Patient Safety During Laparoscopic Monopolar Electrosurgery – Principles and Guidelines

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INTRODUCTION

Since its modern introduction in the early 1970s, minimally invasive surgery has revolutionized surgical diagnosis and intervention. Minimally invasive surgery, by definition, offers patients the significant benefits of faster healing and less postoperative pain.

The increase in minimally invasive procedures performed has been accompanied by an increase in the incidence of associated iatrogenic complications. A significant portion of these complications are electrosurgical in nature—stemming from surgical pilot error, improper use or maintenance of electrosurgical instrumentation, or from electrosurgical burns that occur beyond the surgeon's direct vision or control.

A growing number of patient injury reports, insurance claims, and legal cases provide increasing evidence that intra-abdominal electrosurgical injuries during laparoscopic surgery not only threaten patients' health, but can be costly to both surgeons and the institutions in which these procedures take place. As with any form of healthcare delivery, surgeons, operating room nurses, biomedical engineers, risk managers, and healthcare provider organizations all have a responsibility to protect patients against the potentially devastating injuries that can occur during laparoscopic electrosurgery.

Convened and coordinated by Communicore, a strategic medical communications organization dedicated to accelerating the adoption of innovative technologies, products, and services that enhance the delivery of healthcare, the *Consortium on Electrosurgical Safety During Laparoscopy* met in the summer of 1997 to discuss the various perspectives of the above constituencies and explore ways to reduce patients' risk of injury during laparoscopic monopolar electrosurgery. After a lengthy discussion and debate, the Consortium concluded: (i) that the basic principles and physics of laparoscopic electrosurgery are not widely understood and (ii) that there appears to be a growing complacency in the surgical community regarding the risks associated with laparoscopic monopolar electrosurgery, partly because of its popularity and increasingly "routine" nature. The Consortium further concluded that a positive contribution to patient safety during electrosurgery could be made by generating a set of principles and guidelines that reflected the concerns of all constituencies involved.

The Principles and Guidelines generated by the Consortium appear below. Particular attention was given to opportunities for improving training and education, and the value of establishing and standardizing various safety procedures that could help reduce the risk of patient injury during laparoscopic monopolar electrosurgery.

THE ISSUES

A 1992 survey conducted by the Society of Laparoendoscopic Surgeons estimated that by the year 2000, 40% of urology procedures, 50% of general surgery procedures, and 70% of all gynecology procedures will utilize laparoscopy.[1] The vast majority of these laparoscopic procedures will utilize electrosurgical techniques to coagulate and dissect tissue.

Genesis of Direct and Indirect Thermal Injuries

Laparoscopic monopolar electrosurgery is associated with both direct and indirect thermal injury. Direct thermal injury occurs when the surgeon misidentifies anatomic structures or accidentally applies the tip of the active electrode to non-targeted tissue (i.e., surgical "pilot error"). In contrast, indirect thermal injury can result when electrical current is conducted along unintended pathways and burns or vaporizes a non-targeted tissue. Such indirect injuries occur during laparoscopic monopolar electrosurgery as a result of insulation failure, direct coupling, and/or capacitive coupling.

Insulation failure occurs when the layer of insulation covering the shaft of the active electrode breaks down. This breakdown can occur cumulatively over time with repeat-

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ed usage; it may also take place during a single laparoscopic procedure or during instrument cleaning and sterilization procedures.[2] If the insulation breakdown occurs along the shaft of the activated electrode, which may be completely out of the laparoscopic view, thermal injury to non-targeted tissue predictably remains undetected. Paradoxically, small, often undetectable, cracks in electrode insulation are more dangerous than larger breaks because the current is more concentrated, and therefore more likely to produce a significant burn, resulting in potentially serious patient injury.[3] Furthermore, a thin layer of intact insulation may be breached by higher voltages that are generated by the coagulation waveform and during noncontact activation of the electrode.

Direct coupling can occur if the tip of the active electrode comes in direct contact with another metal instrument or conductor within the surgical field. For example, if the active electrode accidentally touches or arcs to the laparoscope, the entire laparoscope becomes electrified. If the laparoscope is placed through a metal cannula, the current on the laparoscope will simply flow to the metal cannula and then harmlessly to the patient's abdominal wall and return electrode. If, however, the laparoscope has been placed in a nonconductive or plastic cannula, the current transferred from the active electrode to the laparoscope will not flow to the patient's abdominal wall; instead, again out of the field of view, the current will be transferred to the bowel or other internal tissue touching the electrified laparoscope. If the density of current is high enough, it will result in significant thermal injury.[2]

Capacitive coupling is the induction of stray current to a surrounding conductor through the intact insulation of an active electrode (e.g., active electrode—insulation—metal trocar sheath). The magnitude of the coupled charge is proportional to the amount of voltage and trocar diameter. As with direct coupling, isolation of the electrified metal trocar from the abdominal wall by an insulator risks catastrophic visceral injury above the field of view.[4]

Difficulties in Detection and Diagnosis

Because the laparoscope provides a limited view of the surgical field (as much as 90% of the active electrode may lie beyond the surgeon's view[5]), it is very easy for even the most experienced surgeon to miss a thermal injury resulting from insulation failure or capacitive coupling. It is therefore not surprising that intraoperative non-targeted tissue burns are not given higher priority in the differential diagnosis of postoperative complications.

Subsequent reparative procedures may also be compromised by the occurrence of secondary infection at the site of thermal injury, which can confound the final histologic diagnosis. In addition, the pathologist may not be able to recognize the unique histological characteristics of thermal injury.

Perioperative Morbidity

Accidental, unsuspected thermal injuries can result in significant complications during and following electrosurgery, most notably vessel hemorrhage and organ damage, perforation, and peritonitis. Depending on their severity and/or location, these conditions may result in significant morbidity or even death if not detected early enough. Fecal peritonitis following intestinal perforation is perhaps the most feared complication of thermal injury, with a mortality rate estimated as high as 25%.[4,6,7]

Prevalence of Complications

Because it is possible to misdiagnose electrosurgical burns or wrongly attribute thermal injuries to punctures or other mechanical errors, the prevalence of complications resulting from laparoscopic monopolar electrosurgery is likely under-reported and under-estimated by the surgical community. Moreover, as healthcare institutions increasingly compete for patients and managed care contracts, physicians and hospitals are often reluctant to report iatrogenic complications. Nevertheless, a recent survey of 2,000 gynecologists, who were questioned in an anonymous survey about adverse incidents associated with laparoendoscopic surgery, revealed that 1,662 respondents had experienced complications of some type. Specifically, 892 reported bleeding trocar sites, 343 reported bowel injuries, 172 reported bladder injuries, 99 reported damage to a major blood vessel, and 74 reported damage to the ureter. Of these injuries, it was estimated that at least 20% of the injuries were attributable to capacitive coupling or insulation failure during monopolar electrosurgery (Feste J., personal communication).

Another survey, conducted at a 1993 American College of Surgeons (ACS) conference, revealed that 54% of the 506 surgeons polled knew of colleagues whose patients had suffered such injuries, and 18% reported that they had personally experienced complications in patients due to capacitive coupling or insulation failure during laparoscopy.[8]

Moreover, the Physician Insurers Association of America (PIAA) published a report in 1994 of 615 patient injury claims over a four-year period for injuries incurred during laparoscopic procedures. The most common injuries reported were to the bile duct; other injury claims were attributable to intestinal perforation, liver trauma, and injuries to hepatic ducts, arteries, and veins.[9] In many of these cases, additional surgery was necessary, though it was generally delayed since the injuries were not detected during the initial laparoscopic procedure. For 11% of the injured patients, postoperative complications compounded by late diagnosis ultimately resulted in death.[9] While the PIAA report did not distinguish among laparoscopic surgical injury claims resulting from aberrant electrical pathway burns, surgical pilot error, or trocar punctures, the volume of total claims gives cause for considerable concern regarding a problem that is likely to grow with the increasing use of laparoscopic rather than open surgical procedures.

Medicolegal Issues

Compounding the potential clinical risks to patients, complications that arise during laparoscopic monopolar electrosurgery have raised a variety of medicolegal issues.

Noting the growing number of patient injuries during laparoscopic surgery, the Association of Trial Lawyers of America (ATLA) founded a special Laparoscopic Litigation Group in 1994.[10] This group has concluded that injury resulting from electrosurgical complications during laparoscopy can provide a strong case for malpractice suits. They also concluded that surgeons and hospitals may be targeted both for specific surgical errors as well as for simply choosing electrosurgery tools and instruments that allowed aberrant electrical current to injure a patient instead of tools and instruments that might prevent such injuries from occurring.[11]

This litigation potential appears to have been substantiated by a survey conducted at the 1995 meeting of the Society of Laparoendoscopic Surgeons, in which 13% of members surveyed reported involvement with one or more active malpractice cases associated with a laparoscopic electrosurgical procedure.[8]

Indeed, in response to the rising number of malpractice claims associated with laparoscopic injuries, some malpractice insurers have increased their rates by 15-20% for surgeons who perform these procedures.[12,13] Inevitably, such costs are passed on to both hospitals and patients.

ADDRESSING THE ISSUES: PRINCIPLES AND GUIDELINES

Having delineated the scope of concern surrounding the various issues relating to patient safety during laparoscopic monopolar electrosurgery, the Consortium discussed various approaches that might be undertaken to address these issues. From this discussion there evolved a set of principles that, if followed, the Consortium believed would result in significant enhancement of patient safety during laparoscopic monopolar electrosurgery. To reinforce these principles, where appropriate, the Consortium developed some practical guidelines.

Training and Education

1. Laparoscopic electrosurgical training should begin during residency to ensure that an adequate standard of knowledge, expertise, and practice is attained and maintained.

Since the number of laparoscopic surgeries performed in the United States is increasing exponentially each year, it is vital that residents receive laparoscopic training as early as possible. Teaching hospitals must teach their residents how to safely and effectively utilize monopolar electrosurgery during laparoscopic surgery. Moreover, as very few currently available textbooks adequately cover laparoscopic electrosurgery, better materials should be developed that can more fully educate both residents and other interested surgeons in the many aspects of this growing surgical subspecialty. In particular, these materials should comprehensively cover the fundamental biophysics of electrosurgery so that surgeons can better understand the therapeutic potential of this surgical modality as well as its significant potential for harm.

2. Formal certification of training and accreditation to practice laparoscopic monopolar electrosurgery is strongly recommended.

For the purposes of credentialing, hospital boards should require that surgeons document proficiency before being allowed to perform laparoscopy in their hospitals. Malpractice insurance incentives should be offered to physicians who demonstrate proficiency through such formal certification of training and accreditation. Some malpractice insurers have already taken a proactive step in this direction by offering no-cost, accredited post graduate training courses in electrosurgery and risk management for

their members,[5] while others have reduced their rates by as much as 7% for laparoscopic surgeons who attended specific training sessions.[14]

3. Standards for performing laparoscopic monopolar electrosurgery should be established by medical societies.

Professional medical societies, rather than generally less informed lay monitoring groups, should set standards of practice for laparoscopic monopolar electrosurgery. These societies should also institute and refresh training and continuing education, recommend appropriate certification and accreditation guidelines, and encourage confidential discussion of appropriate topics and cases among professional colleagues. Mechanisms and protocols should be developed to ensure that deficiencies in individual and collective practice are identified and rectified as early as possible.

4. *Individual surgeons, hospital departments, and regional and national groups should collect and publish data to facilitate progressive enhancement of the safety and efficacy—and hence appropriateness—of laparoscopic monopolar electrosurgery.*

Technology Education

1. Technology in-service instruction and follow-up should be provided to surgeons and perioperative nurses by healthcare institutions.

While sales representatives of laparoscopic electrosurgical equipment manufacturing companies can be helpful in demonstrating how the equipment operates, the primary instructor should be an experienced laparoscopic surgeon. The instructor should not only point out the various ways to utilize each technology, but also educate surgeons and perioperative nurses about the biophysics of electrosurgery and the possible complications that may occur during a procedure.

2. Healthcare institutions should mandate preventative maintenance and inspection of laparoscopic monopolar electrosurgery instruments by biomedical engineers as well as attending nursing staff.

Written protocols should be established and followed. To the extent feasible, equipment problems, such as insulation breakdown along the shaft of an active electrode, should be identified and remedied before an incident occurs. Currently, there are few, if any, inspection or maintenance protocols for laparoscopic electrosurgical equipment at most facilities. Implementing a proactive approach to maintenance and inspection limits liability, reduces patient injuries, and saves money. In particular, biomedical engineering department staff should assure the operating integrity and electrical safety of all associated equipment.

3. Surgeons should utilize laparoscopic surgical techniques that best ensure both successful surgery and patient safety.

While studies show that 86% of all laparoscopic surgeons choose monopolar electrosurgery for efficacy reasons over bipolar and laser surgery, or use of the harmonic scalpel,[8] alternative techniques should be considered for procedures that do not require fulguration or "clean cutting." The use of bipolar electrosurgical techniques should be encouraged for procedures that require hemostasis only.

4. Watchdog groups should consider monitoring or regulating the use of laparoscopic electrosurgery equipment.

It may be in the best interests of surgeons, hospitals, and patients alike to encourage monitoring or regulation by the Occupational Safety and Health Administration (OSHA), the Agency for Health Care Policy and Research (AHCPR), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or other governing bodies to ensure maintenance and inspection protocols are instituted and enforced.

Equipment

1. All-metal (conductive) trocars must be used during laparoscopic monopolar electrosurgical procedures.

The use of plastic or other nonconductive trocar cannulas as well as plastic self-retaining fascial screws can lead to thermal injury during direct or capacitive coupling. All-metal cannulas minimize this risk as the interface between a conductive cannula and the abdominal wall provides a pathway through which electrosurgical current can be safely conducted to the return electrode. Disposable cannulas, which have a conductive channel tube and nonconductive hub and/or valve casing, can also be used provided that the portion of the channel tube that interfaces with the abdominal wall insertion site is conductive.[4]

2. Active electrode monitoring (AEM) should be strongly considered for all laparoscopic monopolar electrosurgery procedures.

AEM technology protects against thermal burns that may occur due to current traveling along aberrant pathways by employing a combination of added electrical shielding and electronic current monitoring. The added electrical insulation and conductive shield absorb any stray electrical currents released through faulty insulation. Moreover, the conductive shield is electrically connected to the return electrode of the electrosurgical unit, allowing capacitively coupled current to flow off harmlessly. In the event of stray energy reaching potentially dangerous levels, the active electrode monitoring circuit interrupts the flow of energy from the electrosurgical unit and sounds an alarm before a burn can occur.

3. Surgeons should use no more electromotive force than is necessary to accomplish the task safely and effectively.

The chance of direct and indirect thermal injury increases significantly at higher voltages, such as when using the coagulation waveform, and after an interval of noncontact activation. Greater awareness of the attendant risks of high voltages may play an important role in reducing the associated morbidity.

CONCLUSION

Minimally invasive surgery clearly offers surgeons, patients, and healthcare institutions substantial benefits over more traditional open surgical procedures. However, clinical data, anecdotal evidence, and an increasing number of legal and insurance claims signal a rise in the number of iatrogenic complications associated with minimally invasive surgical procedures. As such procedures continue to grow in prevalence and popularity, more attention needs to be focused upon training and education in the fundamentals of minimally invasive surgery—particularly in laparoscopic monopolar electrosurgery, which presents a significant number of risks during minimally invasive surgery. The complications associated with these risks should be addressed in a more proactive manner than hitherto by all the constituencies involved—surgeons, nurses, healthcare institutions, professional associations, medical educators, patient advocates, physician insurers, and possibly even regulatory entities.

Specifically, adequate training and credentialing should be a standard component of educating both surgeons and nurses about the underlying biophysics of electrosurgery, and the use of equipment appropriately designed and maintained to enhance safety as well as efficacy should be part of standard patient care. Giving appropriate credit to surgeons and institutions who undertake such training and use such equipment can go a long way toward reducing the risk to patients during laparoscopic monopolar electrosurgery.

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