

*Selected, quality filtered, not subject to external review

Issue: The VA Chief Patient Care Services Officer (CPCSO) asked VATAP to provide evidence from the literature on the incidence of thermal burn injury caused by leakage current during laparoscopic electrosurgery, as well as to identify recommended safety strategies. The injuries of interest are those that take place outside the field of vision of the procedure caused by capacitive coupling or from stray energy escaping through insulation defects. The information would serve as the basis of VA's response to a public inquiry regarding the incidence of stray thermal energy injuries during laparoscopic electrosurgery in the VA patient population and related safety practices.

Encision Active Electrode Monitor (AEM®) Laparoscopic Instruments (Boulder, CO), which manufactures a dynamic electrode monitor that automatically shuts off laparoscopes to prevent burns from stray energy, asserted that such injury is rarely recognized at the time of the procedure and can cause significant injury, even death¹. They claimed a potentially high incidence of such complications based on an estimated 4.4 million laparoscopic procedures performed annually. However, surgeons are divided over the validity of these claims.

Methods: To meet the immediate information needs of its client, VATAP queried members of the International Network of Agencies for Health Technology Assessment (INAHTA)² electronically via their listserv on March 8, 2006 for information on either the Encision system or related reviews of stray thermal energy injuries during laparoscopic electrosurgery.

VATAP conducted searches on MEDLINE and EMBASE through Dialog© from 1990 to March 2006 from several perspectives to capture any evidence-based literature on the related topics of stray energy during electrosurgery, thermal burns or burns resulting from monopolar probes used in laparoscopic surgery. VATAP added the additional topics of safety standards, incidence of injury, complications, and guidelines for laparoscopic electrosurgery. Concepts for electrosurgery included: laparoscop* (N) surger* or laparoscop* (N) electrosurger* or electrosurg* which were combined with: injur* or burn* or complication* or intraoperative complication or safety practice* or guideline* or burn* or incidenc* or equipment safety.

Primary studies or literature reviews reporting data on the incidence of thermal injury from electrosurgery were included, as were articles that reported safety strategies for laparoscopic electrosurgery, focusing on the most recent and comprehensive.

Results: Eight INAHTA members responded to the query: seven in the negative and one report from the Health Technology Inquiry Service of the Canadian Agency for Drugs and Technology in Health (CADTH, formerly the Canadian Coordinating Office for Health Technology Assessment) that addressed porosity detectors and bipolar stick active electrodes used in surgery³. While not directly relevant to this review, the report provided links to information sources that may be helpful.

The searches identified 369 unique references: 28 references were retrieved based on title and abstract information as potentially relevant to the review. Of those, eight citations met criteria

¹ <http://www.encision.com/background.html>, accessed March 8, 2006.

² www.inahta.org

³ CADTH. Electrosurgery Units: 1) porosity "holiday" detectors, and 2) bipolar stick active electrodes. November 25, 2005. Health Technology Information Service, Canadian Agency for Drugs and Technology in Health, Ottawa Canada. www.cadth.ca

for inclusion in the report either as studies reporting incidence data of thermal injury due to electrosurgery (three studies) or articles describing the most recent and comprehensive guidance on safety strategies for laparoscopic electrosurgery (five articles).

Incidence of thermal injury

VATAP's comprehensive literature searches identified one HTA report by ECRI⁴, which based its findings on a review by Bishoff⁵, plus two additional articles reporting data on the incidence of thermal injury^{6,7}(see Table 1). Bishoff found the average percentage of bowel injuries for all laparoscopic monopolar electrosurgery to be about 0.07%, but the incidence of bowel complications due to leakage current from insulation breakdown or capacitive coupling, which are the injuries of interest, were not specifically reported. ECRI was not aware of any other data specific to those causes. Results from Meikle (1997) and Smith (2001) confirm the findings from the Bishoff review. All reports stress the difficulty in capturing the exact incidence of thermal burns due to laparoscopic electrosurgery.

Table 1. Incidence of thermal injury from laparoscopic electrosurgery

Citation	Specialty	Total N	Incidence	Comments
Bishoff (1999) Literature review cited in Health Devices (2005)	Primarily GYN, some general surgery & urology	205,969	Bowel injury caused by electrocautery =154 (0.075%)	Thermal injury not differentiated
Meikle (1997) Literature review from 1989-Sept 1995	GYN-LAVH, TAH procedures	2,273	Bowel trauma due to thermal injury= 2 (0.09%)	Thermal injury not differentiated
Smith (2001) Survey of 620 members of Society of Univ. Otolaryngologists in July 1999	ENT	99,664	Thermal injury due to capacitive coupling= 48 (0.05%)	Electrosurgery not done in all total cases reported

ENT, otolaryngologists
GYN, gynecology
LAVH, laparoscopic assisted vaginal hysterectomy
TAH, total abdominal hysterectomy

Recommended safety practices

From the searches VATAP identified detailed and current guidance encompassing both general safety recommendations during electrosurgery and specific guidance for laparoscopic monopolar electrosurgical procedures. The type of evidence supporting each recommendation is not stated, but the recommendations take into account basic scientific principles guided by clinical expertise.

⁴ ECRI. Safety technologies for laparoscopic monopolar electrosurgery. Devices for managing burn risk. Health Devices. August 2005;34(8):259-72.

⁵ Bishoff JT, Allaf ME, Kirkels W, et al. Laparoscopic bowel injury: incidence and clinical presentation. Journal of Urology. 1999;161:887-90.

⁶ Meikle S, Weston Nugent E, Orleans M. Complications and recovery from laparoscopy-assisted vaginal hysterectomy compared with abdominal and vaginal hysterectomy. Obstetrics & Gynecology. 1997;89(2):304-11.

⁷ Smith TL and Smith JM. Electrosurgery in Otolaryngology—head and neck surgery: principles, advances, and complications. Laryngoscope. 2001; 111:769-80.

ECRI⁸ evaluated four products designed to reduce the risk of leakage-current burns during monopolar laparoscopic electrosurgery, including the Encision EM2+ AEM®. While ECRI rated the Encision EM2+AEM® the highest of the four products, the low incidence of thermal injury complications and discussions with clinicians indicated that none of the technologies was viewed as essential to safe laparoscopic monopolar electrosurgery. Rather, these technologies were regarded as supplemental safety measures to general safety practices required during these procedures.

Among the most commonly cited recommendations are those from the Association of Perioperative Registered Nurses (AORN)^{9,10}, and there has been an appeal for guidance on this topic from medical societies, most notably from the Society of Laparoendoscopic Surgeons¹¹. While both organizations mention active electrode monitoring equipment as a means of minimizing risks to patients and personnel, both emphasized general safety practices, monitoring adverse outcomes, and education and training of surgeons and operating room personnel. Brill and colleagues refer to their own guidance as a “call to arms” of medical staff for improved credentialing through education of electrosurgical principles and documented training of procedure proficiency¹².

ECRI's recommendations summarize the general safety recommendations found in the literature for laparoscopic monopolar electrosurgery:

1. Use conductive trocar cannulas.
2. Ensure adequate electrode insulation through visual inspection of the electrode and the tip preoperatively and postoperatively, and periodic replacement (consider replacing after one year of use unless specified by the manufacturer).
3. Select optimal electrosurgical output, power setting, and techniques.
4. Appropriately train and credential medical and technical personnel.

⁸ ECRI. Health Devices. August 2005;34(8):259-72.

⁹ Recommended practices for electrosurgery. AORN Journal, 2005. 81(3): p. 616-8, 621-6, 629-32 passim.
http://www.findarticles.com/p/articles/mi_m0FSL/is_3_81/ai_n13471132

¹⁰ Laparoscopic electrosurgical complications and their prevention. AORN Journal. 1995;62(1):51-3, 58-9.

¹¹ Brill AI, Feste JR, Hamilton TL, et al. Patient safety during laparoscopic monopolar electrosurgery--principles and guidelines. Consortium on electrosurgical safety during laparoscopy. Journal of Society of Laparoscopic Surgeons. 1998;2(3):221-5.

¹² Safety in laparoscopic electrosurgery. OR Manager. May 1999;15(5): 30.

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