Communication from the ASGE Technology Committee

TECHNOLOGY STATUS EVALUATION REPORT

Automated endoscope reprocessors

The 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 (U.S. 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 February 2010 for articles related to automated endoscope reprocessors, 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 endoscopes.[1] National standards have been adopted to ensure that endoscope reprocessing is performed consistently, by using a standardized protocol.[2] Automated endoscope reprocessors (AERs) are designed to replace some manual reprocessing steps.[3-5] In addition, AERs may limit exposure of personnel to liquid chemical germicides (LCGs).

TECHNICAL CONSIDERATIONS

HLD refers to treatment of medical devices to remove all viable microorganisms except a small residual of spores.[6] National consensus standards for endoscope reprocessing emphasize (1) bedside cleaning and aspiration of enzymatic detergent through the suction channel, (2) manual washing and brushing of accessible channels, (3) subsequent disinfection via immersion for an appropriate duration in an LCG of appropriate concentration, followed by (4) 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).[7,8]

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 ultrasound waves, (4) LCG vapor recovery systems, (5) heating to optimize LCG efficacy, (6) 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 LCG 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 on flow of LCG under pressure through the endoscope channels and continuous bathing of the exterior of the instrument with LCG. Some AERs consume and dispose of limited amounts of LCG per HLD cycle, whereas others use a reservoir of LCG that is reused over many cycles. The latter design results in gradual dilution of the LCG with repeated use and requires intermittent testing to verify maintenance of the minimum effective LCG concen-

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TABLE 1. Liquid chemical germicides available for high-level disinfection in the United States

Agent/trade name	Manufacturer	HLD conditions (min/*C)	AER specific	Maximum duration for reuse (days)	Comments
Glutaraldehyde					
2.4%					
Procide 14	Cottrell Ltd (Denver, Col)	45/20	No	14	Inexpensive
Omnicide Long-Life	Cottrell Ltd	45/20	No	28	Extensive experience
CIDEX activated dialdehyde solution	Advanced Sterilization Products, (Irvine, Calif)	45/20	No	14	Excellent material compatibility
2.5%					
Rapicide	Medivators Reprocessing Systems Minntech Medivators Reprocessing Systems Minntech	5/35	No	28	Fixes tissues and blood to surfaces. Relatively slow mycobacterial activity
CIDEX Formula-7	Advanced Sterilization Products	90/25	No	28	
Metricide 28	Metrex Research, Inc (Romulus, Mich)	90/25	No	28	
Procide D	Metrex Research, Inc	90/25	No	28	
Wavicide-01	Medical Chemical Corp (Torrance, Calif)	45/22	No	30	
2.6%					
Metricide	Metrex Research, Inc	45/25	No	28	
2.65%					
TD-5	PCI Medical Inc (Deep River, Conn)	25/25	No	28	
3.2%					
Cetylcide-G	Cetylite Industries (Pennsauken, NJ)	40/20	No	28	
3.4%					
Omnicide Plus	Cottrell, Ltd	45/20	No	28	
Metricide Plus 30	Metrex Research, Inc	90/25	No	28	
Procide D Plus	Metrex Research, Inc	90/25	No	28	
CIDEXPlus	Advanced Sterilization Products	20/25	No	28	
3.5%					
Banicide Advanced	Pascal Co, Inc (Bellevue, Wash)	45/25	No	30	
Glutaraldehyde/isopropanol					
3.4%/26%					
Aldahol III HLD	Healthpoint Ltd (Fort Worth, Tex)	10/20	No	14	
Glutaraldehyde/phenol/phenate					
1.12%/1.93%					
Sporicidin	Sporicidin International Co (Rockville, Md)	20/25	No	14	Lowest glutaraldehyde concentration for HLD
OPA					Fast action
0.55%					
CIDEX	Advanced Sterilization Products	12/20* 5/25†	No	14	'Materials compatibility Expensive

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