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Research Article

Surgery Safety Protocol for Patients and Staff During the COVID-19 Global Pandemic – A Prospective Study of 78 Consecutive, Open and Laparoscopic Surgical Procedures

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ABSTRACT

Background: To evaluate safety, for patients and staff, and efficacy of a protocol for the surgical treatment of patients during COVID-19 pandemic (50 days period) in a hospital located in the northern Italy.

Methods: Two different pathways were adopted (non-COVID-19 and COVID-19), with dedicated OR and ICU, and PPE for personnel. A monitoring of patients and staff for COVID-19 was carried out.

Results: 78 patients were included. Laparoscopy was used in 33.4% without gas filtration. COVID-19-positive patients (11.5%) were older men (0.04%), with elevated ASA score (0.002), and two or more comorbidities (0.02). They experienced longer hospitalization (0.003), more complications and more deaths (0.0001). All COVID-19 related deaths were due to severe acute respiratory syndrome. None of the patients included resulted infected, but one out of 47 staff personnel (<2%).

Conclusion: COVID-19 is largely unknown, but a safe and effective surgical pathway is feasible.

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Introduction

The World Health Organization (WHO) announced the Coronavirus disease 2019 (COVID-19) reached the status of a pandemic on March the 11th, 2020 (Link 1) [1]. However, Northern Italy, and the Lombardy Region in particular, was in the middle of a devastating outbreak from February the 21st. Only 8 weeks later, more than 1.24 million swabs have been performed, 172.434 individuals have been infected (14%), and 22.745 patients died (13%) (Link 2). On March the 1st, substantial restrictions in Lombardy (10.1 million people) were applied, and on March the 9th, the complete lockdown of the whole country was decreed by the Central Government.

COVID-19 can occur with no or mild symptoms in nearly 80% of the cases, with moderate to severe respiratory distress in 15%, and with severe acute respiratory syndrome due to corona virus 2 (SARS-CoV-2) in 5%. Thus, about 20% of patients need intensive care treatment [2]. The exponential afflux of patients needing intensive care management forced the Regional Government to an unforeseeable, unprecedented, and radical modification of Regional Health System. Many hospitals were transformed in a few days to be entirely dedicated to the treatment of COVID-19 patients, their operating rooms (OR) transformed into intensive care units (ICU), with an ICU beds availability increased from 859 to more than 1600.

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While the nation-wide lockdown has substantially reduced trauma cases, the need for emergency surgical procedure for acute abdomen, as well as oncologic surgery remained unchanged. Worldwide, several guidance has been proposed in order to help hospitals to safely and effectively guarantee the essential surgical services, even under the pressure placed by the novel coronavirus pandemic. The key point is how to combine the whole hospital engagement with the response to the outbreak, the prevention of COVID-19 spread among patients and staff, and the surgical needs. However, few evidences are available from clinical studies, based on the implementation of real-life protocols.

Aims of this prospective, observational, snap-shot study was to verify safety, for patients and staff, and efficacy of a protocol for the surgical treatment of emergent and urgent patients, operated on by open and laparoscopic surgery, during COVID-19 outbreak.

Methods

Rho Memorial Hospital is part of a four-hospitals trust (ASST Rhodense) in north-west Milano (Lombardy - Italy), with a total of 935 beds, in an area of 490.000 inhabitants, with a population density of 2290/Km². Two hospitals are dedicated to the management of acute cases (Garbagnate Milanese and Rho Memorial), one for chronic patients and rehabilitation, and one for day-hospital and territorial services. Starting February 27th, Garbagnate Milanese Hospital was completely transformed and dedicated to moderate and severe patients, including 110 ICU-beds for SARS-CoV-2, while Rho Memorial to mild COVID-19 cases and COVID-19-negative emergent and urgent surgical procedure. In addition to the Emergency Department, that is part of the Regional network for emergencies, Rho Memorial is the home of multidisciplinary teams for the treatment of breast and colorectal cancer, and for inflammatory bowel diseases (IBD).

Starting March, the 2nd 2020, all the non-urgent scheduled surgical procedures have been postponed. All the outpatient clinics, including cancer screening programs and private practice, have been closed, with the exception of post-operative controls and requests for urgent visits from the general practitioners. A safety protocol for the surgical management of emergent cases and for the triage of urgent cancer and IBD cases was established, following the WHO recommendations (Link 1).

I Emergency Patients COVID-19-Positive

COVID-19 patients with acute abdomen admitted in the emergency room (ER) or referred from other hospitals were all screened with arterial blood gasses (ABGs) and thoracic CT scan, together with complete evaluation for the acute abdomen condition (blood exams, abdominal ultrasonography, or CT scan where appropriate).

Patients with diagnosis of SARS-CoV-2 were re-evaluated by multidisciplinary counseling involving anaesthesiologist, surgeon, internist and gastroenterologist or pediatrician when necessary. Age, comorbidities, and prognostic implications of non-operative management were considered. Patients without SARS-CoV-2 were referred to the COVID-19-positive surgical pathway, which includes a dedicated OR, postoperative ICU admission when necessary, and a COVID-19 ward (see later).

II Emergency Patients Unknown for COVID-19

When a surgical indication emerged from primary evaluation in patients' unknown for COVID-19 referred to the ER, a swab, ABGs, and thoracic CT scan were obtained. Pediatric patients were evaluated by swab, oxygen saturation and thoracic ultrasonography. If it was possible, according to the clinical scenario, the result of the swab was expected, and in case of positivity the same multidisciplinary evaluation as for COVID-19-positive patients was performed. In case the operative treatment was not deferrable; the patient entered the COVID-19-positive pathway (see later). In case of negative swab, a standard surgical pathway was used.

III Urgent Cancer and IBD Patients Unknown for COVID-19

The medical records of all the patients with a diagnosis of breast cancer, colorectal cancer and IBD who were scheduled for surgery before the COVID-19 outbreak were re-evaluated by referral multidisciplinary teams. Since the engagement of the health system with the response to COVID-19 was expected to be longer than 3 months, most of the cancer and some IBD cases needed a reasonable programming.

Cases that needed to be treated were scheduled for pre-operative assessment 48 hours before surgery, they made a single access to the hospital for pre-operative standard exams, plus ABGs, thoracic CT scan or ultrasonography, and swab. They were then sent home with an indication of absolute isolation and use of surgical masks and gloves, and, in case of negative swab, they were finally admitted to the hospital for surgical procedure in case of negative swab for COVID-19.

IV COVID-19 Surgical Pathway

A dedicated operatory room (OR) was separated from the rest of the operatory theatre, with a definite path from the ER to the COVID-19 ward, and a direct connection with an isolated room in the ICU for post-operative care. A policy of "minimum required", and "expert personnel only" was applied. Junior staff and non-essential personnel were re-assigned to COVID-19 related activities. Anaesthesiologists and dedicated nurses were provided with FP3 face masks, face shield, full body PVC suit with hood, double gloves, and booties. Intubations were performed within OR, extubation within OR, or an isolated ICU room. Surgical teams were provided with the same personal protective equipment (PPE) than anaesthesiologist (including PCV suit with hood), but FFP2 face masks. Laparoscopy was used when indicated as best clinical practice, with no restriction and without filtering the released CO₂ nor surgical smoke. Radiofrequency, monopolar and bipolar cautery were used for dissection and vascular control where appropriate. The use of harmonic devices has been prudentially suspended. OR was already equipped with laminar fluxes, recycled ventilation, and filtration, positive or negative pressure option.

COVID-19-negative patients were treated using standard PPE (surgical mask, waterproof surgical gown and head cover, and face mask or goggles), but FFP2 mask and face shield for anaesthesiologists during intubation and extubation (performed inside the OR). No limitation was applied to laparoscopy, energy devices, and no CO₂ filtering was used. After surgery, COVID-19-positive patients were admitted to a dedicated ward within the hospital, while COVID-19-negative patients to the

surgical department. Those surgeons involved in the ER shifts were excluded from non-COVID-19 surgical procedures and from ward visits.

V Patients

All the consecutive patients undergoing surgery at Rho Memorial for an emergent or urgent procedure, between March the 2nd and April the 17th 2020, were recruited in the study. For each patient were considered: history, characteristics, comorbidities, indication for surgery, American Society of Anesthesiology Physical Status Classification System (ASA), cancer or IBD staging, COVID-19 infection, open or laparoscopic procedure, hospitalization, and Clavien-Dindo's classification of postoperative complications [3]. All the patients were re-evaluated for COVID-19 related symptoms within 10 days after hospital discharge. An informed consent for the surgical procedures and data auditing was obtained from all the patients after specific counseling.

VI Staff

At the beginning of their shift, all doctors and nurses were screened by thermo-scanner. In case of body temperature $>37.5^{\circ}\text{C}$, or any other alarm symptom for COVID-19 (anosmia, ageusia, cough, cold, tiredness, muscle pain, conjunctivitis, diarrhea) a diagnostic swab was obtained, together with ABGs and thoracic CT scan were necessary. Within 4 weeks from the end of the prospective study, all the surgeons, anaesthesiologist and nurses among the staff involved in the protocol were tested for Immunoglobulin G (IgG) against the novel Coronavirus.

VII Outcome Measures

This is a prospective, snap-shot study, of all consecutive patients operated on during a period of 50 days. Primary endpoint was to verify the safety, for patients and staff, of a specifically designed pathway for surgical procedures during the COVID-19 global pandemic.

Secondary endpoint was to verify if the hospital engagement with the response to the COVID-19 out-brake had an impact on surgical efficacy, in terms of complications and results. Postoperative complications were classified using the Clavien-Dindo's classification, in terms of maximum complication per patient, where major complications correspond to grade III and IV, and mortality to grade V [4, 5].

VIII Statistical Analysis

Continuous variables, expressed by mean and standard deviation (SD), were analysed using a two-tailed, unpair, Student's t-test, and categorical variables were compared using two-tailed, Fisher's exact or chi-square test, where appropriate. Significance was considered for p-value inferior to 0.05. Statistical analysis was performed using GraphPad Prism version 8.4.2 for macOS, GraphPad Software, San Diego, California USA. The study was approved and conducted according to the ethical standards of the Declaration of Helsinki (2013 version) and of the ethics committee of our Institution, and it was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology [STROBE] guidelines [6, 7].

Results

Between March the 2nd and April the 19th 2020, 78 consecutive patients were operated on at Rho Memorial Hospital. Oncological urgent cases were 38 (48.7%), 7 patients were IBD (9%), and 33 came from the ER (42.3%). Among cancer patients 26 were breast cancers, 6 were colorectal cancers, while the last 6 patients underwent other oncological-referred procedures. Two out of 7 IBD patients, as much as 2 out of 33 emergency procedure, were colorectal cancer. So, the total number of oncologic patients were 42 (53.8%). Males were 28 (35.9%) and females 50 (64.1%) (M/F ratio, 0.56), mean age was 57 (± 21 SD), and mean Body Mass Index (BMI) was 24 (± 5 SD).

Table 1: Comparison of proportions between COVID-19- positive and -negative patients.

	COVID-19 Negative Patients (n=69) [%]	COVID-19 Positive Patients (n=9) [%]	p
Gender			
Males	22 (31.9%)	6 (66.7%)	
Females	47 (68.1%)	3 (33.3%)	0.04
Age (years, mean \pm SD)	56 \pm 18	69 \pm 20	0.04
BMI (mean \pm SD)	24 \pm 4.2	25 \pm 7	0.4
ASA score			
1	25 (36.2%)	2 (22.2%)	
2	35 (50.7%)	1 (11.1%)	
3	8 (11.6%)	6 (66.7%)	
4	1 (1.5%)	0	0.002
Comorbidities			
0-1	56 (82.3%)	4 (44.4%)	
2-4	12 (17.7%)	5 (55.6%)	0.02
Indication for Surgery			
Emergency	28 (40.6%)	5 (55.6%)	
Oncologic	35 (50.7%)	3 (33.3%)	
IBD	6 (8.7%)	1 (11.1%)	0.4
Surgical Access			

Open	11 (15.9%)	3 (33.3%)	
Laparoscopic	22 (31.9%)	4 (44.4%)	
Non-abdominal	36 (52.2%)	2 (22.3%)	0.1
Emergency	29 (42%)	6 (66.7%)	
Urgent (Oncological, IBD)	40 (58%)	3 (33.3%)	0.2
Severe Complications			
Clavien-Dindo III-IV	2 (2.9%)	5 (55.6%)	
Clavien-Dindo V (Mortality) [4, 5]	1 (1.4%)	3 (33.3%)	0.0001
Postoperative Hospitalization (days)	5 ± 4	11 ± 7	0.0003

Thirty-seven patients (47.4%) presented at least one among cardiovascular, metabolic, oncologic, and other comorbidities. In particular, 21 patients presented 1 comorbidity (26.9%), 9 patients had 2 comorbidities (11.5%), 6 patients reported 3 or more comorbidities (7.7%). Cardiovascular comorbidity was present in 22 patients (28.2%), metabolic in 11 (14.1%), oncologic in 4 (5.1%), and other comorbidities (mainly obstructive pulmonary diseases) in 24 cases (30.8%). The ASA score was ASA1 in 27 patients (34.6%), ASA2 in 36 patients (46.2%), ASA3 in 14 patients (18%), and ASA4 in one patient (1.2%). Postoperative complications occurred in 14 patients (18%). Clavien-Dindo grade I occurred in 2 patients (2.5%), grade II in 6 patients (7.7%), grade IIIb in 1 patient (1.2%), grade IVa in one patient (1.2%), and grade V (death) in 4 patients (5.1%). Mean postoperative hospitalization was 6 days (± 6 SD), minimum 1 day, maximum 30 days. Laparoscopy was used in 26 patients, 33.4% of the total, and 65% of abdominal procedures. Nine patients resulted COVID-19-positive (11.5%), 5 developed the SARS-CoV-2 complication (6.4%), and 4 patients finally died (5.1% of the series, 45% among COVID-19-positive patients).

In (Table 1) are reported the differences between COVID-19 and non-COVID-19 patients. Comparison of the two groups showed that patients affected by COVID-19 were mostly men ($p=0.04$), with older age ($p=0.04$), elevated ASA score ($p=0.002$), and two or more comorbidities ($p=0.02$). COVID-19-positive patients experienced more severe complications, more deaths ($p=0.0001$), and a longer hospitalization ($p=0.003$), than non-COVID-19 patients.

None of the urgent oncologic and IBD patients who entered the safety protocol for surgery resulted later on infected. All the oncologic cases were treated by breast and colorectal teams as best clinical practice, including the use of laparoscopic surgery, without contracting the infection. One oncologic patient was infected during postoperative recovery by his sister during a visit, but he never developed SARS-CoV-2 complication. He was transferred to the COVID-19 ward, and he was discharged after a D3 laparoscopic right colectomy on postoperative day 14. After this, visits from relatives in the surgical ward were prohibited. Another oncologic positive patient was received from a COVID-19 hospital for obstructive and bleeding rectal cancer. He was admitted to a COVID-19-positive ward, re-evaluated, and he received a laparoscopic proctectomy with total mesorectal excision and colostomy. He never developed SARS-CoV-2 complication, and he was referred to a COVID-19 rehabilitation hospital on post-operative day 25. One IBD patient was referred for fistulizing small bowel disease, with a retro-peritoneal abscess, associated to a short bowel syndrome after multiple, small bowel, extensive resection from one of the regional red zones hospitals, and developed a SARS on post-operative day 3. She had 3 consecutive

negative swabs, with a clinical diagnosis of SARS-CoV-2 made by ABGs and thoracic CT scan.

All the other COVID-19 patients came from the ER or other hospitals. In terms of mortality, all three COVID-19 deceased patients (two men and one woman; 70, 88 and 79-year-old respectively) developed SARS-CoV-2 complication during post-operative period, and died from irreversible respiratory failure, within 72. The death among COVID-19-negative patient occurred in a 90-year-old woman, admitted from the ER for fecal peritonitis due to a perforated right colon cancer, within 48 hours from surgery.

Among the surgical, anaesthesiological, and scrub-nurse teams involved in the surgical procedures, for a total of 47 people, one surgeon developed moderate respiratory symptoms with positive ABGs and thoracic CT scan, but negative swab (<2%). At serological controls performed within 4 weeks from the end of the study, one scrub nurse and one anaesthesiologist were found to have positive IgG values for COVID-19, even if they have always remained asymptomatic (4.2%).

Discussion

The novel Coronavirus outbreak has literally transformed the northern Italy in a war zone, so that the entire Regional Health System had to deal with an unexpected, catastrophic threat in a few days. Many criticisms have been made about crisis management, but the purpose to save as many patients as possible from the COVID-19 has forced the authorities to make dramatic choices: in many hospitals, the OR have been transformed into ICU, while the rest of the hospital has been entirely dedicated to the care of COVID-19 patients and the surgical activities cancelled. To very few hospitals have been asked to maintain a surgical activity for emergencies, reduced but still present, and for non-deferrable patients. A completely new network, covering the whole Region, was created to reconfigure the pathway for any type of emergency, and for oncological patient triage.

Not surprisingly, the epidemiology of this snap-shot series reflects some peculiar aspects that COVID-19 showed worldwide [2]. First of all, there was an opposite percentage of males and females between COVID-19 and non-COVID-19 patients, with a significant higher rate of older males among the COVID-19-positive series ($p=0.04$). Less than 20% of the cases in the non-COVID-19 group has 2 or more comorbidities, compared to more than 50% in the COVID-19 group ($p=0.02$). Furthermore, COVID-19-positive patients had a significantly higher severe Clavien-Dindo complication (55.6% vs 2.9%), and death (33.3% vs 1.4%) [8]. Those COVID-19 patients that did not develop the SARS-CoV-2 complication required a significantly longer hospitalization

($p=0.0003$). However, the latter difference should be due to a prudential policy for the monitoring of a disease with poorly understood course.

The cases of death were probably unavoidable, as the three COVID-19 operated patients would have died anyway as a result of SARS-CoV-2, as well as the non-COVID-19 patient presented with fecal peritonitis, caused by a perforated colon cancer, in 90-year-old, cardiopathic woman. From a surgical point of view, the main decision-making element is not the COVID-19, but the presence of SARS-CoV-2 complication. However, a positive patient could theoretically develop SARS at any time during post-operative course, and no predictive elements are available to foresee the complication at the moment to decide for surgery.

It is also important to notice what emerged from the case review, i.e., probably due to the outbreak, many patients (both COVID-19 and non-COVID-19) arrived in ER with considerable delay. Maybe, partly because of the fear of going to the ER generated by the pandemic, and partly due to the reduced efficiency of the territorial care system also engaged in the management of the epidemic.

In terms of staff safety, the rules suggested by the WHO and taken up by the American College of Surgeons seem appropriate to guarantee the safety of patients and staff (Link 3). However, the indications for the management of the entire surgical pathway present in the world literature are rather generic and somehow based on the rules of common sense. In fact, this is the first time in history that medicine, at any level, from basic science to surgery, face a situation like this [9]. Results from this preliminary study suggests that a safety protocol is feasible, for emergency and urgent elective surgery, for COVID-19 and non-COVID-19 patients, and that adequate protection of the staff is achievable. Off course, the global volume of patients was substantially reduced in order to maintain isolation in the ward, for disinfection of OR, and due to the partial re-assignment of anaesthesiologists and nurses to COVID-19 related appointments.

A particular consideration should be given to the use of laparoscopy. Some Authors suggest caution in the use of pneumoperitoneum and some energy devices (laser and harmonic), due to the potential release of infected smoke during surgery, but the criticisms on this topic are mainly theoretical, based on old, episodic papers never confirmed later on [10-13]. Furthermore, the largest evidence about the risk of viral infection (mainly papilloma viruses) from the surgical smoke is related to laser use, and not harmonic nor radiofrequency energy devices, and the possibility of airborne transmission of HIV, HBV, and HCV remains to date far to be proven [14, 15].

The benefits of laparoscopy, especially in patients affected by or at risk of developing SARS-CoV-2, with the need of intubation and pronation in the post-operative period, far outweigh some theoretical resistances. The current generation of surgeons is used to operating patients affected by HIV, HBV, and HCV, viruses as insidious as the novel Coronavirus, and there is no evidence of the need to change a prudent attitude and the best clinical practice consolidated over years. This novel Coronavirus is largely unknown, extremely sophisticated, with different symptoms and organ involvement, and dramatically different prognosis. Its contagion mechanism is not yet fully understood, and neither is its progression to SARS-CoV-2 and death. In less than a week, on the bases of very few

scientific evidences, we completely re-design our triage system, remodel OR and equipment, and re-assigned nurses and doctors, with an enormous effort by everyone, and no one knew if it would work, but in the end it did [9].

Conclusion

This is a simple study, but it offers some interesting information: first, the epidemiology of COVID-19 in surgical patients reflects that of general population, with almost the same mortality; second, much ado about laparoscopy and gas filtration is not confirmed from our prospective data; last, the protocols theorized by many, but never tried on the field, would seem to work.

Highlights

- A surgical pathway has been designed and validated during COVID-19 pandemic.
- A protocol to obtain safety for patients and staff, and efficacy of the surgical procedure.
- The morbidity and mortality were higher in COVID-19 patients.
- All COVID-19 related deaths were due to severe acute respiratory syndrome.

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