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First reorganization in Europe of a regional cardiac surgery system to deal with the coronavirus-2019 pandemic

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INTRODUCTION

The current novel coronavirus outbreak, which began in December 2019 in the Wuhan region in China, represents a massive challenge for the entire world [1]. In this era of globalization, illnesses, as well as information and people, travel much more quickly today than they did even 10 years ago. Worldwide health systems are currently under great pressure, trying to tackle the emergency based on previous decennial experience in dealing with other infectious diseases such as an influenza epidemic.

By the end of February 2020, the coronavirus disease 2019 (COVID-2019) had spread in Northern Italy, with thousands of patients infected with severe acute respiratory syndrome (SARS)-CoV-2, thus requiring the Italian government to quickly introduce emergency quarantine measures. Lombardy, an important productive region in Northern Italy, was one of the most affected, with thousands of patients who tested positive for the virus. Consequently, almost all elective medical activity (out-patient and surgical) was stopped. Entire hospitals were transformed into COVID-19 units. In-hospital dedicated pathways were identified. Whole new COVID-19 intensive care units (ICUs) were created in a few days, as have new non-COVID emergency rooms to treat urgent cases.

The emergency situation in Italy caused by the COVID-19 pandemic has also changed the way of treating patients requiring cardiac surgery. The Lombardy regional government recently introduced new rules on how to reorganize hospitals by creating 4 hubs for adult and 1 for paediatric cardiac surgery, which will handle all emergency/urgent cases (~150–200 cases/month). This situation has never happened before in the modern era and obviously represents a challenge in terms of rapidity and effectiveness of the actions needed.

As far as human resources are concerned, most of the cardiac surgeons not working in the hub centres have been part of multidisciplinary teams caring for patients affected by COVID-19 in internal medicine and ICUs. Of course, being admitted to a hospital with COVID-19 patients significantly increases the risk of becoming infected, especially for patients with cardiovascular disease. However, patients with cardiac emergencies/urgencies deserve to be treated. So far, only a few papers have been published on the COVID-19 pandemic, and even fewer have been published on the challenges of restructuring the medical care system under these emergency conditions.

Herein, we briefly summarize how, for the first time in Europe since the start of the COVID-19 outbreak, the entire cardiac surgery system in the North Italian region of Lombardy was modified to deal with this emergency.

THE SARS-CoV-2

The family of coronaviruses is common across the world in animals and humans. These viruses generally are transmitted by droplets and cause the common cold. Occasionally they are responsible for more severe diseases like the Middle East respiratory syndrome and the SARS, both of which often lead to pneumonia.

The illness caused by SARS-CoV-2, a new strain of coronavirus not previously seen in humans, has been named COVID-19 (COVID-19: CO = corona; VI = virus; D = disease; 19 = year of outbreak) [1].

Because SARS-CoV-2 is a new virus, the lack of immunity in the population and the absence of an effective vaccine explain its worldwide spread. On 31 December 2019, Chinese authorities notified the World Health Organization (WHO) of an outbreak of pneumonia in Wuhan City, which was later classified as a new disease (named COVID-19), whereas 1 month later the WHO declared the outbreak of COVID-19 a 'Public Health Emergency of International Concern', and finally designated it a pandemic on 11 March 2020 [2].

FROM THE CHINESE TO THE ITALIAN OUTBREAK

On 21 February 2020, Italy had its first SARS-CoV-2-positive patient. He was a 38-year-old man with no comorbidities, who came in contact with a friend who had recently moved from China. The patient, living in Codogno (a small town near Milan), developed severe pneumonia requiring intubation. Then, the Italian outbreak began.

To date, Italy has been more seriously affected than China by COVID-19 in terms of coronavirus cases per 1 million of population. The unexpected Italian outbreak may be explained by the recent expansion of airline connections with China. On 8 March 2020, the Italian government announced the lockdown of the affected regions. Two days, the quarantine was extended to the entire country (the first in the world), as new COVID-19 cases were detected across the country. Emergency measures included social distancing; the suspension of community and sporting events; and the closure of commercial activities, restaurants, educational institutes and universities.

EPIDEMIOLOGY

By 31 March 2020, Italy had 77 635 cases positive for SARS-CoV-2; 15 729 recovered individuals and 12 428 patients killed by the virus, with a total of 105 792 people involved (Table 1) [3]. However, the data are changing every minute and, unfortunately, they are significantly underestimated due to false-negative testing results and the high number of paucisymptomatic patients.

Current evidence shows that the mortality rate from COVID-19 in Italy (~10%) could be higher than the global mortality rate of 3.4% estimated by the WHO and significantly greater than the 0.1% from the seasonal influenza in the USA reported by the Centers for Disease Control and Prevention [4]. These alarming data may be partially explained by the ageing of the Italian population and the underestimated incidence of the SARS-CoV-2 due to restrictive indications for swab testing.

SIGNS AND SYMPTOMS

According to the US Centers for Disease Control and Prevention, the incubation period is between 2 and 14 days [5]. Early data show that SARS-CoV-2 could be asymptomatic or affect people with a mild illness similar to seasonal influenza [6] but that, in some cases pneumonia develops, with severe complications leading to death. Dyspnoea, cough and general discomfort and fever are the most common symptoms, whereas haemoptysis and diarrhoea seem to be rare.

It has been reported that elderly persons infected with SARS-CoV-2 are at increased risk for complications. Similar to the situation with seasonal influenza, underlying comorbidities (such as obesity, hypertension and diabetes mellitus) represent important risk factors for unfavourable outcomes [7].

Currently, neither a vaccine against SARS-CoV-2 nor any specific antiviral drug is available to defeat the infection [2]. Therefore, most therapies target symptoms and provide support to patients with complications, and most patients treat themselves at home.

HUB-AND-SPOKE MODEL

On 8 March 2020, in order to deal with the COVID-19 outbreak, the Lombardy regional government revised the entire regional healthcare system by introducing a temporary 'hub and spoke' model [8].

The hub-and-spoke system is an organizational model comprising a network of primary anchor centres (hubs), able to provide a wide spectrum of services, and secondary satellite establishments (spokes), which offer more limited assistance [9]. Patients in the spokes needing more intensive care are routed to their hubs. This model provides a highly efficient organization and enhanced quality of care. It has been used in several countries (i.e. Willis-Knighton Health System's hub-and-spoke network, Shreveport, LA, USA) and even in rural areas with beneficial results (i.e. catheterization laboratories in the Tamil Nadu region of India). However, some disadvantages include hub congestion and transportation challenges.

As defined by the Lombardy ordinance, hub centres should:

1. Guarantee patient access/hospitalization by providing multiple available medical teams (with at least 1 team on active duty 24/7).
2. Activate a 'fast track' for non-COVID emergency/urgent patients, thereby avoiding COVID-19 emergency room transit.
3. Welcome spoke teams in their respective hubs and encourage collaboration.
4. Ensure that patient transport is managed by the forwarding hospital.

A decision was made to apply this model to major trauma, stroke, emergencies/urgencies in neurosurgery, cardiovascular surgery and interventional cardiology (in particular for acute myocardial infarction and electrophysiological procedures). An ordinary extracorporeal membrane oxygenation network was maintained as well.

A mean of 150–200 adult and 50 paediatric cardiac surgical procedures have been estimated per month in Lombardy, a region with almost 10 million inhabitants. In contrast to our usual

Table 1: Italian epidemiological situation updated on 31 March 2020 (Italian Ministry of Health data; see online version for current up-to-date data: <http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioNotizieNuovoCoronavirus.jsp?lingua=italiano&menu=notizie&p=dalministro&id=4648>)

Region	SARS-CoV-2 positive				Discharged healed	Deaths	Total	Naso-/oropharyngeal swab
	Hospitalized with symptoms	ICU	Quarantine	Total				
Lombardy	11 883	1324	11 917	25 124	10 885	7199	43 208	114 640
Emilia Romagna	3765	353	6835	10 953	1477	1644	14 074	54 532
Veneto	1680	356	5814	7850	828	477	9155	106 238
Piedmont	3174	452	4456	8082	365	854	9301	27 658
Tuscany	1120	293	2813	4226	138	244	4608	33 165
Marche	946	169	2237	3352	21	452	3825	11 724
Liguria	1153	179	1176	2508	480	428	3416	10 376
Lazio	1127	173	1342	2642	291	162	3095	34 677
Campania	501	133	1237	1871	88	133	2092	14 403
Trento	354	80	955	1389	193	164	1746	6973
Apulia	609	105	940	1654	39	110	1803	14 073
Friuli V. G.	215	60	885	1160	320	113	1593	14 899
Sicily	503	72	917	1492	74	81	1647	15 634
Abruzzo	335	73	783	1191	95	115	1401	8758
Bolzano	249	62	831	1142	153	76	1371	11 275
Umbria	176	43	632	851	190	37	1078	8685
Sardinia	113	28	516	657	34	31	722	5257
Calabria	132	17	457	606	17	36	659	9327
Aosta Valley	91	26	435	552	20	56	628	1582
Basilicata	37	17	162	216	3	7	226	2043
Molise	29	8	80	117	18	9	144	1049
Total	28 192	4023	45 420	77 635	15 729	12 428	105 792	506 968

ICU: intensive care unit; SARS: severe acute respiratory syndrome.

practice, patients from other regions are now treated in their own district because of transfer limitations.

Four adult and 1 paediatric cardiac surgery hubs have been identified (Fig. 1). In the decision-making process, the following criteria were considered for the choice of the hub centres: the presence of dedicated 24/7 operating rooms (at least 3 simultaneously) and the presence of a COVID-free postoperative cardiovascular ICU.

LOMBARDY CARDIAC SURGERY EMERGENCY REORGANIZATION

As a consequence of the ordinance, on 10 March 2020, the organizers of the cardiac surgery hub centres reached a consensus about the following issues:

1. Hub definitions for emergency, urgent and non-deferrable (surgery needed within 2 months) conditions (Table 2) were agreed on.
2. Naso- or oropharyngeal swabs must be performed pre-operatively in all patients either in the spoke or in the hub hospital. In addition, patients with symptoms who tested positive for the SARS-CoV-2 needing surgery within 2 months (so-called 'non-deferrable') will not be operated on whereas emergency/urgent patients with symptoms who tested positive will be operated on (if surgery is the only suitable therapeutic option).
3. The number of ICU beds available in each hub centre must be declared (S. Raffaele, $n = 14-20$; Monzino, $n = 11$; Legnano, $n = 8$; Brescia, $n = 4-6$; total $n = 37/45$).

4. A hub centre must have or must be provided with laboratory facilities for rapid diagnosis of SARS-CoV-2 (i.e. using reverse transcription polymerase chain reaction).
5. Weekly video meetings among hub centres will be held to share up-to-date reports.
6. Hub-and-spoke units must cooperate, particularly as relates to the rotation of the surgical teams in case of exhausting working shifts.
7. Transcatheter options (i.e. transcatheter aortic valve implantation, percutaneous balloon aortic valvuloplasty, percutaneous coronary intervention) should be considered in non-deferrable/emergency/urgent COVID patients affected by aortic stenosis and/or ischaemic cardiopathy.
8. Considering the limited number of ICU beds, surgical triage must favour emergency and urgent cases.

The following issues were also considered:

- The length of hospital stay after cardiac surgery is longer than that after percutaneous procedures. In addition, although hub centres have to have COVID-free wards, hospital congestion is likely to increase the risk of in-hospital transmissions. As a consequence, under these extraordinary circumstances, transcatheter options may be considered more liberally [10].
- Whenever possible, the postoperative in-hospital stay and rehabilitation period should be reduced to a minimum, encouraging 'early discharge', thereby lowering the risk of SARS-CoV-2 transmission.
- Patients who are SARS-CoV-2 positive and who require emergency/urgent/non-deferrable cardiac surgery have to



Figure 1: Lombardy emergency cardiac surgery hub-and-spoke system during the coronavirus disease 2019 epidemic. This map shows the reorganization of the cardiac surgery system for emergency and urgent situations during the coronavirus disease-2019 outbreak in Lombardy: 4 adult (**A-D**) hubs and 1 paediatric (**E**) hub have been identified; satellite spoke centres (in numbers) are asked to transfer patients needing emergency/urgent surgery to their respective hubs.

Table 2: Definitions of emergency/urgent cardiac surgery cases adopted in Lombardy during the COVID-19 outbreak

Acute aortic syndrome	<ol style="list-style-type: none"> 1. Acute aortic dissection/intramural haematoma (excluding patients with coma OR age >80 years with stroke and/or evident visceral malperfusion) 2. Ascending aortic aneurysm ≥ 6 cm 3. Ascending aortic aneurysm ≥ 5.5 cm AND: <ol style="list-style-type: none"> a. Marfan syndrome/other collagenopathy OR b. Aneurysm increase >5 mm/year OR c. Uncontrolled hypertension
Aortic valve	<ol style="list-style-type: none"> 1. Severe aortic stenosis AND symptoms (i.e. lipotimia OR angina OR dyspnoea NYHA III/IV) 2. Severe aortic regurgitation AND: <ol style="list-style-type: none"> a. Pulmonary oedema b. Haemodynamic instability
Mitral valve	<ol style="list-style-type: none"> 1. Severe mitral stenosis AND: <ol style="list-style-type: none"> a. Pulmonary oedema OR b. Haemodynamic instability 2. Acute mitral insufficiency due to papillary muscle/chordal rupture leading to pulmonary oedema
Ischaemic cardiopathy	<ol style="list-style-type: none"> 1. Unstable angina 2. Severe LMCA stenosis $\geq 70\%$ 3. Subocclusive proximal LAD stenosis not suitable for PCI 4. Postinfarction ventricular septal/cardiac rupture
Acute endocarditis	Emergency or urgent cases (as defined by European Society of Cardiology/European Association of Cardio-Thoracic Surgery Guidelines)
Severe bioprosthetic/mechanical valve dysfunction	Emergency or urgent cases resulting in: <ol style="list-style-type: none"> a. Heart failure OR b. Haemodynamic instability
Heart failure	Non-deferrable need for LVAD implantation
Miscellaneous	<ol style="list-style-type: none"> 1. Cardiac tamponade 2. Atrial myxoma OR other cardiac tumours with: <ol style="list-style-type: none"> a. High embolic risk OR b. In the presence of AV valve obstruction

AV: atrioventricular; COVID-19: coronavirus disease 2019; LAD: left anterior descending; LMCA: left main coronary artery; LVAD: left ventricular assist device; NYHA: New York Heart Association; PCI: percutaneous coronary intervention.

be treated in a specific COVID-19 pathway, which comprises dedicated COVID-19 negative pressure operating rooms, with specific protocols for cleaning; the postoperative stay will be confined to COVID-ICU/wards. Cardiovascular healthcare personnel directly involved in the treatment of SARS-CoV-2-positive patients are required to use specific protective equipment (i.e. FFP2/FFP3 masks), similar to those used in COVID wards. In addition, in emergency situations in which the result of swab testing is not available at the moment of surgery (it usually takes some hours to complete reverse transcription polymerase chain reaction laboratory testing), it must be assumed that the patient could be SARS-CoV-2 positive; therefore, as a precaution, the operation will be performed in a dedicated COVID operating room.

- Patients who have had a recent cardiac operation are at increased risk of acquiring the infection during the postoperative period despite the establishment of COVID-free pathways. In case of novel coronavirus superinfection in the interval after cardiac surgery, aggressive ventilation support and early antiviral therapy should be provided.

CONCLUSIONS

The Italian COVID-19 emergency, on a scale never before seen, represents a tremendous burden for society as a whole. The government quickly established quarantine measures, but the first positive effects will only be seen after some weeks. Unfortunately, the mortality rate seems much higher than that reported for other countries. Further investigations are necessary to clarify the reasons for such virulence. The entire healthcare system is facing difficult challenges, but the introduction of a different organization model during the COVID-19 outbreak may be extremely helpful and should be able to satisfy all emergency needs, especially in the cardiovascular field. The results of this new network will be determined only at the end of this pandemic. By describing the Lombardy cardiac surgery reorganization model, we are sharing with the cardiovascular community our response to this

amazing challenge. We hope, by so doing, to be of help to other countries facing this pandemic.

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