Recent advances in low temperature sterilization - Moving ahead from Cidex™/ETO to OPA/Ozone: An update

Sir,

Low temperature sterilization (LTS) has invaded the operation theatre (OT) because many components of advanced minimally invasive surgical (MIS) instruments, including robotic surgery equipment, have zero tolerance for high temperature steam sterilizers. Modern low-temperature sterilization processes[1-7] include ethylene oxide (ETO), hydrogen peroxide plasma, low-temperature steam and formaldehyde (LTSF), gamma radiation, electron beam technology and liquid chemical sterilizing (LCS), with the latest addition being ozone ($\text{O}_3$).

Cidex™ (2.4% glutaraldehyde, Advanced Sterilization Products; Cilag GmbH International), a five decade old, widely prevalent and effective LTS technique has several drawbacks including inadequate disinfection if used within 2 hours of activation. Immersion in Cidex[1] for 20 mins at 20ºC provides high level disinfection. Sporicidal activity/sterilization requires 10 hours contact time which is seldom possible in busy OTs. The same instruments are reused after immersion for merely 20 minutes in the mistaken belief that they are sterile or that antibiotics will take care of any remaining spores. Asthma, nausea, dermatitis, headache, eye irritation can occur in OT personnel, it is incompatible with “Green OT” concept, and it is incompatible with robotic instruments.

Advantages of ETO gas sterilization include no damage to instruments from excessive heat, moisture or radiation. However it requires prolonged aeration times besides being mutagenic, carcinogenic, irritant to the eye, skin and airway, and can cause neurological, liver and kidney damage.[1-2] Gas plasma sterilization is safe, quick and requires no aeration. Vacuum, injection, diffusion, plasma and vent are the five steps followed by the Sterrad™ gas plasma system that are completed within 30 minutes.[1,2] A hand held plasma jet capable of inactivating all surface bacteria in 20 sec (airflow rate 5 l/min; distance 2 cm) is now available.[3] Both gamma and electron beam radiation are used commercially and have no harmful emissions. Gas-permeable packaging is not needed and Gamma rays can penetrate to all parts of the product. On the flipside, radiation degrades some plastic gels, teflon, rubber, polypropylene and products with batteries or electronic components. $\text{O}_3$ sterilization comprises two identical half cycles of vacuum, followed by humidification and $\text{O}_3$ injection, followed by the ventilation phase, and is completed within 10 minutes.[4,5] $\text{O}_3$ can process ophthalmic lenses, cables and cords, power batteries and Doppler probes. Ortho-phthalaldehyde (OPA) Cidex™ is 6500 times more toxic to aquatic life than glutaraldehyde requiring neutralization with glycine before drain disposal.

We have compared several LTS techniques[1-7] based on efficacy, penetration, organic matter resistance, duration of action, material compatibility and incompatibility, toxicity and cost [Table 1] for a quick update.

Reprocessing of instruments entails six steps: cleaning, inspection, packaging, sterilization, sterile storage
Letters to Editor

| Sterilant                     | Efficacy                  | Penetration and Organic material resistance | Action time | Material compatibility | Cannot process | Toxicity                  | Cost               |
|-------------------------------|---------------------------|--------------------------------------------|-------------|------------------------|----------------|----------------------------|--------------------|
| Ethylene oxide (Eto)          | All microbes and Spores   | Excellent Penetrates even long lumens       | 12-24 Hours | Metal Plastic rubber   | Flexible Scopes | Carcinogenic flammable     | High $7.35 Per cycle |
|                               |                           |                                            |             |                        |                | Harms Environment           |                    |
|                               |                           |                                            |             |                        |                | Non toxic by-products       | Processor $65,000 - $130,000 |
|                               |                           |                                            |             |                        |                | water vapour and oxygen     | (5-10 lac-local) |
|                               |                           |                                            |             |                        |                | Low                         | 10 Dollar per cycle |
|                               |                           |                                            |             |                        |                | Toxic                       | Low $10 Cents/cycle; |
|                               |                           |                                            |             |                        |                | Irritant                    | Smaller inventory  |
|                               |                           |                                            |             |                        |                | to eyes and nose            | required           |
|                               |                           |                                            |             |                        |                | Non toxic by-products       |                    |
| Gas plasma/vaporized hydrogen | All microbes and Spores   | Cannot penetrate long lumens               | 30 Mins     | Metal plastic Flexible scopes cameras | Liquids Paper Powder Cellulose Rubber Latex | Non toxic by-products: | Processor $255/Cycle |
| peroxide                      |                           |                                            | for gas plasma | Plastic | PVC; nylon teflon | Textile | water and oxygen | $500 For processor ($7/cycle) |
|                               |                           |                                            | 55 Mins     | Silicone Flexiglass | Rubber | Osha:<0.3 O₂ ppm | $18,200 Peracetic acid cups ($7/cup) |
|                               |                           |                                            | Humidity    | Pyrexglass Aluminium | | O₂ detected by nose | | |
| Ozone (O₃)                    | All microbes and Spores   | 2Mm lumen with <25 cm length; 3Mm lumen with <47 cm length | 20000-30000 ppm 80% humidity 3-5 min; 15000 Ppm 90% humidity 7-10 mins | Stainless steel Plastic; pvc Nylon teflon Silicone Flexiglass | | | | $25/Gallon |
|                               | Even prions               |                                            |             | Endoscopes Rigid laryngo scope blades | | | | $25/Gallon |
| Low-temp steam and formaldeh | All microbes and Spores    | Excellent at 60-78°C                        | Pre-vacuum | Endoscopes Rigid laryngo scope blades | | | | $500 For processor ($7/cycle) |
| yde (LTSF)                    |                           |                                            | pre-pulses  | | | | | Processor $18,200 Peracetic acid cups ($7/cup) |
|                               |                           |                                            | of steam    | | | | | |
|                               |                           |                                            | formaldehyde sterilization washing pulses air pulses. | | | | | |
|                               |                           |                                            |             | | | | | Processor $18,200 Peracetic acid cups ($7/cup) |
|                               |                           |                                            |             | | | | | |
| Nitrogen di oxide (Eniware)   | All microbes and Spores   | Excellent                                  | 20-40 Mins  | Stainless steel; glass Vinyl; aluminium Silicon | Nylon Paper Polyester Thermopla elastomer | Supplied as liquid; turns to vapour at room temp | $500 For processor ($7/cycle) |
|                               |                           |                                            |             |                        |                | | | |
| Per acetic acid (35%)         | All microbes and Spores   | Does not require activation                 | 25 Mins     | Endoscopes Broncho scopes | Lead, brass, copper, zinc | Environmental friendly by-products (acetic acid, O₂, H₂O) | $255/Cycle |
| Ortho-phthalaldehyde (OPA)    | All microbes and Spores   | Does not require activation                 | 5 Hours     | Metals Plastic Elastomers | | | | Low $25/Gallon |
| Cidex (2.4% Glutaraldehyde)   | Some mycobacteria are resistant | Requires activation                        | 10 Hrs      | Stainless steel aluminium brass copper elastomer plastic | | | | Low $930/5-Litre |

and quality assurance (bioindicator strains: spores of Geobacillus stearothermophilus).

According to a survey, 54% of Indian anaesthesiologists reuse standard rigid laryngoscope blades without disinfecting them, and only 1% used gas plasma sterilized blades. According to a survey, 54% of Indian anaesthesiologists reuse standard rigid laryngoscope blades without disinfecting them, and only 1% used gas plasma sterilized blades. 40% of handles deemed patient-ready tested positive for occult blood and 86% of them harboured S. aureus, Acinetobacter and other pathogens. High level disinfection/sterilization is hence recommended for laryngoscope blades (gas plasma sterilization) and handles followed by wrapping in sterile towel for short term storage. ETO/HP gas plasma is recommended for McGrath (Medtronic; Minneapolis; MN) videolaryngoscope instead of wipe-based cleaning. Manufacturers recommend HLD for soiled video batons and reusable blade and sterilization for Glide Rite™ rigid stylets.
The C-MAC™ D blade reprocessing is compatible with low temperature (upto 60°) disinfection and sterilization (Sterrad™, Sterris, ETO).

Low temperature sterilization techniques are constantly being improved and updated with introduction of new technology to cater for MIS instruments, videolaryngoscopes and the green OT concept. Need of the hour is replacement of Cidex™ and ETO with more effective, quicker, safer and environment-friendly sterilization options like OPA and ozone.

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