seems more fundamental to me to come back to the existing rules of manual disinfection rather than studying the sophisticated characteristics of the different disinfecting machines.

Manual disinfection

Without deeply investigating into what is done abroad (and which is nevertheless very similar to our practice), I would like to underline the well-documented work of the "Conseil Supéieur d'Hygiène", under the aegis of the "Ministères des Affaires Sociales et de la Santé Publique", that published early 1996 a brochure (4) enacting the rules of "good practice" in this area, a procedure recently confirmed by the European Society of Gastrointestinal Endoscopy (5). Unfortunately, these recommendations seem not to have been circulated widely enough and I therefore believe necessary to repeat the key principles. The flexible endoscopes disinfection procedure is made up of four main steps which are essential, indispensable and complementary. washing, intermediate rinsing, disinfection and final rinsing. *Washing* must be done immediately at the end of the endoscopic examination in order to prevent the secretions from drying and avoid the risk of appearance of biofilms. The 'scope must methodically be brushed as well as the valves and pistons which have obviously been removed. It is important to carefully irrigate the channels and to turn on the continuous insufflation system (air/water). The recommended product is a non-abrasive detergent, preferably containing enzymes (their actual superority over the usual detergents is however not clearly established). Then comes the *intermediate rinsing* aimed at eliminating the organic molecules present in suspension after the vigorous washing. Rinsing is generally done with tap water. At this point, it is important to also carefully check the waterproofness of the instrument as the immersion in the disinfectant can seriously damage some components of the endoscope. The third step is the *disinfection* itself. The reference product is glutareldehyde solution at 2% concentration, at room temperature. This product remains stable for 15 days or 25 baths. The endoscope must be completely immerged in the dedicated tub along with the different accessories (pistons, valves, washing brushes ...) and it is necessary to perfectly irrigate the different channels.

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The normal duration of this step must be at least 10 minutes (level I disinfection). This period must be extended to 30 minutes in case of perceived increased risk (B hepatitis, tuberculosis) or at the end of the day (level II disinfection). Finally, it is appropriate to perform *final rinsing* in sterile water with, once more, complete irrigation of all channels of the 'scope. This rinsing water must be changed regularly and the endoscope must be dried with medical compressed air if it is not immediately re-used. Concerning the accessories, the washing flask must be cleaned every day, rinsed, disinfected and sterilized. Additionally, the flask and aspiration pipes should only be used once or alternatively, disinfected or sterilized on a daily basis.

There are also rules regarding the "*minor endoscopic materiel*" : the biopsy forceps and polypectomy snares must ideally be sterile whether they are or not re-used. The accessories that cannot be autoclaved (dilatation candles, balloons) must go through an extensive disinfection cycle (3 hours in glutaraldehyde 2%). The injection needles must be single-use, in particular to limit the additionnal risk of injuries during the maintenance of such material, given the difficulty to wash inside the needles to remove the blood and the population treated with these techniques (higher risk of hepatitis). Finally, the accessories used in ERCP should be sterile, used only once or alternatively autoclaved (except for the balloons).

The strict respect of these basic rules will ensure endoscopic safety while reducing the risk of contamination to virtually zero.

Use of automated machines

Over the last few years, different "automatic" disinfection machines have emerged on the market. Each of these have specific and interesting characteristics but they all require fairly in-depth knowledge if one wants to use them effectively and in line with his own needs. The very word "automatic" can lead to think that all various steps described above are performed without human intervention but this is completely wrong. In reality, the fact that these systems currently offer an increasing number of functionnalities (6) does not mean that the manual procedure of decontamination (cleaning/brushing) of the endoscope can be skipped right at the end of the examination. However, I will not repeat the major interest of this particular phase mandatory for bacteriological security.

The *main advantage* of such automated machines is that they offer a solution to the major drawbacks of the manual method : non-reproducibility of the procedures and allergic and/or toxic risk for personnal exposed to glutaraldehyde. Consequently, the automation of certain steps will theoretically prove interesting to help : reduce workload, protect employees from direct contact with glutaraldehyde, standardize procedures (incompressible exposure time and monitoring on disinfectant concentration), improve the operations follow-up process (printing of a detailed report), test waterproofness automatically.

The *key drawbacks* of automated techniques can be described as follows : the length of the procedure, sometimes leading to invest in purchasing new endoscopes, the installation and running constraints of the equipment, the purchase price and maintenance cost, the risk of shortening life expectancy of the 'scopes exposed to high temperatures in some machines and to too high pressure when irrigating the channels, risk of internal contamination of the machine by the endoscope, highlighting the necessity for the equipment to offer reliable self-disinfection cycles. Regarding this last point, the quality of the water used is a major element which can be not neglected (possible contamination from tap water). Another perceived major disadvantage is the risk of demotivation of the staff who could erroneously believe that these machines would allow them to skip the basic manual washing/brushing, a step which central role has been demonstrated both by American and European studies (2,3,5,7,8).

Conclusions

In summary, it is wise to remind that the reference in terms of disinfection procedure for flexible endoscopes remains the manual procedure because it has largely proved its efficiency. Nowadays and without any objective scientific data establishing the superiority of automatic disinfection over the manual technique, it is a perfect nonsense to try to impose that automatic equipment as the unique bacteriological reference. If some large hospitals are willing to invest in this field, it is important to remind that all machines are not equivalent and that it would be necessary to respect a precise schedule of conditions, both from a technical and bacteriological point of view. The medical centers and private offices should legitimately keep on working with the current disinfection procedures, as long as the rules described above are scrupulously respected.

No doubt that the use of automated washing/disinfectants do present some advantages, more far for the protection of the staff than from a pure bacteriological point of view.

Whatever the option chosen, I strongly advise to keep a register with all details of the procedures for each patient who has undergone an endoscopy. In this respect, I suggest to create a Quality Control Service for the centers equipped with automatic disinfection machines as well as for the other ones, Service that could deliver certificates of "good quality".

Finally, I am convinced of the necessity for all Scientific Societies, in each medical discipline confronted to this problem, to initiate an in-depth reflection on the subject and then enact appropriate specific decontamination rules depending on the actions they carry out and their own specificity. In fact, as precisely stated by Delwaide *et al.* (9), Gastroenterologists are

not the only specialists confronted with the potential risk of iatrogenic contamination resulting from the use of medical techniques.

In conclusion, both methods are reliable, provided that some basic working rules are scrupulously respected. Therefore, there is no serious justification to favor one or the other method, based on the bacteriological criteria alone.

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JURY OPINION : J. Delwaide (1), P. Pelckmans (2), P. Defrance (3), M. Adler (4)

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A number of questions concerning the disinfection procedures and the potential adverse reactions associated with disinfectants were considered during the session.

Can endoscopy (with or without biopsies) occasionally transmit infection ?

It is clearly demonstrated that endoscopy can transmit infections. There is a variety of sources of contamination. Contamination can result from a patient-to-patient transmission of infectious agents, either by an oral route (as for *Salmonella* or *Clostridium difficile*), or by a parenteral route (as for *HIV, HCV, HBV*). In this latter route of transmission, the role of ancillary equipment is probably more important than endoscopic procedure by itself. Infections can also be associated with contaminations by organisms from the environment that colonize endoscopes and ancillary equipments during cleaning, disinfection, rinsing procedures or during storage (as for *Pseudomonas aeruginosa*, or atypical mycobacteria).

Is manual disinfection, when performed following recommended guidelines, effective for preventing transmission of infection ?

It has been demonstrated that manual disinfection is effective for preventing infections. Prospective in vivo studies have shown that infectious agents could be found occasionnally on the outer surface of the endoscope or in the channels immediately after removal of the endoscope, but that they were eliminated after correct disinfection procedure. The detailed rules of good clinical practice in endoscope disinfection has been reviewed in a brochure published by the Ministry of Public Health in 1996 (1). Disinfection is a specialised procedure and should be carried out by personnel who have been trained for this purpose and who have an understanding of the principles involved. An important aspect of the process is the manual cleaning of instruments with detergent immediately after endoscopy to avoid that organic materials become fixed on the endoscope surface or the internal channels and prevent the disinfectant to come in contact with infectious agents. The next step is rinsing with tape water. For the disinfection, 2% activated glutaraldehyde is still considered as the preferred disinfectant product. A 10-minute immersion of the endoscope (at room temperature) between each patient is recommended for a low-level disinfection, and a 30-minute immersion for an intermediate-level disinfection (patients with AIDS, other immunodeficiency states, pulmonary tuberculosis, HBV, and at the end of the session). The aim of the final rinsing is to remove all traces of disinfectant from the channels. Then the endoscope has to be dried carefully.

Does automated endoscope washers offer advantages over manual disinfection for preventing transmission of infection ?

Clinical studies have failed to demonstrate a superiority of automated procedures (with first generation machines) over well-performed manual disinfection in terms of contamination rates.

Some articles, however, have highlighted the lack of universal compliance with basic principles of manual decontamination. This gap between rules and some actual practice was principally related to a lack of complete knowledge of guidelines or to a too heavy workload. Automated endoscope washers theoretically

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On behalf of the Jury (D. Bouilliez, R. Brenard, M. Closon, J. Deviere, A. Elewaut, J. Fevery, R. Fiasse, M. Hautekeete, J. Houben, M. Melange, C. Melot, D. Urbain).

should ensure a more reliable and reproducible decontamination procedure, especially in terms of respect of exposure time to the disinfectant, as well as in terms of quality control of the procedure. They also permit a reduction of the nurses' workload.

Nevertheless, as for the manual procedure, it has to be stressed that the use of automated washers makes it essential to follow specific guidelines of good clinical practice. These rules have been issued in the brochure of Ministry of Public Health (1). Manual cleaning immediatelly after the endoscopic procedure remains an essential prerequisite to automated disinfection. Furthermore, a regular maintenance of the washers needs to be done.

At last, some washers do not offer enough guarantees of efficiency. The brochure of the Ministry of Public Health (1) and a Working Party of the British Society of Gastroenterology Endoscopy Committee (2) propose a list of criteria for the selection of washers. Clinical efficiency of automated washers should have been evaluated by in vivo controls ; they should clean, disinfect and rinse external surfaces and internal channels of the various endoscopes used in the endoscopy unit ; washers should have a cycle counter, a fault indicator, a facility to detect leak or obstruction, a water treatment system which prevents recontamination during rinsing, ... It has to be noted that the leaflet provided by manufacturers are often incomplete. As a consequence, users are advised to test the washers before purchasing the machine and to proceed to regular quality control.

Are there adverse reactions associated with the use of aldehyde disinfectants ?

A number of studies have described dermatitis, conjunctivitis, nasal irritation, asthma among workers in endoscopic units. Glutaraldehyde is a recognised cause of occupational asthma and therefore acknowledged as an occupational disease in some countries.

Guidelines have also been issued in order to minimize the risks related to the use of glutaraldehyde (1) : disinfection should be carried out in a special room, equipped with a ventilation system to evacuate glutaraldehyde fumes. Protective equipment should be worn including goggles and gloves long enough to protect the forearms from splashes. In addition, endoscopy staff must be informed of the risks of exposure to glutaraldehyde and trained in the safety procedures of its use.

Do automated endoscope washers offer advantages over manual disinfection for preventing adverse reaction due to glutaraldehyde ?

Automated washers considerably reduce the likelihood of eye, skin, and respiratory exposure to glutaraldehyde.

Nevertheless, the above guidelines of protection remain mandatory.

Conclusions

Endoscopy is a potential route of transmission of infectious agents. As a consequence systematic disinfection between each procedure is mandatory.

Both manual and automatic disinfections procedures are effective and can virtually eliminate the risk of nosocomial infections. The choice between the two methods depends on a local evaluation of the cost of automatic procedures as well as on the patient throughput. When possible, however, automatic washers are preferred because they offer the patient a more reliable and reproducible decontamination process, and offer the endoscopy staff a reduction of the workload, and a reduction of the likelihood of eye, skin and often respiratory exposure to the disinfectant. The choice of a particular machine should be guided by criteria that should guarantee their efficiency. Especially automated washers which efficiency has been evaluated by in vivo controls should be taken into consideration. A list of these criteria can be found in the two references below.

Finally, regardless the decontamination procedure choosen, specific rules have to be followed scrupulously. This stresses the need of continuous training of all endoscopy staff in order to optimize the practices. Moreover, each centre should organize regular and independent quality control.

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