

Informed consent and a risk-based approach to oncologic surgery in a cancer center during the COVID-19 pandemic

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Abstract

Background: Cancer patients configure a risk group for complications or death by COVID-19. For many of them, postponing or replacing their surgical treatments is not recommended. During this pandemic, surgeons must discuss the risks and

benefits of treatment, and patients should sign a specific comprehensive Informed consent (IC).

Objectives: To report an IC and an algorithm developed for oncologic surgery during the COVID-19 outbreak.

Methods: We developed an IC and a process flowchart containing a preoperative symptoms questionnaire and a PCR SARS-CoV-2 test and described all perioperative steps of this program.

Results: Patients with negative questionnaires and tests go to surgery, those with positive ones must wait 21 days and undergo a second test before surgery is scheduled. The IC focused both on risks and benefits inherent each surgery and on the risks of perioperative SARS-CoV-2 infections or related complications. Also, the IC discusses the possibility of sudden replacement of medical staff member(s) due to the pandemic; the possibility of unexpected complications demanding emergency procedures that cannot be specifically discussed in advance is addressed.

Conclusions: During the pandemic, specific tools must be developed to ensure safe experiences for surgical patients and prevent them from having misunderstandings concerning their care.

KEYWORDS

algorithm, cancer surgery, COVID-19, informed consent, oncologic surgery, SARS-CoV-2

1 | INTRODUCTION

Since the end of January 2020, when the World Health Organization (WHO) declared the novel coronavirus outbreak a public health emergency of international concern,^{1,2} a profound global transformation in health care has been promoted. The worldwide concern increased in March, when the WHO declared that COVID-19 was a pandemic disease.^{3,4} The majority of health care infrastructure, materials, and personnel resources have been diverted in favor of facing this pandemic and to provide personal protective equipment to health professionals.^{2,4,5} One of the most important population recommendations has been social distancing, which is effective in reducing the transmission of SARS-CoV-2.⁶ This sanitary policy is considered fundamental, but some adverse effects have been verified in patients with chronic non-communicable diseases, such as cardiovascular disorders and cancer. There are reports of increased numbers of fatal acute cardiovascular events at home, because patients are avoiding going to hospitals or emergency rooms out of fear of becoming infected during hospital admission.⁷⁻⁹

In this scenario, the treatment of cancer remains a great challenge. The main risk factors for cancer (older age, obesity, diabetes, arterial hypertension, smoking, respiratory diseases, metabolic syndromes) are also competing risk factors for infection by COVID-19 and its potentially lethal complications.^{10,11} Small series studied in the first countries to be affected suggest that cancer patients are almost twice as likely to become infected¹² and present more severe events in comparison with nononcologic patients (39% vs. 8%,

respectively; $p = 0.0003$; odds ratio, 4.7 [95% CI, 1.23–13.43]; $p = 0.02$).^{11,12} A recent report of an international cohort study showed a high risk of pulmonary complications and mortality among 1128 SARS-CoV-2-infected patients who underwent surgery.¹³

Despite the fact that oncologic surgery is one of the pillars of the treatment of solid tumors, its indication constitutes a dilemma in this pandemic period: if all patients undergo invasive procedures, many of them would be at risk of becoming infected and developing severe complications.^{11,14,15} Conversely, for many patients with aggressive or life-threatening tumors, when surgery is postponed (or changed for alternative therapies), the odds of being cured or of adequate cancer control are lessened.¹⁵

Regarding surgical staff, many surgical or anesthetic teams may be reduced in number, due to the work impediment for groups such as older colleagues or groups at risk of infection, as well as young colleagues who contract the infection or who have been displaced from their teams to attend to the front lines of infection.⁵ Thus, it is important to optimize the management of human and material resources for surgical treatment of cancer at this moment. Reports of infected colleagues and nursing teams must also be taken into account to ensure a safe surgical environment and to respect the recommendations to avoid virus dissemination through intraoperative aerosols or secretions to the surgical room.¹⁵⁻²²

To reach the best and safest decisions, it is necessary to base them on the natural history of each specific tumor and the patient's health status. For indolent and less aggressive tumors, postponement of surgery and active surveillance protocols might be the best option. For aggressive

malignancies, prompt surgery could be indicated. Between these two extreme scenarios, there are intermediate situations which could be managed by alternative measures, such as short-term postponement (60–90 days, with re-evaluation of imaging studies), outpatient thermal ablative procedures, or a nonsurgical approach, such as radiotherapy and/or systemic treatments (such as hormonal therapy, chemotherapy, targeted therapy, and/or immunotherapy).^{15,22} In addition, other characteristics must be taken into account when deciding on the timing of surgical treatment during the pandemic, such as maintenance of a protected cancer flow within the hospital, the hospital occupancy rate, the intensive care unit (ICU) occupancy rate, the availability of hospital supplies including personal protective equipment (PPE), and patient anxiety regarding possible postponement of surgical treatment.

To support surgeons in their therapeutic decisions, many medical specialty societies have published adapted guidelines and recommendations.^{15,22} Although following such guidelines is to be recommended, many statements are based on specialists' opinions and it is impossible to guarantee the effectiveness of these measures for all cases. On the other hand, some patients are absolutely refractory or for personal reasons do not follow medical recommendations and demand prompt surgery.

Historically, high-volume and highly specialized cancer centers have achieved their best results in treating several kinds of solid tumors, in comparison with low-volume or non-specialized centers.^{23,24} Oncologic referral teams must establish the best conditions in which to offer the best multidisciplinary personalized approach for each patient. Better individualized therapeutic decisions must be the result of a risk-based approach (based on tumor and patient characteristics), shared among surgeons, anesthesiologists, patients, and their relatives or caregivers. After the discussion of risks and benefits, an adapted informed consent (IC) document must be agreed on by the parties involved. Despite a recent Indian proposal of a model of IC for general surgery during the pandemic,²⁶ and a discussion from the Milan group²⁷ about the need for IC for treatment of COVID-19 patients, there were no publications regarding a specific IC adapted for oncologic surgeries during the pandemic before January 2021.¹⁹

At our cancer center the clinical, legal and administrative teams developed an IC document dedicated to cancer surgery during this pandemic period. Concomitantly, based on the recommendations of the Sociedade Brasileira de Cirurgia Oncológica (Brazilian Society of Oncologic Surgery, SBCO)¹⁸ and other previous general surgical publications and guidance from recognized surgical and oncological societies,^{15-17,22,29-34} they developed a risk-based algorithmic approach for managing these surgical candidates, aiming to ensure as safe an experience as possible for both patients and health care staff. The aim of this study is to report our IC model and our proposed management algorithm.

2 | MATERIALS AND METHODS

We searched the English, Portuguese, Italian, and Spanish literature using the Mesh terms *informed consent*, *COVID-19*, *SARS-Cov-2*, *pandemic*, and *oncologic surgery*. We wrote a description of the

institution-specific IC and algorithm for surgery during the COVID-19 pandemic that have been in use at the ACCCC since May 5, 2020.

3 | RESULTS

3.1 | The informed consent

The IC is shown in Figure 1. The form is divided into two sections: the first section provides information regarding disease and the procedure: *clinical condition; proposed procedure, objectives and justifications; benefits, and risks and eventual consequences*. This section is completed by the surgeon. The second section is not limited to discussing the risks and benefits of the surgery during this pandemic. It advises the patient about medical staff exposure risks, mentioning that team members could be infected or put under quarantine during the patient's treatment. In these situations, they will be replaced by other colleagues. Finally, the IC clarifies that unexpected complications can occur and can require new urgent procedures, and it reinforces recommendations that patients maintain social distancing after the surgery.

3.2 | Algorithm for the surgical treatment of cancer

The surgical treatment algorithm was developed by a task force composed of surgeons, anesthesiologists, infectologists, ICU professionals, nurses, diagnosticians, laboratory teams, lawyers, hospital managers, and institutional stakeholders, and it was based on the recommendations proposed by SBCO¹⁸ and publications about best practices for safe surgery during the COVID 19 pandemic (Figure 2).^{15-17,19-22,28-34}

In summary, 5 days before an elective surgery, patients are advised by phone or email about the algorithm and they are invited to answer the questionnaire about any flu-like symptoms in the last 72 h. They are asked about suspicious symptoms or signs of COVID-19 infection and about any recent contact with infected people. This questionnaire was an adaptation prepared by SBCO¹⁸ from the Brazilian Ministry of Health's COVID-19 questionnaire (Figure 3).³¹

If the answers to this survey are positive, the patient and physician are informed and the surgery is postponed for 21 days. If the questionnaire is negative, patients are instructed to come to the hospital within 72 h before the surgery and undergo a nasopharyngeal swab polymerase chain reaction (PCR) test for SARS-CoV-2. After this, they are counseled to return their homes and maintain strict social distancing until the day of the operation. The patients are informed of the results by phone call or e-mail.

If the patient's survey and PCR test are both negative, they can proceed to surgery. If they have a positive test result or a positive questionnaire, the surgery can be postponed and it is recommended that patients stay in quarantine for 16 days. After this 16-day period,

I, patient _____ represented, assisted by my legal guardian (XXXXXX), consent to perform the surgical treatment called _____, composed by the doctor _____), to be performed by him/her and by his/her team members and or by others professionals selected by him, on the premises of the A.C. Camargo Cancer Center.

I declare that the surgical procedure /treatment to which I will be submitted, the objective(s) and the justification(s) that underlie its performance have been explained to me in detail.

I understood that there is no absolute guarantee regarding the result.

I was informed about alternative method (s) and possible consequence (s) if the surgical procedure / treatment is not performed.

I received information about the benefit (s) resulting from the surgical procedure/ treatment.

I was adequately informed about the risks, complications, and the possibility of complications(s) related to the execution of the surgical procedure/treatment, and if necessary, I can contact the institution at any time to clarify doubts.

In this sense, it should be noted, regarding the risks, complications and possible complications, after receiving clarifications regarding my cancer diagnosis, I was informed about the possible repercussions in the postponement of my surgical treatment, in case I do not decide do it this time.

I was informed by Dr. _____, Professional Registry ID: _____, that, based on scientific data, my cancer diagnosis was considered, at this time, as a tumor with a high probability of progression, and the delay in surgery may result in worsening of the cancer prognosis.

I was advised that in my case there is no treatment, at that moment, capable of safely replacing or postponing the indicated cancer surgery.

I received information from the medical team based on resolutions from the Brazilian Society of Oncological Surgery that says that:

- Healthy elective surgery patients can contract COVID 19 during hospitalization;

FIGURE 1 The A.C. Camargo Cancer Center informed consent form for invasive oncological procedures and surgical treatments during COVID 19 pandemic

they submit to a new PCR test. If the patients are asymptomatic, and their tests are negative, the surgery is re-scheduled for the 21st day. We strongly recommend maintenance of social distancing for 2–4 weeks after the operation, to reduce the risk of becoming infected after procedure.

If it is not possible to wait when the test results are positive or uncertain, these patients are considered suspect for the coronavirus, and the surgery is performed in specifically dedicated surgical rooms (with negative pressure) for COVID-19-positive patients. Extreme

caution is exercised by using PPE, including face shields, protective glasses, N-95 masks, and impermeable surgical gowns, and by taking care to avoid producing aerosols or liquid particles during surgery, as advised by surgical societies.^{15-22,28-34}

During their hospitalization, patients have a special nosocomial transportation protocol and are monitored by our hospitalist group for any sign of new coronavirus infection or clinical deterioration. If necessary, our rapid response team, trained for COVID pandemic situations, takes emergency actions for respiratory failure.

- Healthy elective surgery patients who contract COVID 19 in the postoperative period may develop more severe conditions due to the immunological changes caused by the surgery;
- Patients who have contracted the infection a few days ago may not yet have developed symptoms and mechanical ventilation during surgery may result in worsening cases;
- Patients with asymptomatic infection by COVID 19 can transmit infection to the team;
- Elective surgery patients who have respiratory complications may have symptoms similar to COVID infection 19, causing diagnostic confusion;
- Elective surgery patients who develop severe COVID 19 infection in the postoperative period may have more associated surgical complications.

I am aware that we are currently experiencing a pandemic situation due to COVID-19 and that there is a risk of contamination during my cancer treatment. I know that I belong to a group at risk of more serious complications, in addition to a higher risk of postoperative death, in an eventual infection with the new Corona Virus."

My main doubts are: (if necessary, use the back of this document. If there is no doubt, please record the negative in writing) _____

After having been given the opportunity to point out and to resolve all my doubts about the performance of the invasive procedure / treatment, and to be aware that during the period of my treatment, as a result of the pandemic, removal of member(s) from the my medical team, including the attending physician, can resulting in the transfer of my care to other professionals of the institution.

I was informed about the precautions to be taken after the surgical procedure/ treatment was performed.

I authorize the realization of any other treatment/procedure in unforeseen situations that may occur, and that require care other than those initially proposed, and I declare to be aware that the performance of the team.

The hospital's medical staff is guided by the constitutional and infraconstitutional provisions, which implies the duty of physicians to provide assistance, avoiding death, in

FIGURE 1 Continued

If necessary, patients are transferred to ICU beds without COVID-19 patients or to a COVID-19-positive ICU if they became infected.

Visits by patients' relatives are restricted to only one per day, and the visitor is advised to spend as little time as possible in the institution. At admission, patients are evaluated by nurses to detect disabilities or specific weaknesses that need full-time monitoring by their family members or caregivers, who receive guidance and a booklet of intrahospital recommendations during the pandemic.

For urgent clinical conditions, patients must enter by the emergency room and, if it is possible, we order an urgent PCR test, the result of which must be available within 24–48 h. While waiting, patients are located in a transition area with an infirmary with no COVID-19 positive patients. According to their negative or positive test results, they are moved to COVID-19 negative or positive wards, respectively.

When feasible, we suggest the adoption of minimally invasive surgeries and early hospital discharge.

the name of the principle of beneficence, which means that the necessary procedures in this case are considered as a safety maneuver. clinic, therefore, mandatory medical act, as recommended by the Federal Council of Medicine-CFM and civil and penal legislation in force.

I am aware that my non-consent does not imply any penalty.

I have been informed that I can withdraw my consent at any time, without this leading to any penalty.

Sao Paulo, Date:

Patient Signature.

Patient Caregiver Signature

Physician signature

FIGURE 1 Continued

4 | DISCUSSION

Due to the great challenge the pandemic has brought us and to assure the window of opportunity for radical surgery, it is fundamental to keep in mind that many surgical candidates with solid tumors present some frailty or some competing risk factors (elderly, high body mass index, cardiovascular or pulmonary diseases, tobacco exposure, or immunosuppressive therapies as systemic chemotherapy or radiotherapy) for the SARS-CoV-2 infection and its severe complications.¹³ Additionally, surgical and anesthetic interventions can result in further immunosuppression in oncologic patients.^{35,36}

For each patient, according their clinical situation, demographics, tumor characteristics, and preferences, a personalized therapeutic decision must be developed to minimize the risks of the usual approach (upfront surgery) versus its postponement or alternative treatments during the pandemic. When skilled professionals discuss each case in tumor boards, taking into account these multiple variables, the probability of more favorable outcomes increases. However, it is not possible to assure that patients treated on the basis of extrapolation of the established guidelines will achieve the same results during the pandemic.

Some patients can be refractory or are not prone to follow medical recommendations in delaying elective surgeries, and they demand immediate procedures. Furthermore, in emergency cases, it might not be possible to follow an algorithm as proposed above.

It is critical that patients and their relatives or caregivers are comprehensively informed about all benefits and risks involved in the surgical treatment. There is no guarantee that the results will be similar to those achieved before the pandemic.¹¹⁻¹⁴

The use of IC forms is well established in surgical routine,^{37,38} being globally recommended by medical and legal authorities. The application of the IC together with an enlightening and realistic conversation, in a welcoming environment, can reduce the risk of future legal disputes between patients, relatives, doctors, and health care institutions.

From this harmonious conversation, a shared therapeutic decision must be achieved. The actual conjunction of uncertainties generated by the cancer diagnosis, the need for surgery, and the risk of COVID-19 must be taken into account and carefully described in the IC specifically adapted to this unique scenario. Surprisingly, in the searched literature, we found only a few papers on the use of IC regarding trials of drugs for COVID-19, or about its use in general surgeries, intubation, and mechanical respiration,^{25-27,32-34,39} and there were few on studies proposing IC documents focused on oncologic surgery during these exceptional times.^{19,40}

Motivated by this situation, physicians and institutional legal teams developed a comprehensive IC, which can be applied by all the oncological surgeons at our center. We took care to prepare a wide list of problems, both expected and unexpected, which could affect patients as well as health professionals. This instrument can also offer the patient a broader view of the surgical treatment process. It is a very dynamic situation and new information regarding COVID-19 is produced continuously, and thus continuous revisions or amendments of our IC might be necessary at any time. This IC includes a section which the patients must fill in by themselves, informing the hospital whether or not they have any doubts regarding the procedure. This reinforces the patients were reasonably informed.

The IC also addresses the fact that, despite all the cautions in the algorithm, it is not possible to avoid all the risks of perioperative COVID-19 infection or its complications. The IC informs the patient of the possibility of immunological changes secondary to surgical trauma or anesthesiology.^{35,36} It also clarifies that respiratory complications can occur after major surgeries and are not necessarily synonymous with COVID-19.

Two points related to legal risk were also addressed in advance: unexpected acute situations demanding emergency procedures without discussion with the patient or family; and the sudden absence or substitution of health professionals without prior notice.

The IC by itself does not guarantee that successful therapeutic choices will be made and without legal questioning. Oncologic

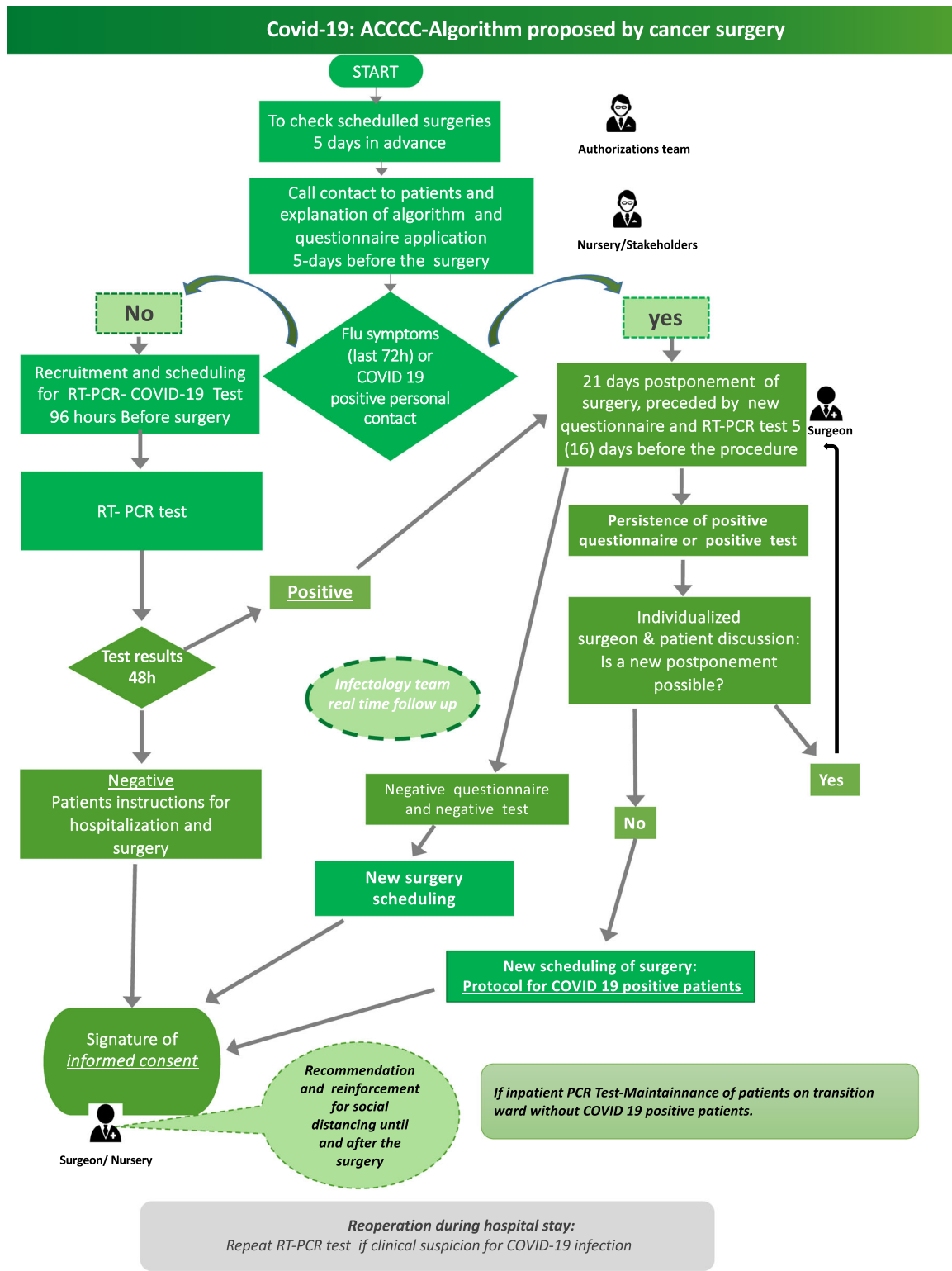


FIGURE 2 A.C. Camargo Cancer Center algorithm for surgical treatment of cancer during COVID -19 pandemic [Color figure can be viewed at wileyonlinelibrary.com]

surgeons and multidisciplinary teams usually stay up-to-date on and aware of the best cancer treatment options, know the natural history of each tumor and, if necessary, can discuss challenging cases in tumor boards. For these reasons, the treatment recommended for

patients referred to a cancer center is based on the best evidence in the literature. It can vary from immediate surgery to safely delayed surgery, or the use of efficacious alternative nonsurgical options during the COVID-19 threat.^{15-22,28-34,39,40}

1-Did you have: cough, sore throat, shortness of breath, runny nose, headache, loss of smell or taste, body pain, chills or fever in the last 14 days?*

YES () NO ()

*IN CHILDREN: Nasal obstruction is also considered, in the absence of another specific diagnosis.

*IN ELDERLY: fever may be absent. Specific aggravation criteria should also be considered, such as syncope, mental confusion, excessive sleepiness, irritability and lack of appetite.

2- During the investigation, did the evaluator observe signs of respiratory distress, runny nose, fatigue?

YES () NO ()

3. IN CHILDREN: in addition to the previous items, observe the flapping of the nose, cyanosis, intercostal circulation, dehydration and loss of appetite

YES () NO ()

4- Have you had close or home contact in the past 7 days with a laboratory confirmed case for COVID? (Consider contact with suspected cases in medium and high prevalence areas as well)

YES () NO ()

Adapted from COVID-19 DIAGNOSIS AND TREATMENT GUIDELINES - Ministry of Health³¹

Unlike general hospitals, cancer centers do not have open emergency rooms to serve general populations with flu-like symptoms, and in theory they are less exposed to the new coronavirus infection. However, their populations can be more frail than general populations. In the face of this, cancer centers must train their personnel and establish as safe a routine as possible for surgical oncologic patients. Continuous safety control and the use of updated information are important tools for proposing improvements in the current guidelines, including changes in previously defined practices.^{41,42}

Besides the risks of patient infection before, during, or after hospitalization, it is also important to clarify to the family the risks involved with the surgical team and even the possibility that part or all of the group will be suddenly substituted with another one due to risk of COVID-19 infection. Another important role of an extensive preoperative conversation is the need to make it clear to the family

FIGURE 3 Clinical and epidemiological A. C. Camargo Cancer Center screening questionnaire for suspicion of COVID-19 symptoms or contact with infected people

or accompanying person that they should follow the same pre- and post-operative protective steps as the patients do, to guarantee a completely safe environment for all.

In our early results, among 540 asymptomatic patients candidates to elective surgeries, we found 41 (7.6%) presenting positive tests for SARS-CoV-2, which had postponed operations. None of them were readmitted due COVID-19 in their postoperative periods.⁴³ Probably, some deaths were avoided, since mortality rates may reach 19.1% up 27.1%, in surgeries performed for COVID-19 positive patients.¹³

Between 2020 April and July, we compared surgical outcomes of 49 asymptomatic RT-PCR positive patients that had their surgeries delayed versus 1:2 matched controls (negatives) who had originally scheduled surgeries. There were no significant differences among the groups regarding general complications; Grade 3-4 or pulmonary complications; and SARS-CoV-2 related infections ($p > 0.05$, for all)⁴⁴

This paper has some limitations. The literature in this area is scarce, and the available papers are based on retrospective studies of limited case series or the opinions of specialists. The accuracy of available SARS-CoV-2 tests is limited, and they can produce false-positive or false-negative results.⁴⁵ Initial reports of test results in pregnant women admitted for delivery in New York City found 13.7% SARS-CoV-2 positivity by PCR.⁴⁶ The rate of positivity in the Brazilian cancer patient population is not known, since they are on average significantly older than pregnant women and probably present more comorbidities and possibly some immunodeficiency. Additionally, we do not know what the best day to test patients is, because asymptomatic patients can develop infection between the test and surgery. Beyond these uncertainties, it may be logistically impossible to test every patient. Regarding the questionnaire, some patients anxious for treatment for their malignancies will omit some relevant information.

We hypothesize that the majority of the population is now concerned about COVID-19 risks and are in solidarity in contributing to minimize them as best as they can. But this understanding can rapidly change in the face of an incurable, progressing tumor. Good communication and understanding are mandatory, and all decisions must be jointly taken by physicians, patients, and family members, and registered in medical charts.^{19,40-42} This new model IC dedicated to the surgical treatment of cancer patients during the COVID-19 pandemic and the new multidisciplinary comprehensive algorithm are tools that can improve safety for patients, health professionals, and institutions.

5 | CONCLUSIONS

Surgical treatment for cancer patients during the COVID-19 pandemic is a remarkable challenge. Cancer patients are at risk for developing the new coronavirus infection and its life-threatening complications. Meanwhile, numerous patients demand prompt surgeries to treat rapidly growing tumors. In these cases, postponing surgical treatment could jeopardize the chance for cancer control and increase the risk of cancer-related death. Skilled health professionals must individualize treatment, indicating surgery for patients with high-risk tumors and delaying or offering alternative treatment for insidious cases or for patients without medical conditions for surgery. The best risk-based therapeutic decision will result from a thorough risk-benefit discussion and shared decisions, documented using a specific and comprehensive informed consent.

DATA AVAILABILITY STATEMENT

We confirm the absence of shared data in this manuscript.

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