Original Research Paper

Volume-9 | Issue-1 | January-2019 | PRINT ISSN - 2249-555X

Urology

EFFECTIVE REPROCESSING OF MEDICAL DEVICES IN UROLOGY WITH SPECIAL REFERENCE TO MINIMAL INVASIVE PROCEDURES: CONSENSUS GUIDELINES

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ABSTRACT Health care–associated infections (HCAIs) are among the most common complications of hospital care. Reprocessing methods of medical devices play an important role in controlling HCAIs as impaired reprocessing of devices can lead to HCAIs. In this article we evaluate sterilization and disinfection processes used for multi-use and single use medical devices engaged in urological practice in India. Cleaning followed by disinfection or sterilization are the procedures available for reprocessing urological medical devices. Every attempt must be made to follow the Spaulding's classification when consideration is given to reprocess a medical device. When properly used, disinfection and sterilization methods can guarantee the safe use of all types of medical devices. Due to the diverse conditions of urological practice in India, laying down minimum essential procedures for reprocessing of urological devices is essential to assure patient safety throughout the country. This document serves the same purpose.

KEYWORDS : Urology, Sterilisation, Disinfection, Medical devices

1. Background

Healthcare associated-infections (HCAIs) or nosocomial infections as they are commonly called, are the most common complications of hospital care. [1] HCAI is a new infection gained by a patient in the hospital who was admitted for another condition other than the new infection. It also includes occupational infections among staff of the facility. [2] According to World Health Organization (WHO), HCAIs occur among 7-12% of the hospitalized patients globally.[1] Developing countries including India reported an overall HAI prevalence of 14.7% in ICU patients. [1] Although, the prevalence of HCAIs in United States (US) and Europe is reported to be 4.5% and 7.1% in respectively.[1]

The causes of HAIs are generally influenced by many factors and are complex. This includes gaps in policies, infrastructure, organization and knowledge, defects in health-care workers' behaviour and even patient related factors. By following best medical practices in infection control, improving infrastructure and improving training of healthcare workers (HCWs) most HCAIs can be prevented. [3] All invasive processes contain contact by either a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. The introduction of microorganisms at the surgery site is a major risk for any surgical site infection (SSI) . These origin of these microorganism's at the surgical site could be due to endogenous or exogenous causes. Among the exogenous causes the skin flora of the surgical team and inappropriate sterilization / disinfection surgical instruments remains the prime causes of SSI with a small proportion attributed to the airborne organsims.4 Thus appropriate sterilization and disinfection practices play a key role in preventing SSIs.

Specific to urology practice, increased workload in endourological procedures in urology has motivated the reusing of the reprocessed devices even in the developed countries. Similarly in India too, single use devices are being reprocessed and concern arises on their reprocessing in areas which do not have dedicated central sterile services department (CSSD).

This is an important patient safety issue and hence there is a need for the developing guidelines ensuring for selection of proper reprocessing techniques which include cleaning, disinfection and sterilization both for multi use and single use devices.. This article serves to put the basics of reprocessing medical devices into proper perspectives to ensure patient safety at its core.

2. Medical devices used in clinical practice

The frequency of urological endoscopic procedures has been increased in last few years due to better and faster recovery of patients from endoscopy versus open procedures. These devices are costly, hence using them in daily practice increases healthcare budget which is often paid out of the patient's pocket. . While some of these devices are designed for multiple use, many of them designed for single-use only (single use medical devices, SUD).[5]

2.1 Classification of medical devices

2.1.1 Reusable medical devices (RMDs)

Reusable medical devices are devices those that health care providers can reprocess and use to diagnose and/or treat multiple patients. These devices are intended for multiple uses and they are made of materials

that can tolerate repeated reprocessing. Examples of reusable medical devices include surgical instruments (such as clamps and forceps), endoscopes (such as cystoscopes, ureteroscopes, nephroscopes, bronchoscopes, duodenoscopes and colonoscopes), accessories to endoscopes (such as graspers and scissors) and laparoscopic surgery accessories (such as arthroscopic shavers).[5,6]

2.1.2 Single used medical devices (SUDs)

A single-used device is a medical device that is intended to be used on a "single patient only" and then discarded. Although, the key emphasis is on "single patient use", a device may be used numerous times on the same/different patients, depending upon how it is reprocessed and its ability to retain function despite repeated reprocessing.[3]

The practice of reusing SUDs began in hospitals in the late 1970s. The reuse of SUDs allows more cost-effective use of resources. The report of a survey conducted in US revealed that almost 20%-30% of healthcare facilities in US confirmed reuse of at least one type of SUD. [5] (Though, before reusing, SUD would be required to fulfil the same regulatory specifications of the device when it was originally manufactured.[5]

2.2 Spaulding's classification

Spaulding's classification is Food and Drug Administration (FDA) approved classification which is used to label the device-being used in the health-care facilities on the basis of the potential risk of infection caused by the use of the device. This system is applied to classify medical devices considering its intended use and level of reprocessing required for its safe use. According to Spaulding's classification medical devices are categorized into critical, semi-critical and non-critical. Table 1 outlines Spaulding's classification used for reprocessing decisions. [3,5]

Table 1: Spaulding's classification for medical devices[3,5]

Risk category	Recommended level of decontamination	Examples of medical devices
High (Critical) Devices that are involved with a break in the skin or mucous membrane or entering a sterile body cavity	Sterilization	Surgical instruments, implants/prostheses, rigid endoscopes, ureteric catheters, double lumen ureteric stents
Intermediate (semicritical) Devices in contact with mucous membranes	Disinfection (high level)	Respiratory equipment, non-invasive flexible endoscopes, cystoscopes, ureteroscopes, nephroscopes, guide wires
Low (non-critical) Devices in contact with intact skin	Disinfection (low to intermediate level)	Blood pressure cuffs, stethoscopes, bedpans, urine bottles

2.3 Urological devices

The commonly used urological devices include ureteric catheters, double lumen ureteric stents, cystoscopes, ureteroscopes, nephroscopes, and guide wires. Despite favourable outcomes of using these devices, there are numerous reports that raise concerns regarding infections transmitted via surgical procedures carried out using these devices. Hence, proper reprocessing of surgical devices should be carried out to avoid further complications. [7, 8]

3. Reprocessing of urological medical devices

The aim of the reprocessing procedure–is to remove pathogenic microorganisms completely from a device and achieve sterility assurance level (SAL) of 10^{-6} so that pathogens do not cause any infection to patients and to personnel handling instruments.[9, 10] It is a validated procedure used to decontaminate medical devices, which have been previously used or contaminated.[5] The reprocessing method of urological medical devices (such as ureteric catheters, double lumen ureteric stents, cystoscopes, ureteroscopes, nephroscopes, guide wires, etc) must have definite effect in the following aspects such as cleaning efficacy, disinfecting efficacy, bactericidal efficacy, mycobactericidal efficacy, fungicidal efficacy, and virucidal efficacy.[9] The type of instrument (Spaulding classification) and targeted area of device are generally considered while selecting procedure for reprocessing of devices. The ability of the device material to withstand repeated disinfection/sterilization should also be considered throughout reprocessing.[5] Cleaning, disinfection and sterilization are the different processes available for reprocessing urological medical devices.[5]

3.1 Cleaning

Cleaning is the removal of visible and foreign material (e.g., soil and organic material) from equipments and is generally done with detergent water or enzymatic products. [11] It is the initial and most crucial step before any procedure of disinfection or sterilization can be carried out.[3] Comprehensive cleaning is necessary before disinfection and sterilization as inorganic and organic materials from the surfaces of devices may interfere with the efficiency of these methods If soiled materials dry onto the devices, the removal of it becomes more challenging, making disinfection and sterilization of devices more difficult and less effective. [11] It has been observed that cleaning decreases the level of microbial contamination by 4–6 $\log_{10}$.[5] Hence, surgical instruments should be pre-soaked to avoid drying of blood or any foreign material.[11]

3.1.1 Cleaning agents

There is no single cleaning agent which is effective against all types of foreign materials. Devices used during surgery are usually covered with blood and tissue remains as they are in touch with chemicals and fluids, dirt and dust. The instruments may have remnants of blood and tissue from the operation. Thus, cleaning agents must remove all organic, inorganic and microbial contaminants, since deposits of dust, soil and microbial residue on device can lead to HAIs. The ideal cleaning agent should have some specific properties such as emulsification, saponification, surfactation, dispersion, peptization, water softening, free rinsing and non-toxicity.[3]

There are two types of cleaning agents, enzymatic and chemical (detergents). The enzymatic cleaners are used, if blood have been dried or hardened. In this case, soaking in a warm solution of an enzymatic cleaner is needed. Enzymatic cleaning agents can be used for sensitive devices, if the manufacturer approves their use. Chemical agents have a function of decreasing surface tension and cut through fat and organic matter. A mild alkaline detergent is usually favoured for manual cleaning, ultrasonic cleaning, or one of the several types of equipment washers.[3]

3.1.2 Cleaning methods

3.1.2.1 Manual cleaning

Manual cleaning procedures can be used to clean devices in facilities with minimal resources. Manual cleaning process cannot be validated; therefore a clear SOP is needed.[3] There are two important constituents of manual cleaning; friction and fluidics. Amongst them, friction (e.g., rubbing/scrubbing the soiled area with a brush) is an old and reliable method. Fluidics (i.e., fluids under pressure) is generally used to eliminate soil and remains from internal channels after brushing.[11]

It is important to perform rinsing after cleaning as it helps to eliminate loosened soil and other remainders from device. Thus, all devices should be rinse thoroughly after cleaning with water to remove residues, which might react with the disinfectant/sterilant. Drying is also an essential process which inhibits microbial growth and dilution of chemical substances. All stainless steel devices should be dried immediately after rinsing to prevent spotting.[3]

3.1.2.2 Mechanical cleaning

Mechanical cleaning of devices usually provide uniformly reliable results. The key advantages of using mechanical cleaning methods include faster performance of devices, superior reliability of results, higher standards for cleaning and less risk to staff. Mechanical cleaners are only effective when they are operated and loaded in compliance with the manufacturer's instructions for use.[3] Equipments used for the mechanical cleaning of medical devices include ultrasonic cleaners, washer-decontaminators, washer-disinfectors, and washer-sterilizers.[11]

Ultrasonic cleaners are used for hard-to-reach parts of surgical utensils, such as box locks, serrations, hinges and lumens. In this process, ultrasonic vibrations pass through the cleaning solution to create bubbles. As the bubbles become unstable, they break down and

this process is called as cavitation. The cavitation process generates a vacuum in the solution which eradicates the debris from the devices into the surrounding fluid.[3]

Washer-decontaminators use a combination of water circulation and detergents to eliminate debris. These elements at times have a cycle that leads the devices to a heat process. Washer-disinfectors are usually computer-controlled items for cleaning, disinfecting, and drying medical apparatus. Washer-sterilizers, also called as modified steam sterilizers, clean the devices by filling the chamber with water and detergent. These sterilizers provide agitation by passing steam through chamber. Devices are then consequently rinsed and are exposed to a short steam-sterilization cycle.[11]

3.1.3 Do's and don'ts in cleaning

3.1.3.1 Do's[3,12]

- Ensure that multi enzymatic detergent is prepared at the correct concentration and temperature and it is used for the recommended contact time.
- Keep instruments moist and clean after the procedure. Dip instruments in plain water or cover them with damp cloth to keep them moist.
- Use RO (reverse osmosis) water for cleaning.
- Disassemble instruments prior to cleaning to ensure access to its all surfaces.
- Use proper sized brushes to clean lumened items. Flush and irrigate lumen well during cleaning.
- Use soft bristle brushes to clean serrations and box locks.
- Clean instruments under the surface of the water to reduce the risk of aerosol production.
- Follow manufacturer's instructions for the cleaning of all medical devices.
- Follow every step of pre-cleaning. Staff training for the same is suggested.
- *3.1.3.1 Don'ts* [3,12]
- Don't use metal brushes or any abrasive thing when cleaning instruments.
- Don't clean devices under running water as this can produce aerosols.
- Don't overload trays in a washer–disinfector.
- Don't submerge power equipment or electrical items (unless they have a waterproof cap).
- Don't use a detergent that is not intended for medical devices.
- Don't use saline or sodium hypochlorite solution for soaking as it damages some medical devices.
- Avoid using tap water for cleaning.

3.1.4 Guideline recommendations

- Soiled medical devices should be handle properly to reduce the risk of exposure and/or injury to staff/visitors/patients/residents or contamination of environmental surfaces.[3]
- Contaminated devices should not be transported through areas designated for the storage of clean or sterile supplies, visitor/patient/resident care areas or high-traffic areas.[3]
- Reusable medical devices must be thoroughly cleaned before disinfection or sterilization and if cleaning cannot be done immediately, the medical device should be pre-treated to prevent organic matter from drying on it.[3]
- The process for cleaning should include written protocols for disassembly, sorting, pre-treatment, physical removal of organic material, rinsing and drying.[3]
- Personnel must use appropriate PPE whenever cleaning reusable medical equipment/ devices. [13]
- Products shall be approved by the committee/ team responsible for product selection; by an individual with reprocessing expertise and by infection prevention expertise.[13]
- Products that are used in cleaning process must be compatible with equipment/ device to be reprocessed and used according to manufacturer's instructions.[13]
- Audits of the cleaning process shall be done on a regular basis.[13]

3.1.5 Preparation and packaging for reprocessing

Medical devices are visually inspected and function-tested by trained staff in the inspection, assembly and packaging (IAP) of reused medical devices (RMDs). The devices are either reassembled or disassembled (as per manufacturer instructions), sorted and packed either as a set of medical devices or as a single medical device after testing. All medical devices should be examined in a place selected to enhance the effect of the sterilization process and reduce contamination. A bright light with a magnifying or a magnification light should be used for the process.[3]

3.1.5.1 Inspection

Each set of medical devices should be inspected separately after cleaning. Hand and workbench hygiene is required before carrying out this activity. Devices especially which have an outer insulation coating, e.g. diathermy forceps, need close inspection to confirm the intactness of insulation. An insulation diathermy pinpoint tester should be used to check insulated devices. Each device must be inspected after each cleaning cycle to confirm that all screws on jointed devices are tight and have not become loose during the cleaning process. Each medical device should also be checked to ensure free movement of all parts. [3]

3.1.5.2 Assembly

The main purpose of assembly and checking is to ensure that all devices are assembled correctly in accordance with the manufacturers' instructions and are placed in the correct tray in a user friendly manner. It is important to present all surfaces of the device to the sterilization media (i.e. steam) while preparing for packaging and sterilization. Devices should be spread evenly (by weight) over the tray surface; since it helps to prevent condensate flowing together. The user should ensure that sharp devices are assembled correctly to avoid penetration of the outer packaging. [3]

3.1.5.3 Packaging and wrapping

The packaging of devices is needed prior to sterilization. Proper packaging material and techniques are selected to protect the devices in order to maintain sterility. The selection of material must comply international standards and is frequently based on the recommended method of sterilisation. Every package should have an external and internal chemical indicator, and an identification or label of the content, lot number, expiry date and initials of the operator. The capability of each specific product to meet requirements and criteria should be evaluated, while selecting the packaging system. [3]

Packaging materials should be stored at room temperature 18°C to 22°C and at a relative humidity of 35% to 70%. Temperature and humidity balance of packaging material is important to maintain the integrity of the product. Packaging materials should not be stored adjacent to external walls or other surfaces, which may be at a lower temperature or a higher temperature than the ambient temperature of the store room. [3]

The different types of packaging materials include, sterilization wraps, rigid reusable containers, reusable fabrics, non-perforated containers of glass or metal, and single use packaging. [3] Effective packaging materials for sterilization should, as a minimum, allow adequate air removal, sterilizing agent penetration, provide an adequate barrier to microorganisms, resist tearing or puncture, provide complete seal and integrity, free of toxic ingredients, non-linting and cost-effective.[13]

Devices wrapped with sheet material using either the envelope or parcel fold technique. In the parcel fold technique, the device set is placed on the wrap, approximately in the centre of the packaging material, whereas in envelop wrapping method, the device set is placed on the wrap diagonally and slightly off the centre line. The wrap is secured in position using sterilization indicator tape. It is important to wrap the device securely to avoid gapping, billowing and the formation of air pockets, which could compromise sterility.[3]

Heat sealing equipment is crucial in all devices that use the pouch system for individual devices. The use of alternatives, such as rubber bands and glue or paste, is not acceptable. Packages should be labelled before sterilization. Label information should be documented on sterilization chemical indicator tape or label and not on the packaging material. [3] The instruments will go in either single or double pack for sterilization depending upon the packaging material. [12]

3.2 Disinfection

Disinfection is a procedure that eradicates many or all pathogenic microorganisms, excluding bacterial spores. Devices are commonly disinfected by liquid chemical in most of healthcare facilities. Disinfection process is not sporicidal like sterilization, though, a few

disinfectants, also called as "chemical sterilants", may kill spores with prolonged exposure times (3-12 hours). [5]

The disinfectants such as ortho-phthaladehyde, glutaraldehyde, , peracetic acid, hydrogen peroxide, , alcohol, and chlorine dioxide are widely used for disinfection of medical devices.[3] Amongst them, glutaraldehyde and ortho-phthalaldehyde (OPA) are commonly used in urology practice. [5]

According to United States (US) FDA, the minimum requirement for reprocessing of semi-critical devices is high level disinfection using chemical disinfectants such as glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde (OPA), peracetic acid with hydrogen peroxide, and chlorine.[14]

Glutaraldehyde is an aldehyde compound which is available in both acidic and alkaline form. Immersion times of glutaraldehyde may vary with countries, though 10 minutes is the minimum requirement for bactericidal activity. It is also observed that 20 minutes of immersion time is needed for tuberculocidal activity, whereas it may require longer contact times (> 3 hours) for sporicidal activity. A >2% concentration of glutaraldehyde at 25°C range from 20-90 minutes is recommended for high level disinfection. It usually acts on microorganisms by causing alkylation of cellular components that alters the protein synthesis of DNA and RNA. Major disadvantages of glutaraldehyde include irritancy and potential toxicity.[3,15]

Ortho-phthaladehyde (OPA) is a chemical agent used for high-level disinfection. The time required for disinfection may vary according to national standards. The United States FDA standard needs 10 to 12 minutes at 20^0C, whereas Canadian standard requires 10 minutes, and the European standard requires 5 minutes immersion time. It acts directly on nucleic acid and kills microorganisms. A concentration of 0.55% is recommended for disinfection process. [3] Though, reported cases of anaphylaxis-like reaction after using OPA has limited its use.[5]
Peracetic acid is an oxidizing agent which acts by denaturing the proteins and altering the permeability of the cell wall. Though, it can cause eye and skin damage when used in high concentration. Hydrogen peroxide kills microorganisms by the production of destructive hydroxyl free radicals. It can cause serious eye damage with contact. Alcohols are usually used at concentration of 60-70%. They have bactericidal/virucidal activity and act on the cell membrane of microorganism. Since, alcohols do not penetrate well into organic (especially protein based) matter, their use has been limited to disinfect only physically- cleaned hard surfaces or devices.[3]

3.2.1 Precautions to be taken while handling disinfectants

- Concentrated disinfectants should always be handled with care wearing appropriate personal protective equipment (PPE), such as gloves, aprons, respiratory and eye protection. [3]
- Storage containers of disinfectants should never be left open to the air for longer. [3]
- Disinfection procedure should be carried out in an area with easy access to running water, eye wash bottles and appropriate ventilation. [3]
- All chemical disinfectants must be clearly labelled and used within the expiry date. They should be freshly prepared and used at the correct concentration and stored in an appropriate container.[3]
- Disinfectants must be disposed of in accordance with the manufacturer's recommendations. [3]

3.2.2 Guidelines recommendations

- A minimum high-level disinfection for semicritical patient-care equipment (e.g., gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment) that touches either mucous membranes or non-intact skin should be provided.[15]
- A low-level disinfection for noncritical patient-care surfaces (e.g., bedrails, over-the-bed table) and equipment (e.g., blood pressure cuff) that touch intact skin should be performed.[15]
- If dedicated disposable devices are not available, disinfect noncritical patient-care equipment after using it on a patient who is on contact precautions before using this equipment on another patient.[15]
- The chemical disinfectant used for disinfecting medical equipment/devices must be compatible with both the equipment/device manufacturer's instructions for disinfection and the cleaning products involved in the reprocessing of the equipment/device.[13]
- Disinfectant manufacturers must supply recommended usage for the disinfectant to ensure that it is compatible with the medical equipment/ devices on which it will be used.[13]
- The process of high-level disinfection requires monitoring and auditing. If a chemical product is used, the concentration of the active ingredient(s) must be verified and a logbook of daily concentration test results is to be maintained.[13]

3.3 Sterilization

Sterilization method is usually used for reprocessing of critical medical devices, but whenever possible, it can be used for semicritical medical devices also. Since disinfectants do not have sporicidal activity. Sterilization is the process of eliminating all disease-producing/harmful microorganisms, including bacterial spores (e.g. Clostridium and Bacillus spores). [3]

All invasive procedures encompass contact by a medical device with a patient's sterile tissue or mucous membranes. Due to these procedures, risk of device contamination by pathogenic microbes can be increased. Critical devices are associated with high risk of infection due to these pathogens. The devices in this class should be procured as sterile or be sterilized by steam sterilization. If the device is heat sensitive, then the treatment with ethylene oxide, hydrogen peroxide gas plasma, ozone, or vaporized hydrogen peroxide or by liquid chemical sterilants is suggested in urology practice. [5, 16] Table 2 enlists the commonly used sterilization techniques and its advantages and disadvantages.

3.3.1 Device compatibility

For a medical device to be compatible with a particular sterilization method, it must be able to be effectively sterilized and at the same time remain functional following sterilization. The sterilization method selected should be recommended by manufacturer of that specific device. Among other concerns, the ability of the sterilization system to effectively sterilize the medical device will depend on component materials and device design, as well as the level of bioburden (cleanliness) prior to sterilization.[3]

Table 2: Sterilization techniques [3, 15, 16]

Sterilization method	Description	Advantages	Disadvantages
Steam sterilization (Pre-vacuum sterilizers, gravity displacement sterilizers, small table top sterilizers)	A process that uses saturated steam under pressure as the sterilant; Preferred method for sterilizing critical medical devices; Removal of air is essential; Cycle times will vary (3 to 18 minutes)	Nontoxic to patient, staff, environment; Rapidly microbicidal; Rapid cycle time	Deleterious for heat-sensitive instruments; Microsurgical instruments damaged by repeated exposure; May leave instruments wet, causing them to rust; Potential for burns
Flash sterilization (Also referred as Immediate use steam sterilizer, IUSS)	Fast sterilization of non-porous and/or non-cannulated surgical instruments in an unwrapped condition; Cycle times will vary depending on the sterilization temperature	Fast operating;	Devices cannot be stored because they are still wet on cycle completion

Hydrogen peroxide gas plasma	Used for critical devices and some semi-critical devices that will be damaged by moisture or heat;	Safe for the environment; Leaves no toxic residuals; Simple to operate, install (208 V outlet), and monitor; Compatible with most medical devices; Only requires electrical outlet; Fast compared to ETO; Absence of toxic waste; Effective against a wide range of organisms; No aeration required	Cellulose (paper), linens, and liquids cannot be processed; Cannot sterilize materials that absorb hydrogen peroxide (e.g. linen, gauze, cellulose/paper, wood); Low penetration power; Medical devices must be dry before processing
Ethylene oxide (ETO) gas	ETO is a colourless gas that is flammable and explosive; Used for critical and semi critical devices that will be damaged by moisture/heat	Non-corrosive; Penetrates packaging materials, device lumens; Excellent material compatibility; Effective on a wide variety of microorganisms; Simple to operate and monitor	Toxic/carcinogenic to humans; Lengthy cycle due to aeration requirements (8-12 hours); Requires control and monitoring of discharge into the environment; Flammable and explosive; High cost
Formaldehyde gas or low temperature Steam formaldehyde	Formaldehyde gas is considered to be biodegradable over approximately two hours in the environment	Fast compared to ETO; Cost per cycle relatively low; Absence of toxic waste; Easy installation	Suspected carcinogen and mutagenic; Incompatible with moisture-sensitive materials; Papers and woven cloths not compatible

3.3.2 Sterilization process

It is recommended that all critical medical devices should be cleaned and then sterilized to prevent microbial contamination. Semi-critical devices don't penetrate skin but are in contact with non-intact skin or mucous membrane. Therefore, whenever possible and/or as per manufacturer's recommendation, sterilization of semi-critical devices is advised. [3]

Steam sterilization uses saturated steam under pressure as the sterilant. It is a desired method for sterilizing critical medical devices. The removal of air is crucial to assure an efficient sterilization process since sterilization cannot occur in the presence of air. There are distinct types of steam sterilizers which use different methods to remove air from packages and the chamber, such as dynamic air removal (e.g. pre-vacuum) and steam-flush pressure-pulse sterilizers, or passive air removal (e.g. gravity).[3]

Hydrogen peroxide gas plasma sterilization procedure is majorly dependent on the gas concentration, exposure time, and the process temperature. It is generally advised for materials and devices that cannot tolerate high temperatures and humidity, such as some plastics, electrical devices, and corrosion-susceptible metal alloys. Peroxide gas has an effective antimicrobial, including rapid bactericidal, fungicidal, virucidal and sporicidal activity. The gas is also considered safe for use on most device and material types, including electrical components and electronics.[3]

Ethylene oxide (ETO) is a flammable, explosive and colourless gas. The use of ETO emerged when few alternatives existed for sterilizing heat- and moisture-sensitive medical devices. ETO is absorbed by many materials. Thus, items must be fully aerated prior to use following sterilization, according to the device manufacturer's recommendations.[3]

Low temperature steam formaldehyde sterilization method is suggested for all materials used for haemodialysis. Formaldehyde gas is biodegradable gas over approximately two hours in the environment. However, it is known to be a toxic, irritating and allergenic chemical; it is also referenced as a suspected carcinogen. [3]

Flash sterilization (IUSS) describes process of fast sterilization of non-porous and/or non-cannulated surgical instruments in an unwrapped condition. Special high-speed sterilizers are usually placed in the operating room in order to process unwrapped instruments and instruments for extremely urgent use. [3]

A survey conducted by Sabnis et al in India demonstrated a commonly used practices for urology instrument reprocessing. A total of 43 responses were received from practicing urologists who were practicing in individual nursing homes (30.4%), mid-sized hospitals (15.2%), private corporate hospitals (30.4%) or government hospitals (23.9%). Almost 72% of the urologists confirmed that they use chemical sterilization methods for sterilization of urological instruments. The urologists (41.9%) also reported that infection rate in endourological processes was less than 5% or very occasional. Many of them (67.4%) believed that infection rate in lower tract endourological procedures was related to sterilization method while 64.3% of them reported that the infection rate in upper tract endourological procedures (PCNL, Miniperc, RIRS) was mainly related to sterilization method . A survey amongst urologists also expressed (almost 88% of urologists) a need for instrument sterilization policy in Indian scenario. [17]

3.3.3 Guidelines recommendations

- Paper-plastic pouches arranged in a basket on edge or on steriliser carriage with paper side down in a single layer for large items.[13]
- Rigid containers placed on carriages according to the manufacturer's recommendations.
- Devices shall be removed from the sterilizer at the completion of the cycle and shall remain on the carriage for at least 30 min or until the outside is cool to the touch.[13]

4. Urology: The home of endoscopic procedures

Nowadays, the use of rigid and flexible endoscopes in urology has been increased due to growing number of diagnostic and therapeutic procedures. The risk of infection is defined according to the degree of invasiveness of the procedure. Effective decontamination of endoscopes is necessary to protect the patient from infection, make sure the quality of diagnostic procedures and prolong the life of the equipment.[3]Urology is also called as a home of endoscopy as it has been at the forefront of endoscopic use in clinical practice. [18] Endoscopes are the medical devices which are frequently related to health care-associated outbreaks and pseudo-outbreaks. Flexible endoscopes often require low-temperature sterilization or disinfection methods for reprocessing as they have high levels of bacterial contamination. They also exhibit high risk since their design poses substantial challenges to adequate cleaning and disinfection. [4] Rigid endoscopes are rather easy to clean, disinfect and sterilize as they do not have the compatibility issues that exist with flexible endoscopes. [3] Urological endoscopy is used in both diagnosis and therapeutic settings. Presently, endoscopy is used for diagnosis of bladder pathology with the use of flexible instruments under local anaesthesia. It is considered as a gold standard for the identification of urethral stricture disease. However, rigid endoscopy is also used in urology practice to diagnose diseases such as ureteric stone disease. [18]

Endourological procedures and endoscopic surgeries involve the use of certain instruments that are introduced into the urinary system through the urethra and percutaneous techniques that allow ante grade access to the urinary tract. Practice has proved that every urological procedure with use of devices/endoscopes is associated with an increased risk of urological infections. [19]

Table 3 illustrates the type of procedures for using an endoscope and the recommended method of their reprocessing.[3]

Table 3: Recommended reprocessing methods for endoscopes in urology[3]

Types of procedure	Types of endoscopes	Reprocessing method
Invasive	Rigid, flexible	Sterilization by steam or a low temperature method e.g. gas plasma and/or recommended by manufacturer
Non-invasive	Rigid, flexible	High-level disinfection, e.g. immersion in glutaraldehyde, peracetic acid, chlorine dioxide and/or recommended by manufacturer

4.1 Guideline recommendations for reprocessing endoscopes

- The endoscopes should be cleaned meticulously, immediately after use, with an enzymatic cleaner that is compatible with the endoscope. Cleaning is necessary before both automated and manual disinfection.[15]
- Process endoscopes that pass through normally sterile tissues using a sterilization procedure before each use; if this is not feasible, provide at least high-level disinfection.[15]
- High-level disinfection of endoscopes should be followed by a sterile water rinse.[15]

5. Challenges in reprocessing medical devices

5.1 High standards by FDA

FDA requires a very high criteria for standardization of disinfection and sterilization of medical devices. It requires the presence of 5% fetal calf serum dried onto the devices inoculated with 10 colony forming units of most resistant test organisms to test the efficacy of these procedures. It is very difficult for all sterilization processes to meet above mentioned criteria of reprocessing. [5]

5.2 Reprocessing of SUD's

As we have already mentioned, FDA has set very high criteria for standardization of reprocessing techniques. However, considering the strict criteria set by FDA for manufacturers, it is practically difficult for manufacturers to recommend reprocessing and reuse, since manufacturers of urology devices don't recommend reuse of SUDs. Also, no standard guidelines are available regarding reprocessing of SUDs. Thus, there is high chance of developing fear psychosis between urologists regarding reprocessing due to associated medico-legal issues.[5]

5.3 Devices with long and narrow lumen

The immediate cleaning of any narrow-lumen medical device after use is required in urology practice. Though, it also offers a major challenge to reprocessing. It has been observed that retro-flushing with the narrow lumen gives sufficient cleaning. If this process was delayed for more than 24 h, retro-flush cleaning is also no longer effective. [5]

6. Summary

In the last two decades, there was a remarkable increase in the number of urological endoscopic procedures. Though, patient to patient transmission of infection has been noted after inappropriate reprocessing of urological equipments. When properly used, sterilization and disinfection can ensure the safe use of invasive and non-invasive medical devices. The method of disinfection and sterilization depends on the intended use of the medical device, such as critical devices must be sterilized prior to use, whereas semicritical devices must undergo high-level disinfection or sterilization as indicated by manufacture. Since, semi-critical devices are in contact with non-intact skin or mucous membrane, sterilization of these of devices rather than disinfection is advised as a precautionary measure. If FDA guidelines are strictly followed, sterilization and disinfection can ensure the safe reuse of reusable devices and many of the single-use urological devices. With increasing workloads in urological processes, a strict guideline for reprocessing of urological instruments in Indian context is needed for the prevention of further complications.

Conflicts of interest

The authors declare no conflict of interest.

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