

TECHNOLOGY STATUS EVALUATION REPORT



Methods of luminal distention for colonoscopy

The ASGE Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidencebased methodology is used, performing 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 adverse events 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 2012 for relevant articles by using the key words "colonoscopy," "insufflation," "air," "carbon dioxide," and "water." Technology Status Evaluation Reports are scientific reviews provided solely for educational and informational purposes. Technology Status Evaluation Reports are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

BACKGROUND

More than 14 million colonoscopies are performed annually in the United States, with approximately half of these examinations for colorectal cancer screening. An ASGE/ACG Taskforce on Quality in Endoscopy proposed that effective endoscopists should achieve cecal intubation in 90% or more of all cases and 95% or more of screening colonos-

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copies.² During the insertion phase of colonoscopy, at least partial distention of the lumen is needed to allow adequate visualization to safely direct the instrument to the cecum. During withdrawal, a greater degree of luminal distention is desired to allow optimal inspection of the colonic mucosa. Several gaseous and liquid agents have been used for colonic luminal expansion. The ideal agent for colonic luminal expansion would facilitate cecal intubation, provide excellent mucosal visualization, limit intra- and postprocedure pain, and would be safe and inexpensive.

TECHNOLOGY UNDER REVIEW

Air insufflation

Commercially available endoscopic light sources contain an integrated air pump, and air insufflation has remained the most commonly used technique for luminal distention since the advent of colonoscopy in the late 1960s.^{3,4} Occluding the top of the air-water valve with a fingertip shunts air to the tip of the endoscope via the endoscope air channel. The maximal pressures generated by endoscopic light source air pumps range from approximately 300 to 375 mm Hg. However, air pressures at the endoscope tip are typically 30% to 40% less because of air leakage through the air channel itself or through the endoscope-light source connection.^{5,6} This corresponds to flow rates of 1.8 to 2.7 L/min at ambient pressure, with flow rates decreasing as pressure external to the endoscope increases (eg, within the distended colon).⁶ Several newer integrated air pumps have variable settings for air flow regulation (eg, off, low, medium, high). In a study of 34 patients undergoing routine diagnostic colonoscopy with air insufflation, the mean sustained intraluminal air pressure was 22 mm Hg (range 9-57 mm Hg).⁵ The mean amount of air insufflated at routine colonoscopy has ranged from 8.2 to 17.8 L.7,8

CO₂ insufflation

The use of CO_2 as an insufflating agent for the large bowel was initially proposed in 1953 as a method to prevent gas explosions during the electrosurgical removal of polyps at rigid proctoscopy. In addition to being nonflammable, CO_2 is absorbed across the intestines 160 times more rapidly than nitrogen and 13 times more rapidly than oxygen, which are the principal gas components of air. Animal studies have also demonstrated that CO_2 insufflation attenuates the reduced parietal blood flow seen with colonic distention, both caused by more rapid resolution of bowel distention, but also

Vendor	Model	CO ₂ sources accepted	Maximum gas pressure	Variable gas flow	Gas flow rates	Safety features	Price
Bracco Diagonistics, Inc. Princeton, NJ	CO₂EFFICIENT	gas cylinder	375 mmHg	No	3.4 L/min - "Managed flow" setting reduces gas flow from 3.4 L/min to <1 L/min after 10 seconds if air/water button is not touched	Mechanical pressure relief valve, electronic pressure relief valve, timed shut-off, volume shut- off, hydrophobic filter in gas tubing	\$7995
	CO ₂ MPACT	gas cylinder or gas line	375 mmHg	Yes - 3 level flow - automated switch	High - 3.4 L/min Medium - 2.9 L/min Low - 2.0 L/min	Mechanical pressure relief valve, mandatory variable timed shut-off, hydrophobic filter in gas tubing	\$4995
Olympus America, Inc, Center Valley, PA	UCR	gas cylinder or gas line	338 mmHg	Yes - 3 levels of flow - achieved by using different gas tubing kits	Standard gas tube - 1.5 L/min Low flow gas tube - 1.2 L/min Extra low flow gas tube - < 1.2 L/min	Optional variable timed shut-off	\$6200

by a direct vasodilating effect of $\rm CO_2$.^{11,12} In the 1980s, endoscopists began to evaluate $\rm CO_2$ insufflation as a potential method to reduce postcolonoscopy pain and bloating.¹³ More recently, $\rm CO_2$ insufflation has been evaluated in upper endoscopic procedures including ERCP and balloon-assisted enteroscopy. Outcomes data from these upper endoscopic applications are only briefly summarized here; a more complete discussion is beyond the scope of this colonoscopy-focused document.

There are 3 CO₂ regulators designed for use with GI endoscopes that are approved by the U.S. Food and Drug Administration in the United States. These regulators all require a CO2 source, most commonly a medical gas cylinder, although some operative or endoscopy suites may be equipped with a medical gas pipeline for CO₂. A specialty water bottle is required, as well as gas tubing that transmits CO₂ into the water bottle. The air button on the endoscopic light source must be turned off for CO2 to be used. The primary purpose of the regulator is to govern the gas flow to levels that are safe for use in endoscopy, although additional features are available on various models. Operating characteristics for endoscopic CO2 regulators available in the United States are shown in Table 1. The mean volumes of CO₂ used at colonoscopy are similar to those used for air, reported at 8.3 L to 14.0 L.^{7,8}

Water instillation

Reports as early as 1984 described the use of water instillation into the sigmoid colon as a method to facilitate passage of the colonoscope. 14,15 Potential benefits of this method include straightening and/or opening the sigmoid colon, reducing spasm, avoiding air-induced distention and elongation of the colon, and reducing patient discomfort. A large number of studies have recently emerged that evaluate water-assisted colonoscopy, although with variation in some technical aspects. 16 Some studies have allowed limited use of air insufflation, whereas others prohibited air insufflation until the cecum was reached by turning the air button on the light source to "off." Water volumes instilled have ranged substantially (from 200 mL to 2 L), and water temperature has varied from room temperature to 42°C, although most have used 37°C. Last, a potentially relevant dichotomy in technique is whether the instilled water is suctioned back during insertion or on withdrawal. 16 Typically, once cecal intubation is achieved with water-assisted methods, standard air or CO2 insufflation is used during withdrawal.

Other agents

Helium, argon, nitrogen, and xenon have all been evaluated as insufflation gases for laparoscopy.¹⁷ However,

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