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Spine Surgery in Italy in the COVID-19 Era: Proposal for Assessing and Responding to the Regional State of Emergency

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In December 2019, coronavirus disease 2019 (COVID-19) was discovered in Wuhan, Hubei province, from where it spread rapidly worldwide. COVID-19 characteristics (increased infectivity, rapid spread, and general population susceptibility) pose a great challenge to hospitals. Infectious disease, pulmonology, and intensive care units have been strengthened and expanded. All other specialties have been compelled to suspend or reduce clinical and elective surgical activities. The profound effects on spine surgery call for systematic approaches to optimizing the diagnosis and treatment of spinal diseases. Based on the experience of one Italian region, we draw an archetype for assessing the current and predicted level of stress in the health care system, with the aim of enabling hospitals to make better decisions during the pandemic. Further, we provide a framework that may help guide strategies for adapting surgical spine care to the conditions of epidemic surae.

INTRODUCTION

oronavirus disease 2019 (COVID-19) can cause the severe acute respiratory syndrome coronavirus 2 and represents a potentially fatal disease of enormous public health importance. By the time of the World Health Organization classification of the novel coronavirus as a global pandemic,¹ many hospitals in northern Italy were already overcrowded by patients with COVID-19, especially intensive care units (ICUs), in which about 50% of all available beds were occupied by patients with COVID-19.² Physicians from specialties beyond infectious or respiratory diseases, including neurosurgery, were reassigned to the new COVID wards to rationalize the use of resources.³ The COVID-19 pandemic has forced hospitals to progressively reduce surgical volume, both to minimize disease transmission within the hospital and to preserve human resources and personal protective equipment (PPE) and other resources needed to care for patients with COVID-19.⁴

As the COVID-19 burden on hospitals increased, Italian health care services responded with new procedures. These procedures include postponing elective surgical procedures until a more appropriate time, putting in place strategies to ensure urgent/ emergency operations during the pandemic, defining type of hospital and the assistance pathways, designating COVID-19 operating rooms for urgent procedures with guidance information posted conspicuously to all professionals, ensuring systematic and correct use of appropriate PPE, controlling and limiting the number of patients' visitors, developing support strategies for health care professionals, and treating outpatients through telemedicine (teleorientation, telemonitoring, and teleinterconsultation).⁵

Although the severe acute respiratory syndrome coronavirus 2 virus and its expression as COVID-19 do not seem to affect the spinal cord or peripheral nerves, except in rare cases,^{6,7} the disease affects spine surgeons and their patients as a consequence of the overall reorganization of health care outlined earlier. Therefore, it is essential to formulate initiatives to help patients and health care professionals face this challenging situation.

In the context of the pandemic, most surgical spine procedures do not require intensive care⁸ and the suspension of elective surgeries seems to have a relatively minor impact on ICU capacity.⁹ Because of uncertainty about the future severity of the outbreak, there is no reliable timeline for the normalization of elective surgical scheduling; estimates range from several weeks to months or longer.¹⁰

Key words

- COVID-19
- Emergency
- Making decision
- Spine surgery

Abbreviations and Acronyms

COVID-19: Coronavirus disease 2019 FVG: Friuli Venezia Giulia ICU: Intensive care unit PPE: Personal protective equipment From the ¹Section of Spine and Spinal Cord Surgery, Department of Neurological Sciences, Presidio Ospedaliero SMM, Udine; ²Tactile Perception and Learning Laboratory, International School for Advanced Studies (SISSA), Trieste; and ³Regional Spine Department, Azienda Ospedaliero-Universitaria Integrata, Verona, Italy

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The Lombardy Regional Council, situated at the core of the Italian COVID-19 pandemic, decided to reshape the health care system by concentrating all neurosurgical activities that could not be postponed into 4 neurosurgical hub hospitals. Three hub hospitals guarantee 24/7 acceptance of emergency cases. The 3 hospitals were chosen on geographic bases; all other departments have been assigned to 1 of the 3 hubs as a spoke. The fourth hub hospital, the regional neuro-oncologic center, has been reallocated for urgent oncologic patients coming from all other departments in the region.¹¹ This is an example of how a regional health system, overwhelmed by the epidemic wave, reorganized the totality of its hospitals.

Hospitals in Friuli Venezia Giulia (FVG) responded to the COVID-19 pandemic quickly. On March 9, 2020, the prime minister of Italy issued the rules of a strict lockdown for all regions without distinction. To increase hospital capacity for future patients with COVID-19, the FVG health system director on March 11 limited elective surgery in general; in particular, elective spine surgery was completely suspended. Outpatient access was also reduced: thereafter, only urgent and priority B outpatients could access the medical practice. Self-sufficient patients were required to come unaccompanied. Our unit was permitted to perform only urgent spine surgical procedures, such as spinal trauma and emergency spinal oncologic pathology with rapidly evolving spinal cord or roots compression.¹²

In the remainder of this report, we assess trends in the spread of the infection and the pressure that it generates on the health care system, proposing a modus agendi for optimizing surgical activity. Specifically, we report a program to adapt surgical spine care to the ongoing, objectively measured stage of epidemic surge.

METHODS

Setting

The University Hospital of Udine is located in the immediate outskirts of Udine and is a hub medical center of the FVG region. It is associated with the Medical Faculty of the University of Udine. FVG, with 1,215,000 inhabitants, is bordered to the east by Slovenia and to the north by Austria. The hospital has a capacity of 700 beds, 26 of which are ICU beds. The Spine and Spinal Surgery Unit is the only spine-specialized clinic in the region. It is composed of 6 neurosurgeons, 2 of whom are also orthopedic surgeons. An average of 4800 outpatients are evaluated and about 300 surgical procedures are performed per year.

Alert Levels

Our approach is to create a scheme in which the health care authorities can rapidly assess the state of the system and provide indications to the surgery clinics in real time. We define 3 alert levels of the health care system (green, yellow, and red) and identify the surgical procedures appropriate to be undertaken at each level. Our view is that 2 readily available parameters (intensive care occupancy and the estimated doubling time of the number of infected persons) offer the means to compute the stress level of the health care system. These parameters are plotted along with boundaries that are proposed to divide the space into green, yellow, and red alert levels.

First, intensive care occupancy (the number of patients with COVID-19 in ICU divided by the number of beds available in ICU under normal conditions) is a proxy for the current level of resources dedicated to patients with COVID-19. As the occupancy increases, from left to right along the green to yellow to red gradient, the health care system is under increasing stress and is less able to allot resources to non-COVID-19 functions. We used ICU occupancy in the index because it is a readily accessible measure that correlates closely with overall health system stress, because of the enormous demand on personnel and material resources associated with each individual ICU patient.

Second is the doubling time of viral-positive patients in the service region of the hospital. This measure, easily computed from the daily counts of new positive swabs, gives the steepness of viral spread and offers predictive power for the coming week. A forward projection of this kind is essential in planning resource distribution. Doubling time is a preferred measure with respect to the commonly used R_e (effective reproduction number) in that the latter does not have units of time and thus does not offer a forecast of the change in patient population for future time points of interest. R_e sheds light on the expected change in number of infected persons but, unlike doubling time, fails to give a time scale for that change. In Figure 1, as the doubling time decreases, from bottom to top along the green to yellow to red gradient, the health care system can expect increasing future stress and is therefore less able to allot resources to non-COVID-19 functions.

To show the case of the FVG region, the number of new positive cases was acquired daily from the data released by the Protezione Civile.¹³ Doubling time, T_d , in units of days, is

$$T_d = \frac{\ln (2)}{\ln(1 + r/100)} \qquad \qquad \text{Eq. (1)}$$

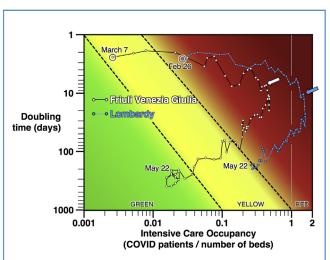


Figure 1. Classification scheme for health care system adaptation to epidemic. Three alert levels (green, yellow, and red) are proposed on the basis of joint values of 2 parameters, intensive care unit occupancy (*abscissa*), and estimated doubling time of the number of infected persons (*ordinate*). The data from the Fruli Venezia Giulia region during the COVID-19 epidemic of 2020 are plotted (*white points*) from March 7 until May 22 and from the Lombardy region (*blue points*) from February 26 until May 22. *Arrows* indicate crisis peaks on March 27 in Fruli Venezia Giulia and March 26 in Lombardy.

where r is daily growth in percent of patients. Analyses can be easily carried out in any statistics software; we used Excel (Microsoft, Redmond, Washington, USA).

The doubling time measure is largely independent of regional differences in the policy or availability of COVID-19 testing. Two service areas with different testing regimes will each detect some percentage of the true carriers in their respective regions. Doubling time within both service areas is sensitive to changes in the regional daily number of detected positive results and accurately charts the projected spread of the virus, notwithstanding differences in testing across regions. A change in testing policy or capacity within a service area does not affect the derived doubling time if the change is effected at a slower time scale than the day-to-day count that yields the doubling time.

Because of the large orders-of-magnitude ranges covered by the data, it is convenient to assess the health care system status using logarithmic scales. The alert level boundaries intersect at occupancy levels of 0.1 (green/yellow) and 1.0 (yellow/red). On the ordinate, the green/yellow alert level boundary intersects at doubling time of 1 day.

The data used for each point are averaged across the previous 3 days (current date included) to smooth away daily fluctuations and to make temporal trends more reliable. In the FVG region, the baseline count of ICU beds is 127.¹⁴ Occupancy of ICU beds was acquired from https://covstat.it/analisi-regioni/#trasmissione-varie-regioni.² Note that our scheme allows occupancy to

surpass 1.0. This seemingly paradoxic situation occurs when the health system builds new ICU facilities in response to epidemic conditions, as occurred in Lombardy. When occupancy of ICU beds by patients with COVID-19 is \geq 1.0, the alert level is, by definition, red.

Decision-Making Grid for Spine Surgery

The proposed decision-making grid for spine surgery, shown in **Table 1**, considers cause of spinal diseases and clinical presentation in relation to alert levels. The cause of spinal diseases is divided into trauma, bone tumors and metastases, intradural tumors, infections, and degenerative diseases. Clinical presentation is defined by spinal cord and/or roots acute compression; spinal cord and/or roots impending or chronic but progressive compression, intractable pain, impending deformity; absent or stable neurologic deficits, absent or minimum pain. By defining these 3 variants, we obtain a dynamic algorithm that can modulate spine surgical activities during the COVID-19 pandemic.

RESULTS

The alert level data points relative to the FVG region of northeast Italy are shown in white points in **Figure 1** for the period extending from March 7 until May 22. By connecting the points to form a trajectory, the dynamics of classification are highlighted. From

	Red: Spinal Cord and/or Roots Acute Compression	Yellow: Spinal Cord and/or Roots Impending or Chronic but Progressive Compression, Intractable Pain, Impending Deformity	Green: Absent or Stable Neurologic Deficits, Absent or Minimum Pain
Trauma	Dislocation and fractures with neurologic characteristics	Fractures without neurologic deficits, pseudarthrosis	Posttraumatic deformities
Bone tumors, metastases	Pathologic fracture-dislocation, epidural compression, neoadjuvant therapeutic window or nonradiochemosensitive bone tumors	Pathologic or impending fractures, instability without spinal cord roots compression	Unique intrasomatic metastases
Intradural tumors	With signs of cord/roots compression, intramedullary	Slow growing tumors	Small tumors without signs of cord/roots compression
Infections	Abscess, wound infection	Spinal infection that fails to respond to medical management	Chronic spinal infection not responsive to therapy, postinfective deformities
Degenerative/ others	Cauda equina syndrome, rapidly progressive myelopathy, epidural hematomas	Pediatric evolutive scoliosis; cervical or thoracic stenosis; cervical or thoracic median herniated disc; mobile, misplaced, failed hardware; spinal conditions causing intractable pain, severe functional limitations and/or excessive opioid use	ldiopathic scoliosis, degenerative deformities

Table 1 Spine Surgery Apress Red/Vallow/Groop Alert Lovals Relationship Retwoop Clinical Presentation Course and Alert Lovals

March 4 to 7, the number of cases increased from 18 to 42, giving an average increase of 33% per day. This result translates to a doubling time of 2.41 days on March 7. With just 1 of the region's 127 ICU beds occupied by patients with COVID, the computed occupancy rate was low. Yet, by virtue of the extremely fast doubling time, an alert level of yellow was appropriate. The rapid spread rate in this earliest stage of the epidemic predicted precipitous increase in the occupancy of the ICU. On March 10, the alert level became red because of the still-rapid doubling time (2 days) together with the increasing occupancy of ICU beds (now 3%). After March 10, there was a modest increase in doubling time (slowing of spread) but a rapid increase in ICU occupation, as predicted by the preceding doubling time. The decisive rightward trajectory brought the crisis to a peak (arrow) on March 27, when doubling time was 7.3 days and ICU occupancy was 43%. In our proposed system, peak is defined as the greatest distance from the yellow/red boundary.

From March 27, the doubling time increased steeply, reaching 16 days on April 1. The increase in doubling predicted a successive reduction in the number of ICU patients. When the expected reduction in ICU stress occurred, it was visible as the long, leftward trajectory that brought the alert level from red to yellow to green. From April 1 to 17, ICU occupancy decreased from 48% to 10%. By the end of the data set (May 22), occupancy was at around 2% and the doubling time was around 250-300 days. In this seemingly stable positioning within the green alert level, the surgical ward may follow the given indications (Table 1) and remain vigilant for trends that might predict regression toward crisis. As a measure of the generality of the alert level classification, we plotted the data obtained from the Lombardy region from February 26 to May 22. At the outset, the red alert level was appropriate because, even with ICU occupancy at only 3%, the doubling time of 2.5 days forecast upcoming stress. As predicted, the ICU occupancy then increased sharply. The trajectory penetrated more deeply into the red zone than that of FVG, with ICU occupancy exceeding 100% as new beds were created in response to the crisis. The red alert level persisted until reentering the yellow level in late May.

Although the boundaries separating the 3 levels might seem arbitrary, the trajectories of FVG and Lombardy show how a framework combining objective data (ICU occupancy and virus spread rate) with experience-based alert levels set according to the subjective stress of the health care system can effectively guide the day-by-day clinical choices.

Surgical Activity Under COVID-19

The proposal for prioritizing surgical activities in relation to health care system alert levels is given in **Table 1**. In FVG, spine surgery practice during the red alert level pandemic (March 10–April 20) was curtailed to urgent care, in an effort to reduce risk of disease transmission and to prevent shortage of valuable resources. During this period, we performed 18 surgical procedures, subdivided by cause as follows: 8 trauma, 6 oncologic, 3 degenerative, and 1 wound dehiscence. All these patients were admitted urgently because of the onset with neurologic deficits and, in 1 case, for early signs of infection. As an example, we report the case of 1 patient with a facial and cervical trauma, with a facet fracture, on February 4. We

prescribed radiography and re-evaluation after 3 weeks. During that period, all nonurgent radiologic examinations were suspended. The patient began to experience neck pain and paresthesia. He then started to lose strength in his hands and notwithstanding the lockdown, he went to the emergency room. After a clinical examination, we detected signs of cord compression. Radiography and magnetic resonance imaging showed a C4-C5 dislocation with cord compression. We operated on the young patient with a double approach. After surgery, all symptoms were resolved.

During the first and second yellow alert level pandemic (7–9 March and April 21–May 4), we performed 6 emergency surgical procedures and 1 programmed with A priority (spinal cord and/or roots impending or chronic but progressive compression, intractable pain, impending deformity). These procedures were subdivided by cause as follows: 3 oncologic, 3 trauma, 2 acute, and 1 subacute with mechanical intractable pain, and 1 degenerative. After the return to green alert level (May 5–22), we performed 5 programmed surgical procedures, all with A priority. Since May 18, we have been allotted 18 hours/week to perform programmed surgery with clinical priority.

From 7 March to 4 May, we admitted 40 patients with spine and spinal cord diseases, 20 of which were trauma. We operated on 25 patients following the clinical criteria according to the yellow and red alert level, shown in **Table 2**. In particular, in the red phase (10 March—20 April), we operated on patients with acute or rapidly evolving neurologic deficits. Of the patients with cervical spinal cord trauma, 2 were in ICU for the entire length of hospital stay, 1 was in ICU for 10 days, and 4 were in ICU only the night after surgery. The average length of stay (18.2 days) was conditioned by the availability of the beds in other units.

In our hospital PPE (e.g., gloves, gowns, and masks), ventilators, ventilator filters, and medications were never lacking. The main factor that led to the reduction or cancellation of elective surgery was the availability of operating room staff, who were focused on COVID-19 treatment.

Clinical decisions were made and acted on before the formulations represented by **Figure 1** and **Table 1**. Retrospectively, we can observe that patients operated on during the 3 alert levels fell into the appropriate categories. For this reason, we can treat the 3-level decision-making grid as the formalization and systematization of practices that had emerged in ipsa hora in "the heat of the battle."

DISCUSSION

The ongoing COVID-19 global pandemic is unprecedented in the last 100 years. It has led to the upheaval of the health care system at all levels and in all specializations. Spine surgery triage has its own unique set of challenges and the acuity of cases may be higher than in many other surgical specialties. The spine surgeon has a crucial role to play as provider, conserver of health care resources, and public health advocate.

Identification and triaging of patients with spinal disease who need urgent surgery versus those who can be delayed for several months is fundamental and there is no consensus on the problem. The American College of Surgeons, U.S. Centers for Disease Control and Prevention, the Orthopedic Trauma Association, and

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Table 2. Spine Surgery Across Red and Yellow Alert Levels: Treated Cases			
	Red (18 Cases): Spinal Cord and/or Roots Acute Compression	Yellow (7 Cases): Spinal Cord and/or Roots Impending or Chronic but Progressive Compression, Intractable Pain, Impending Deformity	
Trauma	1 C1 lateral mass fracture 2 unstable fractures of the basis of the odontoid process of C2 1 old facet fracture that developed a late C4-C5 dislocation and clinical sign of cord compression 2 somatic A4 fracture of L1 with root compression 2 spinal cord contusion with spondylotic cervical stenosis	1 quadriplegic C6-C7 fracture-dislocation 1 somatic A3 fracture of L2 1 old somatic fracture of L3 with pseudarthrosis causing intractable pain	
Bone tumors, metastases	1 T1-T2, 1 T11-T12, 1 T11, and 1 L2-L3 metastasis with worsening signs of cord or roots compression	2 T1 metastases with root and cord compression 1 L4 metastasis with root compression	
Intradural tumors	1 T10-T11 voluminous meningioma 1 T11 intramedullary angioblastoma with acute signs of cord compression		
Infections	1 surgical wound dehiscence		
Degenerative/others	3 herniated disc in spondylotic lumbar stenosis, 2 with cauda equina syndrome and 1 with pluriradicular acute deficits	1 herniated disc and spondylolisthesis L5-S1 causing intractable pain, severe functional limitations, and excessive opioid use	

the Royal College of Surgeons of England have all published guidelines to offer a framework of triage.¹⁵ Recently, the North American Spine Society developed a guidance document and our recommendations for triaging surgical spine patients are largely based on this document.¹⁶

In Lombardy, the Regional Council reorganized the hospitals as described in the Introduction section. Oncologic disease priority has been defined as patients requiring immediate treatment (class A++, rapidly evolving intracranial hypertension with deteriorating state of consciousness, acute hydrocephalus, spinal cord compression with rapid tetraparesis or paraparesis); patients requiring treatment within a maximum of 7–10 days (class A+, tumors with mass effect or with progressive neurologic deficit, without deterioration of consciousness); and patients requiring treatment within a month (class A, oncologic disease that seems malignant and determines a neurologic deficit).¹⁷ This classification was made possible with the active collaboration of the expert surgeons who developed protocols for evaluating which operations had to be performed urgently and which could be delayed.

In this perspective, we propose to incorporate 3 variables (surge level, cause of spinal disease, and clinical presentation) to create a dynamic scheme that prioritizes spine surgery. Every surgeon can apply this algorithm to any clinical scenario and place the patient in the correct box, as exemplified in **Table 1**. Under the green alert level (easily computed through the plot of **Figure 1**), it is possible to perform all spine surgical procedures. Under the yellow alert level, it is possible to perform elective surgery on patients whose spinal disease puts them at risk of worsening neurologic deficit and on patients with intractable, opioid-resistant pain and severe functional limitations. Elective surgery is put on hold, cases are re-evaluated by expert spine surgeons, and nonurgent cases are

postponed. However, keeping in mind the unavoidable backlog of elective cases, nonurgent cases are reviewed weekly so that, over time, patients must be reallocated to the updated priority level by a senior spine surgeon. Under the red alert level, it is possible to perform only emergencies.

"After this pandemic, nothing will ever be the same"; this oftheard statement is especially true for health care providers and surgeons. In this report, we have highlighted opportunities to maximize the benefit and minimize the risk of spine surgery during this pandemic and potentially, any future waves. The alert levels of **Figure 1** allow us to make decisions rapidly and with a solid base of data, using infection doubling time to predict the situation in the coming week.

One of the benefits of the COVID-19 crisis has been the robust implementation of telemedicine and virtual visits. Although it is not intended to replace in-person medical care, telehealth allows for mitigation of patients and avoids exposure to potential contagions by facilitating compliance with home quarantine. In spine surgery, there is the potential to miss a significant neurologic deficit in the course of a telemedicine consultation; spine surgeons must increase the time spent on history acquisition and must be sensitive to descriptors suggestive of a neurologic deficit. We believe that telemedicine could be useful for already established patients and long-term postoperative surveillance patients.

Although there is no single universally agreed plan for recalibrating health systems in the face of the COVID-19 pandemic, we have presented a balanced and succinct description of rational, safe approaches to all surgical/clinical procedures in case of emergencies that we may encounter in the future. This dramatic, unprecedented experience teaches us to reason in terms of the scarce availability of human and material resources (e.g., beds, ventilators gloves, gowns, and masks). Faced with limited resources, we are motivated to set priorities that offer the best possible care for patients with spine disease, seeking to preserve their quality of life. When we emerge from the other side of this pandemic, our hope is to look back and feel confident that no patient suffered because of the unwise use of health care resources.

CRedit AUTHORSHIP CONTRIBUTION STATEMENT

Rossella Rispoli: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation,

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