Urgency and emergency treatments in cardiovascular surgery during the COVID pandemic: results of extremized HUB and spoke organization in northern Italy.

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ABSTRACT

OBJECTIVES: Feasibility and results of cardiovascular hub-spoke networks to face COVID19 pandemic.

The COVID-19 pandemic in Italy had the primary outbreak in the northern part of the country forcing the regional health care system to expand the availability of beds in the wards and intensive care units and to institute a Hub and Spoke hospital network to ensure assistance continuity for urgencies and emergencies. We report a descriptive analysis of the activity of the first 30 days of the Hub center.

METHODS: Role of our Hub center was to guarantee 24/24h 7/7days cardiovascular surgical care for an area of 3.145.312 inhabitants' area. Hub-spoke reorganization permitted a significant increase of ICU and ward beds availability for COVID patients needing hospitalization in all peripheral centers. Records of all consecutive patients admitted were collected and analyzed.

RESULTS: a total of 100 patients were evaluated in the study period. Hub and spoke cooperation have been successful, all patients affected by cardiovascular urgencies or emergencies found a highly specialized hospital and was evaluated and treated. Global reduction of elective and non-deferrable interventions in spoke centers was achieved for both vascular and cardiac surgery while we detected a significant increase of urgent vascular interventions for acute limb ischemia. We did not observe an increase of in-hospital mortality in non-infected patients.

CONCLUSION: Hub and spoke network for cardiovascular pathology is an effective way to face healthcare needs during the pandemic.

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INTRODUCTION

First reported in China[1], the COVID-19 pandemic in Italy had the primary outbreak in the northern part of the country and, in particular, in the Lombardia region. Since the detection of the official first case on the 18th of February 2020, the infection has spread very quickly. On the 16th of April 2020, the confirmed national positive cases were more than 100.000, with more than 20.000 deaths[2]. The explosion of symptomatic patients needing hospitalization has required a complete reorganization of the regional health care system (RHCS) to expand the availability of beds in the wards and intensive care units. A rearrangement of the routine healthcare activity was necessary to clear medical and paramedical staff to face the emergency. Elective non-urgent surgical interventions, outpatient visits, and everyday services were postponed; the emergency surgical and non-surgical activity was rearranged. To ensure assistance continuity for cardio-vascular urgencies and emergencies, the Lombardy RHCS has decided to institute a Hub and Spoke hospital network. Inspired to the already validated idea of one core center offering highly specialized care and multiple referral hospitals [3,4,5,6], the novel organization guarantees 24h/24h 7days/7days care in a similar way to what happens in the US for the treatment of ruptured abdominal aortic aneurysm[7]. This article is a descriptive analysis of the activity of the first 30 days in the Hub center of East Lombardia.

MATERIALS AND METHODS

This is an observational cohort study on all cardio-vascular consecutive patients evaluated and/or treated at Poliambulanza Foundation Hospital in Brescia (Italy) in the first 30 days of activity as a hub center. Written informed consent to participate in anonymous data collection was obtained from all patients. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's committee.

The Lombardia region, with its 10.6 million inhabitants, is the most populated and productive region of the north of Italy, and it was the largest affected area in Europe [8,2]. The Lombardy RHCS decided to establish a hub and spoke network for all the major clinical and surgical pathologies across the region to face the Sars-Cov19 pandemia and to continue to assure highly specialized care. The decree issued the 08th of March 2020 by the RHCS regarding cardiovascular surgical pathologies[9], divided the Lombardy region into four major areas choosing for each of them a core hospital with a referral network of up to 5 cardiac surgery spoke centers and up to 10 vascular surgery spoke centers. Poliambulanza Foundation Hospital, a no-profit private hospital site in Brescia, was appointed Hub center for the cardio-vascular surgical activity to cover an area of 3.145.312 inhabitants located in the east of the region (fig. 1). Role of the Hub hospital was to guarantee 24/7 active guard on-site and at least two on-call teams for both vascular and cardiac surgery urgencies and emergencies. Meanwhile, spoke centers could free human and logistic resources to expand their capability to accept COVID patients requiring hospitalization. Regardless of public or private property, all the hospitals with cardiac or vascular

surgery departments were involved in the new organization extremizing the already existing territorial hub-spoke network. Night and day shifts were organized with mixed staff coming from different centers to collaborate in the Hub surgical activity. Though spokes centers had been converted to treat patients with Covid-19 infection, some of them maintained an on-call team available on site for the management of non-transferable cases linked to Emergency Department direct admittance or emergency complications of other surgical or medical activities (transplant, trauma center, stroke, myocardial infarction etc.)[5]

As in war scenario, Rules of Engagement were established in a collegial remote meeting between Hub centers. Eligibility and exclusion criteria for surgery are summarized in table I. All elective surgery interventions were postponed. Not deferrable cases (class A indication according to Health Care National System recommendations)[10] were singularly discussed to create a co-shared waiting list between hub and spokes.

For what concern vascular diseases, the ones that deserve a non-deferrable vascular intervention were identified and inspired by the "Elective Case Triage Guidelines for Surgical Case" edited by the American College of Surgeon[11] *(tab. I)*.

All urgent and scheduled patients were preoperatively tested with a nasopharyngeal swab and/or a thorax CT scan. In case of emergency surgery, the patient was considered and treated as infected until the results of a complete screening were obtained.

A color-based triage was applied: red tag for COVID affected patients, yellow tag for patients with pending COVID test, and green tag for patient resulted negative at the swab test. Separate track and in-hospital stays were instituted to assure a safe pathway for non-COVID patients from admittance to discharge. Red, yellow, and green wards and ICU units were set up.

All preoperative and perioperative variables were collected and summarized in table III-IV-VI, including referral center and transfer time for acute peripheral ischemia. Patients who underwent evaluation but who were discarded for surgery were collected separately, signaling the reason for the exclusion.

Data entry was managed by physicians directly involved in patients' care. Records were recorded and analyzed with Microsoft Excel (Microsoft Corp, Redmond, Wash). Continuous variables were tested for normality using the Shapiro-Wilk's test. Variables that were normally distributed are presented as means ±standard deviation (SD) and their range; otherwise they are presented as median and interquartile range (IQR). Categorical variables are presented as frequencies and percentages. Categorical variables were analyzed using a chi-square test or Fisher's exact test where necessary. An independent samples Student's T-test was used for continuous variables. All reported P values are 2-sided; a P value <0.05 is considered significant.

RESULTS

A total of 100 patients were evaluated at our HUB hospital during the period considered (16th of March - 16th of April 2020). The geographical origin of patients directly admitted to the Hub center or transferred from other spokes and local hospitals is shown in figure 1. Demographics, comorbidities, risk factors, and type of disease suffered, classified by specialty, are reported in Table II and III.

VASCULAR SURGERY

The majority of patients (n. 70/100, 70%), were of vascular surgical competence. Between them, 19 pts (27.1%) presented positive swab for COVID-19 while in 8 patients (11.4%), the swab was negative, but chest X-ray and/or CT scan were pathognomonic for Covid-19 infection. Interstitial pneumonia was documented in 26 patients (37.1%). 27 patients (38.6%) were transferred from other spokes or other hospital, of which 19 (27.1%) were urgent or emergent. Acute and chronic limb ischemia (Rutherford stage IV-V-VI) were the most observed diseases with an incidence of 28 (40.0%) and 23 (32.9%), respectively. Fifteen patients (21.4%) did not undergo intervention, characteristics and reason for non-intervention indication are listed in table IV. Unsuccessful revascularization, reinterventions and readmissions are listed in table V. In-hospital overall mortality was 14,5 % (8/55), with a 12.7% (7/55) in COVID+ patients and a 1,8% (1/55) in non-infected patients. Perioperative characteristics population are listed in table V.

CARDIAC SURGERY

Cardiac surgery Hub evaluated 30 patients during the first 30 days of activity, 24 (80.0%) of them underwent surgery. Preoperative and perioperative characteristics

are reported in tables III-V. None of the treated patients resulted positive at Sars-COV19 test. The most frequent pathology was coronary artery disease (n. 10, 34.5%), followed by valvulopathy (n.9, 31.1%), endocarditis (n. 2, 6.9%) and thoracic aorta disease (n. 1, 3,5%). Emergency cases represented 13.8% (n.4) of the total, while urgent and not deferrable operations were 41.4% (n.12) and 27.85% (8), respectively. Thirteen patients (54,2%) were transferred from other hospitals. Total in-hospital mortality was 0.0%, no ECMO implantation was necessary. The majority of treated patients were discharged to rehabilitation centers (87.5%). Six patients were discarded from surgery due to prohibitive risk (tab.IV). Two Spoke centers out of 5 had treated a total of five not transferrable emergencies: three patients affected by aortic dissections, one patient with acute endocarditis and hemodynamic instability, one patient with severe cardiac tamponade.

DISCUSSION

The devastating impact of COVID 19 infection in our area, forced the RHCS to arrange an emergency plan to face the pandemic. The majority of regional hospitals were converted entirely to the treatment of COVID patients; as a consequence, all other activities had to be reorganized. Hub-spoke network had been applied to all the major critical areas as trauma, stroke, and myocardial infarction. As far as we know, our region is the first European region to re-arrange the cardio-vascular emergency/urgent network to face the pandemic. In particular the geographical

area covered by our Hub and spoke networks has been the most affected by the pandemic with more than 39.000 confirmed case of Sars-Cov19 infection.

CARDIAC SURGERY

Despite the administrative and logistic difficulties to establish real cooperation between private and public hospitals, the realization of the hub-spoke network had been successful. Reorganizing human and logistic resources took a few days. Nevertheless, all the patients had always found a hospital ready to treat their urgent and emergent pathology regardless of their admittance origin. Furthermore, real cooperation between core and referral centers, difficult to believe since a couple a months ago, has permitted to evaluate and treat also patients with a not deferrable disease, avoiding the worsening of their clinical conditions. In case of not transferrable emergencies, the presence of an on-call team in the spoke center seemed to be useful as happened in five cardiac surgery cases during the analyzed period.

Preoperative COVID screening and subsequent hospital areas and pathways separation has permitted to guarantee patients' safety. No one of the treated cases admitted as COVID-free became later infected, demonstrating substantial adequacy of our safety measure applied.

A further demonstration of efficacy and safety of the hub role is represented by the zero in-hospital mortality achieved in the first 30-days of our cardiac surgery activity. This is absolutely comparable with the high standard results of the previous years.

Non-COVID patients can be treated with no adjunctive risks if all the safety protocols to separate pathways and areas are applied [12]. In cardiac surgery, we showed an important reduction of urgent cases compared to the same period in 2019 in the same area. This impression is confirmed by the data published by others about acute coronary syndromes and cardiovascular pathologies diagnosis during the sars-cov19 pandemic [13,14,15,16]

VASCULAR SURGERY

For what concerns the vascular surgery side, we did not observe a complete flattening of activity at the spokes as expected. To the 34 confirmed surgical interventions performed during the study period at spoke centers, we should probably add the ones that were not disclosed by other affiliated institutions. This scenario could be explained by some reasons, including the one that, historically, vascular pathology is more widespread among the population and associated with a higher incidence of urgency and emergency than cardiac surgery one. As a consequence, some necessary interventions were performed at the spoke centers; nonetheless, the mean number of surgical procedures by spokes was low (7patients/center). Some patients, especially those affected by acute and critical limb ischemia (a total of 30) with severe pneumonia COVID related, could not be transferred from spoke centers due to their severe general condition. In this context, the presence at the spokes of vascular surgeons available for other urgent/emergent networks such as stroke and trauma led to easier management of non-transportable vascular emergencies. Another non-negligible aspect was

represented by the critical organization of transport to the HUB center due to the reduced availability of ambulances during the peak of the pandemic; this is highlighted by observing a protracted time of transfer (median 90 minutes, with a median distance of 55 km). In general, although available data are partial, we had seen a reduction of elective surgical activity compared to the same period of 2019. The main finding after the first 30-days experience of our Institution as a Hub for vascular disease is a significant increase of incidence of urgent interventions especially of acute limb ischemia (ALI) compared to the pre-COVID era. The boost of emergency department access for ALI during the pandemic could be interpreted by a hypercoagulability state of patients affected by this viral infection. Recently published studies showed an abnormal increase of coagulation and cardiac biomarkers in COVID-19 patients, which reflects an inflammatory status characterized by coagulation activation and endothelium dysfunction [17, 18, 19]. This hypercoagulability state leads to a recurrence of arterial and deep venous thrombosis refractory to anticoagulant prophylaxis [20] and, in our series, to surgical intervention. Correlation between coagulation disorders and failure of peripheral arterial revascularization is well known[21] and could explain our disappointing rate of success (23% of all interventions of which 77,8 in COVID + patients). In our experience, we had good results in term of revascularization by adopting a more aggressive therapeutic attitude with intraoperative thrombolysis and postoperative infusion of heparin as proposed in our recently published protocol[22]. Lastly, overall in-hospital mortality was high, especially for patients with concomitant COVID 19

infection; however, the mortality rate of non-infected patients was comparable to the non-COVID era.

CONCLUSION

The impact of this pandemic on our region has overwhelmed the sanitary system and constrained RHCS to a rapid and effective reaction. The development of a Hub and spoke model to ensure the treatment of urgent and emergent diseases was complex and not free from obstacles. However, this health crisis leads public and private Institutions to total cooperation to achieve the objective.

Results from our preliminary experience are encouraging and support the fact that hub and spoke network for cardiovascular disease was functional and adequate to face epidemic emergency. Further considerations could be made only at the end of the pandemic.

LIMITATIONS

Despite the extension of our area of interest, further national and international studies with more extensive data collection are necessary.

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285 **FIGURES**

286 FIG.1 – HUB & SPOKE network East Lombardy, ITALY

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288 **TABLES**

289 TABLE I. Cardiovascular Surgery HUB center Indication in COVID pandemia period

290 TABLE II. CARDIAC SURGERY - Preoperative Population Characteristics

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292 TABLE IV. NOT TREATED PATIENTS – Patients discarded from surgery according

293 Hub center COVID pandemic criteria

294 TABLE V. HUB-SPOKES SURGERY RESULTS - Perioperative Population

295 Characteristics

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