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ORIGINAL ARTICLE

Surgical management protocol during the COVID-19 pandemic in an Italian non-referral center

Andrea BALLA *, Antonio DE CARLO, Daniele AGUZZI, Sergio PETROCCA, Anna GUIDA, Federica SARACENO, Rosa SCARAMUZZO, Gianfranco FANELLO, Alessandro BORRELLO, Fabrizio FERRANTI, Pasquale LEPIANE

General Surgery Unit, San Paolo Hospital, Civitavecchia, Rome, Italy

*Corresponding author: Andrea Balla, General Surgery Unit, San Paolo Hospital, Largo Donatori del Sangue 1, 00053 Civitavecchia, Rome, Italy. E-mail: andrea.balla@gmail.com

ABSTRACT

BACKGROUND: In the surgical scenario, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) diffusion worldwide entails on the one hand the need to continue to perform surgery at least in case of emergency or oncologic surgery, in patients with or without COronaVIrus Disease 2019 (COVID-19); and on the other hand, to avoid the pandemic diffusion both between patients and medical and nursing team. The aim of this study was to report our surgical management protocol during the COVID-19 pandemic in an Italian non-referral center.

METHODS: Data retrieved during the outbreak for the COVID-19 pandemic, from March 8 to May 4, 2020 (study period) were analyzed and compared to data obtained during the same period in 2019 (control period).

RESULTS: During the study period, 41 surgical procedures (24 electives, 17 emergency surgical procedures) underwent surgery in comparison to 99 procedures in the control period. Stratifying the procedures in elective and emergency surgery, and based on the indication for surgery, the only statistically significant difference was observed in the elective surgery regarding the abdominal wall surgery (0 *vs.* 13 procedures, P=0.0339). Statistically significant differences were not observed regarding the colorectal and the breast oncologic surgery. All stuff members were COVID-19 free.

CONCLUSIONS: The present protocol proved to be safe and useful to prevent SARS-CoV-2 infection before and after surgery for both patients and stuff. The pandemic was responsible for the reduction in number of procedures performed, anyway for the oncologic surgery a statistically significant volume reduction in comparison to 2019 was not observed.

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KEY WORDS: COVID-19; SARS-CoV-2; General surgery.

The "Severe Acute Respiratory Syndrome Coronavirus 2" (SARS-CoV-2), cause of the COronaVIrus Disease 2019 (COVID-19), was identified in Wuhan, a province of Hubei, China, in December 2019.[1-3] Since then, the SARS-CoV-2 is responsible for the current outbreak, elevated initially as Public Health Emergency of International Concern and later to pandemic by the World Health Organization (WHO).[4]

SARS-CoV-2 is a highly transmissible enveloped virion of about 50-200 nm with a single positive-sense RNA genome.[1, 2, 5] Its human-human spread is mainly through aerosolization, droplet particles or respiratory secretions, but also direct contact and fecal-oral route.[6] The most common symptoms are the respiratory ones, but atypical symptoms such as abdominal pain, nausea, diarrhea and hypercoagulability

are reported, with an overall mortality rate of 5.8%.[6]

In the surgical scenario, the SARS-CoV-2 diffusion worldwide entails on the one hand the need to continue to perform surgery at least in case of emergency and oncologic surgery, in patients with or without COVID-19, and on the other hand, to avoid the pandemic diffusion both between patients and medical and nursing team.[7-10]

The aim of the present study was to report our surgical management protocol during the COVID-19 pandemic in an Italian non-referral center.

Materials and methods

This study is a retrospective analysis of prospectively collected data, conducted in an Italian non-referral center (San Paolo Hospital, Civitavecchia, Rome, Italy). Institutional review board approval was obtained. Following our surgical management protocol, we recorded and analyzed data retrieved during the outbreak for the COVID-19 pandemic, from March 8 to May 4, 2020 (study period).[11] Data obtained during the study period were compared to data obtained in the same period in 2019 (control period).

Surgical management protocol

Hospital organization

Since the outbreak beginning, a separate pathway has been established for suspected COVID-19 patients for clinical observation and diagnostic and therapeutic routes. A specific Hospital map was designed in order to explain the patients and staff pathways. A dedicated COVID-19 Unit was created in the hospital. The unit was divided in two compartments, one for COVID-19 patients and another one for suspected COVID-19 patients. The unit was isolated from the rest of hospital and a dedicated medical and nursing team worked in the unit during the outbreak.

All hospital staff were into active health surveillance. Each member had a daily diary in which body temperature, symptoms or contact with suspected COVID-19 people were recorded. Each fifteen days a nasopharyngeal swab specimen was performed to all staff members. The entrances to the hospital were limited, such as the expectations for visits.

The Week Surgery Unit was closed, and the General Surgery Unit and the Orthopedics Unit have been merged so the number of beds of our unit decreased from 13 to 6.

Patients admitted in emergency/urgency

All patients admitted to our hospital in the emergency setting undergone two nasopharyngeal swab specimens 24/48 hours apart. If one or more swab resulted positive for SARS-CoV-2 patients were recovered in a COVID-19 Unit. Similarly, if both swabs were negative, but patients were strongly suspected of SARS-CoV-2 infection, patients were referred to COVID-19 Unit. Patients with both swabs negative, needing of surgical care, were recovered in the Unit of General Surgery. The immediate surgical treatment was performed only in cases of non-operative approach, medical treatment, endoscopy or interventional radiology were not feasible.[8] In these cases, patients were considered as COVID-19, up to the negative results of both swabs, and recovered in an isolated compartment of the General Surgery Unit. An undressing room for the stuff was available.

Patients admitted for elective surgery

All elective surgery was indefinitely postponed except for the oncologic surgery. Only asymptomatic patients for COVID-19, affected by cancer were admitted in the General Surgery Unit, after one negative nasopharyngeal swab specimen performed at home, absence of typical COVID-19 symptoms and history of contact with people at risk for COVID-19.

Operative theatre setting

The operative theatre was divided in two compartments, one for the elective surgery (COVID-19 free patients) and one for the emergency surgery (confirmed or suspected COVID-19 patients). Both compartments were shared with the Orthopedics Unit. If possible, laparoscopy is always performed, using an aspiration system to deflate the pneumoperitoneum. The COVID-19 operative room had negative pressure and par-

ticulate air filter. All the staff always wore all the necessary equipment to avoid contagion.[6] An undressing room was available.

Study design

All surgical interventions performed during the study period were stored in a Microsoft Excel program (Microsoft Corporation; Redmond, WA, USA) and compared to the surgical intervention performed in control period. COVID-19 infections or suspicious among the stuff of the unit (including the operative room stuff) were recorded.

The protocol usefulness was evaluated based on the evaluation between the number of elective surgical procedures and the number of SARS-CoV-2 infections among the stuff members of the Unit, comparing the study and the control period.

Statistical analysis

Categorical variables are expressed as frequencies and percentages. The Fisher's Exact test was employed for statistical analysis. A P value lower than 0.05 was considered statistically significant. Statistical analyses were carried out with SPSS software 22.0 (SPSS Inc., Chicago, IL, USA).

Results

Overall, during the study period, 41 surgical procedures (24 elective and 17 emergency surgical procedures) were performed in comparison to 99 procedures performed in the control period (Table I, Figure 1). The number of oncologic procedures (including colorectal, breast, endocrine, gastric, pancreatic, kidney and skin surgery), comparing the study and the control period, was not statistically significant. Stratifying the procedures in elec-

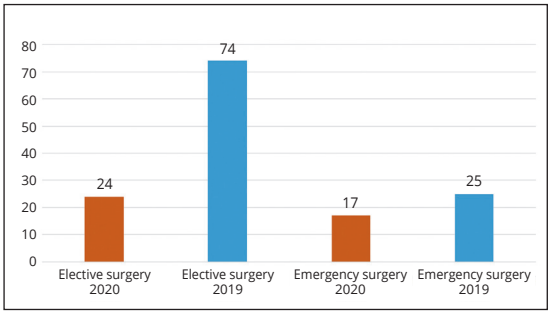

Figure 1.—Overall procedures in 2019 and 2020.

TABLE I.—*Comparison between surgery during the study and the control period.*

Surgery	Study Period March 8 – May 4, 2020 N.=41	Control period March 8 – May 4, 2019 N.=99	P value
Elective surgery, N. (%)			
Colorectal	6 (25)	7 (9.5)	0.0790
Breast	12 (50)	29 (39.2)	0.4755
Endocrine	1 (4.2)	4 (5.4)	1.0000
Oncologic surgery	5 (20.8)	12 (16.2)	0.7568
Abdominal wall	-	13 (17.6)	0.0339*
Cholecystectomy	-	6 (8.1)	0.3310
Other	-	3 (4)	1.0000
Total, N. (%)	24 (58.5)	74 (74.7)	0.0692
Emergency surgery, N. (%)			
Bowel ischemia	2 (11.8)	-	0.1580
Bowel occlusion	2 (11.8)	3 (12)	1.0000
Bowel perforation	3 (17.6)	3 (12)	0.6720
Abdominal trauma	1 (5.8)	1 (4)	1.0000
Appendectomy	2 (11.8)	4 (16)	1.0000
Cholecystectomy	2 (11.8)	3 (12)	1.0000
Abdominal wall	2 (11.8)	1 (4)	0.5557
Pneumothorax	1 (5.8)	4 (16)	0.6323
Urology	2 (11.8)	3 (12)	1.0000
Other	-	3 (12)	0.2596
Total, N. (%)	17 (41.5)	25 (25.3)	0.0692

*Statistically significant difference.

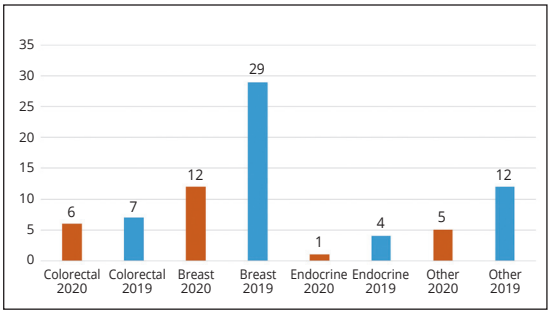

Figure 2.—Oncological procedures in 2019 and 2020.

tive and emergency surgery, and based on the indication for surgery, the only statistically significant difference was observed in the elective surgery regarding the abdominal wall surgery (0 *vs.* 13 procedures, in the study period and in the control period, respectively, P=0.0339) (Table I). No statistically significant differences were observed regarding the oncological surgery (Table I, Figure 2).

All stuff members, including medical doctors and nurses were COVID-19 free, and overall, four nasopharyngeal swab specimens were performed for each member.

Discussion

This study was conducted with the aim of reporting our experience in the management of a Unit of General Surgery during the SARS-CoV-2 pandemic. In order to evaluate the safety and the usefulness of our protocol, the number of elective oncologic surgical procedures and the number of SARS-CoV-2 infections among the stuff members of the unit were considered. Despite a decrease in total number of procedures performed in 2020, a statistically significant reduction of the number of procedures was not observed. This is an encouraging data if we consider that the elective surgery for benign disease has been suspended indefinitely. The reduction of the surgical activity must be attributed to the suspension of elective surgery for benign disease, to the use of surgery only in case of failed alternative strategies (medical treatment, endoscopy or interventional radiology) and to the patients' fear to go to the hospital. This social situation influenced both elective and emergency activity because has greatly reduced the screening procedures (such as the endoscopy and mammography for colorectal and breast surgery, respectively) and delayed or avoided the use of the emergency service by patients. This delay resulted in a severe acute situation that complicated the emergency surgery. In fact, considering our procedures, the two treated cholecystitis were perforated, such as one appendicitis, and two out of three patients with bowel perforation who underwent surgery had symptoms since at least two days, observing severe peritonitis during surgery. The management of patients, also in the emergency settings, was adequate due to the absence of contagious among the stuff.

In the development of this protocol, several guidelines have been adopted, as well different pathways for COVID-19 patients, dedicated unit with its stuff, periodic nasopharyngeal swab specimen for the staff members and for all patients at the admission and the aspiration system in the operative room.[4, 6-9, 11, 12] However, it is important to consider that the possibility of developing protocols in the pandemic scenario depends also on the hospital management and on the government legislation and support.[13-15] Hence, in our opinion, the best protocol management in this phase should be tailored, evaluating all the available resources not only in the hospital.

Limitations of the study

The main limitation of the present study is its retrospective nature.

Conclusions

The present protocol proved to be safe and useful to prevent SARS-CoV-2 infection before and after surgery for both patients and stuff. The pandemic was responsible for the reduction in number of procedures performed, anyway for the oncologic surgery a statistically significant volume reduction in comparison to 2019 was not observed. However, the pandemic is unexpected and unpredictable situation, hence different and new solutions should be considered steadily.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions.—Andrea Balla, Antonio De Carlo, Daniele Aguzzi, Sergio Petrocca, Anna Guida, Federica Saraceno, Rosa Scaramuzzo, Gianfranco Fanello, Alessandro Borrello, Fabrizio Ferranti and Pasquale Lepiane have given substantial contributions to manuscript conception and design, to data acquisition, analysis and interpretation, manuscript writing and critical revision. All authors read and approved the final version of the manuscript.

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