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MEDICO-LEGAL AND MALPRACTICE ISSUES FOR THE SURGICAL ONCOLOGY DURING THE COVID-19 PANDEMIC

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Abstract: As the world had no previous experience to a health crisis such as the COVID-19 pandemic, some of the initial decisions that were taken at the start of the SARS-CoV-2 pandemic appear now questionable. The surgical oncology represents a delicate field, as it is not necessarily an emergency, but however it requires a prompt management. The COVID-19 –related decisions have forced a very difficult to achieve balance between the protection of the cancer patients against SARS-CoV-2 infection and their timely treatment. However, during the pandemic, the screening program and the diagnostic procedures were delayed or even canceled, generating an important number of cases of missed cancer diagnostic. Also, the postponing or even interdiction in some states of the elective surgery for the non-complicated oncological cases resulted in a significant loss of life-years and even lost lives. At the same time, the delayed presentation of the oncological patients with complicated, acute forms of disease associated increased morbidity and mortality rates that could have been avoided with timely surgical treatment. Additionally, the pandemic-related measures caused a significant backlog of cancer cases to be treated after the end of the pandemic, which will require many months or even years to be solved. In such a context, the surgeons could face many malpractice claims, for many years, as the patients' relatives have neither understood, nor accepted the surgeons" limitations during the COVID-19 pandemic.

Keywords: COVID-19 pandemic, surgical oncology, lost years, lost lives, emergency surgery, elective surgery, malpractice claims, delayed treatment.

INTRODUCTION

COVID-19 pandemic has unexpectedly and abruptly forced the medical and decisional society to achieve a very delicate balance between decreasing the risk of patient acquiring SARS-CoV-2 infection and insuring an efficient treatment to those in need, such as those with cancer [1]. However, exactly such frail patient categories were at increased risk of SARS-CoV-2 infection, especially more severe forms [2-4]. It appears that none of these two desiderates, that of limiting SARS-CoV-2 transmission and protection of the frail patients, has been fully accomplished, as the world had no similar experience with such a pandemic [5, 6]. In fact, there were sufficient published reports on the negative consequences of the decisions taken during the COVID-19 pandemic [2, 7-9]. Therefore, a potentially substantial wave of malpractice claims could follow in the near future.

In a desperate tentative of limiting the risk of SARS-CoV-2 exposure of the population and especially of the frail categories of patients, such as the oncological patients, there was a significant delay and even interruption in the required diagnostic and treatment procedures of the non-COVID-19 patients and non-emergent elective procedures, with a relocation of the majority of the human and material resources towards the COVID-19 management [1, 3, 9-12]. In fact, the elective and oncological surgical interventions were even prohibited in some states, for a period of time, the already scheduled operations being postponed for at least two months [5]. Actually, surgical oncology is a delicate field: usually, it does not represent an emergency (unless a life-threatening complication intervenes), but it can neither be regarded as purely elective, since a timely treatment is vital [10].

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For this reason, such COVID-19-related decisions have generated an important negative impact on the surgical and oncological clinics and patients, with the presentation of the patients in the stage of complicated forms of disease and even the progression of cancers from possibly curable to non-curable stages [2, 7, 12]. Worldwide, the incidence of cancer cases is of 18094716, as reported in 2020 by the WHO, responsible for 18.1 million deaths. Therefore, cancer is the second biggest cause of mortality worldwide, the most frequent types being breast, lung, colorectal, prostate, skin and stomach neoplasia [13-16]. Only in the United States, approximately 1.8 million of new patients are diagnosed with cancer each year, with more than 600000 cases cancer-related deaths [10]. Therefore, as a result of the postponing/suspension of the diagnostic, screening procedures and elective therapies for the non-COVID-19 patients, an important number of cancer cases have probably been not diagnosed or have received a delayed diagnostic, with impact on their chances of timely treatment in curable stages and on their survival prognosis [5, 10, 11, 17]. It is speculated that the total number of missed cancer diagnostic cases is unknown as there may still remained cancer patients without a diagnostic, even after the end of the COVID-19 pandemic. For example, it was approximated that the required screening was not performed for almost 3 million people in the United Kingdom in only a few months of pandemic (between March and September, 2020), including breast and colorectal cancer screening for high risk individuals, such as those with family history of neoplasia, adenomatous polyposis and inflammatory bowel disease [3]. Also, for the already diagnosed patients with cancer non-emergent surgical treatment has been delayed and such patients received recommendations for adjusted or alternative non-surgical treatments [5, 10]. For example, radiotherapy instead of surgery or even only hormonal therapy for prostate cancer, chemo- and radiotherapy instead of surgery for cervical cancer, conservative surgery and radiotherapy or even non-surgical treatment such as neoadjuvant chemotherapy or hormonal therapy for positive estrogen receptor breast cancer instead of mastectomy, [2, 7, 18]. Also, neoadjuvant chemotherapy and ostomies were recommended for colorectal cancer, with the postponing of the definitive surgery for several months. Another example is the delivery of only one-day adjuvant chemotherapy for operated breast cancer. On the contrary, trauma patients received the required surgical treatment as usually, even during the pandemic [18]. Such measures might have been potentially responsible for lost life-years and lost lives [8]. Therefore, all these cancer cases could easily become the source of an unprecedented wave of malpractice lawsuits.

The published studies and meta-analyses on the consequences of the delayed oncological surgical operations have revealed several aspects. Even a mild treatment delay for aggressive or advanced-stage cancers (such as: stages 2 and 3 of the esophagus, lung, pancreas, liver, colon, ovary and bladder neoplasia) could result in a significant decrease in the survival rate (approximately 17% at three months and more than 30% at six months) [2, 7]. Therefore, for cancers such as metastatic germ cell tumors, lymphomas, acute leukemia that usually respond well to the oncological regimens and associate a more important mortality than that of COVID-19, an immediate treatment was recommended [2]. Also, there was a significantly worsened prognosis for the patients with T2 renal tumors when the surgery was performed with a 3-4 months delay instead of 2 months for the diagnostic and an even lower survival when the delay was of 5-6 months [1]. On the contrary, comparing COVID-19-associated morbidity and mortality rates with a fast therapeutic management for early stage cancers or neoplasias that usually associate a better prognostic (estrogen-receptor-positive breast cancer, or early–stage colorectal cancer in older patients) a modest treatment delay might be less harmful, with less than 1% impact on the survival prognostic [7]. However, if we consider that COVID-19 pandemics has brought a delay in the diagnosis of cancer in its early stages, we could speculate that there was an important impact on patient survival rates for all neoplasia types. Overall, it is generally considered that a delay longer than 4-8 weeks from the cancer diagnostic to the surgical treatment will result in a significant decrease in patients' survival [10]. Prior to the pandemic, cancer surgery performed each year determined a gain of 1717051 life-years for the operated-on patients, meaning an average gain of 18.1 life-year per patient, which significantly decreased to 17.1 life-years with a 3-months delay and to 15.9 years with a 6-months delay; therefore, a six-month delay of surgery would result in 208275 lost life-years for the patients [7]. In such a context, the target of many states, such as England, of increasing the percentage of cancer diagnostic in early, curable stages (for up to 75% by 2028) has been significantly affected [8]. In fact, due to the cancer screening program suspension in England at the beginning of the pandemic, in March 2020, approximately 8500 with a positive colorectal screening test did not enter into the two week–wait system and

remained uninvestigated and therefore untreated [8].

In the end, the consequences of the COVID-19 pandemic-related decisions could express an uneven and delicate balance between the SARS-CoV-2 relatively low mortality rate and the deaths caused by the lost/delayed cancer cases. At the same time, for the cancer patients, very delicate problems also occurred due to the oncological treatments. Many of the oncological therapies (immune check-point inhibitors, radiotherapy, etc.), with immunosuppressive effects and associating pulmonary toxicity, could aggravate or be confounded with the COVID-19, leading to potential diagnostic and treatment errors. However, on the other hand the delay in the delivery of the radiotherapy or chemotherapy for many cancers can result in a significant mortality rate (e.g.: approximately 16% for each month of delay in case of the otorhinolaryngologic cancers). Also, there is a limited time window between neoadjuvant therapy and the operation, as well [2, 10]. In order to diminish the effects of delay on the survival of cancer patients, an analysis of the cases in tumor board, according to the international guidelines had to be done, with a classification into three categories of priority: urgent; immediate (treatment after a short delay); postponable [2].

In a tentative to decrease patients' exposure to the SARS-CoV-2, there was also a change in the oncological regimens (chemotherapy, radiotherapy, immune therapy), use of alternative therapies instead of the standard therapeutic regimens, with a switch from IV to oral therapies, decrease in the frequency of the oncological treatment delivery (e.g.: radiation delivery in fewer doses) and a reduced number of visits for control/follow-up in the hospitals/clinics [8, 10]. The actual impact of such a change in the oncological scheme remains to be evaluated in time.

Another drawback brought by the COVID-19-associated measures was the almost complete suspension of the non-COVID-19-related clinical trials, with a significant negative impact especially on the frail category of oncological patients. Such a suspension was caused by the allocation of the majority of funds for the COVID-19 management and research , but also due to the social distancing measures and patient's fear of becoming infected with the SARS-CoV-2 that reduced the enrollment in clinical trials. Also, it was estimated that more than 50% of the individuals suspected for cancer did not present to the hospital, due to the lockdown and fear of the SARS-CoV-2 infection [3].

However, as a result of the pandemic, a positive effect was seen as well. The COVID-19 pandemic has shown that clinical trials, the development of new therapeutic regimens and even of vaccines can occur with an unexpected speed, bypassing the usual bureaucracy that impedes the accomplishment of the usual clinical trials. If translated in future research, such an improved attitude towards clinical trials would result in a faster completion of clinical trials, speeding up patients access, including oncological ones, to advanced therapies with increased chances of survival [3, 10].

However, some patients might have not understood the reasons of such delays in their diagnostic and treatment and became anxious, or might have considered the treatment as being insufficient, another cause of malpractice claims [10]. For example, in surgical oncology and oncology, two medicolegal claims have appeared: due to the delay in the diagnostic and treatment; due to potentially hospital-acquired SARS-CoV-2 infection. Therefore forensic studies were used to estimate tumor growth in the delay-interval and its impact on patient survival [2]. Therefore, after a decrease in the performed number of autopsies over many pre-pandemic years, during the COVID-19 era, the autopsies gained a substantial value, being able to determine the exact cause of death, essential in the malpractice claims [19-22]. In such a context, in many states, the legal frame was changed to confer civil liability protection to the healthcare givers (including surgeons) that were active during the COVID-pandemic [10].

In conclusion, COVID-19 pandemic-related measures have caused a delay in the diagnostic and treatment of the oncological patients, and even a difficult to approximate number of missed cancer cases. It is estimated that the delay, limitation or even prohibition of non-emergency surgical oncology interventions during the pandemics have been responsible for a significant number of lost-years and lost-lives. That is, such decisions had a significantly negative impact on the prognostic of the oncological patients [7, 11]. When comparing the overall low mortality of the SARS-CoV-2 infection with the significant morbidity and mortality of the delayed cancer cases, the restrictive decisions taken during the COVID-19 pandemic might appear questionable. However, the world had no previous similar experience and was not prepared for such a crisis, that might explain some of the errors that have occurred. Nonetheless, such cases of errors could easily become the fuel for a substantial wave of malpractice claims, for which the medical society is neither prepared, nor legally protected. Still, the COVID-19 pandemic has also triggered useful changes

and taught us lessons, such as a better management of resources, bypassing of the bureaucracy in clinical trials, and others, that might be of an unexpectable value in the case of a future pandemic. However, the problem of efficient oncological patient management in the case of a resource-limiting pandemic has remained partially unsolved, as well as the healthcare medical liability protection in such extreme situations.

Conflict of interest

The authors declare that they have no conflict of interest.

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