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A MODEL OF PILOT STUDY TO ASSESS THE RISK OF EXPOSURE TO SURGICAL SMOKES FOR OPERATING ROOM PERSONNEL

M. Frascio[(a)], M. Mascherini[(b)], P. Batistotti[(c)], K. Cortese[(d)], R. Fornaro[(e)]

[(a),(b),(c),(e)] DISC Dipartimento di Scienze Chirurgiche e Diagnostiche Integrate Università degli Studi di Genova, Viale Benedetto XV, 6, 16132 Genova, Italy - Ospedale Policlinico IRCCS San Martino Genova - Italy
[(d)] DIMES Dipartimento di Medicina Sperimentale Università di Genova – Italy

[(a)]mfrascio@unige.it , [(b)]mascherini.matteo@gmail.com , [(c)]paola.batistotti@gmail.com , [(d)]cortesek@unige.it, [(e)]rfornaro@unige.it

ABSTRACT
During the last decades the exposure to surgical smokes has been a long-standing concern both in open and laparoscopic surgery. The aim of this project is to assess the health risks for medical operating room (OR) personnel associated with surgical plumes derived from laparoscopic procedures.
The purpose of this model is to check the correlation between the concentration of toxic elements derived from electrosurgical procedures in the operating setting air and the concentration of the same substances in urine and plasma of patients and operating staff. Moreover, it will be considered also the correlation between toxic concentration and time of exposure.
The results of the study could be relevant to indicate if individual protection devices are efficacious to make the surgical procedure safe for patients and staff or if any adequacy has to be considered.
Some unexpected difficulties delayed the expected results.

Keywords: surgery risk, surgical smoke, laparoscopic procedures, electrosurgical procedures.

INTRODUCTION
Surgical smoke (otherwise known as plume) is a dangerous by-product generated from the use of lasers, electro-surgical pencils, ultrasonic devices, and other surgical energy based devices.
During the last decades the exposure to surgical smokes has been a long-standing concern both in open and laparoscopic surgery (Fornaro 2008; Stabilini 2013; Fornaro 2009).
As surgical energy based instruments cauterize vessels and destroy (vaporize) tissue, fluid, and blood, a gaseous material known as surgical smoke plume is created. It is estimated that approximately 95% of all surgical procedures produce some degree of surgical plume (Ulmer 1998).
Laser and electrosurgical devices commonly used in surgical theatre cause targeted cells to heat to the point of rupturing the cellular membrane and spewing cellular contents into the air as surgical smoke. Through continuous exposure, the inhalation of surgical smoke can be harrmful to the surgical team members.
Estimations note that approximately 350,000 health care workers are exposed to surgical smoke each year, thus creating an unsafe work environment. More than 30 years ago (Tomita 1981) delivered laser energy to 1 gram of tissue: the plume, when inhaled, was shown to be comparable to smoking 3 unfiltered cigarettes.
When using an electrosurgical device on 1 gram of tissue, inhaling the plume was equivalent to smoking 6 unfiltered cigarettes.
Recent evidences show that the chemical component of surgical smoke plume contains over 80 different toxic chemicals and by-products; some which have documented harrmful health effects.
The chemical compounds previously isolated from surgical smokes is listed in Table 1, according to IARC classification.
For example, plumes can also be hazardous to patient during laparoscopy since the contaminants of surgical smoke are absorbed into the patient's vascular system.
Several studies already demonstrated that carboxyhemoglobinaemia and methaemoglobinaemia concentrations rise after a laparoscopic procedure (Wu 1997; Ott 1998; Chowdhury 2011).
The physical components from surgical smoke plume consist of particulate that ranges from <0.01 microns to >200 microns with a majority up to 0.3 to 0.5.
Particles smaller than .3 microns can bypass the lungs normal filtration mechanisms, the mucus secretions and cilia, and deposit in the alveoli, where the exchange of blood/gas takes place.
Furthermore, surgical smoke can cause burning, water eyes, nausea and respiratory problems (Ball 1996) as a physical reaction.
In addition to the health risks, plumes reduce the view in laparoscopic approach, by the nucleation of vapor as they cool, thus potentially increasing the risk for complications (Weld 2007).
The biological matter of the plume contains blood, and potentially infectious viruses and bacteria. Several investigations regarding infectivity, mutagenicity and cytotoxicity of elements generated by energy-based instruments have been performed. Indeed, viable cells (In 2015; Fletcher 2009), viral DNA and RNA, Mycobacterium tuberculosis (Chowdhury 2011), and group-I carcinogens (Pierce 2011) were isolated into surgical smokes.

Case reports mentioned HPV positive tonsillar cancer in two gynecologists that used laser ablation (Rioux 2013), as a cause-effect of professional exposition.
Former studies conducted in the '90s highlighted a connection between laparoscopy and viable cells (Hubens 1996; Cavina 1998; Taffinder 1996), and clarified the phenomenon of port-site metastases, also called “chimney effect”.

AIM OF THE STUDY

The aim of this project is to assess the health risks for medical OR personnel associated with surgical plumes derived from laparoscopic procedures.
The purpose of this model is to check the correlation between the concentration of toxic elements derived from electrosurgical procedures in the operating setting air and the concentration of the same substances in urine and plasma of patients and operating staff. Moreover, it will be considered also the correlation between toxic concentration and time of exposure.
The study design has been submitted to regional ethic committee and regularly approved.
The study received a research fund (FRA) from the University of Genova.

MATERIAL AND METHODS

1) Preoperative phase: sampling of urine and plasma for patient and operating staff.
2) Operative phase: during the laparoscopic intervention the surgical plume is sampled by means of desufflation of the peritoneal cavity and through port aspiration. The sampled smoke is analysed for the presence of chemical substances by spectrofhotometer.
To date, a widely used method for the quali-quantitative characterization of abdominal surgical smoke generated during laparoscopy by electro-cauterization exploits the use of a smokes concentration procedure using SPME (solid phase microextraction) and their analysis by gas chromatography coupled to mass spectrometry, GC-MS (Dobrogowski 2015). Furthermore, the method provides that the "trocar" sampling apparatus can be directly connected to the gas chromatograph enrichment and injection system (Dobrogowski 2014; Balog 2013).
Samples have to be examined also by electron microscopy (Minuto 2018) for the evaluation of viral or bacterial fragments.
3) Post operative phase: a) the urine and plasma sampling will be repeated at 15 minutes after the operation closure and at 30 minutes and 6 hours after the operation closure, for patient and operating staff.
The type of surgical procedures inclosed in the present study will be: appendectomy, colecistectomy, colo-rectal resection.
Operating staff inclosed in the study will be: surgeon and assistant, table nurse and anhestesist. The staff has to wear the normal individual protection devices employed in the opeating room activity.
All the people (patients and staff) gave informed consensus to the study.

RESULTS

Because the method that provides the by "trocar" sampling apparatus directly connected to the gas chromatograph enrichment and injection system was not available, several attempts were made to try to characterize, at least qualitatively, the compounds, more or less toxic, present in surgical smokes.
A first approach consisted in collecting the smokes by “trocar” and bubbling them in different solvents (dichloromethane, hexane) in the attempt to dissolve/concentrate the molecules of potential interest. In any case the GC-MS analysis carried out using gas chromatographic columns with different polarity degree did not allow the detection of any compound.
Assuming that this could be due to a reduced amount of smoke, a dedicated experiment was carried out.
A surgical piece was treated for a long time, under a extractor hood, with electrocautery and the considerable quantity of fumes obtained was bubbled, as previously described, in different solvents; subsequently the GC-MS analysis was carried out using different columns. Also in this case it was not possible to detect any molecule of interest. Considering that the problems could also derive from the use of a not appropriate stationary phase, a dedicated , widely used in the literature, chromatographic gas column was also employed for these purposes (INNOVAX 60m, 0.25mm, 0.5μm).
The lack of signals even after this last attempt, makes us believe that, as initially assumed, failures derive from a lack of sensitivity of the system as a whole, starting from the sampling phase and ending with the analytical one.
It is therefore clear that the analytical problem could be faced and solved only by having available a dedicated instrumentation useful for an adequate sampling and for the subsequent concentration and analysis phases. These different preparation and analysis phases of the sample in fact require an instrumental optimization that allows to carry out the whole procedure in-line in order to allow an adequate concentration of the molecules of interest and therefore their detection and characterization.
For the reason of the failure of the kind of analysis we decided to not evaluate any sample of the blood collection.
The Authors are now looking for a solution of this unexpected difficulty, cooperating with the chemical experts of our team.

DISCUSSION

Previous reviews (Barrett 2003; Mowbray 2013; Fan 2009) detailed the potential hazards of surgical smoke, without distinction between open and laparoscopic procedures.
Theoretically, exposition of operating room (OR) personnel to chemical compounds, viable cells and infective material is inferior during endoscopic surgery then using traditional approach, because gas is contained in a closed cavity.
However, since the gas is not appropriately evacuated, this assumption is not completed correct. In fact, during

laparoscopic procedures or at the real end of them, the peritoneal cavity is desufflated through ports, so gas and toxic and infective elements concentrated in the plumes are released in the operative theatre.

The majority of the papers identify the presence of toxic and infective materials in surgical smoke derived from laparoscopic surgery. However, none of the studies analyzed the concentration of particles in the blood or urine of the OR personnel, indicating that no risk evaluation for OR has been taken into account.

Three of the reviewed studies (Gianella 2015; Dobrogowski 2015; Fitzgerald 2012) did not retrieve toxic substances at relevant quantity and thus even exclude adverse health effects for the OR staff, at least in the short-term period. Only one article (Choi 2015) detects toxic concentrations of the isolated compounds and small particles, even if the Authors clarify that the surgical plumes concentrations decreased once the smoke is desufflated from the peritoneal cavity. Hence, neither this article investigates the real hazard of the surgical smokes during laparoscopy for the OR staff. In these studies, the particle size detected ranged from 0,1 to 25 µm (DesCoteaux 1996; Nezhat 1997). Since the standard surgical mask filters up to 5 µm size particles, this common respiratory protection device turns out to be ineffective for smaller sized particle.

It is clear that electrosurgery produces a quantity of toxic or viable elements in laparoscopic interventions too, even if the literature screened did not assess the actual risk for the OR staff.

Most of the analyzed papers conclude assessing that people working in the OR should be aware of potential long-term health risk related to professional exposure, although there are not strong evidences that surgical smoke could directly cause a malignant pathology. Therefore, a slight possibility of surgical plumes harmful effect does exists and simple measures to minimize this risk should be taken. One article (Fitzgerald 2012), for example, highlights the risk based on the cumulative exposure to these identified elements during a long-lasting professional life. Of note, in order to reduce the OR staff health risk, the Association of periOperative Registered Nurse (AORN) published a panel where simple instructions such as adopting a closed evacuation system and high filtration surgical masks were recommended (30).

For these reasons the authors based the project of the study on analysis of surgical smoke limited to laparoscopic procedures.

To obtain a complete evaluation of the risk exposure the authors planned to analyse the smoke contain and the blood and urine sample of patients and of operating room personnel: surgeon, anesthesist and nurse. However, due to the difficulties occurred during the sampling of the smoke, the amount of toxic concentration resulted inconsistent for the sensibility of the spectrophotometer analysis.

CONCLUSION

The authors as previously described encountered unexpected difficulties that have been described.

Despite a consistent body of literature support that electrosurgical devices release toxic chemical products free viable cells and viral components into surgical smokes, but their potential long-term toxic effects on the OR staff, the consistency of this presumption has not been demonstrated yet. As medical personnel is repeatedly exposed to surgical plumes of very diverse toxicity, even at very low concentrations of individual components, the risk to the health of the exposed persons may be significant and thus the problem cannot be ignored. We envisage that further focused research on risk assessment and development of safety guidelines will lead to a safer work environment for OR staff. Meanwhile, we recommend the use of simple-to-use advanced protection systems.

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TABLE 1: chemical by-products previously identified in surgical smoke classified according to IARC

Acrolein
Acetonitrile
Acetylene
Acrylonitrile
Benzaldheyde
Benzene
Butadiene
Butene
Carbon Monoxide
Creosols
Ethane
Ethylene
Formaldehyde
Free radicals
Hydrogen cyanide
Isobutene
Methane
Phenol
Propene
Propylene