



TECHNOLOGY STATUS EVALUATION REPORT

Electrosurgical generators

MAY 2003

INTRODUCTION

In order to promote the appropriate use of newer emerging technologies, the American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee has developed a series of status evaluation papers. This process presents relevant information about these technologies to practicing physicians for the education and care of their patients. In many cases, data from randomized, controlled trials is lacking and only preliminary clinical studies are available. Practitioners should continue to monitor the medical publications for subsequent data about the efficacy, safety, societal, and economic aspects of the technologies.

BACKGROUND

Electrosurgical generators (ESG) are used to facilitate therapeutic endoscopy, supplying electrical energy to endoscopic accessories. Electrosurgical generators generate high frequency (radio frequency) alternating current. When electrical energy is introduced to tissue, it produces excitation of molecules, which results in the generation of heat.¹ Electrosurgical energy is the term that reflects this transformation of electrical to thermal energy in tissue. The application of electrosurgical energy allows transection and/or coagulation of tissue by using polypectomy snares, forceps, sphincterotomes, and thermal hemostasis/ablation accessories. This status evaluation report details the use of ESGs in GI endoscopy.

TECHNOLOGY UNDER REVIEW

Current (I) is the flow of electrons during a period of time and is measured in amperes. A circuit is the pathway of current. Resistance (R) represents the

impediment to current and is measured in ohms. Voltage (V) is the force pushing current through a resistance and is measured in volts. Greater voltage is needed to maintain current flowing through a circuit as the resistance within the circuit increases. This relationship is described in Ohm's law $V = I \times R$. Power, measured in watts, equals current times voltage and represents the amount of energy transferred in a time interval.

Electrosurgical generators may supply two types of circuits, monopolar and bipolar. In the monopolar circuit, current passes from the active electrode (accessory device), through the patient to a distant return electrode (grounding pad), and back to the ESG to complete the circuit. This type of circuit commonly is used for snare polypectomy, sphincterotomy, hot biopsy forceps, argon beam coagulation, and lower esophageal sphincter ablation for control of gastroesophageal reflux. In bipolar circuitry, the device has two or more electrodes at the point of tissue contact, and current flows through the tissue between these electrodes completing the circuit. Thus, no return electrode is needed. The current flows only between the poles on the electrodes so the depth of tissue effect may be limited. Bipolar electrocoagulation most often is used for contact thermal hemostasis.

Electrosurgical generators may deliver monopolar current to produce electrosurgical cutting and/or coagulation. Electrosurgical cutting is achieved by a high voltage (>200 V) continuous current. This cutting effect begins with micro-electric arcs that are concentrated at the area of application via an active electrode (accessory device). This produces a rapid rise in the internal temperature of cells, causing intracellular water to boil and the cells to burst. This path of disrupted cells creates an electrosurgical cut. Dissipation of heat to the tissue at the margins of the cut produces a zone of coagulation along the cut edge.

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0016-5107/2003/\$30.00 + 0

PII:S0016-5107(03)02012-1

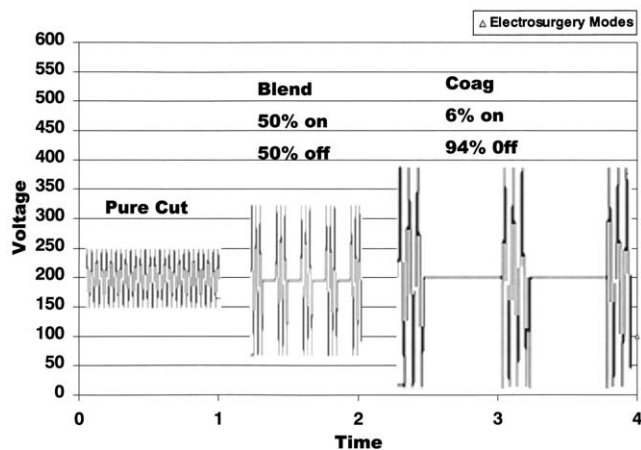


Figure 1. The electrosurgical current modes commonly used in GI endoscopy are represented graphically. Current delivered continuously at 100% duty cycle at volts over 200 is referred to as pure cut. Intermittent current pulsed at a 6% duty cycle is referred to as pure coagulation. Blended current is a mode that uses preset duty cycles ranging from 12% to 80%. To maintain a fixed power setting, lower duty cycles require progressively higher voltage.

Electrosurgical generators may produce coagulation by two mechanisms. Standard electrosurgical coagulation is achieved by using interrupted current. Another means to achieve coagulation is by using lower voltage (<200 V) continuous current. Coagulating currents produce a slower heating, causing tissue desiccation without cell bursting. Interrupted coagulation current generally is quantified by expressing the “on” time as a percentage of the total time, creating a value called the duty cycle (Fig. 1). Current delivered continuously at 100% duty cycle at volts over 200 is referred to as pure cut. Generally, current pulsed at a 6% duty cycle is referred to as pure coagulation current. Blended current is a mode that uses preset duty cycles that may range from 12% to 80%. To maintain a fixed power setting, lower duty cycles require progressively higher voltage. The tissue effects are device and operator dependent.

Each electrosurgical unit produces monopolar power in one of three configurations: (1) a conventional power source generates a narrow power curve such that as resistance rises, the power (voltage times current) falls quickly; (2) a constant power source generates a broad power curve and, as resistance rises, power stays constant by increasing the voltage; (3) a constant voltage source keeps voltage constant when the resistance varies, thus, current and power increases when the resistance decreases, and current and power decreases when the resistance rises. Some ESGs have proprietary software to produce a specific tissue effect. For

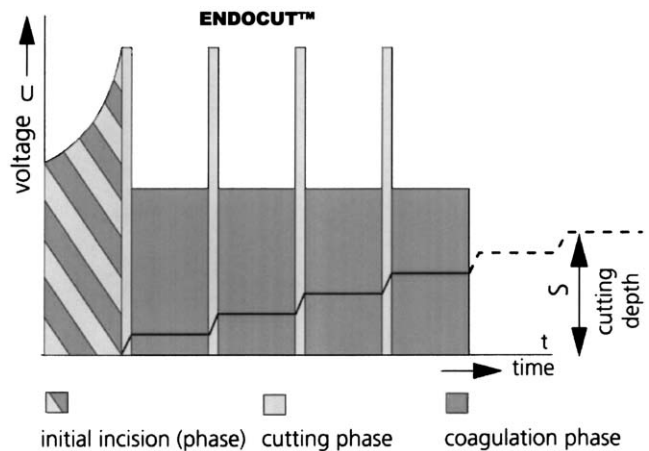


Figure 2. The ERBE Endocut current mode is represented graphically. This mode controls output to produce tissue transection with a low-voltage, continuous current followed by bursts of cutting current interspersed with interrupted coagulation current in a constant voltage configuration. (Image courtesy of ERBE, Marietta, Ga.)

example, ERBE Endocut (ERBE, Tübingen, Germany) controls output to produce tissue transection with a low-voltage, continuous current followed by bursts of cutting current interspersed with interrupted coagulation current in a constant voltage configuration (Fig. 2).

A variety of ESGs, with a range of features, are available for use in endoscopy (Table 1). Electrosurgical generators vary in their display of energy output. The selected power may be displayed digitally as watts or as a numeric value and is device specific. Electrosurgical generators that do not display output in watts may differ in their actual output at a given numeric setting, and the power output may not vary in a linear fashion. Preset duty cycles, and their terminology, are not standardized and vary among commercially available ESGs.

Electrosurgical generators typically are activated by depressing a foot pedal. Some units have an integrated water pump, also activated by a foot pedal, to facilitate endoscopic visualization. Reference to technical material supplied with each device is advised.

Several variables that impact the electric circuit and the desired tissue effect are not related directly to the ESG.² The most important of these is the current density, which is defined as the current concentration at a given point in the circuit. The current density at the contact point of the device and the tissue is responsible for the effect. Variables that may affect current density include the size and configuration of the electrode wire (e.g., braided vs. monofilament wires in a polypectomy snare or

Table 1. Electrosurgical generator manufacturers

Company	Address	Web site
Boston Scientific	One Boston Scientific Place, Natick, MA 01760-1537	www.bsci.com
Bovie Company	7100 30th Ave., N., St Petersburg, FL 33710-2902	www.boviemedical.com
Circon ACMI	136 Turnpike Rd., Southborough, MA 01772-2104	www.circoncorp.com
Conmed	525 French Rd., Utica, NY 13502	www.conmed.com
Ellman	1135 Railroad Ave., Hewlett, NY 11557	www.ellman.com
Elmed	60 West Fay Ave., Addison, IL 60101	www.elmed.com
ERBE	2275 Northwest Parkway, Suite 105, Marietta, GA 30067	www.erbe-usa.com
Johnson and Johnson	4545 Creek Rd., Cincinnati, OH 45242	www.jnjgateway.com
Valleylab	5920 Longbow Dr., Boulder, CO 80301-3299	www.valleylab.com

sphincterotome), the manipulation of the active electrode, and the placement and configuration of the return electrode.^{1,3} Patient or tissue characteristics that may affect the circuit include the size of the patient and the presence of fibrous or fatty tissue in the circuit path. Finally, the technique used by the physician and endoscopic assistant impacts the circuit and the resulting electrosurgical effect. Examples include the force with which the device is manipulated and the duration of activation. Familiarity determines optimal settings and technique to achieve the desired outcome.

Dedicated accessory/application-specific ESGs for the Heat Probe⁴ (Olympus America Corp., Melville, N.Y.) and Stretta⁵ (Curon Medical, Palo Alto, Calif.) are not further addressed in this document. The Heat Probe generator electrically generates heat at the tip of a Teflon-coated probe and is, therefore, unlike the ESGs described in this status evaluation report.

INDICATIONS AND EFFICACY

Snare polypectomy

There are no reports comparing various ESGs for snare polypectomy. There are no published human trials comparing monopolar and bipolar snare polypectomy. A retrospective analysis of blended vs. pure coagulation current for colonoscopic polypectomy reported no significant differences in the overall complication rates between the two groups.⁶ However, a significant difference was seen in the timing of bleeding, with all of the major hemorrhages occurring immediately or within 12 hours when blended current was used (3/758), and all were delayed (2-8 days) when pure coagulation current was used (6/727). These findings were corroborated by another retrospective analysis that used a pure cutting current.⁷

Endoscopic sphincterotomy

An unblinded, randomized trial comparing ERBE Endocut mode to blended current (settings not detailed) for biliary sphincterotomy found no difference in the incidence of pancreatitis. There were no

differences in moderate or severe bleeding, but there was an increase in the frequency of mild bleeding with blended current ($p = 0.002$).⁸ Investigators' subjective assessment of degree of control favored the ERBE Endocut mode.

Three studies comparing ERBE Endocut with conventional ESG modes for pancreaticobiliary sphincterotomy, presented in abstract form, did not demonstrate a difference in rates of pancreatitis or clinically significant bleeding.⁹⁻¹¹

A randomized trial compared bipolar sphincterotomy with conventional monopolar sphincterotomy (35 watts; current not reported) on 100 patients. There was a significant decrease in incidence of pancreatitis in the bipolar sphincterotomy group.¹² There are no additional published clinical trials on this accessory, and it has not been widely adopted.

Three randomized trials were designed to assess the impact of pure cut vs. blended current on clinical outcomes after sphincterotomy. A randomized, blinded trial comparing 30 watts of blended vs. 30 watts of pure cutting current from a single generator was performed on 170 patients undergoing biliary sphincterotomy. Complications were seen in 4/86 patients in the pure cutting current group (1 bleed, 3 mild pancreatitis) and 12/84 patients in the blended current group (7 mild pancreatitis, 2 moderate pancreatitis, 1 severe pancreatitis, 1 cholangitis, and 1 bleed). There were significantly fewer complications in the pure cut group ($p < 0.05$).¹³ A randomized trial of 142 patients compared sphincterotomy with 30 watts of pure cut throughout vs. initiating the sphincterotomy with pure cut for 75% to 80% of the total distance and completing the cut with 30 watts of blended current. No significant differences were seen in pancreatitis or bleeding requiring transfusion, although significantly less minor bleeding was seen in the combined cut/coagulation group.¹⁴

A randomized trial in 186 patients with bile duct stones compared complications in three equal groups of 62 patients undergoing sphincterotomy with 34 watts of pure cutting current (group 1), vs. 34 watts of

blended current (group 2), vs. pure cutting current for the first 3 to 5 mm and then blended current to complete the sphincterotomy (group 3). There was statistically less pancreatitis in group 1 (3.2%) compared with group 2 (12.9%) and group 3 (12.9%; $p = 0.048$). Immediate bleeding was more common in group 1 (32.3%) compared with group 2 (9.6%) and group 3 (14.5%; $p = 0.003$). However, bleeding requiring endoscopic intervention occurred only in two patients, both in the pure cut group. Delayed bleeding requiring transfusion was seen in 3 patients, one in each group.¹⁵

Miscellaneous procedures

There is no report comparing ESGs for use with hot biopsy forceps or endoscopic hemostasis/ablation. Please refer to dedicated status evaluation reports on hot biopsy forceps,¹⁶ bipolar and multipolar accessories,¹⁷ endoscopic hemostatic devices,⁴ and argon plasma coagulation.¹⁸

SAFETY

Adverse outcomes related to ESGs are classified as device malfunctions. Electrosurgical generator malfunction may result in failure to generate current, current in the specified mode, and/or current at the desired power output. Complications directly related to ESGs are rare. A search of the MAUDE database on March 8, 2003, for 2001 to 2002 entries with using "electrosurgical generators" as a search term revealed 186 entries.¹⁹ A qualitative review of these entries indicated that the majority of events were operator or accessory related. Complications from specific endoscopic therapeutic techniques and accessories that use ESGs are discussed in separate ASGE guidelines and status evaluation reports.^{4,5,16-18}

When monopolar current is used, the large surface area of the return electrode decreases current density to prevent skin burns. Electrosurgical generators may have a contact quality monitoring system (CQMS) feature that monitors the patient-to-return electrode interface. By using dual foil (split)-plate return electrodes, CQMS disables the ESG and alerts the staff when a pad-fault condition occurs. This system is intended to reduce the risk of return electrode pad site burns.

There are no peer-reviewed studies in human beings on the placement location of the return electrode. Placement location is important to ensure good contact. Placement of the return electrode over metal-tipped objects that can conduct electricity (e.g., EKG lead electrodes) has been associated with cutaneous burns.²⁰

The high frequencies produced by ESGs do not cause neuromuscular stimulation when used in GI

endoscopy. Thus, there is no stimulation of skeletal, smooth, or cardiac muscle. Most modern cardiac pacemakers are unaffected by ESG current, provided the grounding pad and electrode tip are remote from the pacemaker site.²¹ Before use of ESGs in patients with implantable ventricular defibrillators and defibrillating pacemakers, cardiology consultation and/or disabling these implanted cardiac device is recommended to avoid inadvertent discharge.

FINANCIAL CONSIDERATIONS

Electrosurgical generators vary widely in cost, dependent on manufacturer and features. Return electrodes are available from ESG manufacturers and other distributors. Multipurpose ESGs commonly are used in operating rooms, and opportunities for sharing equipment with endoscopy units exist.

CONCLUSIONS

The application of electrosurgical energy facilitates therapeutic endoscopy. A variety of ESGs are available. Multipurpose ESGs supply monopolar and bipolar current. Familiarity with device-specific settings is required for safe and effective use.

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