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Surgeons don't know what they don't know about the safe use of energy in surgery

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Abstract
Background Surgeons are not required to train on energy-based devices or document their knowledge of safety issues related to their use. Their understanding of how to safely use the devices has never formally been tested. This study assessed that knowledge in a cohort of gastrointestinal surgeons and determined if key facts could be learned in a half-day course.
Methods SAGES piloted a postgraduate CME course on the Fundamental Use of Surgical Energy™ (FUSE) at the 2011 SAGES meeting. Course faculty prepared an 11-item multiple-choice examination (pretest) of critical knowledge. We administered it to members of the SAGES board; Quality, Outcomes and Safety Committee; and FUSE Task Force. Postgraduate course participants took the pretest, and at the end of the course they took a 10-item post-test that covered the same content. Data are expressed as median (interquartile range, IQR).
Results Forty-eight SAGES leaders completed the test: the median percent of correct answers was 59 % (IQR = 55–73 %; range = 0–100 %). Thirty-one percent did not know how to correctly handle a fire on the patient; 31 % could not identify the device least likely to interfere with a pacemaker; 13 % did not know that thermal injury can extend beyond the jaws of a bipolar instrument; and 10 % thought a dispersive pad should be cut to fit a child. Pretest results for 27 participants in the postgraduate course were similar, with a median of 55 % correct (IQR = 46–82 %). Participants were not told the correct answers. At the end of the course, 25 of them completed a different 10-item post-test, with a median of 90 % correct (IQR = 70–90 %).
Conclusions Many surgeons have knowledge gaps in the safe use of widely used energy-based devices. A formal curriculum in this area can address this gap and contribute to increased safety.

Keywords Energy-based surgical devices · Operating room safety · Pretest · Post-test · Curriculum development · FUSE

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The vast majority of surgical procedures in every specialty performed throughout the world today involve the use of devices that apply energy to tissue. This approach has been used therapeutically for thousands of years. Cautery, the

direct application of heat to tissue, was used by the Egyptians around 3000 BCE to treat tumors and in trauma to control hemorrhage [1]. In the early 20th century, Bovie invented an electrosurgical unit in which high-frequency alternating current passed through the body was used for cutting and coagulation [2]. Cushing introduced this device into clinical practice in the United States over 85 years ago [2], and the basic principles have changed very little since then. Radiofrequency electrosurgery is ubiquitous in operating rooms, endoscopy suites, and countless other procedure rooms worldwide.

A dramatic increase in the number and complexity of energy devices has taken place in the last decade. While bipolar devices were introduced in the 1940s, recent developments (i.e., the incorporation of cutting blades and real-time impedance measurement) have led to "advanced" bipolar technologies. The 1990s saw the development of ultrasonically generated vibration as a source of mechanical energy. Advances in the design of surgical energy devices continue to this day, with newer bipolar and ultrasonic devices considered key enabling technologies in the development of advanced minimally invasive surgical procedures [2]. The variety of devices and technologies available has mushroomed, with multiple vendors, configurations, energy platforms, generators and cost points.

Since energy devices are used on a daily basis by all surgeons, some may question the need for an educational program. The combination of electrical current and heat generation, the wide variety of devices, and the complex environments in which they are used can cause complications. Surgical burns and fires are common and are listed in the emergency care research Institute's (ECRI) Top 10 health technology hazards for 2012 [3]. In laparoscopic surgery, the incidence of injury related to electrosurgery alone is estimated at 1–2 per 1,000 patients [4]. Results, including mortality from delayed bowel perforation, are potentially devastating.

To use energy devices to their fullest potential, prevent complications, and improve the safety of surgery and its outcomes, users need to understand the principles underlying the function of each device, how it is set up and interfaces with other devices, and its potential pitfalls. Nonetheless, there is no standard curriculum outside of training offered by commercial vendors on the use of their proprietary systems. With the exception of laser surgery, which requires specific credentialing, no such standards exist for other energy devices.

To address this safety issue, The Society of American gastrointestinal and endoscopic surgeons (SAGES) is creating the Fundamental Use of Surgical Energy (FUSE) program, an educational resource that includes a curriculum and validated assessment to verify learning. As a first step, the FUSE Task Force created a curriculum delivered as a half-day postgraduate course at the 2011 SAGES meeting. The purpose of this study was to assess knowledge in a cohort of gastrointestinal surgeons, including surgical leaders, and to determine if key facts could be transmitted in a half-day course.

Methods

The FUSE Task Force was convened in October 2010 and was charged with developing a curriculum on surgical energy devices leading to certification. The committee consisted of mainly general surgeons with subspecialty interests in hepatobiliary, bariatric, gastrointestinal, abdominal wall, minimally invasive, pediatric, and endoscopic surgery. Each member had additional expertise in energy devices and/or education. The group first developed a postgraduate course for the SAGES meeting in April 2011. The course faculty included a gynecologic surgeon and two anesthesiologists with particular expertise in electrosurgery.

Pilot course content was used as the basis for the FUSE manual (Springer, 2012) and the FUSE multimedia curriculum, currently in development, with a beta launch date of Fall, 2012. It informed the process to define the knowledge and skills (competencies) required to use energy devices safely and served as the basis for a certification exam being developed with psychometric experts (www.kryterionline.com). Further expertise added to the committee included nursing, engineering, and additional surgical subject matter experts. Sixty-three curriculum and assessment objectives were defined.

Pilot postgraduate course content was divided into 11 sections:

1. Fundamentals of electrosurgery part 1, with a general focus on principles of radiofrequency energy
2. Fundamentals of electrosurgery part 2, which covered mechanisms and prevention of adverse events with electrosurgery, including OR fires
3. Monopolar devices
4. Bipolar devices
5. Radiofrequency for soft tissue ablation
6. Endoscopic devices
7. Ultrasonic energy systems part 1, which focused on general principles
8. Ultrasonic energy systems part 2, which focused on cavitron ultrasonic surgical aspirators
9. Microwave energy systems
10. Energy devices in pediatric surgery
11. Integration of energy systems with other medical devices

Course faculty received a document on how to effectively write multiple-choice questions. They submitted a

minimum of three in areas considered critical knowledge. A subject matter expert reviewed a total of 79 questions for consistency and nomenclature. One question from each of the 11 course content domains was used to create the pretest. The post-test consisted of a second 10-item examination from the same content domains (excluding pediatric surgery).

Each item could be mapped to a curriculum objective. For the pretest, these included (1) define proper electrosurgical terms, (2) identify how to respond to an OR fire, (3) identify the different input and output functions of an electrosurgical generator, (4) identify the characteristics of basic and advanced bipolar electrosurgical instruments, (5) identify the similarities and differences between typical RF electrosurgical and RF ablation systems, (6) identify the steps for safe energy use during a polypectomy, (7) identify the mechanism by which ultrasonic devices achieve tissue effects, (8) identify functions of a cavitron ultrasonic surgical aspirator (CUSA) device, (9) identify the differences between RF energy and microwave energy systems, (10) identify unique considerations for choice of and placement of dispersive electrodes for infants and children, and (11) identify surgical devices that can cause electromagnetic interference (EMI).

The pretest was administered to SAGES leaders attending the Quality, Outcomes and Safety (QOS) Committee, the Board of Directors, and the FUSE Task Force meetings. The pretest was then given to FUSE postgraduate course participants, who also completed the 10-item post-test at the conclusion of the morning session of the course. The answers to each item were tabulated in a spreadsheet and reported as proportions or medians (IQR).

Results

Forty-eight SAGES leaders (18 members of the QOS Committee, 24 board members, and 6 members of the FUSE Task Force) took the 11-item pretest. The median number of correct answers was 6.5 (IQR = 6–8), or 59 % (IQR = 55–73 %). The number of correct answers ranged from 3 to 11. One person left the entire test blank with the comment, "Don't know nothing HELP! Will take course next time." Another had one correct item out of the first five, and left the next six blank.

The first two items pertained to electrosurgical nomenclature and generator outputs. Of the SAGES leaders, only 35 % and 20 %, respectively, provided correct answers. Thirty-one percent (31 %) failed to correctly answer the item on how to handle a fire in the operating room; 31 % could not identify the device that does not interfere with cardiac pacemakers; 13 % did not recognize that thermal injury can extend beyond the tissue grasped in a bipolar device; and 10 % thought a dispersive electrode should be cut to fit a child.

Twenty-seven FUSE course participants completed the same pretest. The median number of correct answers, 6 (IQR = 5–9), was very similar to that of the SAGES leaders. At the end of the half-day course, 25 participants completed the second 10-item post-test covering the same domains, excluding pediatric surgery. The median percent correct increased from 55 % (IQR = 50–82 %) to 90 % (IQR = 70–90 %).

The objectives associated with each item on the pretest and the percentage of test takers' correct answers is summarized in Table 1.

Discussion

Electrosurgical and other energy devices are used in virtually every surgical procedure around the world. While they contribute to safer and more efficient surgery, they can also cause serious complications. It is reasonable to expect that surgeons and other health professionals have a fundamental knowledge of how the devices they use on a daily basis function, and how to prevent, recognize, and react to complications. However, many surgeons who took the short pretest developed for a pilot postgraduate course for the FUSE program showed suboptimal understanding of the devices they use on a daily basis and train others to use.

Knowledge gaps were particularly evident in electrosurgical nomenclature, generator settings, responses to operating room fires, and interactions with other implantable devices. Similar results were seen with surgeons attending the pilot FUSE postgraduate course on surgical energy devices. Their performance improved immediately after the course, suggesting that key facts could be transmitted using this course format, with at least short-term retention.

The strength of the conclusions that can be drawn from this report is preliminary. Limitations include a convenience sample and an unvalidated exam. We do not know if the improved performance on the post-test was durable, as participants were not retested at a later date, and we have no evidence linking performance on this test with the risk of complications related to energy devices.

Despite these limitations, these results highlight a training and assessment gap in surgical safety that is gaining wider attention, including stories about operating room burns in the lay press [5]. The ECRI estimates that 550–650 fires occur in operating rooms in the United States each year [6], with some causing serious disfigurement or even death. The FDA has responded by creating a new "Preventing Surgical Fires" initiative to increase

Table 1 Percentage of correct answers for each item and the curriculum objective addressed by that item on the FUSE pilot postgraduate course pretest

Item no.	Domain objective	% Correct		Total ($n = 75$)
		SAGES leaders ($n = 48$)	FUSE course attendees ($n = 27$)	
1	Define proper electrosurgical terms	35	44	39
2	Identify the different input and output functions of an electrosurgical (RF) generator	20	30	25
3	Identify how to respond to an OR fire	69	56	64
4	Identify the characteristics of basic and advanced bipolar electrosurgical instruments	54	70	60
5	Identify the similarities and differences between typical RF electrosurgical and RF ablation systems	54	74	61
6	Identify the steps for safe energy use during a polypectomy	79	78	79
7	Identify the mechanism by which ultrasonic devices achieve tissue effects	75	74	75
8	Identify functions of a cavitron ultrasonic surgical aspirator (CUSA) device	81	70	77
9	Identify the differences between RF energy and microwave energy systems	29	37	32
10	Identify unique considerations for choice and placement of dispersive electrodes for infants and children	79	74	77
11	Identify surgical devices that can cause electromagnetic interference (EMI)	60	70	70

Members of the FUSE (Fundamental Use of Surgical Energy™) Task Force include: Daniel B. Jones MD (Chair), Liane S. Feldman MD (Co-Chair), Pascal Fuchshuber MD (Co-Chair), Sharon L. Bachman MD, L. Michael Brunt MD, James Choi MD, Suvranu De ScD, Brian J. Dunkin MD, Warren Grundfest MD, Charlotte Gugliemi RN, Jeffrey W. Hazey MD, Scott Helton MD, Daniel M. Herron MD, David Iannitti MD, Gretchen Purcell Jackson MD, Stephanie Jones MD, Jarrod Kaufman MD, Leena Khaitan MD, Dean J. Mikami MD, William S. Richardson MD, Thomas N. Robinson MD, Marc Rozner MD, Steven D. Schwaitzberg MD, Daniel J. Scott MD, Victoria J. Steelman PhD, Thadeus L. Trus MD, J. Esteban Varela MD, C. Randy Voyles MD, and Eelco Wassenaar MD

RF radiofrequency

awareness of the risks and promote the adoption of safe practices [7].

The incidence of injury related to energy devices used in laparoscopic surgery is reported to be between 1 and 2 per 1,000 [4]. This is comparable to other high-profile surgical safety issues, including the incidence of retained surgical foreign bodies, estimated at 0.7-1 per 1,000 abdominal operations [8], and wrong-site surgery, estimated as 1 in 9,000 cases [9]. Injuries with monopolar devices may be hard to detect, with the depth of injury difficult to judge even if noticed intraoperatively [10]. The affected area may be much larger than is superficially apparent. Moreover, delayed presentations are common and may be difficult to diagnose as traditional signs and symptoms of peritonitis may be absent after laparoscopic surgery [11]. Thus, prevention is critical.

The Society of Laparoendoscopic Surgeons called for improved education on electrosurgical principles and improved credentialing more than a decade ago [12]. However, no standard curriculum to train surgeons, nurses, and other operating room personnel in the use of electrosurgery and other energy devices exists, nor is there a well-defined requirement to demonstrate competency in their use.

Although some excellent resources are available, such as the recommendations from the association of perioperative registered nurses (AORN) on the safe use of electrosurgery, these do not address the full range of devices and have no assessment component [13, 14]. Limited information is available to general surgeons through their standard textbooks. Indeed, most training, including that during residency, comes from industry-sponsored talks or even from energy device sales representatives when new systems are purchased.

The SAGES FUSE program aims to address training and assessment gaps in areas where the lack of a standardized curriculum for energy devices may contribute to risk of injury. FUSE will be the third program in SAGES' "Fundamentals" series, all of which include a curriculum and validated assessment component. The other two are Fundamentals of Laparoscopic Surgery (FLS), a requirement for general surgery residents to take the qualifying exam for the American Board of Surgery, and Fundamentals of Endoscopic Surgery (FES), which is about to be released.

This report indicates that, in general, the SAGES leadership lacks content expertise in the use of energy devices. Thus, specific content experts (including engineers, scientists, surgeons, nurses, and anesthesiologists) have been tapped to provide this knowledge. FUSE will offer a multidisciplinary (surgeons, nurses, anesthesia providers, technicians), multispecialty approach to the safe use of

surgical energy. It will fill the unmet curricular and competency assessment needs that exist in operating room environments in hospitals and outpatient surgical centers.

In summary, surgical leaders lack knowledge about energy devices despite their widespread use and the risk for complications. The FUSE program being developed by SAGES aims to rectify this situation via a comprehensive curriculum and certification process. This report shows that health-care professionals who attended a half-day course learned key facts that substantially improved performance on a subsequent post-test, suggesting that the FUSE program can achieve its objectives.

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