Use of ultrasonic devices in laparoscopic surgery and risk of COVID-19 contamination: What does the evidence say?

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Abstract
With the emergence and spread of Coronavirus Disease 2019 (COVID-19), surgical care of patients has been disrupted for surgeons across the world. Recently several surgical societies are raising concerns about using ultrasonic devices during laparoscopic surgery due to questions regarding a proposed risk of viral transmission of COVID-19. In this review, we will provide an overview of COVID-19’s transmission, evaluate available evidence on surgical smoke production and possible risk of viral contamination and discuss the optimization of ultrasonic device use during the ongoing COVID-19 global pandemic.

Introduction
A pneumonia of unknown cause detected in Wuhan, China, on December 27th was first reported to the World Health Organization (WHO) Country Office in China on December 31st, 2019 [1]. Early in January, it was determined that these pneumonia cases were due to a novel coronavirus, named SARS-CoV-2, causing a disease called COVID-19.

SARS-CoV-2 is a positive-sense single-stranded RNA virus, whose virion is 60–140 nm in diameter [2]. SARS-CoV-2 has four structural proteins: proteins E (envelope), M (membrane), and S (spike) which create the viral envelope and, through protein S, attach to and fuse with the membrane of a host cell. Protein N (nucleocapsid) holds the RNA genome [2].

SARS-CoV-2 is responsible for a worldwide epidemic, which was declared as a pandemic by the WHO on March 11th, 2020. This pandemic severely limited elective surgical activity throughout the world, as well as triggered multiple surgical societies (e.g., SAGES/EAES, ESGE, AAGL) [3-5] to issue “recommendations” on ways to reduce the risk of virus transmission to the operating room (OR) personnel caring for COVID-19 patients or patients with unknown COVID-19 status. Most of the recommendations are focused on ways to reduce potential exposure via personal protective equipment (PPE), smoke evacuation and potential aerosolization of SARS-CoV-2 by electrosurgical devices or CO2 insufflation of the pneumoperitoneum. These recommendations include setting electrosurgical units to the lowest possible settings for the desired tissue effect and minimizing the use of monopolar electrosurgery, ultrasonic dissectors, and advanced bipolar devices, as they can lead to particle formation in the resulting surgical smoke.

These recommendations were initially focused on laparoscopic surgery, where the risk of viral aerosolization from CO2 insufflation was considered, along with the potential concentration of aerosol created from the use of energy devices.

Concerns have been raised regarding the use of ultrasonic devices where several authors speculated these devices may produce a low-temperature aerosol which do not effectively deactivate the cellular components of virus in patients [6] or may cause more aerosol formation [7]. Even though there is no evidence supporting these theories, different surgical societies, as well as some published literature, are suggesting not to use ultrasonic energy, in favour of electrosurgery.

The aim of this review is to analyse available evidence related to the surgical smoke created by ultrasonic devices as it relates to the risk of COVID-19 transmission during laparoscopic surgery.

Modes of transmission of COVID-19
The current available evidence suggests the main source of transmission of SARS-CoV-2 is through respiratory droplets (particles > 5-10 μm in diameter) [8] from infected people and through contact with contaminated surfaces [1,9-13].

The detection of viable SARS-CoV-2 in stools of COVID-19 patients, who can shed the virus in the feces for days after respiratory symptoms have disappeared [14,15] and virus RNA has been found in sewage [16,17]. This evidence raises the possibility of fecal-oral transmission, even though there is no data available to support this hypothesis.

Other means of transmission of the virus have not been confirmed. Some studies found the presence of SARS-CoV-2 RNA in blood, but in a very limited number of cases (10-11%) [18,19]. Data on the presence or absence of the infectious virus in blood, plasma or serum has not been reported, as well as blood-borne transmission of COVID-19 disease.

Vertical transmission of the virus from an affected mother to her child seems to be unlikely, even though 4 affected children out of

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Can SARS-CoV-2 be aerosolized?

As already stated, pulmonary droplets, close contact with affected people and surface contacts are the main accepted means of transmission of SARS-CoV-2 virus.

Airborne transmission is different from droplet transmission as it refers to the presence of microbes within droplet nuclei, which are generally considered to be particles <5 μm in diameter. Airborne particles can remain in the air for longer periods of time than droplets and can be transmitted to others over distances greater than 1 meter. In an analysis of 75,465 COVID-19 cases in China, airborne transmission was not reported [23]. Thus, airborne transmission for SARS-CoV-2 has not yet been clearly established.

Nevertheless, there is some evidence which may indicate aerosol-driven infection. A number of case reports suggest that transmission for asymptomatic individuals in association with normal breathing and talking producing predominantly small droplets [24].

Some studies have demonstrated the presence of SARS-CoV-2 and SARS-CoV-1 (a similar virus from the same family) in aerosol form that lingers in the air and has been reported to travel intra-building and over long distances from the sources in medical and laboratory settings. In a hospital setting, viral RNA has been detected in the air inside COVID-19 patient rooms and in nearby hallways [25]. Another study evaluated SARS-CoV-2 aerosol deposition at 30 sites (i.e., patient areas, medical staff areas, and public areas) in two COVID-19 hospitals in Wuhan, China and found viral RNA in some of the patient areas and in the medical staff protective apparel removal rooms of one of the hospitals, in addition to two public areas (i.e., a department store and a site where the public including outpatients passed by) [26]. These results confirmed that the lung and the intestine were the only two organs where presence of SARS-CoV was confirmed.

Two case reports investigating the presence of SARS-CoV-2 in the peritoneal fluid from COVID-19 patients were recently published. Nagesrin et al. [29] published a case of a 21-year old male with no pre-existing co-morbidities under active quarantine as part of a known cluster of COVID-19 with acute pain in the right iliac fossa and vomiting. A nasopharyngeal COVID-19 polymerase chain reaction (PCR) swab test was positive, and the patient underwent laparoscopic appendectomy. Upon entry in the abdominal cavity, 5 ml of seropurulent peritoneal fluid from the Morrison’s pouch, right paracolic gutter and pelvis was aspirated and sent for COVID-19 PCR. After appendectomy, peritoneal washings were also collected prior to the end of the case and sent for COVID-19 PCR. The peritoneal fluid samples on entry and just before extraction of the appendix were both found to be negative for COVID-19 by PCR.

Coccolini et al. [30] published a case of a 78-year-old man who presented for abdominal pain associated with alteration of the bowel function. He had fever, cough and mild respiratory symptoms; the respiratory nasal swab was positive for SARS-CoV-2. The patient was admitted with a diagnosis of intestinal mechanical obstruction due to small bowel volvulus associated to SARS-CoV-2 pneumonia. While conducting a laparotomy, it was found that the volvulus was due to an omental band attached to the right iliac fossa. The band was dissected, and no bowel resection was performed. Two swabs were obtained from peritoneal fluid and sent for SARS-CoV-2 detection. The authors demonstrated the presence of a high concentration of viral RNA, but virus isolation - which would have provided stronger evidence of infectivity - could not be performed. Notwithstanding the demonstration of the presence of the sole RNA, the authors strongly commented the surgical procedure should have been considered as a risk of infection to the OR team.

The available evidence are inconclusive and contrasting. The presence of a transmittable form of SARS-CoV-2 in the peritoneal cavity has not been demonstrated and thus the presence of virus in the aerosol of the pneumoperitoneum still remains a hypothesis.

Ultrasonic devices and aerosol formation

Energy devices, including electrosurgery devices, ultrasonic devices, lasers and high-speed drills, burrs and saws, all produce surgical smoke. Surgical smoke is a gaseous by-product produced during surgical procedures and is referred also as aerosol, cautery smoke, diathermy plume, plume, or smoke plume.
Surgical smoke contains approximately 95% water or steam, and 5% particulate matter from cellular debris and chemical compounds in the gaseous phase [31,32]. Data on the morphology, size, and composition of surgical smoke are scant [33-35].

There are significant differences in how ultrasonic and electrosurgical instruments cut and coagulate tissues and, thus, in how they produce surgical smoke. The ultrasonic device denatures protein by the transfer of mechanical energy to the tissues that is sufficient to break hydrogen bonds and by the generation of heat from friction that results from the interaction of the blade with the tissue. During this time, the blade becomes warm to the touch [36]. In his initial experiment ultrasonic blades (i.e., no clamp arm), Amaral [36] observed that heat generated in the tissues as a result of stress and friction is limited. In that study, a personal communication to the author indicated that thermographic analysis has demonstrated that ultrasonically activated coagulation does not heat tissues above 80°C. As a result, tissues do not desiccate from the loss of moisture, and they do not burn.

Different recommendations and articles on the use of energy devices in laparoscopy during the COVID-19 pandemic argue against the use of ultrasonic scalpels, based on the belief that this mode of energy is causing higher amounts of surgical smoke, which is also believed to be cooler and, thus, possibly not able to inactivate the virus [6,37].

It is quite difficult to compare the amount of actual smoke volume production from different energy sources, but there are several studies evaluating the amount of smoke particles produced when using electrosurgical or ultrasonic devices.

Ott et al. [38] determined the distribution and concentration of aerosol particles caused by an ultrasonic scalpel with different end effectors (ball, hook and blade) during simulated surgical use with the monitor probe mounted at fixed distances ranging from 10 to 30 cm from the site of aerosol production. In addition, they compared ultrasonic to a monopolar device, and also evaluated the effect of a smoke evacuation system on particle concentration. The interaction of ultrasonically activated devices with tissue produces a biphasic bioaerosol composed of tissue particles and a blood aerosol [38] and a minimal smoke production has been reported for this device [39]. Ott et al. [38] found that fatty tissue generated more particles than lean tissue, but more interestingly, that the local exhaust ventilation smoke-evacuation system dramatically reduced particle concentration exposure and that monopolar electrosurgery (30 W) showed a fourfold increase in particle concentration.

Weld et al. [40] characterized the smoke produced by four energy-based laparoscopic instruments, bipolar macroforceps, ultrasonic scalpel, floating ball, and monopolar shears applied in vitro to porcine psoas muscle. Bipolar energy produced the smallest number of large particles, while bipolar energy and the ultrasonic scalpel both created a relatively small number of small particles (Table 1). In contrast, the standard monopolar scissors and the floating ball device both created a large number of both small (< 500 nm) and large (> 500 nm) particles (Table 1). In the same study, the authors demonstrated that bipolar and ultrasonic devices had the least effect on visibility by the smoke particles generated.

Another study from Lamberton et al. [41] measured particulates in vapor of ultrasonic scalpel and three other advanced bipolar devices using a laser photometer at a distance of 5 cm. They demonstrated that the ultrasonic scalpel produced the least amount of smoke (mean 2.88 ppm versus 74.1 ppm and 21.6 ppm, p = 0.0001) of two other devices and similar (mean 12.5 ppm, p = 0.11) of the third advanced bipolar.

From this evidence, it can be concluded that smaller particles (mainly produced by monopolar devices) which have higher concentrations remained in suspension longer due to their lighter mass, which increased the visual obstruction of plume, while larger particles (mainly produced by ultrasonic devices) dissipated more quickly because of their greater mass. More obstruction could suggest a higher concentration of plume. Moreover, it does not seem that ultrasonic produces more smoke but, on the contrary, it may be even less.

Another opinion that has been suggested is that ultrasonic produces a cooler surgical smoke than electrosurgical devices. Although a number of articles report this information [37,42-47] none of them performed or referenced a scientific experiment demonstrating this statement. The articles all point back to the original work from Amaral, cited above, where the author reports a personal communication about the fact that thermographic analysis would have demonstrated that ultrasonically activated coagulation does not heat tissues above 80°C [36].

A recent study by Hayami et al. evaluated the temperature of the steam from an ultrasonic shear and compared it to an advanced bipolar device [48]. These authors performed an ex vivo animal study using porcine muscle and tested the devices in four different combinations of device and muscle conditions, including dry–dry, dry–wet, wet–dry, and wet–wet. In addition, grasping range (proportion of the length of tissue held between the jaw of devices to that of the jaw) changed to 1/3, 2/3, and 3/3, under each condition.

The temperatures of energy devices and steam were measured using thermography at 0-, 1-, 3-, 5-, and 10-mm away from the energy device. Although the maximum temperature of the devices was significantly higher with ultrasonic shears than with advanced bipolar, the maximum temperature of steam was significantly higher with the latter, in almost all situations. It should be stressed though, that ultrasonic devices reached the critical temperature of 60°C (the study was performed to evaluate possible thermal damage to nervous structures) 1 mm away from the device using a 1/3 grasp for the wet/wet and wet/dry condition and that also advanced bipolar did not reach this critical temperature in many situations at the same distance. Moreover, the advance bipolar, as well as ultrasonic shears, did not reach 600°C at distances > 1 mm.

The authors acknowledged a number of limitations of the study [48]. The experimental nature of the study could not reflect its application to humans and the porcine tissues may not have accurately reflected the in vivo setting, mainly due to the lack of a blood supply. Furthermore, the starting temperature of the experiment (significantly cooler than clinical settings) might have had a significant impact on the temperature of energy device. The temperature and the direction of steam from the energy device may have been dependent on the grasping range, the volume of the moisture content between the jaws, and the distribution of the heat source at the contact surface of the jaws.

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<th>Table 1. Concentration of particles in surgical smoke from several different energy devices (Modified from Weld)</th>
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<td>Concentrations of particles (per cm³)</td>
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<td>Particles &lt; 500 nm</td>
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* Data regarding particles generated by advanced bipolar devices was not available in the scientific literature at the time of writing.
Lastly, a pattern of which direction the steam goes in and the influence of several conditions, including pneumoperitoneum or gravity/patient position, on it are very important.

A study which showed opposite results was performed by Emam et al. [49], who compared two ultrasonic devices at the three power settings (3, 4, and 5) in random fashion in an experimental setting in pigs. Thermography was used for real-time mapping of the heat production during use of the ultrasonic shears and it was observed that the zone around the jaws that exceeded 60°C with continuous ultrasonic dissection for 10 to 15 seconds at level 5 measured 25.3 and 25.7 mm for the two different ultrasonic devices. At this power setting and an activation time of 15 seconds, the temperature 1.0 cm away from the tips of the instrument exceeded 140°C. All results are reported in Table 2. It can be observed that temperatures 1 cm away from the jaws of both instruments were all above 80°C for power settings level 4 and level 5.

The limited and contrasting evidence around the temperature of surgical smoke produced by ultrasonic devices vary and are difficult to interpret, necessitating the need for more clinical studies to address this question.

Is there infectious material in the aerosol from ultrasonic or can this transmit viruses?

The potential dangers related to the inhalation of surgical smoke has been a question pondered dating long before the COVID-19 pandemic. Indeed, Eubanks et al. [50] published a study evaluating measures to reduce the risk of human immunodeficiency virus (HIV) transmission during laparoscopic procedures almost 30 years ago.

There have been reports of varying infectious material detected in surgical smoke. A recent systematic review investigating the potential risks to the OR team discussed six separate studies which assessed the presence of infectious material in surgical smoke [47]. All six of the studies reviewed were on CO2 laser-produced smoke, except for one that compared laser with electrocautery [51]. One study confirmed the potential for bacterial cell culture growth in laser-derived smoke [52], demonstrating that 5 of 13 participants showed a growth of the potential for bacterial cell culture growth in laser-derived smoke studies reviewed were on CO2 laser-produced smoke, except for one.

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contained highly mitotic cells including irregularly shaped nuclei, consistent with malignant tumours [63].

How can the risk of virus transmission from surgical smoke be reduced?

All recommendations issued to address the risk of OR staff virus transmission put an emphasis on the use of appropriate personal protective equipment, as well as the adoption of smoke evacuation systems [3-5].

In particular, when aerosol generating procedures are conducted on patients suspected or positive for COVID-19 and when assisting on procedures on airways in all patients, surgeons are advised to wear PAPR (Powered Air Purifying Respirator) or N95 respirator plus face shield or eye protection, gown, and double gloves [64]. When caring for patients suspected or positive for COVID-19, eye protection/face shield, gown and gloves should also be worn, but a surgical mask may also be suitable [64].

An N95 mask or respirator is a particulate-filtering tool that meets the U.S. National Institute for Occupational Safety and Health (NIOSH) standards and are classified to filter at least 95% of airborne particles >300nm [65]. N95 respirators are considered functionally equivalent to certain respirators regulated under non-U.S. jurisdictions, such as FFP2 respirators of the European Union and KN95 respirators of China. In contrast, surgical masks are intended to provide a barrier to splashes and droplets that may impact the wearer’s nose, mouth and respiratory tract. They do not provide protection against airborne (aerosol) particles [66].

Smoke evacuation systems are designed to reduce surgical smoke for improved visibility and a cleaner OR environment. They are normally equipped with High-Efficiency Particulate Air (HEPA) or, more frequently, with greater performing Ultra-Low Particulate Air (ULPA) filter. HEPA filters have a minimum 99.97% efficiency rating for removing particles greater than or equal to 300 nm [67], while ULPA filters can remove from a minimum of 99.999% of airborne particles with a maximum particle penetration size of 50-120 nm [68].

Currently, it is assumed that SARS-CoV-2 is transmitted as it attaches to larger respiratory water droplets that are in excess of 20,000 nm [69]. Additionally, when SARS-CoV-2 is aerosolized in a CO₂ gas suspension the droplet size is assumed to be less than 10,000 nm in size [69]. As mentioned previously, it is unknown if SARS-CoV-2 is contained in surgical smoke and thus the actual particle size, if it exists, is unknown. But, if intact viable virus is attached to a water droplet found in surgical smoke it is reasonable to assume that it will be captured and filtered by an N95 mask, as well as both HEPA and ULPA filters, as shown in figure 1.

Given the potential, yet not demonstrated, risk with SARS-CoV-2 being present in surgical smoke, a smoke evacuation system should be used. The diligent use of a smoke evacuation system with a high-efficiency filter has been identified as a feasible and potentially useful way for surgical smoke to be reduced [38,70]. The smoke evacuator should be activated at all times when airborne particles are produced during all surgical or other procedures.

Other measures can be taken to reduce the risk of escape of aerosol from the pneumoperitoneum. In particular, incisions for ports should be as small as possible to allow for the insertion of ports but not allow for leakage around ports, the pressure in the pneumoperitoneum should be as low as possible for the desired effect to minimize CO₂ leakage from the trocar, reduce the number of times instruments are removed from the trocar to minimize leakage of CO₂ from the pneumoperitoneum (e.g., by taking advantage of the multifunctional nature of an advanced energy device, and in particular of ultrasonic) can reduce leakage of CO₂ due to reduced instrument exchanges and all pneumoperitoneum should be safely evacuated via a filtration system before closure, trocar removal, specimen extraction or conversion to open [3]. There is no evidence to date that balloon trocars are more effective at reducing CO₂ leakage, as they are primarily designed to improve retention in the abdomen [70].

Conclusions

The COVID-19 pandemic has put an unprecedented amount of pressure on healthcare systems worldwide, causing a temporary pause...
of elective surgical procedures, as well as the need to adopt strategies to reduce the risks of viral transmission for both patients and healthcare professionals.

In this challenging scenario, surgical societies felt the need to take immediate action to define ways to protect OR teams who are caring for suspected or confirmed COVID-19 patients. For these reasons, recommendations were issued which are based mainly upon potential risks, but not exactly on the available evidence. This resulted in recommendations to completely avoid laparoscopy in favor of laparotomy in the face of potentially higher exposure risks due to the concentration of aerosol in the pneumoperitoneum. Fortunately, this recommendation was short-lived after the surgical societies reflected on the scant evidence regarding the risks of transmission of SARS-CoV-2. Instead, they shifted their focus on the real risks of performing all surgeries with an open approach in the face of completely abandoning the significant patient advantages of minimally invasive surgery.

Some of these recommendations, as well as a number of published literature, seem to argue against the use of ultrasonic shears, claiming this type of energy device produces cooler smoke where more viable viral particles could be present, thus increasing the risk of virus transmission. Given the evidence discussed in this review, it is clear that there is no objective evidence to neither confirm these opinions, nor suggest other energy devices as a lower risk or safer.

In summary, the available evidence suggests that:

- The main ways of transmission of SARS-CoV-2 are through respiratory droplets and through contact with contaminated surfaces.
- Other means of transmissions, such as through aerosol, oro-fecal, and vertical (materno-fetal) have been hypothesized but not confirmed.
- Even though SARS-CoV-2 has been detected in aerosolized form in the environment, the implications for transmission are unknown.
- The presence of an intact, transmissible and infective form of SARS-CoV-2 in the peritoneal cavity has not been found. Indeed, only viral RNA was found in one case report and no viral material in the other two.
- It has not been demonstrated that ultrasonic devices produce more smoke, but rather that, in a study, they produced less smoke than monopolar. Ultrasonic devices do produce larger particles that dissipate more quickly, demonstrating greater visibility than monopolar. Larger particle sizes are also more easily filtered by N95 masks and smoke evacuation systems.
- The limited evidence suggests the aerosol from ultrasonic devices may be cooler than the smoke from bipolar. But this difference was only shown in some conditions tested and only within 1 mm from the tip of the instrument. Beyond that 1 mm distance both ultrasonic and bipolar devices produced smoke and/or aerosol cooler than 60°C, which is considered the lowest temperature responsible for producing irreversible cellular damage.
- There is evidence indicating that some viruses (HIV, HBV, HPV) can be present in the smoke of energy devices. Nevertheless, most of the studies were on open procedures using a CO2 laser, only a few focused on electrosurgical devices and none on ultrasonic shears.
- The only evidence to date illustrating viral transmission through surgical smoke is via the CO2 laser used in an open approach while treating vaginal warts. There is no data to date demonstrating the transmission of any infectious disease through surgical smoke to the OR team during minimally invasive approaches.

It is understandable that a situation like the COVID-19 pandemic would initiate heightened caution and precaution. Our community of healthcare professionals tend to be more conservative for the sake of patient safety, as well as the healthcare professionals who care for them. But we also have a responsibility to make recommendations and decisions based on the entirety of the available data. Care should be taken not to convey inaccurate, and potentially dangerous, opinions not based on evidence. Rather, we feel strongly that it is task of the medical community to provide balanced evidence-based recommendations which highlight the “knowns” and the “unknowns” of the topic under evaluation.

In this regard, we echo the SAGES and EAES recommendations [3] over the use of energy devices. When using monopolar electrosurgery, laser, ultrasonic dissectors and advanced bipolar devices, minimize the creation of surgical smoke. If available, energized devices with attached smoke evacuators should be used.

- Minimize activating any energy devices in a fluid environment.
- Minimize the length of time for a given activation of an energy device and allow the device to cool down between activations.
- For devices with jaws, avoid forcing too much tissue into the jaws.
- Energy devices should be set to the lowest possible power setting for the desired tissue effect.

We should also leverage the increased awareness around the need for a safer laparoscopic environment to introduce the routine use of smoke evacuation and CO2 filtering in all laparoscopic procedures, as well as to set up specific research strategies to increase the evidence that are still missing.

Conflict of interest

Giovanni A. Tommaselli, Crystal Ricketts, Jeffrey Clymer, and Raymond Fryrear, II are employees of Johnson & Johnson Medical Devices.

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