

Safety of urologic elective surgery in a Covid-hospital: our experience in Milan

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Title: Safety of urologic elective surgery in a Covid-hospital: our experience in Milan

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Abstract

Purpose

To demonstrate safety of a new internal protocol for patients and health workers adopted for elective urologic surgical activity during COVID-19 pandemic.

Methods

From March 9 to April 24, 2020 we have retrospectively evaluated 62 patients who underwent elective surgery in the urology department of IRCCS Policlinico San Donato which became a COVID-hospital. We identified non-deferrable patients that needed to be treated within one month. All patients followed a dedicated pathway from the day-hospital till the discharge. Clinical data, nasopharyngeal swabs, chest X-ray, type of anaesthesia, surgical procedure and days of hospitalization were collected. All patients were interviewed 14 days after surgery to check any Covid-related complications.

Results

The population included 48 (77.42%) men and 14 (22.58%) women, aged between 17 and 88 years old. We performed sixty-four (64) preoperative screenings and two (2) patients were excluded. 47 (75.81%) patients underwent oncological procedures while 15 (24.19%) patients underwent non-oncological surgery. The average hospitalization time was 2.39 ± 2.21 days.

After at least 14 postoperative days (25.00 ± 10.35 days), we interviewed all patients to check their conditions. No patients showed symptoms related to COVID-19, except for 2 (3.23%) who manifested coryza, 28 and 35 days after discharge respectively. Neither patients nor hospital workers developed COVID-19 infection.

Conclusion

The duration of pandemic period is undefined; therefore, our protocol could be considered a good model for every type of surgery and its application could ensure a continuous treatment for non-deferrable conditions, in a safe way for both the patients and health workers.

Manuscript

Background

At the end of December 2019, Wuhan (China) became the centre of an outbreak of pneumonia of an unknown aetiology, called “Coronavirus disease 2019” (COVID-19), triggered by SARS-CoV-2. In a quite short time, it rapidly spreads worldwide, reaching Europe and the USA [1].

On February 20th 2020, a 38-year-old man in Lombardy region was admitted to hospital due to an atypical pneumonia that later proved to be the first case of COVID-19 in Italy [2]. 233.515 confirmed total cases and 33.530 deaths were reported in Italy to date. 71% of cases were located in Northern Italy, especially in Lombardy region. [3]. The mortality rate in the Lombardy region alone, with a total of 14294 deaths, is greater than the number of deaths in China [3]

In response to the rising COVID-19 pandemic, the Italian Government implemented extraordinary measures trying to limit the viral transmission. The restriction of the population movement except for work and health related circumstances were implemented [4,5].

Starting from 21st February, Italian Health Ministry announced the creation of a “red zone” of 11 small cities in northern Italy. On 8th March Italian authorities extended the lockdown to the entire national territory. [6]

Italian doctors were overwhelmed in this unprecedented pandemic and, as a result, many hospitals and governments have requested that elective procedures had to be delayed until the end of the emergency due to priority being given to utilizing resources for managing COVID-19 patients [7,8].

Severe consequences for general health have been reported due to this management. In some countries the number of acute stroke admission has fallen as much as 50%, suggesting that many patients with severe stroke were not admitted to hospital [7] and a large delay in patients with STEMI to seek medical help has been reported [9]. To avoid a bad management of urological patients, it was fundamental to continue elective surgical activity for non-deferrable health conditions.

From the beginning of the pandemic to the end of April 2020, more than 600 hospitalized patients with COVID-19 have been treated in our institution, IRCCS Policlinico San Donato (Milan, Lombardy), and many critical patients required respiratory support in the Intensive Care Unit (ICU).

The aim of the study is to present our approved and safe protocol to keep performing surgical elective procedures in oncological and non-oncological non-deferrable patients in a hospital involved in the fight against the COVID-19. According to the literature, no dedicated pathways for elective surgery have been proposed in clinical practice so far.

Material and methods

We have retrospectively evaluated all patients who underwent elective surgery in the urology department of our institution from March 9 to April 24, 2020.

All patients were listed in order of priority: red, yellow and green codes in order to stratify the risk of disease progression or immediate complications.

We identified non-deferrable patients (red codes) that needed to be treated within one month: Muscle Invasive Bladder Cancer (MIBC), high risk non-MIBC, first observation bladder cancers >2cm, renal cancers, testis cancer, high grade Upper Tract Urothelial Cancers (UTUC), high risk locally advanced prostatic cancer, obstructive or acute infected stones. All patients included have followed a dedicated pathway from the day-hospital till the discharge.

The exclusion criteria were deferrable benign urologic conditions and critical patients who required or likely to require ICU assistance postoperatively that were transferred to non-COVID-19 hospitals in consideration of the limited availability of anaesthesiologists and ventilators.

The diagnosis of infection was based on clinical suspect of SARS-CoV-2 infection, radiological imaging features at chest X-ray and/or virological diagnosis confirmed through real-time PCR.

If the patients did not pass any of the “check-points” before the admission to hospital because of a suspected infection, they were ruled out and started again the protocol after a 14 days waiting.

Sixty-four (64) patients were enrolled. Two (2) of them were found to be infected because of radiological and swab positivity.

Clinical data, as nasopharyngeal swabs, chest X-ray, type of anaesthesia, type of surgical procedure and days of hospitalization were collected. Moreover, individual risk factors for COVID-19 pneumonia, as advanced age, ongoing malignancy, high blood pressure and coronary artery disease, were analysed.

The onset of possible COVID-19 symptoms, as fever, cough, dyspnoea, anosmia or ageusia, headache and gastrointestinal symptoms were collected by telephone interviews. A median follow-up of at least 14 days after discharge has been adopted.

Protocol: Safe pathway for elective surgical patients

1. Phone call

All patients were phone-called 2/3 days before the day-hospital. The patients' interview was focused on suspected symptoms for COVID-19, professional exposure or contacts with infected people in the last 14 days.

If a possible infection was suspected, the patient had to respect a home quarantine, as indicated by the Lombardy Region in DPCM of 8th March 2020 [6], and the protocol would be repeated after 14 days.

Conversely, the physician gave to the patient an appointment for the day-hospital. If the patient developed symptoms in the two days before the admission to hospital, he had to take a nasopharyngeal swab, performed externally, and had to inform the staff.

2. Hospital entrance check

The day-hospital was programmed 24-48 hours before the planned operation-day.

At the hospital entrance every patient was controlled. A nurse verified the body temperature and made the same focused interview on COVID-symptoms, to have a second security check. In case of suspect, the nurse suggested to reach directly the Emergency Department (ED).

If check point was passed, the patient would be admitted to hospital. A surgical mask and alcohol based hand gel were given. The use of masks for patients and all the hospital workers is compulsory.

3. Day Hospital

The patient reached the dedicated area. A nurse performed a nasopharyngeal swab, blood sample with pre-operative exam and an electrocardiogram. The patient also underwent a Chest X-Ray. Last steps were the consultations with the urologist and the anesthesiologist.

4. Nasopharyngeal swab and chest x-ray result

24 hours after the day-hospital, if one of swab or X-ray resulted positive or suspected for COVID-19, the patient was called and suggested to follow the indication for a home quarantine. If all the exams were negative, the patient was programmed for surgery the next day.

5. Surgery day

Patients had to perform once again the same control at the hospital entrance (point 2). After that, they reached directly the "free ward", a dedicated ward in which only patients checked negative were allowed.

The patients were not allowed to exit from their room and must wear surgical masks all time.

To reach the surgical theater, the patients were transported in a different path from the one used for the COVID-19 patients and a dedicated operating room for not infected patients was used.

All health workers wore constantly surgical mask and gloves.

6. Post-operative hospitalization

During the hospitalization if patient developed fever or suspected symptoms, a Chest imaging was performed. If there was a suspect of infection, the patient was soon transferred to a "grey ward" in a single room to guarantee the isolation and repeated the nasopharyngeal swab.

A summarized flowchart of the protocol that we have proposed is represented on Figure 1.

Results

We retrospectively collected the data of 62 patients who underwent surgical procedures between March 9th and April 24th, 2020 in the Urology Department of our institution.

The study population included 48 (77.42%) men and 14 (22.58%) women, aged between 17 and 88. The average age of the population was 66.23 ± 13.58 years old.

We have performed sixty-four (64) preoperative screenings. One patient had a positive nasopharyngeal swab and another one a suspected pneumonia at the chest X-Ray, both were asymptomatic. They were invited to observe a quarantine and they restarted the protocol after 14 days.

Overall, 47 (75.81%) patients underwent oncological procedures while 15 (24.19%) patients underwent non-oncological surgery, especially for lithiasis. Detailed surgical procedures are illustrated in the Figure 2.

Spinal and general anesthesia were performed in 39 (62,90%) and 23 (37,10%) patients respectively. Urological postoperative complications were haematuria, irritative voiding symptoms and anastomosis leakage post-RALP in 5 (8,06%), 3 (4,84%) and 1 (1,61%) patients respectively.

The average number of hospitalization days was 2.39 ± 2.21 , with a maximum of 14 days in a patient who underwent robot-assisted partial nephrectomy. This outlier was due to the migration of a kidney stone into the ureter in the postoperative period, associated with a urinary tract infection. During the hospitalization 3 (4.84%) patients developed fever, higher than 37.5°C , but the chest X-ray and a nasopharyngeal swab resulted negative for COVID-19. After at least 14 days after discharge (25.00 ± 10.35 days), we called all patients to check their conditions. No patients showed symptoms related to COVID-19, except for 2 (3.23%) patients who manifested coryza, 28 and 35 days after discharge respectively.

We also analyzed clinical characteristics of the study participants in relation to develop SARS CoV-2: 77.42% of patients were males, 75.81% of total was oncological, 58.08% of patients was > 65 years old, 61.29% of patients suffered from hypertension, 20.97% had coronary artery disease. 54% of patients had 2 or more risk factors for developing COVID-19 and 48% of total had 3 or more risk factors.

In addition, none of hospital workers that were part of this pathway had the COVID-19 infection.

Discussion

At the moment of submission of this paper, no previous literature shows a practical approach for a safe management of surgical non-deferrable patients (Pubmed, Scopus, Medline, Embase, Google Scholar and Web of Science). SARS COV-2 is highly contagious, after a median time of incubation of 11.6 days, with three main routes for transmission including human-to-human contact, aerosol transmission, and transmission by touch. Furthermore, hidden transmission can occur from asymptomatic patients [10].

Italian healthcare system faced one of the darkest moments of its history due to handling an enormous number of infected patients. The Italian government imposed a temporary suspension of all non-urgent elective surgeries [11, 12], and the limitation of inpatient and outpatient services to only critical conditions.

During pandemic spread, the focus of the global healthcare has been addressed to the management of infected patient, but on the other hand, non-deferrable urological conditions did not disappear. Wise [13] supports the hypothesis that during COVID-19 pandemic cancer mortality could rise at least 20%: in the UK the findings are a 76% decrease in urgent referrals from general physicians of people with suspected cancers and a 60% reduction in chemotherapy appointments. Clearly, these large declines might be due to redirection of health workers and resources to care for patients with COVID-19 and the desire of clinicians and patients to minimise the risks of infection.

According to the report by Liang et al. [14] it is recommended to delay all elective cancer surgeries or adjuvant chemotherapy in patients with stable cancer, increase the protective measures for cancer patients or cancer survivors, considering their particular susceptibility for developing several forms of SARS COV-2 disease. Liang et al, did not offer a solution to treat non-deferrable conditions and their sample of patients is quite low (n=18) and it is particularly heterogeneity for considering their statements as generalizable on a larger scale. On the contrary, Wang H et al [15] reported that the major risk factor for cancer patients is the inability to receive sufficient medical support, while they do not offer a protocol for continuing their assistance.

Ficarra et al [16] have elaborated a table with urological procedures that should not be delayed and recommended an implementation of “free”-surgical areas in COVID-hospitals, or the creation of non-COVID-hospitals network in order to transfer urgent patients.

In our opinion, transferring all non-deferrable patients as suggested by Ficarra et al [16] could lead to an important elongation of waiting time for surgery procedure. Thus, the effects of delaying surgery in certain conditions may negatively affect oncological or functional outcomes. This is particularly true for patients with urological cancers and obstructing stones [8,17]. Delaying transurethral resection of bladder tumour for cT1 lesions represents a significant risk. MIBC can be missed and understaging can reach up to 50% of cases [18]. Delaying cystectomy for MIBC by 90 days may cause an increase of the pN + rate [19], a decrease of the overall survival and progression-free survival [20,21]. High risk prostate cancer biochemical recurrence rates may be higher in patients if definitive treatments are delayed, but there is not a clear cut-off time for this treatment benefit [22,23,24]. It has also been observed that a 3-months delay to surgery for UTUC inevitably leads to disease progression [25]. Finally, obstructing or infected urinary stones can lead to systemic infection or renal chronic injury [8].

Based on these proposals, we demonstrated in our study the safety of surgical activity in a COVID hospital with real clinical data. The demonstration of protocol's safety is supported by patients' characteristics: most of them (48%) had 3 or more risk factors for SARS CoV-2 disease as shown by Grasselli et al [26], but thanks to our management none of them contracted COVID-19.

Following the general recommendation by Stensland [8] and Ficarra [16], we analysed all the urological patients awaiting surgical interventions, performing a risk stratification.

After internal hospital and regional authority permission, we structured an internal protocol for keeping a safe surgical activity. Our data showed no COVID-related complication at a minimum requested follow-up of 14 days post discharge as suggested by Lauer et al [27].

In the authors' opinion, this kind of protocol has demonstrated a total security of the surgical activity both for health workers and fragile patients such as the oncological ones [28].

The strong points of the protocol, that support authors' thesis, are:

1. "out-out" flowchart, which exclude the candidates at minimal suspect of COVID-19.
2. Dedicated internal hospital areas and paths: "clean units", non-COVID operating rooms, separated elevators
3. Dedicated health workers: medical and nursing staff, well trained [29] and informed about all preventive procedures, working only in COVID-free units
4. Accurate post-operative management: short hospitalization and an institution of a "grey zone" for patients waiting for swab or with suspected postoperative fever
5. Triple check: first at phone interview, second at the time of day-hospital and third at the admission to COVID-free unit.

On the other hand, the study's limit is a restricted number of cases and it could be extremely interesting to increase it to verify protocol's safety on a larger scale.

The grey zone, as earlier defined, had a big importance for safety of both the patients and the health workers. In case of post-operative fever, the grey zone would be used for a temporary patient transfer, in order to separate these patients from the others.

The duration of pandemic period is undefined; therefore, our protocol could be considered a good model for every type of surgery and its application could ensure a continuous treatment for non-deferrable conditions, even during healthcare emergencies.

Conclusions

Our protocol could be considered a safe key to continue the surgical activities during COVID-19 pandemic, and in the immediate future, in order to ensure the requested treatment for non-deferrable conditions, in a safe way for patients and health workers.

Declarations:

Funding: none

Conflict of interest: none of the authors have nothing to declare. The protocol has not been evaluated by an ethical committee, due to healthcare emergency and it has been approved by direction of our institution. All patients signed an informed consent for surgery and the use of clinical data for scientific purposes in the respect of privacy policy.

Availability of data and material: data available on reasonable request from the authors

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Figures

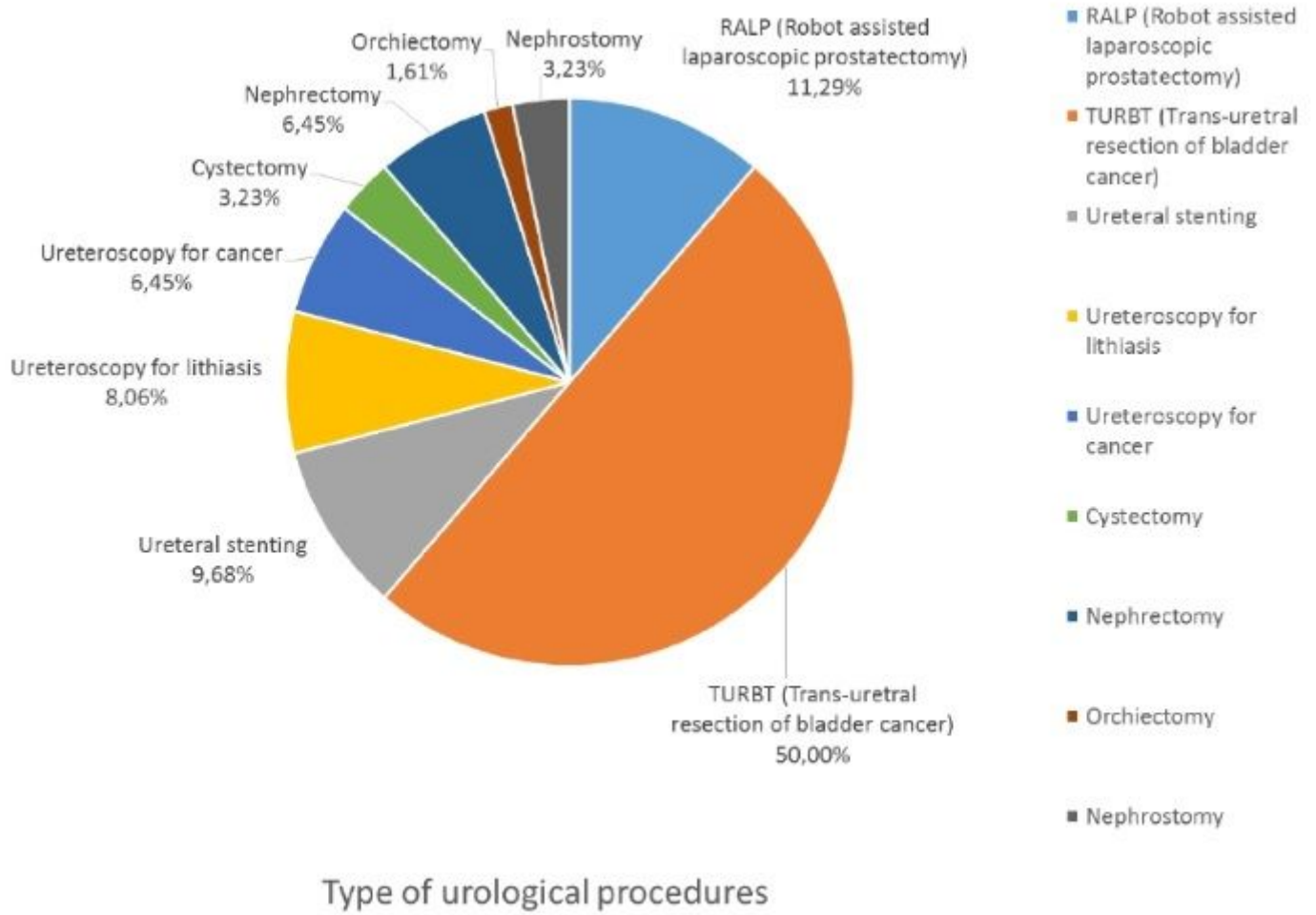


Figure 1

Surgical procedures

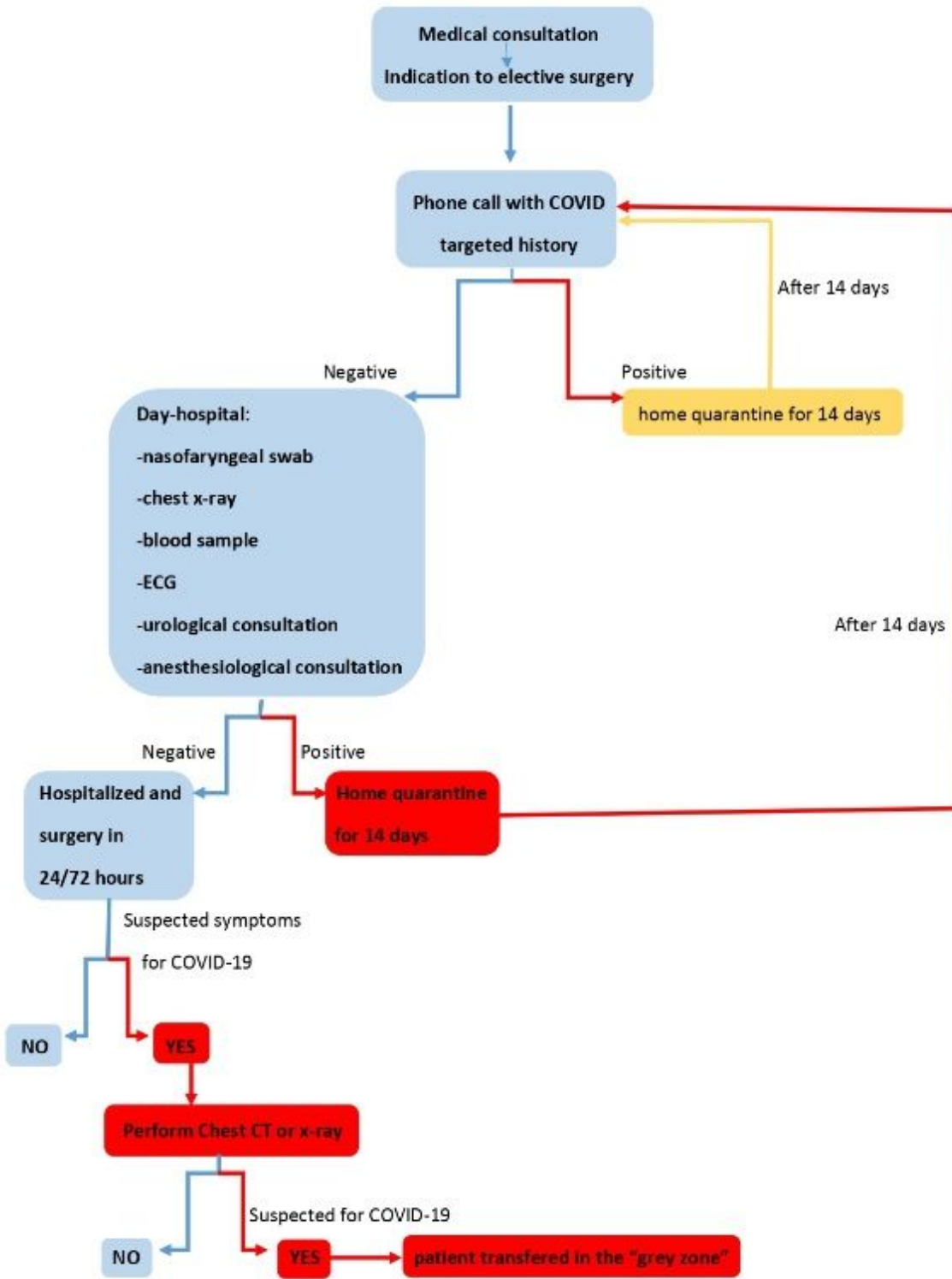


Figure 2

Safe Protocol For Elective Surgical Patient In A COVID Hospital