COVID-19 OUTBREAK IN NORTHERN ITALY: VIEWPOINT OF THE MILAN AREA SURGICAL COMMUNITY

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SUMMARY

In February 2020, 2019 novel coronavirus (2019-nCoV) outbreak put the whole health system of Lombardy (Northern Italy) under severe pressure. The system response was immediate, nevertheless the aggressiveness of the infection causing severe acute respiratory syndrome with immediate need of hundreds of ICU beds exceeded surge capacity. The impact on surgical activities has been massive and surgeons had to deal with several problems, such as cancelling surgical lists, supporting other medical areas, putting in place operating rooms dedicated to 2019-nCoV and setting up COVID-19 specific pathways. In the following weeks the infection rate has been growing exponentially and spread to the rest of the Country. Restrictive measures to contain the infection have been undertaken from the Regional Government and soon after by the National Government; at this moment in time the peak of the infection has not been reached and the health system is still under pressure. On March 11, 2020 the World Health Organization declared coronavirus as pandemic; surgeons should be therefore aware on the impact of this virus on surgical activities.

COVID-19 OUTBREAK IN NORTHERN ITALY

The first Italian case of a patient tested positive for 2019 novel coronavirus has been reported in Codogno Hospital (Lodi, Lombardy, Italy) on February 20, 2020; the patient was a healthy 38 years old man who developed severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2). Within 24 hours, 36 new cases were reported in the Codogno and Lodi area and although a containment strategy, through constitution of a "red zone" with mobility restrictions was established by Regional authorities, due to secondary clusters, the outbreak of the COVID-19 was not stopped and the virus spread all over Northern Italy and the rest of the Country (Fig. 1). Due to the rapid growth of the infection, associated to pneumonia causing serious hypoxic respiratory failure, a low threshold for assisted ventilation, intubation and mechanical ventilation was needed. On March 12, 2020, three weeks after Case N. 1, the total number of COVID-19 positive patients in Italy was 12.839 and 1.153 patients were admitted in ICU (8,9%) while 6650 patients needed to be admitted to hospital (51%) (Graph. 1).

From the beginning of the outbreak it has been immediately clear that the major problem was related to ICU surge capacity. With a population of 10 million people Lombardy is one of the richest region in Italy and probably in Europe, nevertheless the health system went soon under pressure. As reported by Grasselli and others¹ in Lombardy, the precrisis total ICU capacity was approximately 720 beds (2.9% of total hospital beds at a total of 74 hospitals) with a 85% to 90% occupancy during winter months; furthermore another challenge was represented by the need of a high number of hospital beds for patients with respiratory symptoms not needing immediate mechanical ventilation.

Another critical key-point was represented by the massive overload of patients in the Emergency Department and consequent necessity to redesign the infrastructures and dedicated pathways for potentially COVID19 positive patients.

Under the coordination of the Regional Emergency Task Force the response to ICU surge was immediate and in 48 hours the first new ICU beds were provided while in the following 10 days other 200 staffed ICU beds were available. In total, over the first 18 days, the network created 482 beds¹.

The exponential ICU and standard hospital beds demand and the massive overload of patients in the emergency department exceeding each hospital capacity had an enormous impact on surgical activities affecting all specialities.

IMPACT ON SURGICAL COMMUNITY

At this moment in time we are convinced that the surgical community should be aware of the consequences of 2019-nCoV outbreak.

Hospital and health system resources high demand due to an uncontrolled outbreak, such as the one we observed with the 2019-nCoV burst, affected the surgical community mainly in different ways (Fig. 2):

- Cancellation of unnecessary immediate surgery.
- Shortage of blood components.

- Shift of surgeons in other areas rather than operating theater, outpatient clinic and patient care
 in the surgical wards.
- Limit visitors to patients.
- Need to setup dedicated operating theaters for COVID-19 positive.
- Creation of specific pathways for suspected COVID-19 positive patients with surgical needs.
- Postoperative surgical care.

CANCELLATION OF UNNECESSARY SURGERY

In order to increase ICU surge capacity the demand, in terms of ventilators, qualified nurse staff, anesthesiologists and intensivists, is very high and unnecessary scheduled surgery must be cancelled. Under the coordination of the Regional authorities and the emergency task force this hard choice has been imposed to all hospitals in Lombardy. In some hospitals surgical blocks have been set up together with dedicated COVID-19 pathways.

As suggested by Cecconi and others in the website of the European Society for Intensive Care Medicine (ESICM), at this stage it is very important not to work "in silo", but in coordination with hospital management and all healthcare professionals².

In our experience the rapid endemic escalation required an immediate response from the Regional Emergency Task Force, but the cancellation of surgical and interventional procedures aroused many concerns especially in specific areas such as oncologic and cardiovascular surgery; nevertheless, the lack of blood components and available ICU beds for major oncologic and

cardiovascular surgery forced each hospital to select carefully the patients. Regarding surgical oncology for example the selection criteria were surgery planned after neoadjuvant chemotherapy, borderline resectable cancers, etc.).

In order to avoid a complete cessation of oncological and cardiovascular procedures whose delay could have been harmful for the patients care, the Regional Emergency Task Force designed a Hub system diverting these patients to dedicated hospitals. This was different from other published experience in Asia³. For time dependent diseases and related networks, like trauma, stroke, cardiovascular surgery and coronary disease, systems were redesigned, in order to limit the access of patients potentially requiring ICU in the hospitals overcrowded by SARS-Cov2.

The infection containment policy and restrictive traffic mobility caused a reduction in terms of motor-vehicle accidents, nevertheless the hub and spoke trauma system has been strengthened in order to concentrate injured patients in the three Level I trauma centers of the Region. The Hub system that was set in place in Lombardy required to transfer surgeons from one hospital to another in order to balance the staff resources and direct agreements between each hospital administrations were signed under the coordination of the Regional Emergency Task Force. Since at present time this Hub system has just been set in place we still have no data regarding the real effectiveness of the network. Similar plans were established for the stroke, cardiology and cardiovascular surgery networks.

SHORTAGE OF BLOOD COMPONENTS

One of the most unexpected scenarios linked to the Northern Italy COVID-19 outbreak was represented by immediate shortage of blood components due to lack of blood donations. Although we do not have clear data about this issue the estimation, generally reported from many centers, was reported to be about a reduction, in terms of donation, of about 70%. This might be explained to forced containment measures with mobility restrictions and fear of usual donors to get infected.

Regarding this scenario the main concerns were related at the early stage of the outbreak, but afterwards, with the forced decrease of major surgery the blood components shortage had less impact. The awareness of this problem entailed the launch of media campaign, that seems to have partially overcome the lack of blood resources.

SHIFT OF SURGEONS IN OTHER MEDICAL SPECIALTIES

The high demands of medical personnel in the emergency departments and in medical wards dedicated to COVID19 positive on one hand and the reduced surgical elective activity on the other allowed to reallocate surgeons in other areas rather than in the OR.

In Italy and in Europe in general very few surgeons have a surgical critical care background, therefore most of the surgeons were assigned to treat and assist non critical patients. In some hospitals short educational sessions on how to use effectively personal protection equipment (PPE) and on medical treatment and observation of COVID-19 positive or suspected patients were set in place. Following simple, but quite strict pathways (Fig. 3) for suspected COVID-19

patients have been extremely useful. Surgeons skilled in lung point-of-care ultrasound resulted also to be helpful to identify patients needing thoracic CT-scan. In some hospitals, surgeons received basic education in the use of non-invasive ventilation and as far as we know many of them have been happy to learn. Regional Agency for Emergency Education of Lombardy also started to organize wandering one-day courses for improving skills of non-intensivists.

LIMIT VISITORS TO PATIENTS

Due to need of containment and self quarantine policy, visits to patients should be strictly limited to *end of life* situations, therefore patients' relatives should be contacted by phone; this means that a communicative organizational model should be set in place, for example, through dedicated phone lines. Once more, non-technical skills play a major role and this issue need to be focused very soon. We would recommend assigning this task to senior surgeons with good communicative skills.

DEDICATED OPERATING ROOM SET UP FOR COVID-19 POSITIVE PATIENTS

Due to the sudden and extended 2019-nCoV burst one of the main worries among the Northern Italian and soon after, among the Italian surgical community was related to the criteria on how to set up a dedicated OR for COVID-19 positive patients requiring surgery and in particular requiring unscheduled cases such as emergency surgery. At the moment there are just few reports with almost anedoctal experiences. The issue regarding the need of dedicated area and specific pathways affected many differente areas of our hospitals, such as radiology department, endoscopy department⁴ and, of course emergency department. It's clear that a *one-size-fits-all* solutions is not possible due to different logistic in each hospital, but also based on the

experience of other colleagues from China and Singapore^{3, 4, 5} we agreed on some basic keypoints:

- 1. Negative pressure OR, with high rate of air changes (>20 full volume replacements/h)
- 2. Understanding the airflow within the OR is crucial to minimize the risk of the infections
- 3. Full protection with PPE
- 4. Separate in/out access for all confirmed or suspected positive COVID-19 patients, including recovery room
- 5. Disposable plastic sheet protection of OR equipment (ventilators, ultrasound machines, LAP rack, laptop, etc), whenever possible
- 6. Careful handling of clinical documentation (limiting paper needs in OR)
- 7. Limiting personnel entrance/exit from the OR during the procedure
- 8. An established protocol for cleaning of OR, equipment and ventilators (hydrogen peroxide vaporizer should be used)
- 9. An extensive and paranoid use of checklists and step by step instructions
- 10. A detailed description of transfer of patient to/from OR.

To our experience many concerns regarding the correct use PPE were raised by medical and nursing staff and at the beginning of the outbreak we did not have clear rules on the correct level of protection to use in order to reduce exposure to hazards potentially causing workplace injuries and illnesses.

Based on the current knowledge on the transmission of COVID-19, in which respiratory droplets seem to play a major role (although airborne transmission cannot be ruled out at this stage), at this stage we decided to follow the indications of the European Centre for Disease Prevention and Control (ECDC)⁶; according to ECDC the ideal set of PPE for droplet, contact and airborne transmission is represented by gloves, goggles, gown and FFP2/FFP3 respirator mask. Since some hospitals ran quite early out of stock of PPE, we recommend a rational use of PPE. To this purpose simple but clear infographics and designated areas for donning and doffing procedures. In general, FFP2/FFP3 respirator mask can be used continuously for 4 hours and then need to be changed, unless the manufacturer explicitly advises differently. Male should have their face shaved in order to guarantee adequate mask to face sealing.

Educational and training are important and personnel assisting during donning and doffing procedures is very helpful to avoid droplets.

CREATION OF SPECIFIC PATHWAYS FOR SUSPECTED COVID-19 POSITIVE PATIENTS

Simple, but strict triage protocol to identify suspected patients in order to guide them to the right cohort were generally already established in the emergency department, nevertheless, due to high COVID-19 infection rate among asymptomatic population a screening of candidate to surgery must be setup (Fig. 4).

In case of emergency general surgery cases a rapid identification of the right cohort of patients is of paramount importance to decrease the risk of disease transmission to healthcare professionals and to other patients; due to overload of cases sometimes the result of 2019-nCoV test takes too much time, while COVID-19 pathognomonic signs on chest CT-scan might be very helpful to identify correctly asymptomatic patients with 2019-nCoV related pneumonia. Use of CT-scan to rule out negative patients might be therefore extremely useful in patients with emergency surgery procedures demands. In such patients a 2019-nCoV test is of course requested thereafter. The radiological findings at thoracic CT-scan are bilateral in 98% of patients and are typically represented by subpleural distribution of the pneumonia with a *ground-glass* pattern (Fig. 5).

POSTOPERATIVE CARE

To our experience postoperative monitoring of any patients operated on during COVID-19 outbreak is paramount, even if deemed "COVID-19 free". Surgical trauma can suddenly disclose the disease in an otherwise asymptomatic patient. Any mild respiratory related symptom (tachypnea, desaturation, etc.) should be immediately addressed. A low threshold for continuous vital signs monitoring is advised and underestimation should be avoided.

CONCLUSION

The Northern Italy COVID-19 outbreak put a strain on health resources. ICU, medical wards and emergency departments surge response needs forced the whole health system to retrieve extra medical equipment and re-allocate medical and nursing staff resources. Time pressure and decision making in such scenario is very important and surgical community should take leadership immediately in their respective institutes and get ready to swift and offer their competences outside their comfort zone. It's important to set clear goals and actions and plans

should be set in place with other specialities, but in sync with human resources team and and hospital management.

Setting up simple surgical pathways, checklists and educational model beyond a new assessment of dedicated OR are hard tasks that should be accomplished under the leadership of the local surgical community.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Fig. 1: Total number of COVID-19 cases diagnosed by the Italian Regional Reference Laboratories by regions (*Update of March 15, 2020. Source Istituto Superiore di Sanità*)

Graph. 1: COVID-19 cases growth in Italy

Fig. 2: Impact of COVID-19 on surgical activities

Fig. 3: COVID-19 triage

Fig. 4: Emergency surgery pathway during COVID-19 outbreak

Fig. 5: Radiological findings of 2019-nCoV related pneumonia on chest CT-scan (A: typical ground glass pattern; B: generally subpleural signs and in 98% of cases with a bilateral distribution)

Figure 1

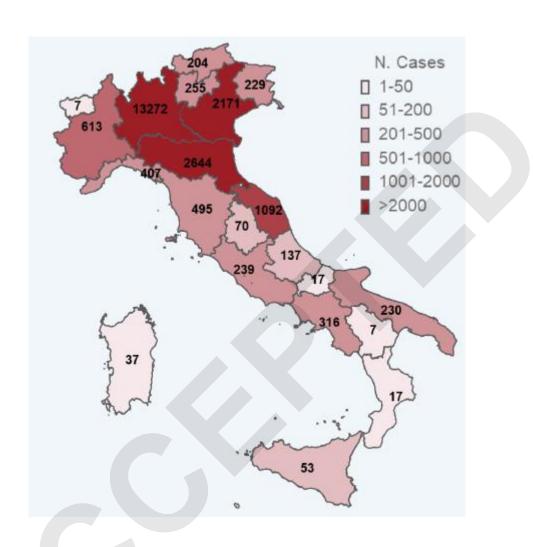


Figure 2

CANCELLATION OF SCHEDULED SURGERY

Unnecessary surgery should be cancelled in order to increase surge capacity





SHORTAGE OF BLOOD COMPONENTS

Less donations due to containment and fear to get infected

POSTOPERATIVE SURGICAL CARE

COVID-19 respiratory complications might occur postoperatively



IMPACT ON SURGERY DURING COVID-19 OUTBREAK IN NORTHERN ITALY



Surge capacity needs and decrease of surgical activity shift surgeons to other area

SHIFT OF SURGEONS TO OTHER



COVID-19 SURGICAL PATHWAY

Specific pathway to correctly cohort suspected COVID-19 patients



LIMIT VISITORS TIME

Communication system must be set in place to communicate with patients' relatives



Need to set up an O.R. for COVID-19 positive patients



Figure 3

COVID-19 TRIAGE

Identify COVID-19 patients with no need of hospital admission

Establish pathways for patients with respiratory failure

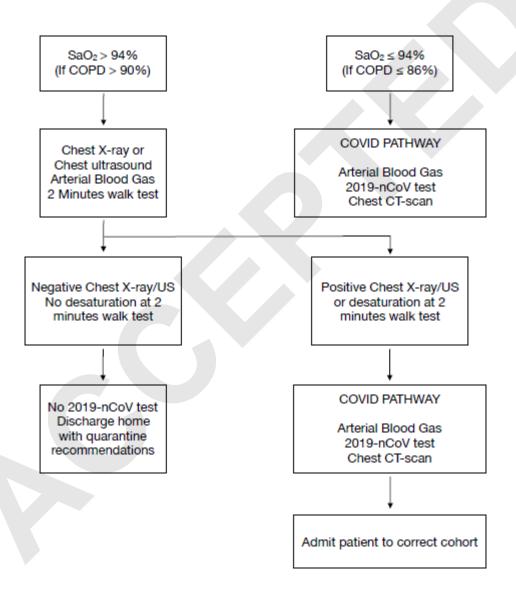


Figure 4

EMERGENCY SURGERY PATHWAY DURING COVID-19 OUTBREAK

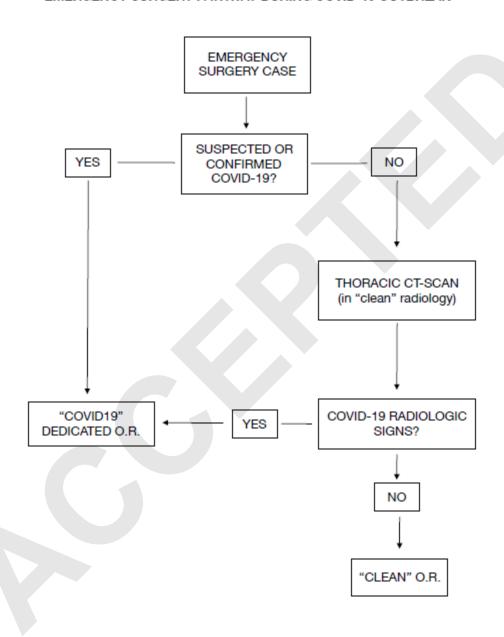
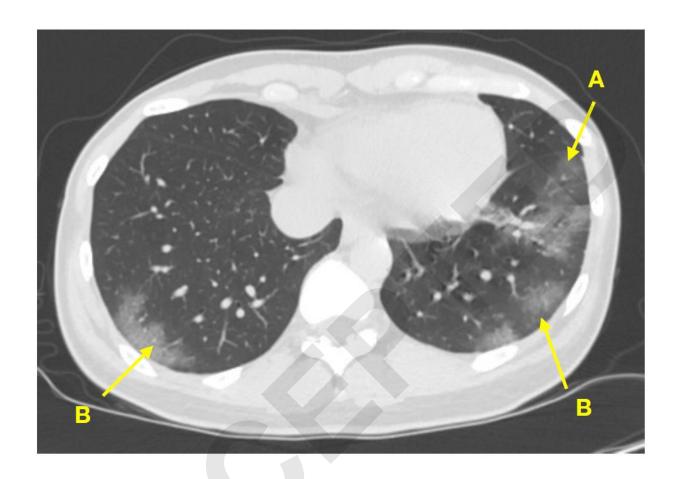


Figure 5



Graph 1

