"Endoscopic Disinfection"

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Important Definitions

Cleaning means physical removal of organic material and/or soil from objects usually using water with detergents to remove rather than kill organisms.

Sterilization is the act of killing all microbial life and elimination of bacterial spores, commonly achieved with heat or ethylene oxide gas. More specifically, the FDA defines it as a minimum of 12 log reduction in bacterial spores. While FDA accepts a 6-log reduction of micro-organisms as proof of **high level disinfection (HLD)**. However, current data suggests that high level disinfection provides the same degree of safety as sterilization because the spores that tend to survive HLD are non pathogenic.

Endoscopic Disinfection

The complex and delicate construction of modern GI endoscopes makes them poor candidates for traditional steam based sterilization methods and has provided the driving force for the development of new low temperature liquid disinfectant technologies. In April 1994, Johnson&Johnson Medical, Inc. received the first written certificate from the FDA for their glutaraldehyde based disinfectant products (Cidex). Its high level disinfection time was 45 minutes at 25 ◦C. But it harbors some problems, first: there is larger potential health hazard to personnel from exposure to disinfectant fumes when glutaraldehyde is heated to 25 ◦C. Second: given the limited number of endoscopes in the inventory at most endoscopy centers and the need for rapid turnover of these expensive instruments, there are economic penalties associated with prolonged disinfectant immersion times. Third: during clinical use blood, fecal matter, mucus and other biological substances can be expected to adhere to the endoscope and its channels. Theoretically, microorganisms embedded within this biofilm could be sheltered from the effects of the disinfectant and inadequate cleaning may yield suboptimal results. Current guidelines from the Association For Practitioners in Infection Control (APIC) and the ASGE suggests that a 20 minute immersion time in 2% glutaraldehyde at room temperature is adequate for endoscopic disinfection provided that thorough instrument cleaning is first performed. The reported rate of endoscopically transmitted infection since 1998 is only 1 in 1.8 million which supports the fact that current practices are adequate and safe for the patient.

There is growing concern for emerging pathogens resistant to glutaraldehyde. New agents currently being evaluated may provide more suitable alternatives. Orthophthalaldehyde, a high level disinfectant most recently approved by the FDA, contains 0.55% 1.20- benzenedicarbox-aldehyde. Studies have shown superior mycobactericidal activity compared with glutaraldehyde (5-log reduction of mycobacteria in 5 minutes). Furthermore, it produces no noxious fumes, requires no activation and is stable at a wider pH range of 3 to 9. Other emerging technologies include vapor phase disinfectants (hydrogen peroxide, peracetic acid), ozone sterilization, gaseous chloride dioxide and ionizing radiation.

What to do with the Endoscope?

A standard previously validated manual cleaning protocol was used for all experiments. The inoculated endoscope was immersed in a solution containing 1 ounce of Enzol enzymatic detergent (Johnson&Johnson Med Inc.) mixed with 1 gallon of sterile water. The exterior surface of the insertion tube was wiped 3 times with a sterile EndoZyme sponge (Ruhof Corp.). The channel openings of the endoscope (suction valve housing, air/water valve housing, and instrument channel port) were brushed 5 times back and forth across the mouth of each opening with a sterile channel opening cleaning brush (MH-507, Olympus) soaked in Enzol solution. The duodenoscope elevator was also brushed 5 times with a simple in and out motion in both the unlocked and locked positions. A sterile, single use endoscopic cleaning brush (Telemed Systems, Inc. Marlborough, Mass.) soaked in Enzol solution was passed through the proximal end of the suction channel (on the control section) down the length of the insertion tube and out the distal tip as well as up through the umbilicus. This was performed through 5 times with a simple in and out motion, dipping the brush into the Enzol solution after each pass. The instrument channel was brushed 5 times through the proximal end and out the distal tip. Because the elevator channel and the auxiliary water inlet channel are too small to allow passage of a brush, a 10 mL syringe containing Enzol solution was used to rinse each of these channels through the proximal end of the endoscope. To remove any residual bacteriostatic Enzol, a total of 180 mL of sterile water was then forced through each of the air, water, instrument, and auxiliary water inlet channels, and the elevator channel was irrigated with 10 mL of sterile water. Cultures were obtained from each channel to determine the reduction of bacterial colony counts achieved by manual cleaning alone.

The endoscope was then completely immersed in a freshly activated bath of disinfectant. Each endoscope was subjected to either of the following :

2% glutaraldehyde (Cidex) at 20 °C for 20 minutes, 7.5% hydrogen peroxide (Sporox) at 20 ° C for 30 minutes, 0.2% peracetic acid (Steris 20) at 50 ◦C to 56 ◦C for 12 minutes inside the Steris System 1 processor, 70% isopropyl alcohol at 20 ◦C for 20 minutes, or ethylene oxide gas during separate experiments.
Cultures were obtained to demonstrate the reduction of bacterial colony counts achieved by each disinfection process.

Infection control during gastrointestinal endoscopy

Endoscopy related infection might occur in several situations:

1- Microorganisms may be spread from patient to patient by contaminated equipment.
2- Microorganisms may spread, during endoscopy, from the gastrointestinal tract through the bloodstream to potentially susceptible tissues or prostheses, possibly resulting in infection (e.g. bacterial endocarditis).
3- Microorganisms may be transmitted from patients to endoscopy personnel, and vice versa.

Facts direct antibiotic usage in endoscopic procedures

1- Risk of infection from most gastrointestinal endoscopic procedures is very low.
2- No prospective controlled trials have shown that antibiotic prophylaxis prevents infective endocarditis.
3- Indiscriminate use of antibiotics is to be discouraged.
4- Transient bacteremia may occur after gastrointestinal endoscopy at rates similar to those occurring with other activities or procedures (brushing teeth, barium enema…etc).
5- A relatively higher incidence of bacteremia has been reported after esophageal stricture dilation and injection sclerotherapy of esophageal varices.
6- The risk of bacteremia does not appear to increase with biopsy, polypectomy or sphincterotomy.
7- The risk of a transient bacteremia causing seeding and clinically evident distant infection varies with the type of cardiac lesion and the interval after vascular graft placement.

Given these various factors, recommendations for antibiotic prophylaxis have been made procedure and patient specific. Patients are stratified into high, intermediate and low risk groups based upon the susceptibility of underlying cardiac conditions to infection during bacteremia and the potential outcome should endocarditis develop.
Patients with a history of endocarditis, prosthetic cardiac valve placement, systemic pulmonary surgical shunts, cyanotic congenital heart disease or

synthetic vascular grafts less than 1 year old should receive antibiotic prophylaxis prior to those procedures at greatest risk of inducing bacteremia. They are esophageal stricture dilation, variceal sclerotherapy and cholangiography with biliary obstruction. Prophylaxis should be individualized when high risk patients undergo lower risk procedures. The AHA guidelines suggest prophylaxis also for those patients with moderate risk cardiac lesions (rheumatic valvular dysfunction, mitral valve prolapse with insufficiency, hypertrophic cardiomyopathy and most congenital cardiac lesions) undergoing the higher risk procedures. While the endoscopist is given considerable leeway regarding antibiotic use in other clinical scenarios, prophylaxis is not routinely recommended for patients with moderate risk cardiac lesions undergoing low risk procedures or for patients with low risk cardiac lesions (history of coronary bypass grafting, pace makers, implantable defibrillators) or prosthetic joints undergoing any procedure. Several oral and parenteral antibiotic regimens have been proposed and are noted in the references. The most recent AHA regimen for endocarditis forgoes use of post procedure dosing.

Antibiotic prophylaxis against soft tissue infection is advised for all patients undergoing percutaneous endoscopic gastrostomy (PEG) placement. Regimens should provide optimal coverage of cutaneous organisms (e.g. cefazolin 1 gm IV). Patients with anticipated biliary obstruction or pancreatic pseudo cysts undergoing ERCP should receive prophylaxis with agents providing good biliary penetration. Several acceptable regimens are available. When such patients have high risk cardiac lesions as well they require standard SBE prophylaxis regimens, which may be more aggressive.