Communication from the ASGE Technology Committee

TECHNOLOGY STATUS EVALUATION REPORT

Automated endoscope reprocessors

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, with a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but, in many cases, data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the governing board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through August 2008 for articles related to automated endoscope reprocessors by using the words "endoscope reprocessing," "endoscope cleaning," "automated endoscope reprocessors," and "high level disinfection."

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BACKGROUND

High-level disinfection (HLD) is the accepted standard for the reprocessing of flexible GI instruments.[1] National standards were adopted to ensure that endoscope reprocessing is performed consistently by using a standardized protocol.[2] Automated endoscope reprocessors (AER) are designed to replace some manual reprocessing steps.[3-5] In addition, AERs may limit exposure of personnel to liquid chemical germicides (LCG).

TECHNICAL CONSIDERATIONS

HLD refers to the treatment of medical devices to remove all viable microorganisms, except some spores when present in a significant load. National consensus standards for endoscope reprocessing emphasize (a) bedside cleaning and aspiration of enzymatic detergent through the suction channel, (b) manual washing and brushing of accessible channels, (c) subsequent disinfection via immersion for an appropriate duration in a LCG of appropriate concentration, followed by (d) a water rinse, alcohol flush, and air-drying of all channels. A variety of LCGs with differing contact and concentration requirements are available for the disinfection step (Table 1).[6]

A variety of capabilities are incorporated into the available AERs (Table 2). All models have disinfection and rinsing cycles, and some have detergent cleaning, alcohol flush, and/or extended forced–air-drying cycles. Additional features or designs may include (1) variable cycle times, (2) printed documentation of the process, (3) low-intensity US waves, (4) LCG vapor recovery systems, (5) heating to optimize LCG efficacy, (6) a variable number of endoscopes processed per cycle, (7) automated leak testing, (8) automated detection of channel obstruction, and (9) table top, floor standing, and cart-mounted models.

Not all reprocessors are compatible with all LCGs or with endoscopes from all manufacturers. Some models are designed for use with specific LCGs types and/or formulations, often on a proprietary basis. Other variations that may require attention to the design of the facility include requirements for (1) water pressure, temperature, and filtration, (2) ventilation, (3) plumbing, (4) power supply, and (5) space.

All AERs rely upon high pressure and flow rates of LCG through the endoscope channels and continuous bathing of the exterior of the instrument. Some consume and dispose of limited amounts of LCG per endoscope cycle, whereas others use a reservoir of LCG that is reused over many cycles. The latter design risks gradual dilution of LCG with repeated use and requires intermittent testing to verify maintenance of the appropriate minimum

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TABLE 1. LCGs available for HLD in the United States*

Agent/trade name	Manufacturer	HLD conditions (min/°C)	AER specific?	Single use or multiuse	Comment†
GLUTARALDEHYDE					Inexpensive; extensive experience; excellent material compatibility; respiratory irritant; irritating odor; fixes tissues and blood to surfaces; relatively slow mycobacterial activity
2.4%					
ProCide 14	Cottrell Ltd, Englewood, Colo	45/20	No	14-d max reuse	
Omnicide Long Life	Cottrell Ltd	45/20	No	28-d max reuse	
CIDEX activated dialdehyde solution	Advanced Sterilization Products, Irvine, Calif (A Johnson and Johnson Co)	45/25	No	14-d max reuse	
2.5%					
Rapicide	Medivators Reprocessing Systems, Minntech Corp, Minneapolis, Minn	5/35	No	28-d max reuse	
CIDEX Formula-7	Advanced Sterilization Products	90/25	No	28-d max reuse	
Metricide 28	Metrex Research, Inc, Romulus, Mich	90/25	No	28-d max reuse	
Wavicide-01	Medical Chemical Corp, Torrance, Calif	45/22	No	30-d max reuse	
2.6%					
Metricide	Metrex Research	45/25	No	28-d max reuse	
2.65%					
TD-5‡	PCI Medical Inc, Deep River, Conn	25/25	No	28-d max reuse	
3.2%					
Cetylcide-G	Cetylite Industries, Pennsauken, NJ	40/20	No	28-d max reuse	
3.4%					
Omnicide Plus	Cottrell Ltd	45/20	No	28-d max reuse	
Metricide Plus 30	Metrex Research	90/25	No	28-d max reuse	
CIDEX Plus	Advanced Sterilization Products	20/25	No	28-d max reuse	
3.5%					
Banicide Advanced	Pascal Co, Inc, Bellevue, Wash	45/25	No	30-d max reuse	
GLUTARALDEHYDE/ ISOPROPANOL					
3.4%/26%					
Aldahol III HLD	Healthpoint Ltd, Fort Worth, Tex	10/20	No	14-d max reuse	

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