

COVID 19— Perspective of an Italian Center

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Abstract

Italy has been hard hit by severe acute respiratory syndrome coronavirus 2 infection with more than 240,000 cases and 35,000 deaths. During the acute phase of the pandemic, the Italian government decided on the lockdown which lasted about 2 months. During this period, all surgical activities were limited to nondeferable procedures only. The sudden closure posed problems with the management of the heart surgery waiting which at that time included 135 patients. Among these were selected cases with the worst clinical characteristics that were progressively operated on. Compared with a similar period in 2019, the cardiac surgery activity of the "Lancisi Cardiovascular Center" in Ancona has been reduced by 65%. With pandemic mitigation, heart surgery activity has gradually resumed but many open questions remain. Above all, there is the problem of living with a low but persistent level of presence of the virus with the need to organize the activity to ensure patients and staff safety and an optimal level of performance.

KEYWORDS

adult cardiac surgery, clinical management, COVID-19, emergent surgery, waiting list

1 | INTRODUCTION

The first cases of interstitial pneumonia in Wuhan, China, were reported in late December 2019.¹ The causative agent, isolated in January 2020, was a novel coronavirus, similar to others involved in recent outbreaks: It was named "2019 novel coronavirus," 2019 nCov or severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease was called coronavirus disease 2019 (COVID-19).²

SARS-CoV-2 generates asymptomatic or mildly symptomatic cases up to severe interstitial pneumonia requiring mechanical ventilator care with a high mortality rate.³⁻⁵

The infection rapidly spread through countries and reached all continents. On March 11th, the World Health Organization officially declared a state of a pandemic.

Italy was the first European country to deal with COVID-19.

2 | THE SARS-COV-2 IN ITALY

The first documentation of the SARS-CoV-2 in Italy dates back to January 30, 2020, when two Chinese tourists from the province of

Hubei were hospitalized in Rome. Subsequently, on February 5th, an Italian citizen returning from the Chinese province of Wuhan tested positive.

The first two major outbreaks in Italy took place in Lombardia and Veneto. SARS-CoV-2 was detected on February 19th in a young patient hospitalized for pneumonia in the Lombard Hospital of Codogno and in five other cases. As of February 26th, there were 403 cases in Lombardy. On February 20th, two cases were recorded in Veneto, one of which died the next day, from the municipality of Vo. On February 27th, there were 151 confirmed cases. On that date, there had been 70 cases coming from the municipality of Vo which had been placed in quarantine in the meantime.

Rapidly new cases were reported in other regions, with or without connection to the two initial outbreaks.

On February 23rd, the Italian government declared quarantine for some northern territories with the involvement of around 50,000 people. After further measures which had progressively extended the quarantine areas to include 14 million inhabitants, the lockdown was finally declared for the entire national territory on March 9th (Phase 1).

The Italian situation rapidly worsened with a high rate of contagion and high mortality rate: mortality was initially in line with the one reported in China, around 2.4%, but subsequently increased exponentially until it peaked at 8%–12%.⁶

The Italian health system rapidly reached a tipping point, mainly in the northern regions, due to the massive influx of patients into hospitals, often requiring intensive respiratory care. Hospital managers create dedicated inpatient wards both semi-intensive and, above all, intensive. The lack of staff, personal protective equipment (PPE), and mechanical ventilators, together with the need to avoid contagion, led to the suspension of ordinary and outpatient activity for almost 3 months while hospital resources were diverted to the treatment of patients with COVID-19.

The prolonged lockdown has proven effective in reducing infections. With the progressive lowering of the epidemic curve, the Italian government has decided to move to the so-called "phase 2" on May 4, 2020, by loosening some of the restrictions previously instated. Since June 15th, given the further improvement of the epidemic and the reduced pressure on hospitals, the government has launched "phase 3," enacting a series of measures aimed at freeing the movement of people, resuming

productive and commercial activities, and maintaining a surveillance system for the "coexistence with Covid19" (Figure 1).

Currently, the total number of cases in Italy is 245,864, the total number of deceased is 35,102. There are 41 patients in intensive care (they were more than 4000 in the most acute phase).⁷

It has been a short time since the start of Phase 3 and not enough data is available to assess the overall impact of the pandemic on heart surgery activity in Italy. On the basis of collected experience from other centers around the country, we have learned that there has been an overall reduction in the activity of heart surgery centers, although unevenly distributed. For example, in the Lombardia region, the most affected by the pandemic, there has been a reorganization of the 20 heart surgeries present in the regional system (serving about 10 million inhabitants): 16 suspended the activity completely while 4 formed hubs.^{8,9} The Italian Society of Cardiac Surgery has also created a task force that has published some editorials, works, and position papers. The society started collecting data related to the outcomes of patients undergoing heart surgery during the lockdown period.¹⁰ However, the collected data have not been published yet. As found in a recent survey by the association of Italian hospital surgeons, there has been an overall reduction of about 80% of all surgical procedures.¹¹

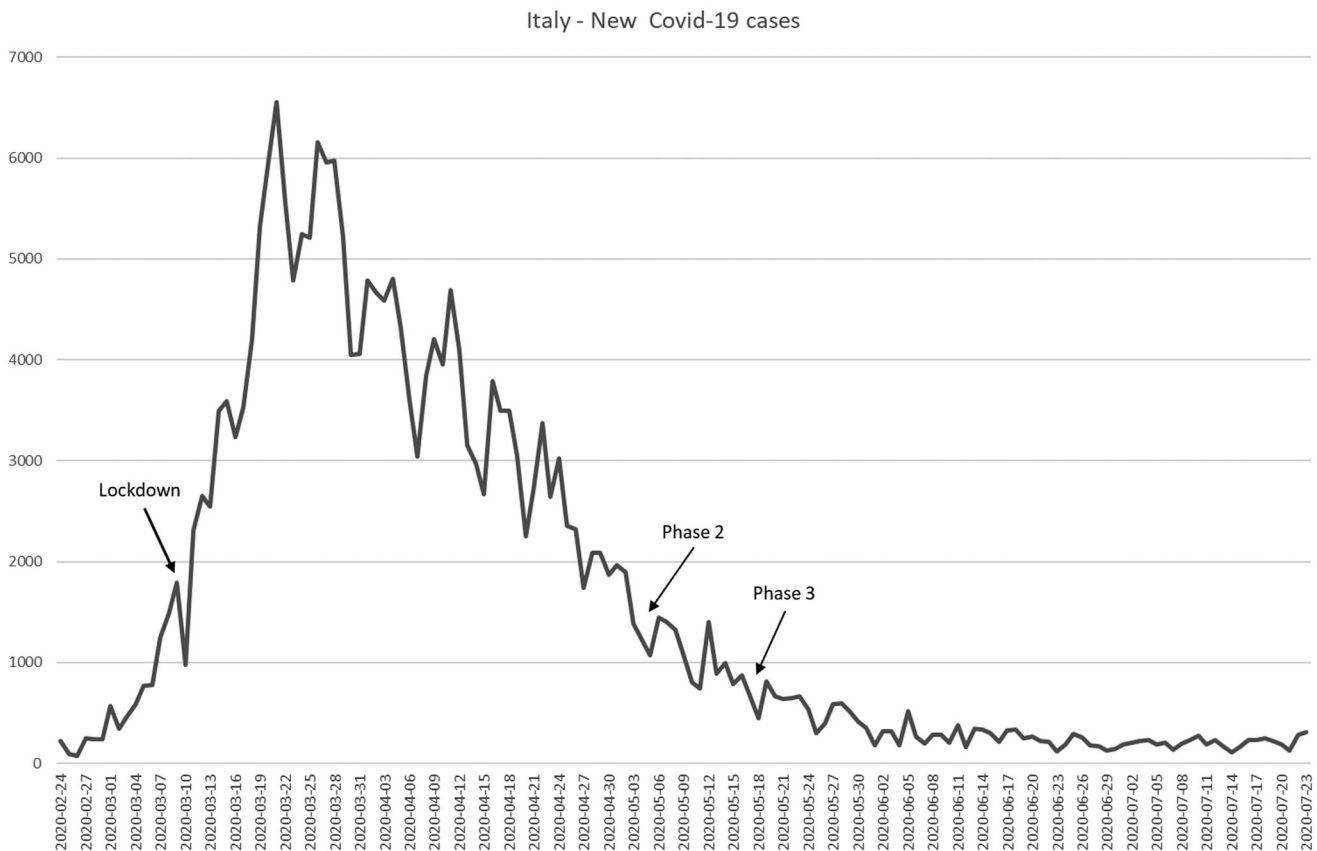


FIGURE 1 Coronavirus disease 2019 (COVID-19) in Italy. Pandemic curve

3 | THE SARS-COV-2 IN THE MARCHE REGION

The Cardiac Surgery Department of "Lancisi Cardiovascular Center," part of the "United Hospitals of Ancona" in one of the highest volume cardiac surgery performer in Italy. Our department serves about 1.5 million inhabitants and is the only structure in which cardiac surgery is performed in the Marche region. Our department performs all types of adult cardiac surgery procedures: mainly coronary, valvular, and aorta surgery, and it is a center of excellence in the field of minimally invasive surgery and aortic surgery. There is also a percutaneous valvulopathy treatment program run by surgeons. Being the only regional cardiac surgery center, it also guarantees coverage for all cardiac surgical emergencies in the area.

Before the SARS-CoV-2 epidemic, approximately 1300 major procedures were performed every year, over 100 per month. The department had three dedicated operating rooms and an additional one dedicated to emergencies. It has a dedicated intensive care unit with 10 beds and a ward with 28 beds including 8 for subintensive care.

The first cases of COVID-19 in the Marche region were recorded in the northern areas and related to a cluster involving the nearby Emilia Romagna region.

Starting from March 8th, the hospital structure was gradually reorganized following the deliberations of the general management of the hospital to create specific areas dedicated to deal with the

massive influx of patients with COVID-19. On March 12th, a resolution of the regional government asked to suspend the planned hospitalization activities with the exception of emergency activities.

At the beginning of April, there were 12 "Covid" departments within the hospital, divided by level of severity (intensive, sub-intensive, and nonintensive) which had replaced other departments and absorbed personnel freed by the reduction of ordinary activity. At the start of Phase 2, the "Covid" departments had grown to 19.

Surgeries in our department progressively reduced as the number of patients with COVID-19 admitted in our hospital increased, requiring more space, supplies, and personnel. When the regional and hospital management approved the suspension of elective assistance: all surgical specialties, including cardiac surgery, were requested to limit their activity to emergency only and nondeferrable cases, while some operating rooms were reorganized to function as intensive care units (Figure 2).

The drastically reduced surgical activity freed up resources, both in terms of space and staff. The cardiac surgery semi-intensive ward was reduced to four beds; the nonintensive ward to 10 beds; and the post-surgical intensive care unit has been cut to have only two beds available. Surgeons, nurses, and intensivists have been assigned to treat patients with COVID-19 while a nucleus of staff surgeons, nurses, and auxiliary staff remained in active service to deal with emergencies.

At the time of suspension of ordinary activities, there were 135 patients on the waiting list for cardiac surgery procedures. A telephone review was immediately organized, questioning patients about

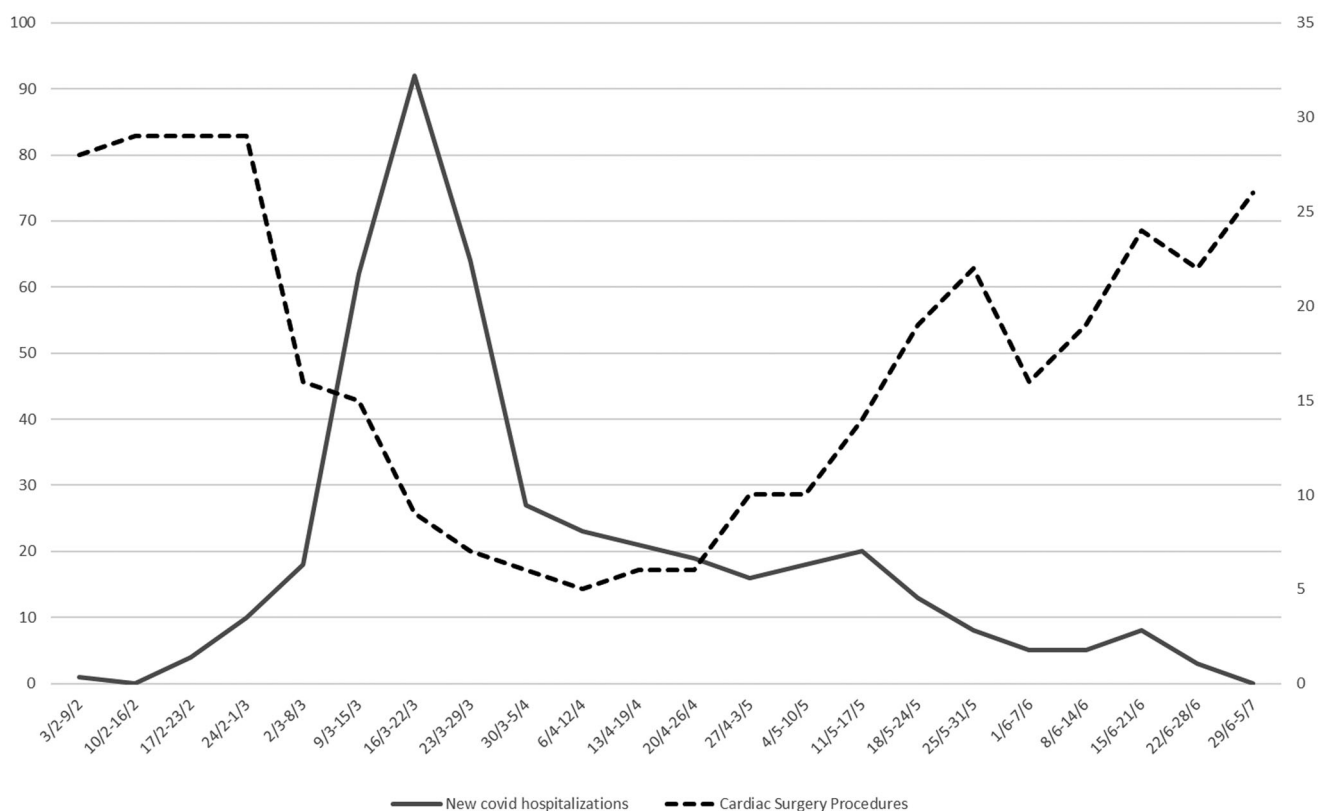


FIGURE 2 Patients admitted with coronavirus disease 2019 (left scale) and heart surgery procedures (right) at the United Hospitals of Ancona

symptoms and cross-referencing their answers with admission booking forms to identify cases that could be postponed and patients for whom, due to anatomical and/or clinical characteristics, referrals could prove dangerous. There were 120 patients assigned to the first group ("quiet" patients). They were recommended to promptly notify us of any alteration in their clinical status. The patients of the second group (15) had a more worrying clinical picture: with these patients, we decided to keep a daily telephone contact and to operate them as soon as possible ("worrying" patients). This waiting list reorganization involved two doctors and administrative staff for about 2 days. When possible, family doctors and cardiologists were also involved in monitoring patients whose procedure was postponed.

The mitigation measure revealed effective in flattening the contagion curve, so when a progressive decline of COVID-19 cases was observed, resources were regained and the regional and hospital management arranged to resume the ordinary activity.

Our waiting list at that point was composed of two sections: the postponed patients, with surgery scheduled before the lockdown and the new patients, who turned up after the pandemic was under control. Currently, the "new" post COVID-19 cardiac surgery waiting list counts about 170 patients, including those who had been postponed on the prepandemic list.

Following constant monitoring, through daily telephone contacts with patients and their doctors, and the determination to operate

patients at the slightest sign of clinical worsening, we have not recorded deaths among the patients whose intervention has been postponed.

In March and April 2020, roughly matching the tight lockdown phase, 77 cardiac surgery procedures were performed in our department. During the same months in 2019, 220 surgeries had been performed (65% reduction) (Figure 3).

Surgery to the aorta has seen the greatest reduction overall (31 cases in 2 months of April–May 2019 versus 8 cases in 2 months of April–May 2020, minus 74%); percutaneous treatment of aortic valve disease had the slightest decrease (13 vs. 10 cases, respectively, minus 23%).

The teaching activity was also interrupted. An international course on minimally invasive surgery that we were organizing was quickly converted into a virtual live course with videoconferences that had a considerable number of online contacts.¹² Because of the pandemic, this way of organizing courses and congresses will be increasingly used in the future.

4 | DISCUSSION

All of our nation's hospitals were involved in the lockdown and temporarily suppressed ordinary, nonurgent, and outpatient activities. This

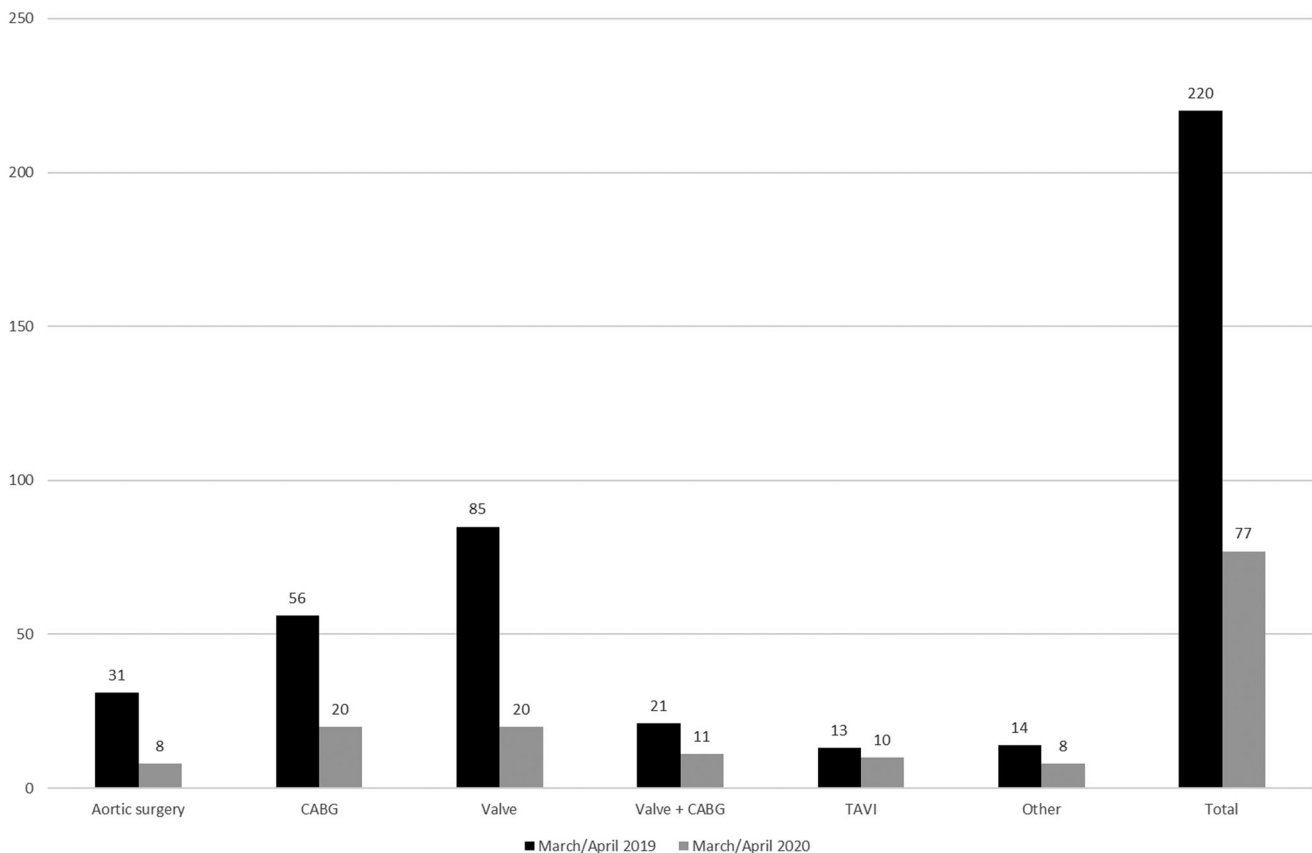


FIGURE 3 Heart surgery procedures performed at the United Hospitals of Ancona during the pandemic, compared to the previous year. CABG, coronary artery bypass grafting; TAVI, transcatheter aortic valve implantation

had an impact on the treatment of cardiovascular diseases which, together with chronic obstructive pulmonary disease and cancer, represent the main cause of mortality in the western world.¹³

The SARS-CoV-2 had a strong impact on patients with heart disease: patients with cardiovascular disease (and also hypertension and diabetes) showed more severe clinical manifestation and higher mortality when infected with SARS-CoV-2.^{5,14} Cardiac surgery also involves other specific factors that expose patients to the risk of contracting the infection and developing its most severe and lethal forms. The use of extracorporeal circulation, for example, causes a systemic inflammatory response, the activation of the mechanisms of coagulation, and of the complement system.^{15,16} The target organ of some of these inflammatory and humoral stimuli is the lung.¹⁷ In addition, patients undergoing cardiac surgery procedures require intubation and mechanical ventilation, a variably long stay in intensive care units, and the need to access different hospital services (e.g., radiology and echocardiography).

In Italy, following the institution of lockdown, many local governments and hospital administrations have suspended some clinical activities. In the Marche region, the "regional emergency plan" of the local government decided to guarantee only nondelayable procedures. The cardiac surgery unit was included in this decision and part of its department was evicted to accommodate a general surgery department which was then moved to create COVID-19 wards while some of the staff was assigned to the COVID departments.

It is impossible to quantify the overall reduction of the cardiac surgery activity, as there are variations between the countries also in relation to the temporal differences in the spread of the pandemic and the decisions of the political, governmental, and hospital management authorities. Gaudino et al.¹⁸ conducted a survey of 60 cardiac surgery centers finding a median reduction in cardiac surgery activity of 50%–75%. These data are in line with what has been found by Ad et al.¹⁹ that examining data of 67 cardiac surgery centers in North America have found a 45% reduction in activity compared to the same period of 2019. In Greece, at two large hospitals in the metropolitan area of Athens, Lazaros et al.²⁰ found a 67% reduction in cardiac surgery.

In Italy, an estimate of the reduction in surgical volume has not been published yet. At our hospital in Ancona, cardiac surgical procedures have decreased by 65%.

It can be expected that the failure to treat cardiology patients during the pandemic period may be the basis of a wave of post pandemic cardiology problems.

One of the major difficulties we encountered in dealing with the provisions relating to the reduction of activity was in the definition of "urgency" when applied to patients deemed worthy of cardiac surgery. What defines the urgent cases in heart surgery? And how to deal with the waiting list? George et al.²¹ described the process applied to reclassify patients on the waiting list to identify urgent cases to prioritize according to the pandemic phase. Our approach was to contact the patients to identify nondeferrable cases and those to be monitored more closely with daily telephone contacts, as described above. This way, we were able to optimize resources while still

managing to operate on the more worrying patients, as well as ensuring the extra- and intrahospital emergencies.

Another way of maximizing scarce resources while minimizing the risks of contagion is to treat patients to less invasive treatments, even in spite of current guidelines.²²

While significantly limiting their activities, the cardiac surgery departments have maintained the management of emergencies. Some national scientific societies have activated task forces to provide management protocols to guarantee the safety of patients and health personnel.²³ Recommendations include pressure positive operating room with surrounding rooms with negative pressure; distancing; droplet and contact precaution; minimizing staff; precaution for intubation; recovery in a negative pressure room; and tailoring a surgical technique to minimize the exposure.

One of the most pressing recommendations is to test patients for SARS-CoV-2 before procedures. In fact, the rapid spread of SARS-CoV-2 across the globe suggests that transmission from asymptomatic vectors may have been underestimated.^{24,25} If patients who tested positive to SARS-CoV-2 require urgent undeferrable surgery, the theatre team should adopt full PPE, goggles, face shield, gowns, double-layered gloves, and protective footwear. The same precautions should be adopted for patients exposed to SARS-CoV-2 and patients with symptoms without a negative test for all the procedures performed during the acute phase of the pandemic.

The policy of our hospital, which is still in force today, is to request swabs before admission from all patients to be hospitalized. Patients requiring hospitalization and without swabs are admitted to isolation areas until swabs are completed. Patients who require urgent or emerging interventions and who have not performed swabs or with swabs' results not yet known are treated as positive, using dedicated operating rooms and paths.

There are many concerns that the use of these precautions may have a negative impact on surgical outcomes due to difficulties in communication, vision, movement, and fatigue,^{25,26} but there is still not enough data available on the outcomes of positive patients undergoing cardiac surgery.

Ad et al.¹⁹ pooling the collective experience of 67 North American cardiac surgery centers found that the overall unadjusted mortality rate for patients with confirmed or suspected COVID-19 was 8%.¹⁹ Other isolated cases of cardiac surgery in positive patients are reported with variable outcomes.^{27,28} At our center, we treated an acute dissection of the aorta in a patient already known as positive to SARS-CoV-2 while isolating at home. The course was burdened by respiratory complications and the need for prolonged ventilation, but in the end, the patient survived and was discharged.²⁹

The only case of death we recorded during the lockdown period was of a patient with acute dissection who died during the preparation for surgery. In this case, the time dilation due to the need to treat the patient as infected may have played a role in the outcome.

Even patients who need surgery and who have a negative swab should be treated with great caution, due to the presence of false negatives, and because cardiac surgery is associated with a lung

vulnerability that could facilitate complications and death in case of subsequent SARS-CoV-2 infection.

In addition to the measure that needs to be adopted during the pandemic phase, there are still doubts about how to behave during the recovery phase after the reduction of the pandemic curve and the end of the lockdown.

Scientific societies, experts, and hospital administrations have produced a significant amount of guidelines and recommendations relating to how patients should be handled and the precautions that need to be taken.³⁰⁻³² The reality is that we know little about this pathology and cannot accurately predict how it will evolve, whether or not there will be new pandemic peaks or if widespread immunity will be achieved. The same guidelines and recommendations are based on low levels of evidence and are often outdated by the course of events.

5 | ITALIAN PERSPECTIVE

The current situation in Italy is characterized by a low incidence of infections that have made it possible to free up a large part of the hospital resources previously dedicated to COVID-19. Our hospital has long been "Covid free" and the surgical activity has resumed almost normally. However, there are limited outbreaks that are in isolation and small areas are quarantined. Some experts fear a possible new high-intensity spread in autumn.

We believe that we must take advantage of this "truce" phase to both maintain the safeguards placed to avoid further waves of infection but to also ensure that the cardiac surgery activity will not be drastically suspended once again leaving the cardiology patients without adequate treatment.

In addition to all the recommended precautions, such as extensive testing, filters and access restrictions, extensive use of masks, and spacing measures, it is necessary to devise "emergency plans" that would help us to manage a new high influx of patients without compromising health services.

For example, providing dedicated areas and routes for positive patients with the ability to quickly convert part of the operating ward, intensive therapy beds, and wards in "isolated" areas; identifying "ad hoc" routes for positive patients and "gray areas" for suspect patients, avoiding the shortage of PPE by preparing adequate storage supplies.

Some regional governments, including ours, have ordered the creation of "Covid Hospitals" in which to bring together and adequately treat COVID-positive patients avoiding the risk of virus dissemination associated with "mixed" hospital environments. There are some criticisms of this approach due to the fact that these dedicated hospitals cannot offer all the diagnostic and therapeutic opportunities of any regular facility (also because, in the absence of patients, they would remain closed); therefore, patients would need to be transferred between "covid" hospitals and "non covid" hospitals, thus undermining the usefulness of these dedicated centers.

The creation of specific and well-documented protocols based on evidence, the development of telemedicine systems, and better

integration between hospital departments and territorial medicine are fundamental for this purpose.

In the specific field of cardiac surgery, it will be useful to enhance the minimally invasive and percutaneous activity by spreading its use and carrying out an intensive mentoring activity, along with the development of protocols for fast-track recovery.³³ This way, we should be able to offer patients effective and long-lasting procedures, even during a pandemic, without running the risk of providing subpar treatments due to extreme conditions.

6 | CONCLUSION

The peak of the pandemic has been reached in the European countries, but in other countries (America, Brazil), the SARS-CoV-2 diffusion seems to be still growing or in a plateau phase. The risk of an epidemic resumption is seriously being considered as well as the possibility that COVID-19 becomes an endemic pathology such as HIV.

The preparation of a vaccine could significantly improve the situation, but it is currently not yet clear when it may be available and how effective it will be.

In this context, it is necessary to take advantage of the experience gained so far to avoid the suspension of essential health services (such as cardiac surgery and cancer treatment).

Cardiac surgeons, armed as always with resilience and planning skills, will have to reinvent their activity to offer patients suitable treatments in safe settings.

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