



Available online at
ScienceDirect
www.sciencedirect.com

Elsevier Masson France
EM|consulte
www.em-consulte.com/en



ORIGINAL ARTICLE

Risk management for surgical energy-driven devices used in the operating room

Gestion des risques liés à l'utilisation des sources d'énergie au bloc opératoire

F. Borie*, M. Mathonnet, A. Deleuze, B. Millat,
J.-F. Gravié, H. Johanet, J.-P. Lesage, J. Gugenheim

Fédération de chirurgie viscérale et digestive (FCVD), 6, rue Pétrarque, 31000 Toulouse, France

KEYWORDS

Energy sources;
Operating room;
Risk management

Summary Complications related to energy sources in the operating room are not well-recognized or published, despite occasionally dramatic consequences for the patient and the responsible surgeon. The goal of this study was to evaluate the risks and consequences related to use of energy sources in the operating room.

Patients and methods: Between 2009 and 2015, 876 adverse events related to health care (AERHC) linked to energy sources in the operating room were declared in the French experience feedback data base "REX". We performed a descriptive analysis of these AERHC and analyzed the root causes of these events and of the indications for non-elective repeat operations, for each energy source.

Results: Five different energy sources were used, producing 876 declared AERHC: monopolar electrocoagulation: 614 (70%) AERHC, advanced bipolar coagulation (thermofusion): 137 (16%) AERHC, ultrasonic devices: 69 (8%) AERHC, traditional bipolar electrocoagulation: 32 AERHC, and cold light: 24 AERHC. The adverse events reported were skin burns (27.5% of AERHC), insulation defects (16% of AERHC), visceral burns or perforation (30% of AERHC), fires (11% of AERHC), bleeding (7.5% of AERHC) and misuse or miscellaneous causes (8% of AERHC). For the five energy sources, the root causes were essentially misuse, imperfect training and/or cost-related reasons regarding equipment purchase or maintenance. One hundred and forty-six non-elective procedures (17% of AERHC) were performed for complications related to the use of energy sources in the operating room.

Conclusion: This study illustrates the risks related to the use of energy sources on the OR and their consequences. Most cases were related to persistent misunderstanding of appropriate usage within the medical and paramedical teams, but complications are also related to administrative decisions concerning the purchase and maintenance of these devices.

© 2017 Elsevier Masson SAS. All rights reserved.

* Corresponding author.

E-mail address: frederic.borie@chu-nimes.fr (F. Borie).

<https://doi.org/10.1016/j.jviscsurg.2017.12.003>

1878-7886/© 2017 Elsevier Masson SAS. All rights reserved.

Introduction

In 2017, surgeons routinely use several energy sources for dissection and coagulation in the operating room that varies according to various surgical indications.

Evidence-based literature regarding the superiority of these sources in terms of efficacy and safety is sparse. Each surgeon has his or her preferences for coagulation/dissection, adapted to daily practice. Yet, each device, associating a generator and specific accessories, can be a source of intraoperative events or accidents. Promoting and/or aggravating factors for eventual adverse events are related to operating room equipment, the liquid and gas products used, the misuse of the material as well as to patient-related factors. These incidents, mainly burns and internal or external injuries, can have serious consequences for the patient if they are unrecognized or poorly managed.

Just as an example, hundreds of operating room fires are declared every year in the United States; these are responsible for two to five deaths per year [1]. Approximately 40,000 patients sustain burns by electric instruments. In 1999, the costs related to these events were estimated at 600 million dollars [2].

However, the true (overall) incidence is difficult to discern in view of the absence of a prospective registry and in spite of the compulsory vigilance regulations for surgical equipment. It is easy to understand that all voluntary declarative inquiries can under-estimate the true prevalence. There were 376 material vigilance declarations in 2015 in France related to energy source or mechanical problems (source: French National Agency for Medicines and Health Products Safety or Agence Nationale de Sécurité du Médicament et des Produits de Santé [ANSM]). Ten percent of accidents were severe or critical (one death).

The goal of this study was to evaluate the risks related to the use of energy sources in the operating room and their consequences.

Material and methods

Between 2009 and 2015, 876 adverse events related to health care (AERHC) due to energy sources in the operating room were recorded in the French REX experience feedback data bank. This data bank is composed of all AERHC from surgeons participating in the accreditation programs for at-risk procedures (gastro-intestinal surgery, urology, plastic surgery, gynecology/obstetrics, orthopedics, cardiovascular surgery). All surgeons made anonymous and voluntary declarations during this period.

Several different energy source systems and associated events were described:

Energy sources

The energy sources studied included monopolar electrocoagulation, bipolar electrocoagulation, advanced bipolar (thermofusion) coagulation, ultrasound coagulation and use of cold light. Their modes of action are described as follows:

- *monopolar electrocoagulation* uses an active electrode that transmits an electric current to a ground plate in contact with the patient;
- *bipolar electrocoagulation* uses two electrodes incorporated into the same instrument. The current passes from

one electrode through the grasped tissues to the other but does not diffuse through the patient;

- *advanced bipolar coagulation (thermofusion)* is a device that modulates the electric current delivered to gauge the rise in temperature and decrease lateral thermal spread thanks to feedback controlled by the generator that detects the impedance of the tissues. When hemostasis is accomplished and the corresponding impedance is reached, the generator stops energy delivery and alerts the user with a sound signal;
- *ultrasound coagulation* is the result of transformation of electric energy to mechanical energy in the form of longitudinal mechanical vibrations that are transmitted along the axis of the instrument and creates:
 - a cavitation effect (creation of transient depression zone similar to the wake of a boat's propeller) that allows anatomic separation of tissue planes, thus facilitating dissection;
 - backcutting (division/coagulation with the hind portion of the blade), which allows to dissect the tissues with a forward swing and rapidly access the target in the operative field,
- *cold light*. Cold light sources use natural white light produced by xenon and an integrated ventilator that absorbs most of emitted heat. A light bulb, for instance, produces about 2% light and 98% of heat. A cold light source produces more light than heat, but the heat production is never zero. This implies that the heat produced is proportional to the power of the source. The heat is dispersed along the connecting cable and the optical device.

Accidents

The accidents related to utilization of energy sources in the operating room studied included fires, isolation defects (laparoscopic instruments), skin burns, visceral burns (thermal diffusion), visceral injuries and bleeding.

Analysis

Descriptive analysis of the AERHC, the root causes of these events according to the energy source used, and the indications for non-elective re-intervention used were studied and analyzed according to the energy source.

Results

Five energy sources were incriminated in 876 declared AERHC: monopolar electrocoagulation, bipolar electrocoagulation, thermofusion (advanced bipolar: biclamp; Ligasure®), ultrasound coagulation: (Harmonic®, Sonicision®, Thunderbeat®) and cold light. The distribution of events among the various sources was as follows: 614 (70%) by monopolar electrocoagulation, 137 (16%) by thermofusion, 69 (8%) by ultrasound, 32 by traditional bipolar coagulation and 24 by cold light (Table 1).

Monopolar electrocoagulation AERHC

Four main types of events occurred: fires, insulation defects (laparoscopy), skin burns and visceral burns (thermic diffusion).

Download English Version:

<https://daneshyari.com/en/article/8957744>

Download Persian Version:

<https://daneshyari.com/article/8957744>

[Daneshyari.com](https://daneshyari.com)