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Research Paper

Impact on clinical practice of the preoperative screening of Covid-19 infection in surgical oncological patients. Prospective cohort study

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ABSTRACT

Background: In the oncological patient, an COVID-19-infection, whether symptomatic or asymptomatic, a surgical procedure may carry a higher postoperative morbidity and mortality. The aim of this study was to describe the impact on clinical practice of sequential preoperative screening for COVID-19-infection in deciding whether to proceed or postpone surgery.

Methods: Prospective, cohort study, based on consecutive patients' candidates for an oncological surgical intervention. Sequential preoperative screening for COVID-19-infection: two-time medical history (tel-ematic and face-to-face), PCR and chest CT, 48 h before of surgical intervention. COVID-19-infection was considered positive if the patient had a suggestive medical history and/or PCR-positive and/or CT of pneumonia.

Results: Between April 15th and May 4th, 2020, 179 patients were studied, 97 were male (54%), mean (sd) age 66.7 (13,6). Sequential preoperative screening was performed within 48 h before to surgical intervention. The prevalence of preoperative COVID-19-infection was 4.5%, 95%CI:2.3–8.6% (8 patients). Of the operated patients (171), all had a negative medical history, PCR and chest CT. The complications was 14.8% (I-II) and 2.5% (III-IV). There was no mortality. The hospital stay was 3.1 (sd 2.7) days.

In the 8 patients with COVID-19-infection, the medical history was suggestive in all of them, 7 presented PCR-positive and 5 had a chest CT suggestive of pneumonia. The surgical intervention was postponed between 15 and 21 days.

Conclusion: Preoperative screening for COVID-19-infection using medical history and PCR helped the surgeon to decide whether to go ahead or postpone surgery in oncological patients. The chest CT may be useful in unclear cases.

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1. Introduction

In the present situation of COVID-19 pandemia, it has been reported that oncological surgical patients have a higher risk of being infected with COVID-19 than other non-oncological surgical

patients due to the cancer itself, the immunosuppression related to it as well as to the oncological and surgical treatments [1–4].

Patients with cancer and specially those who will undergo surgery or neoadjuvant treatment and developed COVID-19-infection, have a higher rate of morbidity and mortality as well as ICU (Intensive Cure Unit) admissions. Furthermore, the clinical deterioration of these patients is much more acute when compared with non-infected patients [1]. In the current climate of maximal pandemic extension, it has been necessary to postpone the surgical intervention (SI) in these patients and, in some cases, offer them alternative neoadjuvant treatment.

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The European Cancer Organisation (ECCO) advises that oncological patients who require a SI, adjuvant or neoadjuvant treatment, must be tested and cleared for infection to reduce their morbidity and mortality. Three preoperative screening tests have been proposed: a detailed history, a COVID-19 PCR determination and a chest radiological imaging (CT or Xray), despite not having any control studies available [6–12]. There is controversy over the use of PCR, due to its limited availability as well as over its negative predictive value, so some units suggest carrying out a preoperative CT chest due to its high sensitivity and high negative predictive value [6,7,13–15]. We must stress out that as of yet there are no available clinical studies that have tested the diagnostic efficacy of these preoperative screening diagnostic tools for the COVID-19 virus.

With this in mind, it is necessary to evaluate if these preoperative screening tests for COVID-19 are accurate for the diagnosis of symptomatic or asymptomatic COVID-19 infection and/or an asymptomatic latent pneumonia prior to a SI, in order to help the clinician decide. This will allow to i) reduce morbidity and mortality in oncological patients and ii) protect the healthcare professionals involved in treating these patients. Therefore, our working hypothesis is that sequential preoperative screening: clinical (detailed history), PCR and radiology (chest CT) of COVID-19 infection and pneumonia will identify symptomatic and asymptomatic infected patients. This information will be crucial for the surgeon at the time of deciding for or against a SI in the oncological patient.

Therefore, the aim of this study is to describe the impact of sequential preoperative screening for COVID-19-infection at the point of deciding to proceed or postpone surgery.

2. Patients and methods

2.1. Study design

This is a single-centre, prospective, longitudinal study based on consecutive patient candidates for an oncological surgical intervention which require a general anaesthesia and hospitalization between April 15th and May 4th, 2020. In our geographical area the COVID-19 alarm started officially on March 14th. The original scheduled surgery was postponed until April 15th. This date was considered our starting point. The data collection was closed when the last patient included had at least 28 days of follow-up after hospital discharge. The project received approval from the Research Ethical Committee. The written informed consent was obtained from all included patients. This study was carried out according to the guidelines of the Declaration of Helsinki and the level of protection of confidentiality concerning the protection of personal data as required by Spanish laws (LOPD 3/2018) was ensured. The work has been reported in line with the STROCSS criteria [16].

2.2. Study population

The eligibility criteria for inclusion in the study were: age ≥ 18 years, affected by a neoplasm (gastrointestinal, urological, gynaecological, ear, nose and throat -ENT-, breast, endocrine), hospital admission and to require general anaesthesia with intubation. The only exclusion criterium was a life expectancy of less than 7 days.

The following data were recorded: age, gender, type of neoplasm and disease staging, history suggestive of COVID-19-infection, COVID-19 status (positive/negative), CT findings (pneumonia, yes/no), contact with people positive to COVID-19-infection (yes/no), date of hospital discharge, blood transfusion requirements (yes/no), postoperative complications (Clavien-Dindo) and clinical status at 28 days after hospital discharge.

Symptoms suggestive of COVID-19-infection evaluated were cough, fever -including low-grade fever-, asthenia, dyspnoea, diarrhoea, anosmia and ageusia. In all cases, axillary temperature was taken at the time of face to face history taking.

2.3. Preoperative screening for COVID-19 infection

Facing the COVID-19 crisis scenario, our hospital, developed an “empirical” clinical protocol for the screening of COVID-19-infection to prevent the morbidity and mortality in cancer patients related to this infection and to prevent the infection of professionals involved in the treatment of these patients. The algorithm used consisted of performing a thorough clinical history (telematic, 7 days maximum before the surgery and face-to-face 2 days maximum before surgery) and a PCR for COVID-19 (2 days maximum before surgery). The same day of screening a chest CT was done.

In case of suspicion of COVID-19-infection during the screening, the intervention was delayed. If the patient presented symptoms suggestive of COVID-19 infection during the postoperative period, a PCR was performed. If the patient had a PCR positive result, he/she was isolated and a chest CT was performed.

2.4. Study definitions

Since there is no definitive gold standard diagnostic test for asymptomatic COVID-19-infection, COVID-19-infection was considered if the patient had a history suggestive of COVID-19 infection in the previous 4 weeks and/or a positive PCR for COVID-19 2 days before surgery and/or a radiographic image of pneumonia 2 days before surgery.

The impact on clinical practice was evaluated by the number of patients in whom surgery was delayed either due to suspected COVID-19-infection or due to the patient objecting to being operated because of fear of COVID-infection.

2.5. Statistical analysis

Sample Size: due to the exploratory nature of our aim, no formal calculation of sample size was performed. The sample size was defined as all oncological patients screened for COVID-19-infection before being operated during the inclusion period.

Statistical Procedures: baseline characteristics were summarized using standard descriptive statistics, and a descriptive analysis was carried out.

Prevalence (95% confidence intervals - 95% CI) was calculated based on the number of individuals with a COVID-19-infection. An exploratory analysis of predictive factors of prevalence was done using logistic regression. The degree of agreement among diagnostic tests (clinical result, PCR and chest CT) was analysed using the kappa index (k), where k values are between 0 and 1, with 0 representing absence of concordance and 1 complete concordance.

An exploratory analysis of the diagnostic accuracy (sensitivity, specificity and predictive values) of the diagnostic tests for COVID-19-infection was performed. Since there is no definitive gold standard diagnostic test available for asymptomatic COVID-19-infection, to be positive to any diagnostic test for COVID-19-infection was used as a reference standard.

A p-value ≤ 0.05 was considered statistically significant. Data analysis was carried out using R (R Core Team, Vienna, Austria, 2015) [19] and the Stata 13.0 statistical package (Stata Corp., College Station, Texas, 2015) was used for the statistical analysis.

3. Results

3.1. Patient characteristics

A total of 181 consecutive oncological patients were contacted by phone and proposed to be operated. Due to the COVID-19 pandemic, in 80% of these patients the scheduled surgery had been postponed. Two of them rejected the surgery due to fear of being operated during the pandemic period. Therefore, the study population for the analysis was of 179 patients. Fig. 1 presents the patients' flow chart. Table 1 shows the baseline characteristics. 90% (161 patients) were older than 60 years. Similar number of men and women were analysed. The types of cancer surgery were gastrointestinal [40 patients (22%)], urological [71 patients (40%)], breast [40 patients (22%)], gynaecological [13 patients (7%)] and ENT [15 patients (8%)].

3.2. Preoperative screening for COVID-19 infection

Telematic history was performed on 181 patients, face to face history and PCR for COVID-19-infection on 179 patients (analysis population) and chest CT on 140 (78%) patients.

Eight out of 179 patients were diagnosed of COVID-19-infection in the preoperative screening for COVID-19 infection, the prevalence was of 4.5%, 95%CI: 2.3–8.6%. At the time of face to face history, 2 of them had a temperature of 37.2 and 37.5 and fatigue, 1 had ageusia and anosmia. The rest were asymptomatic, but all of them had had symptoms of COVID-19 infection weeks before. Four had fever, fatigue and muscle pain, 4 had cough and 2 had gastrointestinal symptoms. All of them had a suggestive history of COVID-

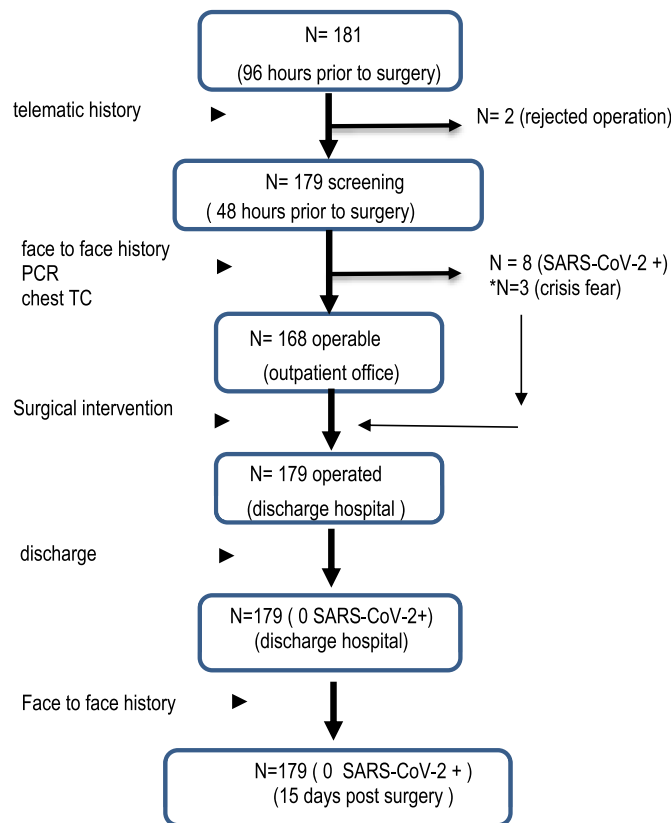


Fig. 1. Flow Chart. *All patients were operated at 48 h to initiate the screening, except 3 patients who needed more time to accept to be operated due to the COVID-19 crisis fear. They were operated before 15 days.

Table 1
Baseline characteristics (n = 179).

Age (yr)	mean (SD)	65,7 (13,6)
Male/female	n (%)/n (%)	97 (54%)/83 (46%)
BMI	mean (SD)	27,1 (5,5)
ASA		
I + II	n (%)	142 (79%)
III + IV	n (%)	37 (21%)
Comorbidities		
Diabetes	n (%)	32 (18%)
Hypertension	n (%)	89 (50%)
Neoadjuvant	n (%)	16 (9%)

19 infection, 7 patients had a positive COVID-19 PCR and 5 had asymptomatic pneumonia on CT. Two patients had mild symptoms (diarrhoea and abdominal pain at the time of the preoperative examination) but negative PCR and normal CT. After discussion with the surgical team they were not considered positive COVID-19-infection and they were operated. Hence, the 171 oncological patients operated had a negative medical history and negative PCR, and negative CT when this was available, except 1 patient. This patient with a positive chest CT had an episode of COVID-19 42 days before. At preoperative screening he/she had a positive IgG and negative IgM. Therefore, one patient had had a COVID-19 infection but had resolved at the time of surgery. Had we included this patient in the prevalence analysis, this would be 5.0%, 95%CI: 2.7–9.3%. No predictive factor was associated with prevalence.

The sequential preoperative screening was performed within 48 h in all patients and all except 3 were operated 48 h of starting the screening. These 3 patients needed more time to agree to be operated due to COVID-19 fear, but they were operated within 15 days (with a new screening).

3.3. Impact on clinical practice

The impact of the COVID-19 pandemic on our clinical practice affected 13 (7.2%, 95%CI: 4.3–11.9%) out of 181 patients: 2 (1.1%) patients objected to being operated, 3 patients (1.7%) chose to delay the surgery beyond 48 h and 8 (4.4%) patients had surgery delayed due to COVID-19-infection until symptoms, PCR and CT were negative.

None of the operated patients developed COVID-19-infection during admission, and only one developed a COVID-19-infection on day 21 after discharge (cumulative incidence of COVID-19-infection: 0.6%, 95%CI: 0.1–3.1%). There were no deaths up to 28 days after hospital discharge. The Clavien-Dindo complication rate was 14.8% (I-II) and 2.5% (III-IV). Six (3.4%) out of 179 patients required a blood transfusion. The average stay (SD) was 3.1 (2.7) days. Six (3.5%) patients had to be re-admitted after hospital discharge.

3.4. Accuracy of preoperative screening test for COVID-19-infection

An exploratory analysis of the accuracy of preoperative screening test for COVID-19 diagnosis. The number of observed agreements between a medical history and COVID-19 diagnosis was of 100%, k: 1.0 (95%CI: 1.0–1.0); the number of observed agreements between PCR and COVID-19 diagnosis was of 99.4%, k: 0.93 (95%CI: 0.8–1.0); and the number of observed agreements between chest CT and COVID-19 diagnosis was of 97.1%, k: 0.70 (95%CI: 0.42–0.98). Table 2 shows the sensitivity and specificity of the test for COVID-19 infection.

Table 2

Accuracy of test for SARS-CoV-2/COVID-19 infection. “Gold standard” was defined as a positive result in any test.

	Sensitivity %	Specificity %	Positive predictive values %	Negative predictive values %
Medical history	100	100	100	100
Medical history ^a	100	98.8	80	100
PCR	87.5	100	87.5	100
CT ^b	62.5	99.2	83.3	97.8

^a Considering 2 patients, with some slight symptom (diarrhoea and abdominal pain) at preoperative exploration but negative PCR and CT for pneumonia, as positive for SARS-CoV-2/COVID-19 infection.

^b Only available in 140 patients.

4. Discussion

As expected, the rapid pandemic spread has dramatically affected the surgical of oncological patients. The aim of this study was to describe the impact of the pandemia on clinical practice in oncological surgical patients. Our results provide evidence that the COVID-19 pandemia has resulted in significant changes in our clinical practice:

First, during the crisis, in our institution all the planned surgical procedures were progressively stopped for at least for 4 weeks, including the surgery for oncological patients (80% of our oncological patients). Some of them, during this period, received neo-adjuvant treatments in order to contain the progression of the disease even knowing the risk.

Second, 3% of our surgical patients showed fear of being operated during the pandemia, and 1% of them with malignant tumours objected on being operated.

Third, once this latency period was over, it was necessary to offer these patients and those diagnosed de novo the appropriate treatment in order not to worsen their prognosis. A new logistics had to be implemented for the screening of COVID-19-infection prior to surgery, and the added difficulty of performing the surgery in 48 h after 4 weeks of having stopped the surgery.

Cancer patients, due to their immunosuppression, are more vulnerable to infection and the morbidity and mortality during treatment are higher [1–4]. Hence, it is essential to ensure the absence of COVID-19 during the peri-operative period, minimize its contagion during admission and, at the same time, avoid possible contamination to health care workers. To our knowledge, there are no studies that support that screening tests are necessary to rule out COVID-19 infection as accurately as possible. However, different medical bodies support, without much evidence, that various recommendations such as history, PCR, chest X-ray, chest CT and serology could be of great help in this screening [4–7,9,10,12]. None of these by itself could exclude the others. Our findings suggest that a screening program, based on medical history, PCR and chest CT, has helped in our clinical practice, in detecting symptomatic or asymptomatic COVID-19-infection resulting in delaying surgery.

In our cohort of 179 patients, 8 were diagnosed with COVID-19-infection (4,5% prevalence). This prevalence is expected in our geographical area. We expected this to be lower than that of the general population.

Telematic and face to face history pointed towards the possibility of COVID-19-infection. None of the patients who had surgery had symptoms at the time of the screening. We must point out that in telematic history 75% of patients did not mention any symptoms while in face to face discussion, as the questioning was more detailed, 100% of patients with infection were highlighted. All of them were confirmed with a positive PCR except for 1 patient who had a negative PCR while the chest CT showed findings suggestive of COVID-19 pneumonia. At the time of taking the history none of

the patients had symptoms of a viral disease and the temperature was normal in all of them. The results in our study show that a detailed medical history is crucial and could be a good screening tool towards the diagnosis of possible active disease, asymptomatic infections and previous infections.

Virus PCR was positive in 7 out of the 8 diagnosed patients with a positive history. The only possible false negative rose suspicion at the medical history and the diagnosis was confirmed by chest CT, which showed a picture of bilateral pneumonia with ground glass opacities. Virus PCR is known to have a remarkably high sensitivity and specificity [7]. Nevertheless, it can give false negatives when determined early (first 5 days) of the infection, if the sampling technique is insufficient and after day 15 when the viral load is decreasing [7]. For this reason, in highly suspicious cases on history taking and a negative PCR, one should allow a latency period, if surgery can be delayed, and repeat the PCR and/or request a chest CT scan.

The chest CT showed patterns suggestive of pneumonia in 5 out of the 8 infected patients. Not all patients with COVID-19-infection developed pneumonia. In all non-infected patients the chest CT did not show pneumonia, except for 1 patient (false positive) with a negative PCR and a suggestive history of past infection. This patient showed ground glass opacities consistent with COVID-19 pneumonia. Further questioning revealed that the patient had COVID-19 symptoms 42 days before. He underwent serological testing showing negative IgM and positive IgG, suggesting an earlier infection. The CT findings were interpreted as residual changes, the patient was operated and did not develop infection. These data confirms that the capability for chest CT to detect pneumonia associated to COVID infection [8–10,14,15,17]. Moreover, this confirms the role of chest CT in ruling out borderline cases.

Only one patient who underwent surgery developed COVID-19-infection in the postoperative follow-up period (up to 28 days post discharge). This patient presented COVID-19 like symptoms 21 days post discharge. Bearing in mind the incubation period for this viral disease the patient probably became infected at home. There has been no mortality associated with the surgical intervention nor with the viral infection. These data support the validity this screening method for COVID-19-infection and have identified asymptomatic infected cases. The mean hospital stay and complications has been very low. The early discharge with postoperative recovery at home may contribute to these results.

The combination of a detailed history together with the PCR accurately identified 100% of the COVID-19 infected cases. Furthermore, none of the negative cases in the study developed the infection after the surgical intervention and 15 days after discharge. Both tools conjoined have an excellent capability to discriminate the infection and therefore discriminate whether to proceed or postpone the SI. In unclear cases of past infection, chest CT could be, conjointly with serology, a good option to decide whether the infection is active or we are facing the sequelae.

We believe that an exhaustive and detailed history is the main screening tool and the foundation for screening for infection. PCR data can be a good support for the history. The chest CT would not be necessary in all cases. On the other hand, CT has a very high sensitivity when the patient has pneumonia [1]. Therefore, chest CT should not be a routine part of the screening battery except in unclear cases. We have not included the plain chest Xray in our study as it has a 40% of false negative results for diagnosis of pneumonia, and since we're dealing with high risk patients [13–15].

Our study is subject to some limitations. This study only involved one centre, which might underestimate or overestimate the results beyond the population and conditions studied. Likewise, the sample size, and the period of inclusion (3 weeks during COVID-19 pandemic) and follow-up (28 days), may also underestimate or overestimate the results. We must also highlight the lack of a gold standard diagnostic test for asymptomatic COVID-19-infection.

In conclusion, the preoperative screening for COVID-19-infection using medical history and PCR helped the surgeon decide whether to proceed or postpone surgery in oncological patients during the COVID crisis. The chest CT scan may bring useful information in doubtful cases.

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Ethical approval

The work has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and the subjects gave informed consent to the work. Ref: PR179 20 (CSI 20 45).

The data were collected anonymously in a database. This database is available for assessment, without breaching any patient information laws.

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Author contribution

J Castellvi: Investigation. Conception and design of the study Project administration. Review & editing. Supervision. Validation. Roles: Writing - original draft; Writing - review & editing.

C. Jerico: Conception and design of the study. Investigation; Methodology. Review & editing.

A De Miguel: Acquisition of data curation. Software.

D Camacho: Acquisition of data.

JM. Mullerat: Review & editing.

J. Catala: Methodology. Conceptualization.

R Cliville: Methodology. Conceptualization.

S. Videla: Conception and design of the study. Analysis and interpretation of data. Roles: Writing - original draft; Writing - review & editing. Formal analysis. Validation; Visualization. Review & editing.

Conflict of interest statement

None.

Guarantor

The authors accept full responsibility for the work and the conduct of the study, had access to the data, and controlled the decision to publish.

Submission declaration and verification.

The work described has not been published previously and it is not under consideration for publication elsewhere. The publication is

approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder.

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1. Name of the registry: Research Registry
2. Unique Identifying number or registration ID: researchregistry5680
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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijso.2020.08.003>.

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