# A Risk-Based Screening Approach to Patients Needing Surgery During the De-Escalation Phase of COVID-19 Pandemic

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#### **Abstract**

Since the outbreak of COVID-19 pandemic, many national and international surgical societies have produced guidelines regarding the management of surgical patients. During the mitigation phase of the pandemic, most documents suggested to consider postponing elective procedures, unless this might have impacted the life expectancy of patients. As awareness and knowledge about COVID-19 are gradually increasing, and as we enter a phase when surgical services are resuming their activities, surgical strategies have to adapt to this rapidly evolving scenario. This is particularly relevant when considering screening policies and the associated findings. We herein describe a risk-based approach to the management of patients with surgical diseases, which might be useful in order to limit the risks for healthcare workers and patients, while allowing for resuming elective surgical practice safely.

#### **Keywords**

surgery, COVID-19, 2019-nCoV, guidelines, prevention, diagnosis, management

### Introduction

Since the World Health Organization (WHO) declared coronavirus disease 2019 (COVID-19), caused by COVID-19, a pandemic, several guidelines have been published concerning the management of surgical patients. Most guidelines adopted a mitigation strategy, meaning that the majority of nononcologic elective cases have been postponed, and outpatient consultation canceled.<sup>2</sup> However, since evidence are becoming available slowly, most documents are based on expert opinions and low-quality data, thereby requiring continuous updating.<sup>3-6</sup> No universally agreed recommendations are available concerning the perioperative screening of patients needing surgical treatment during the de-escalation phase of the pandemic, at a time when most centers are considering resuming elective procedures and outpatient clinics.

The aim of this report is to propose a risk-based strategy based on preoperative screening and local rates of COVID-19 infections, suitable to manage patients in centers that are resuming their surgical services and treat both COVID-19–negative and –positive patients.

# General Considerations on the New Coronavirus

Coronaviruses are enveloped nonsegmented positive-sense RNA viruses that belong to the *Orthocoronavirinae* subfamily. Although most human coronavirus infections are mild, severe acute respiratory syndrome coronavirus (SARS-CoV) and the Middle East respiratory syndrome

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coronavirus (MERS-CoV), and zoonotic betacoronaviruses, have been associated with potentially lethal disease during the outbreaks in 2003 and 2012, respectively. Respectively. Although it is currently difficult to estimate, the mortality rate of COVID-19 is about .3-06%, which is lower than 10% for SARS-CoV and 34% for MERS-CoV. However, SARS-CoV-2 has potentially higher transmissibility than both SARS-CoV and MERS-CoV<sup>12</sup>; moreover, individuals affected with COVID-19 are infectious even during the incubation phase. COVID-19's higher transmissibility among people must be graded according to the time and infectivity grade during the pandemic. Depending on the time, country, season, geographical areas, health authorities should adapt specific strategies.

The incubation period for the first COVID-19 cases has been estimated between 2 and 12 days in most individuals, but it could be up to 14 days if considering that of other betacoronaviruses (i.e., MERS-CoV and SARS-CoV). 13 Others have reported up to 24 days of incubation for COVID-19.<sup>14</sup> Clinical symptoms are variable, and COVID-19 may present with mild (cold type) manifestations, until fever, cough, and pneumonia or acute respiratory distress occur. Fever may not be present in some patients, for example, in very young or elderly individuals, especially in patients receiving immunosuppressors, or nonsteroidal anti-inflammatory drugs. This must be considered when evaluating patients. Patients might also present with gastro intestinal symptoms, anosmia, and ageusia, whereas early reports suggested that in pediatric patients, COVID-19 might cause a systemic response like that observed in Kawasaki disease.

Besides, additional issues are represented by atypical symptoms and asymptomatic patients. <sup>15-17</sup> Therefore, it is important that the individual risk is contextualized based on the general population data of each specific community; in other words, an individual with no clinical symptoms should be rightfully considered at "low risk" if the infectivity rate among the population is low. Each surgical department should adapt their policies based on national and local data when planning how to screen surgical patients during the upcoming de-escalation phase. <sup>18</sup>

As the curve of the infection of COVID-19 pandemic has begun to flatten in several countries, lockdowns are being loosened, and the mitigation strategies for the healthcare system are being modified. The previous restrictive measures were drawn during the time of maximal transmissibility among the population, when intensive care unit facilities were collapsed and surgical departments completely reshaped their daily activity. A gradual de-escalation is being therefore carried out, and hospitals are planning to restart elective surgery. Ideally, some conditions should be met, including (a) an acceptable immunization rate of the population, (b) a low level of

transmissibility, and (c) the active participation of patients in adhering to the correct preventive measures toward other individuals and healthcare workers. A crucial aspect of the de-escalation phase is to plan a strategy for a rapid and accurate COVID-19 diagnosis, in order to prevent outbreaks and plan adequate measures to be taken for each individual patient. In this context, a risk-based management of patients can be useful to ease the resumption of elective activities and the management of emergency surgical patients during the transition phase. Many national and international societies have proposed different recommendations for restarting surgery operating rooms as before the SARS-CoV pandemic, including the possibility to treat both COVID-19–positive and –negative patients.

# Strategy for Risk-Based Management

In order to develop a comprehensive tool, several aspects need to be assessed: (1) epidemiological patient-related factors, (2) laboratory tests and imaging, and (3) local context.

# Epidemiological Classification of Patients Undergoing Surgery

Several classification systems have been proposed to stratify the epidemiological risks of patients scheduled for surgery. It is useful to screen patients for fever, travel, occupation, contact, and clustering risk factors.

The WHO<sup>21</sup> recommends combining the epidemiological and clinical features. A case would be considered suspect if one epidemiological and 2 clinical manifestations are met, or if 3 clinical manifestations are observed, if no clear epidemiological risk is observed. The features are as follows:

Epidemiological history. (1) A history of contact with COVID-19 infectious cases (with positive nucleic acid test), (2) a history of contacting with patients with fever or respiratory symptoms from communities where COVID-19 had been reported in the last 14 days before symptom onset, and (3) a history of contacting with cluster of confirmed cases (≥2 cases with fever and/or respiratory symptoms occurred within 2 weeks in small areas, such as home, office, and class of school).

Clinical manifestations. (1) Fever and/or respiratory symptoms, (2) with imaging features of COVID-19 infection, (3) total white blood cell count showing normal, decreased, or reduced lymphocyte count in the early onset stage. A major limitation of the above-reported classification is the absence of symptoms that have been recently associated with COVID-19 infection (e.g., diarrhea and anosmia). These must not be overlooked.

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| <b>Table 1.</b> Sensitivity and Specificity of the Diagnosis Methods for SARS-COVID-19 ( | (36.3/). |  |
|--|----------|--|
|--|----------|--|

|                 | RT-PCR | CT Scan | RT-PCR + CT Scan | IgM/IgG Serological Testing |
|-----------------|--------|---------|------------------|-----------------------------|
| Sensitivity (%) | 79     | 77      | 88               | 88.66                       |
| Specificity (%) | 100    | 96      | 100              | 90.63                       |

Abbrevations: RT-PCR = reverse transcriptase polymerase chain reaction; IgM = immunoglobulin type M; IgG = immunoglobulin type G; CT = Computerized Tomography.

# Laboratory Test and Imaging

*rT-PCR*. The real-time reverse transcriptase polymerase chain reaction (RT-PCR) is the ideal tool for diagnosing COVID-19. However, molecular detection can result in false negatives because of low viral loads in samples or because the swab is not properly taken. These modifications based on the researchers' continued work to search for an optimal nucleic acid detection kit for rapid diagnosis, as well as the samples from respiratory tract including blood sampling, which increased the availability of different specimens. For rT-PCR, a delay of hours to days is necessary to obtain a result. (Table 1)

Serological testing. Serological testing is based on antibody detection.<sup>22</sup> Little is known concerning serology of SARS-CoV-2. It would be useful to repeat the test in different phases to assess the status of COVID-19 infection. Rapid assays for detecting COVID-19-specific IgM IgG have been developed.<sup>23</sup> Seroconversion has been reported to occur after 7 days in 50% of patients, and after 14 days in 100%, but it might not be followed by a rapid decline in viral load.<sup>24</sup> immunoglobulin type M (IgM) responses are notoriously nonspecific, whereas COVID-19-specific immunoglobulin type G (IgG) are usually developed weeks after the exposure. Moreover, IgM levels decrease and disappear after 2 weeks; an individual tested at that time can have undetectable IgM. Serological methods, when consistently available, will probably play an important role to monitor the evolution of the disease, to assess the immune status of asymptomatic individuals, or to determine the immunity of healthcare workers to be allocated to COVID-free areas, but are unlikely to play any role in screening or for the diagnosis of early infections. 25,26 Cross-reactivity to other coronaviruses represents another challenge, but serological tests are currently under development, taking this facet into account.<sup>22</sup> Some studies with COVID-19 serological data on clinical samples have been published.<sup>27,28</sup> Some surgical societies, like the Spanish Surgeons Association and the Spanish Health Ministry, have already launched recommendations for the correct interpretation of serological findings.<sup>29,30</sup> It appears to be a heterogeneous assay performance. The use of serology will require evaluations covering the full spectrum of SARS-CoV-2 infections, from asymptomatic and mild infection to severe disease, and later convalescence.<sup>27</sup>

Radiological findings. There is no agreement about the role of chest imaging for the purpose of screening patients for COVID-19. In COVID-19 patients, chest x-ray has been reported to show bilateral lung consolidation of the basis, which is more commonly observed 10-12 days after symptom onset.<sup>31</sup> Chest Computerized Tomography (CT) scan plays an important role in the initial diagnosis of the novel coronavirus pneumonia. Typical CT features of COVID-19 pneumonia include bilateral, peripheral, multiple, patchy ground-glass opacities. Chest CT has proven to have high sensibility on pneumonia detection when correlated with RT-PCR.32 However, CT scan has not always been recommended for screening.<sup>33</sup> Therefore, it could be considered in individuals needing a CT scan due to surgical emergency and in those patients at high risk of death should an undetected pneumonia occur postoperatively. However, using chest CT routinely before elective procedures might not be feasible in all surgical services during the next months. Other societies such as the Association of Coloproctology of Great Britain and Ireland recommend that patients scheduled for elective surgery will need to be prepared preoperatively to minimize the risks of nosocomial infection with a strict selfisolation for 14 days prior to admission, negative preoperative screening for symptoms, a negative preoperative swab testing, and a clear chest CT within 24 hours of surgery.<sup>34</sup> The British Society of Thoracic Imaging and the British Society of Gastrointestinal and Abdominal Radiology have proposed the use of CT scan in specific situations, including the surgical emergency.<sup>35,36</sup>

Sensitivity of CT results is related to the severity of illness and found that almost all mild patients had normal CT images.<sup>37</sup> In addition to severity of illness, the performance of radiologists in reading chest CT images of COVID-19 which found the experience of radiologists had a great impact on the diagnosis accuracy of chest CT. Overall, chest CT has a great sensitivity for detecting COVID-19, especially in regions with severe epidemic situation, and could be helpful to early detect suspicious cases, which is vital to control the epidemic.<sup>37</sup>

According to the combination of both epidemiological and radiological/serological test, patients can be

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classified into 4 different categories, irrespective of the setting in which the patients are being evaluated (outpatient clinic, elective admission, and emergency department).

#### Patients' surgical classification

"Non-COVID-19" case or "COVID-immunized" patient. Patients with a negative epidemiological history and who tested negative for IgG or IgM (non-COVID), and patients known to have had COVID-19, recovered from the disease, and who tested positive for both COVID-19–specific IgG antibody or IgG-only serum test fit in this category (COVID-immunized).

Suspected case. Patients with epidemiological history and negative serological tests are considered suspected cases. These patients should be screened for the virus with nucleic acid amplification tests (NAAT), such as rT-PCR.<sup>36</sup> In a surgical emergency, complete preoperative workup including chest CT scan should be considered.

Confirmed active COVID-19 case. Confirmed COVID-19 patients are suspect cases with any one item of pathogenic or serological evidence as follows: (1) rT-PCR test positive for COVID-19 and (2) viral whole genome sequencing showing high homogeneity to the known novel coronaviruses. Patients should be considered "confirmed active cases" in the case of positive epidemiological history and negative serologies for IgG. IgM could be positive and positive with NAAT, for example, RT-PCR.<sup>23</sup>

# **Local Conditions**

The proposed classification should be used after carefully considering the local condition in terms of the COVID-19 outbreak. In areas where COVID-19 infection is widely spread, a simpler algorithm might be adopted in which, for example, the use of rT-PCR for screening is considered sufficient according to WHO recommendations. Anesthesiologists will play a major role, as surgeons, in order

to screen surgical patients during the preoperative review of tests and telematic or presential visit in the outpatient clinic.<sup>38</sup>

The proposed classification might be useful to manage patients before surgery during the postmitigation phase of the pandemic, when elective surgery is resumed. The proposed tool allows stratifying patients according to the risk and COVID status, choosing the ideal strategy of management, and optimizing resource allocation. A management algorithm is proposed and showed in Figure 1.

The proposed algorithm is comprehensive of several aspects, including imaging. Even if the role of imaging for screening purposes is debated, for its cost, adding this to the preoperative assessment could be useful. Chest X-ray or CT scan could identify potential pulmonary or cardiac problems and reveal signs suggestive of active/or past COVID-19. Even if the patient is considered "COVID immunized" serologically, chest X-ray/CT could help raise the suspicion of active past infection and adapt the strategy as appropriate (e.g., postpone an elective surgery and repeat testing). Data regarding cost-effectiveness of CT scan for asymptomatic patients should be analyzed and specially according to the epidemiological situation of each region. Since the beginning of the pandemic and the quarantine for massive areas of the population in many states of the world, it has been desirable that a multidisciplinary approach is used to prioritize patients for surgery based on their COVID risk/status, which should include an infectious disease specialist. Decision-making concerning de-escalation of surgical patients and epidemiological situation has changed in different countries, even according to political decisions. Forty lessons learnt from experience should be considered that a negative test does not rule out the possibility of COVID-19 infection. Several factors for false-negative results have been described, including poor quality of the specimen, or specimen collection at a late or very early stage of the

| Epidemiological questions | SerologicaL rapid test    | Patient classification    | Emergent surgery<br><1 hour       | Urgent surgery<br>6-24 hours                         | Elective<br>>24 hours                                |
|---------------------------|---------------------------|---------------------------|-----------------------------------|--|--|
| Postitive<br>Negative     | Positive for Ig G or Ig M | Inmunized COVID PAtient   | YES * Consider pulmonary function | YES<br>Consider pulmonary<br>function                | YES<br>Consider pulmonary<br>function                |
|                           | Negative for Ig G or Ig M | Consider "Susepcted Case" | CONSIDER COVID<br>AND SURGERY     | CONSIDER<br>COVID and TEST<br>RT-PCR *               | Consider COVIE<br>and RT-PCR *                       |
|                           | Positive for Ig G or Ig M | Inmunized COVID PAtient   | YES                               | YES  | YES  |
|                           | Negative for Ig G or Ig M | "non-COVID-19" case       | YES                               | YES ConsiderRT-CRP in epidemic outbreak intense R0>1 | YES ConsiderRT-CRP in epidemic outbreak intense R0>1 |

Figure 1. Management algorithm for patients undergoing surgery.

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infection, unappropriated handling or technical reasons inherent in the test, for example, virus mutation or PCR inhibition.<sup>39</sup> If a negative result is obtained from a patient with a high index of suspicion for COVID-19 virus infection, particularly when only upper respiratory tract samples were collected, additional samples, including the lower respiratory tract if possible, should be collected and tested, whichever procedure the patient has been scheduled to receive.

# **Conclusive Remarks**

The current situation is to be considered dynamic, given the rapidly evolving situation in the upcoming months. Guidelines on ideal de-escalation policies need to adapt to this changing scenario, while transition to postlockdown phases is being planned by local authorities, and different criteria might be advocated as more evidence become available.

Strategies should be planned to ensure safety in operation theatres, not only to prevent COVID-19 spread but also for viruses that can become a threat for surgical patients in the future. The herein described management pathway requires—as a matter of priority—that appropriate testing policies are in place for healthcare workers and that adequate personal protective equipment are available. If these conditions are not met, resuming clinical activities could expose both patients and physicians to avoidable risks, irrespective of the management pathways.

# **Author Contributions**

All the authors have participated in the design, data collection and interpretation, drafting and revising of this manuscript. Ramon Vilallonga also supervised this work.

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