

## COVID-19 MEDICO-LEGAL AND MALPRACTICE PROBLEMS: IMPLICATIONS FOR SURGEONS

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**Abstract:** The COVID-19 pandemic has already raised medico-legal issues and could trigger an unexpected wave of malpractice claims for many years in future. In a desperate effort to limit SARS-CoV-2 transmission and to relocate the healthcare resources towards the COVID-19 management, the screening and diagnostic procedures, as well as the elective surgical treatments have been postponed or even canceled for an undetermined period of time. Therefore, only the emergency cases were surgically treated. Such decisions resulted in the presentation of the patients with more severe and complicated forms of disease, associating increased morbidity and mortality rates. A complex issue was whether a patient died of COVID-19, or the viral infection was only additional to another cause of fatality; also, whether the COVID-19 was acquired in the hospital or not. At the same time, there were debates on the ideal therapeutic management of the COVID-19 cases, as well as the best time window for the surgical intervention in such cases. Another problem, potentially fueling future malpractice claims was in the surgeons' relocation towards treating non-surgical COVID-19 cases, for which they had neither a previous specialization, nor experience. In some states, there was a change in the legal frame in order to protect the healthcare personnel, including surgeons in such cases. However, in the states where no such decisions were taken, the surgeons are at future risk of being unjustly accused by the patients or their relatives for many years from now on.

**Keywords:** COVID-19 pandemic, general surgery, malpractice, protective legal frame, hospital-acquired infection, delayed treatment, emergency surgery, elective surgery.

### INTRODUCTION

COVID-19 has been a devastating pandemic, with an impressive number of 758390564 confirmed cases and a mortality of 6859093 people worldwide, as reported by the World Health Organization (WHO) on the 28<sup>th</sup> of February 2023 [1]. It has raised unprecedented medical challenges, significant medico-legal aspects and malpractice issues [2-6]. As expected, similar to other processes, there was a learning curve of how to manage such a pandemic, with faults, insufficient knowledge, lack of preparedness and limitations in the initial phase and significant improvement with time [7]. Although some of the important, useful conclusions came at last, they will consist an extremely valuable tool to manage a similar future epidemic or pandemic. Nowadays, besides COVID-19, we are also the witnesses of tremendous viral mutations and reemergence of past

diseases, such as Monkey-pox or even variola viruses. Some are expected to result naturally, while others can even be brought in the tentative of bio-terrorism [8-10]. Also, we could anticipate, as already speculated, that SARS-CoV-2 family of viruses will not suddenly disappear. Instead, we are likely to face repeated waves of mutated SARS-CoV viruses [11]. Therefore, in the current context of viral diseases, war and earthquakes, the lessons taught by the COVID-19 pandemics might prove of unexpected usefulness for a more prepared and efficient management of critical situations and crises. The only question that remains in place is whether we have indeed learned our lessons [12].

*The delay, cancellation or limitation of the elective and emergency surgery in non-COVID-19 patients during the pandemic*

During the COVID-19 pandemic, worldwide,

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in the majority of the states, there was a unanimous decision of delaying, postponing, cancellation or limiting non-emergent diagnostic interventions and treatments to insure the desiderates of minimizing SARS-CoV-2 exposure and the relocation of resources for the management of the COVID-19 pandemic [13, 14]. In fact, the patients' diagnostic and therapeutic delay during the pandemic had multiple causes: the regulated decisions of home confinement and social distancing; patients' fear of acquiring a potential fatal SARS-CoV-2 infection that limited their addressability to the hospital, making them stay at home and delay their presentation to the hospital until the occurrence of complications; the prolonged time of waiting at the emergency room for SARS-CoV-2 testing; official medical recommendations for the patients to remain at home when they have fever (although fever could have been a symptom of abdominal infection not linked to COVID-19); the relocation / shift of the human, material, and infrastructural resources from their normal function towards the COVID-19 units (especially in the case of ventilators); shortage of protective equipment and even of viral tests, suboptimal to the WHO recommendations; SARS-CoV-2 infection with the quarantine of the healthcare personnel; the associated higher risk of infectivity and more important COVID-19-associated morbidity and mortality rates for the patients with important comorbidities, such as cancer; cancellation of screening and diagnostic procedures, such as biopsy and endoscopy, in favor of alternative diagnostic tools such as CT colonography or barium exploration. [13-17].

Therefore, only urgent life-saving surgical interventions were performed, such as operations for bowel obstruction, perforation or hemorrhage, perforated diverticulitis, symptomatic and complicated cancer, while elective surgery was postponed for an undetermined period of time [2, 18]. For example, Hubner et al. report in their study, that at Lausanne University Hospital (CHUV) in Switzerland, during the initial phase of the pandemic (March-April) 50% of the operating rooms were transformed into intensive care units (ICUs), with several anesthetists and surgeons being transferred there. There was a 43% decrease in the elective visceral surgical operations, especially in the case of the usually most frequent types, such as cholecystectomies, bariatric and proctologic surgery, as well as in the number of outpatient consultations. Also, the number of colorectal and transplant surgical interventions has decreased [14, 18]. Also, in Italy, one of the most affected countries by the pandemic, there was

a significant change in the structure and functionality of the surgical departments, with several members relocated to non-surgical units, decrease in the number of elective operations in favor of complicated emergency cases, frequently resorting to minimally invasive techniques [15]. Especially laparoscopic operations were initially affected as it was thought that such a type of surgery would increase the risk of SARS-CoV-2 exposure via the viral aerosolization (smoke) through the trocars, similar to HPV, HIV, HBV. In the initial period, based on surgeons' experience and preferences, the laparoscopy was still used, coming in conflict with the official recommendations, source of malpractice claims, as reported in Italy [15]. However, later, no significant difference in the SARS-CoV-2 transmission between the laparoscopic and the classic surgery was found. Therefore, laparoscopic interventions were regarded as safe and recommended even for the COVID-19 patients provided adequate preventive measures were taken to prevent viral transmission [15, 18].

A complex issue during the COVID-19 era was whether to continue to perform transplant surgery or not. The transplant surgery associates an additional problem, as transplant recipients require an immunosuppressive regimen that could predispose to severe forms of SARS-CoV-2 infection [19]. However, the reported results of various studies have shown that, if adequate preventive strategies to lower the risk of viral transmission were taken, transplant surgery could be effectively performed even during the COVID-19 pandemic, especially for those with severe forms of disease, after a judicious risk-benefit analysis [18, 19]. However, it was recommended that timing of the transplant surgery be taken based on the local SARS-CoV-2 infection incidence, severity of the disease, length of the waitlist, available resources, provided that both the donor and recipient are SARS-CoV-2 negative and from the same city, after a quarantine of 14-21 days before the actual procedure. However, transplant patients have higher risk of SARS-CoV-2 infection, especially in the case of heart or kidney recipients, rather than in liver recipients [18]. In transplant recipients that acquired postoperative SARS-CoV-2 infection (especially in the case of aged patients with comorbidities) the rate of all-cause mortality was significant, between 11.8% and even 20%, the main cause of death being respiratory failure. It was reported that various treatments for SARS-CoV-2 infection (tocilizumab, lopinavir, ritonavir, hydroxychloroquine, corticosteroids, heparin) were used in transplant

recipients as well, although usually their dose was recommended to be reduced. Also, the dose of the immunosuppressive medications was decreased [18].

At the same time, even the number of urgent operations, such as those for bowel obstruction, acute cholecystitis surgery, perforated diverticulitis, symptomatic and complicated cancer, bleeding, complicated appendicitis, has dropped significantly, by 39% [4, 14, 15]. Also, the symptomatic patients unusually waited for longer periods of time at home before addressing to the hospital, with more severe/complicated forms of disease than usually [4, 15, 18].

#### ***Timing of the elective surgery and the emergency surgical treatment of COVID-19 patients***

At the same time, the surgical treatment of COVID-19 patients has raised several complex problems, with a potential of generating medicolegal consequences and malpractice issues. Several studies have shown that performing a surgical operation on a COVID-19 patient associated significantly increased morbidity and mortality rates when compared to a controllable operation performed for a COVID-19-cured patient [20]. However, other authors reported only an increase in the hospitalization time, with no impact on the morbidity and mortality rates. Even more, emergency surgery in the case of acute disease has contributed to a faster resolution of the SARS-CoV-2 pulmonary disease and it was considered feasible as long as preventing measures against the SARS-CoV-2 spreading were taken. Instead, other authors have reported only a higher morbidity rate associated to the emergency-surgery of the SARS-CoV-2 cases and no increase in the mortality rate [18]. As reported by Bunch et al., the postoperative morbidity and mortality rates were significantly higher when operating-on patients with a recent diagnostic of SARS-CoV-2 infection, especially for the symptomatic patients and for those in the first two weeks from the initial diagnostic than when operating-on non-COVID-19 patients or resolved, asymptomatic cases of SARS-CoV-2 infection, with more than 7 weeks from the initial diagnostic. Such a difference was seen due to the COVID-19 associated immune, thrombotic, thromboembolic and pulmonary complications [3, 20]. At the same time, such a difference was also generated by the frequent frailer overall status of the SARS-CoV-2 infected patients that were usually of older age and associated multiple comorbidities (cardiovascular, diabetes, kidney disease, immunosuppression, malignancies) when compared to non-infected patients [20]. In fact, the 30-day mortality

rates was of approximately 9.1% for the patients with a recent diagnostic of SARS-COV-2 infection, in the first two weeks; 6.9% for the patients that were operated after 3-4 weeks from the COVID-19 diagnostic; 5.5% 30-day postoperative mortality rate for the patients operated at 5-6 weeks from the SARS-CoV-2 infection diagnostic; and of 2% 30-day postoperative mortality rate, similar to the baseline mortality rate, for control subjects, when the operation was achieved after more than 7 weeks from the COVID-19 diagnostic. However, even after more than 7 weeks from the initial diagnostic, if the patient remained symptomatic (long COVID), the morbidity and mortality rates were significantly higher (of approximately 6%) when compared to asymptomatic COVID-10 patients (approximately 2.4%). As a result, the majority of the surgical societies have proposed to delay as much as possible the operation of COVID-19 patients, at least 4 to 7 weeks, until their cure, and to operate immediately only the emergency cases [20]. Such emergency cases referred to bowel obstruction, perforation or ischemia, bleeding, ischiorectal, perianal and soft tissue abscesses, incarcerated hernias, complicated diverticulitis, acute limb ischemia, aortic dissection or ruptured aortic aneurysm. Instead, uncomplicated appendicitis or cholecystitis were conservatively managed as often as possible, with a limitation and postponing of the surgical procedures, such as percutaneous drainage for appendicitis complicated with abscess [19]. Except for certain urgent surgical cases, it was considered that ideally a patient could be operated after more than 7 weeks from the COVID-19 diagnostic and after the resolution of his/her symptoms [13, 18, 20]. There were higher mortality rates in the case of the elective surgery for the gastrointestinal cancer COVID-19 patients, especially when the cases associated other risk factors such as increased age over 70 years, male sex, advanced cancer stage and postoperative anastomotic leak. Also, intestinal cancer surgery has led more frequently to the formation of ostomies when compared to the non-COVID-19 patients. Instead, in the case of the bariatric and metabolic surgery of the COVID-19 patients, no significant difference in the morbidity and mortality rates were seen when compared to non-COVID-19 cases. In fact, the obese patients with previous bariatric surgery had a significantly lower risk of mechanical ventilation. Therefore, it was suggested that bariatric surgery should be performed for the COVID-19 patients, provided adequate measures to prevent viral transmission are taken [18].

However, emergency surgery is usually

associated to a higher morbidity and mortality than the surgical operation of the scheduled cases, even in the case of non-COVID-19 cases. The risk is even higher when associating other risk factors such as advanced age, male sex, major surgery, associated comorbidities (ASA more than 3), cancer. Therefore, the decision to operate on a COVID-19 patient had to be judiciously taken only when absolutely required, when considered a life-saving procedure [18]. At the same time, the elective surgery for the COVID-19 patients was delayed in order to diminish the viral exposure to the medical personnel and the operating theatre, especially when dealing with aerodigestive tract tumors/interventions [13]. Instead, for the Long-COVID patients, an even longer delay until the operation has been recommended [20]. In such a context, an important problem for the surgeon has become the decision on the best dose and timing of the anticoagulation for the operated-on COVID-19 patients, with a delicate balance between the thrombotic and the hemorrhagic risk [20].

***Consequences of the delay, cancellation or limitation of the surgical operations during the COVID-19. Various potential medico-legal issues brought by the COVID-19 pandemic***

The delay in the elective surgical operations has generated an important number of complicated surgical cases of high technical complexity and associating high morbidity and mortality rates, such as severe abdominal sepsis from complicated appendicitis or cholecystitis [4]. Therefore, such cases count for a decrease in the survival rates and increase in the morbidity rate and more financial costs for the healthcare system, as an elective early operation for the same category of patients would have associated a substantially better prognostic [14, 21].

The restrictive and delaying decisions taken during the COVID-19 pandemic had also huge negative consequences on the surgical oncology patients, with misdiagnosis or delayed diagnostic resulting in advanced, complicated, even non-curable stages instead of efficacious screening and cancer treatment in the early stages, suitable for curable surgery and oncologic regimens. [6, 21, 22].

A major consequence of the delay/canceling in the diagnostic and treatment of the non-emergency cases during the COVID-19 pandemic was the backlog of an important number of patients at the resumption of the normal healthcare frame [14, 21]. Such an accumulation of patients was responsible for significant waiting lists and secondary delay of treatment,

additional need for patient re-prioritization, limited resources, with negative impact on patient treatment results and survival, with loss of other lives, as well as a new substantial pressure on the healthcare system [13, 15, 16]. It was estimated that, after the pandemic, resolving the backlog would require approximately 45 weeks of surgical activity functioning at a 20% increased capacity compared to normal conditions [18].

Another issue could come from the surgeon's requirement for an often difficult prioritization and decision concerning the categories of patients that could be managed *via* online-platforms [13, 19], that could associate errors and complications with putative legal repercussions. For example, in Italy, that has confronted severe COVID-19 crisis, a simple and efficient patient prioritization was based on the urgent character of the case, tumor-and patient factors. Another prioritization score (Emory University Healthcare) was based on the patient age, type of cancer, delay that would impact on patient survival, hospital resources [13]. Such an aspect has been especially a problem at the start of the pandemics when no clear guidelines of treatment or results from earlier studies existed. A similar issue has affected the oncologists, as they had to decide often for the cessation/delay in the delivery of immune therapies for the cancer patients in the context of the patients' SARS-CoV-2 infection [13].

A less discussed but still actual COVID-19-related putative malpractice issue is in the consequences of the switch of the normal, direct physical patient diagnostic and treatment to telemedicine. The implementation of virtual healthcare platform has triggered several negative consequences, along with its clear benefits. One came from the potential misdiagnosis of several conditions that might have been precociously diagnosed by the specialist. Another came from the created inequality of treatment, as the elderly and poorer patients had limited access to virtual healthcare if not at all. An additionally concerning aspect was related to the breaches in the intimacy and personal protection data of the patients that had to use such distance virtual diagnostic, treatment and follow-up alternatives [17].

***The potential acquirement of the SARS-CoV-2 infection from the hospital -another medico-legal issue***

Contrasting with the medico-legal aspects generated by the delay/cessation/change in the non-COVID-19 patients' diagnostic and treatment regimens, another source of malpractice issues was the potential SARS-CoV-2 acquirement from the hospitals. In such



a context, an important question has become whether the SARS-CoV-2 infection could have been prevented by a more attentive and prepared behavior of the medical personnel [7], therefore whether the infection was “inevitable” or “avoidable”. There were several reports of hospital acquired SARS-CoV-2 infection, despite the protective measures that were taken, that sometimes led to higher morbidity and mortality rates, increased duration of hospital stay and more important costs [4, 21], another potential cause of malpractice claims [7]. According to various studies, the percent of patient hospital-acquired SARS-CoV-2 infection varied largely between regions and hospitals, between 6.9% (as reported in Japan) to 10-20% in England, especially due to inadequate isolation, overcrowded hospitals or COVID-19 units, insufficient protective measures and mobility of the potentially infected personnel. The transmission of the SARS-CoV-2 was mainly via the respiratory route, but also by fecal-oral or hand-mouth, being prevented *via* rigorous personal hygiene, advanced protective equipment and isolation. The lowest rates of hospital-acquired COVID-19 were in Hong Kong (zero transmission) and in the United States [7]. The biggest percent of hospital-acquired SARS-CoV-2 infection was reported for the medical personnel, of up to 44% [7, 23]. However, hospital-acquired viral infection associated a mortality of up to 36 % [7, 17].

In this regard, all the healthcare units have taken important measures, as advised by the authorities: the limitation of the patients' visits to the hospitals/clinics with establishment of telemedicine; efficient triage; adequate testing of the hospital-admitted patients or suspected cases; relocation of the human and material resources towards COVID-19 units; retraining via web courses of the healthcare givers that were reassigned to respiratory, COVID and ICU units; virtual meetings of medical personnel; establishment of non-COVID and COVID-19 separate circuits; use of personal protective equipment with clear rules for its usage and disposal; rigorous personal hygiene; rotations of teams of caregivers between the hospital/clinic and the digital platforms; hotel rooming of the medical personnel in order to limit their families' exposure to the virus; prioritization of cases by multidisciplinary teams; even allocation of entire hospitals towards COVID-19 and non-COVID-19 patients' treatment [5, 7, 13, 14]. Also, a special attention was given to the pre-operative room, operating-, anesthesia recovery- and endoscopy rooms, that had to be negative-pressure rooms, to the anesthetic procedures, such as intubation

and extubation, and to the laparoscopic procedures, including pressurized intraperitoneal aerosolized chemotherapy [2]. However, at the beginning of the pandemics, when there was a lack of knowledge on the prevention, transmission and treatment of the virus, such guidelines, safety rules and protective equipment were insufficient or even missing [5, 13]. Or, on the contrary, the initial, expeditious guidelines did contain flaws, proposing potentially ineffective or even harmful recommendations. Another drawback of the guidelines was their simplicity, inflexibility and conflicting nature of their various versions [13]. In such a context, an important mission of the doctors remained the recognition of the limitations of the guidelines, their continuous reassessment, validation, improvement and discard, if proven inadequate [13, 14]. However, some errors derived from the lack of adequate guidelines. In such a context, in the initial phases of the pandemic, it was considered that a hospital acquired SARS-CoV-2 infection was not judged as malpractice. Also, other medical errors that occurred in the initial phases due to the lack of knowledge and of preparedness, excepting gross negligence, were cleared from malpractice claims [5]. Nonetheless, later, when an efficient plan for the prevention of SARS-CoV-2 hospital-acquired infection and COVID-19 management was set, the same issue could be regarded totally different, with malpractice implications [7]. Still, even after the initial wave, there were states/regions, such as in Italy, where due to the heavy, overwhelming number of COVID-19 cases the protective equipment and other material resources were insufficient, while the human resources were diminishing [5, 7, 15]. A source of insufficient human resources was exhaustion, as well as the SARS-CoV-2 infection acquirement of the medical personnel involved in the COVID-19 crisis [7]. Therefore, not only the patients, but also the healthcare personnel that potentially acquired SARS-CoV-2 infection from the hospital, when shifting of the personnel to COVID-19 units occurred despite their medical specialization, advanced protective equipment was insufficient, with excessive work burden, could become the source of a significant number of legal claims against the hospitals [15].

#### ***Autopsies during the COVID-19 pandemic***

During the pandemic, another question was whether a patient has died due to COVID-19 or with COVID-19, but due to another disease, as COVID-19 signs and symptoms were variable and overlapable

with other diseases, such as complications of an abdominal emergency (e. g: fever could have been a sign of COVID-19, as well as that of an abdominal infection) or lung cancer. Also, patients frequently had other important comorbidities with a potential of decompensation due to COVID-19 [3, 15, 17]. The answer to such a question remained partially solved. It was only sometimes addressed, as in some cases autopsies were performed, establishing exactly the causes of deaths [5, 6, 24]. However, there was also a limitation and regulation in performing autopsies, due to the fear of viral aerosolization, shortage in the protective equipment and limitations of the morgue facilities [24]. Therefore, many cases remained without clarification, with a persistent suspicion of putative malpractice. However, despite such limitations, the number of autopsies increased during the pandemic when compared to the pre-pandemic era [24]. Fortunately, the autopsies were considered safe provided adequate protective measures were taken and they were able to identify COVID-19 even after long periods of time following the death of the patient [3]. However, initially, the definition of a COVID-19 related death was based mainly on the SARS-CoV-2 positive testing, potentially leading to an overestimation of the deaths caused by COVID-19, when other patient comorbidities were not taken into account sufficiently, an aspect that was later corrected [3].

Therefore, in such a pandemic context, autopsies remained a key factor in confirming the exact cause of death, discriminating between patients that died due to fatal COVID-19 versus those dying with COVID and therefore solving malpractice claims, highlighting potential medical errors, essential for future improvements of the clinical practice [24]. A still unsolved problem, of medico-legal concern, was however in the case of the elderly patients that were relocated to overcrowded nursing homes due to the lack of hospital beds, with a higher risk of acquiring SARS-CoV-2 infection, especially in heavily burdened countries, such as Italy [3, 5]. In fact, in regions of Italy, such as Lombardy, the relocation of COVID-19 patients in overcrowded long-term care facilities, with lack of adequate hygiene measures and of distancing, that rapidly became hot-spots for the viral transmission, has led to impressive mortality rates of up to 51.3% [5].

#### ***Protective legal frame for the healthcare providers during the pandemic***

Worldwide, many states, although not all, have established a protective legal frame for the doctors

(civil liability protection), including surgeons that were involved in the COVID-19 treatment [13]. A specific protective legal frame is important not only to avoid delayed-treatment repercussions, but also to interrupt the wave of malpractice claims to the surgeons and other categories of medical specialists that have been abruptly abstracted from their specialization and redirected towards treating COVID-19 patients, without an infectious diseases/pneumology/intensive care specialization [14]. The insufficient understanding of the patients comes in contrast with their expectations of having been treated with the same efficacy as that of an infectious diseases specialist doctor.

**In conclusion**, the COVID-19 pandemic has brought an unprecedented pressure on the healthcare systems, forcing decisions that have impacted on the survival of the patients and their quality of life, as well as on the health of the healthcare providers. Some of the measures have proved to be beneficial as they reduced the COVID-19 transmissibility, morbidity and mortality rates. They will represent an extremely valuable model of management of potential/expectable future health crises [21]. However, they also negatively impacted on the prognostic of others, especially on the oncological and surgical patients and the frail categories of older patients with co-morbidities [4, 21]. The final effects of the undertaken COVID-19 related measures will only be seen in time and after the completion of several statistical analyses. Until now, the requirement for an accelerated speed imposed by the COVID-19 pandemic has not allowed for enough preparedness from the part of the healthcare systems, for immediate guidelines, establishment of a generally efficient approved standard of care, nor for final conclusions. In such a setting, some explainable errors could have arisen, subject to medical liability [7]. Many states have implemented an absolutely necessary protective law frame, required for a sustained continuum of care of the COVID-19 cases by the overwhelmed and burnout medical personnel, often practicing outside their medical specialty during the COVID-19 pandemics [13, 14]. In other states, as we expect a long-lasting future increase in malpractice claims from the deceased patients' relatives, the current implementation of such a protective legislation should become a requisite.

#### **Conflict of interest**

The authors declare that they have no conflict of interest.

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