

Breast Cancer Surgery During the COVID-19 Pandemic: An Observational Clinical Study of the Breast Surgery Clinic at Ospedale Policlinico San Martino – Genoa, Italy

PIERO FREGATTI^{1,2}, MARCO GIPPONI², MARIA GIACCHINO¹, MARCO SPARAVIGNA¹, FEDERICA MURELLI^{1,2},
MARIA LUISA TONI³, MARIA TERESA CALABRÒ³, LINA ORSINO³ and DANIELE FRIEDMAN^{1,2}

¹Department Surgical Sciences and Integrated Diagnostic (DISC),
School of Medicine, University of Genoa, Genoa, Italy;

²Breast Surgery Clinic, Ospedale Policlinico San Martino, Genoa, Italy;

³Direction Health Professions (DAPS), Ospedale Policlinico San Martino, Genoa, Italy

Abstract. *Background: COVID-19 pandemic required a marked re-allocation of healthcare resources, including at Breast Units. A patient-tailored program was developed to assess its efficacy regarding prevention of COVID-19 infection among patients with breast cancer undergoing surgery and healthcare workers (HCWs). Patients and Methods: From March 9th to April 9th 2020, 91 patients were selected for elective surgery by means of: i) Pre-hospital screening aimed at avoiding hospitalization of symptomatic or suspicious COVID-19 patients, and ii) prioritisation of surgical procedure according to specific disease features. Results: Eighty-five patients (93.4%) were fit for surgery, while five patients (5.5%) were temporarily excluded through ‘telephone triage’; another two patients were excluded at in-hospital triage. A total of 71 out of 85 patients (83.5%) were diagnosed with invasive cancer, most of whom were undergoing breast-conserving surgery (61 out of 85 patients, 71.8%). The mean in-hospital stay was 2.2 days (SD=0.7 days). After hospital discharge, no patient needed re-admission due to post-operative complications; moreover, no COVID-19 infection among patients or HCWs was detected. Conclusion: Safe breast cancer surgery was accomplished for both patients and HCWs by means of a careful preoperative selection of patients and in-hospital preventative measures. This screening program can be transferred to high-volume Breast Units and it may be useful*

in implementing European Community recommendations for prevention of COVID-19 infection.

The Coronavirus Disease 2019 (COVID-19) pandemic has required a significant re-allocation of healthcare resources with a sudden re-organization of all clinical activities, including Breast Units. On February 25th 2020, the first patient with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was diagnosed in our Region Liguria, and on March 9th 2020 109 patients with COVID-19 were identified, 77 of them recovering in regional hospitals (1, 2). Therefore, many surgical units had to re-adapt their activity in order to support the increasing demand for healthcare resources due to this pandemic.

In 2016, our Breast Surgery Clinic at Ospedale Policlinico San Martino in Genoa was designated by the Regional Council as the Regional Hub Centre for breast cancer diseases and, from March 9th 2020, we became the unique collector of all regional patients with breast cancer due to the temporary closure of the remaining Regional Breast Units because of the COVID-19 emergency (3). Thus, our surgical activity was increased despite a shortage of operating theatres and availability of anaesthetists due to their assignment to Intensive Care Units. Moreover, the great challenge was to spare not only our patients with breast cancer but also our healthcare workers (HCWs) any undue risk of exposure to COVID-19 (4).

Herein, the preliminary findings of an observational clinical study at our Breast Surgery Clinic are reported regarding the validation of a patient-tailored program with a double target: i) Pre-hospitalization screening by means of a patient screening flowchart in order to avoid the hospitalization of SARS-CoV-2 symptomatic patients, and ii) prioritisation of the surgical procedure according to specific disease features.

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Correspondence to: Marco Gipponi, MD, Breast Surgery Clinic – Ospedale Policlinico San Martino, Genoa, L.go R. Benzi 10, Genoa 16132, Italy. E-mail: marco.gipponi@hsanmartino.it

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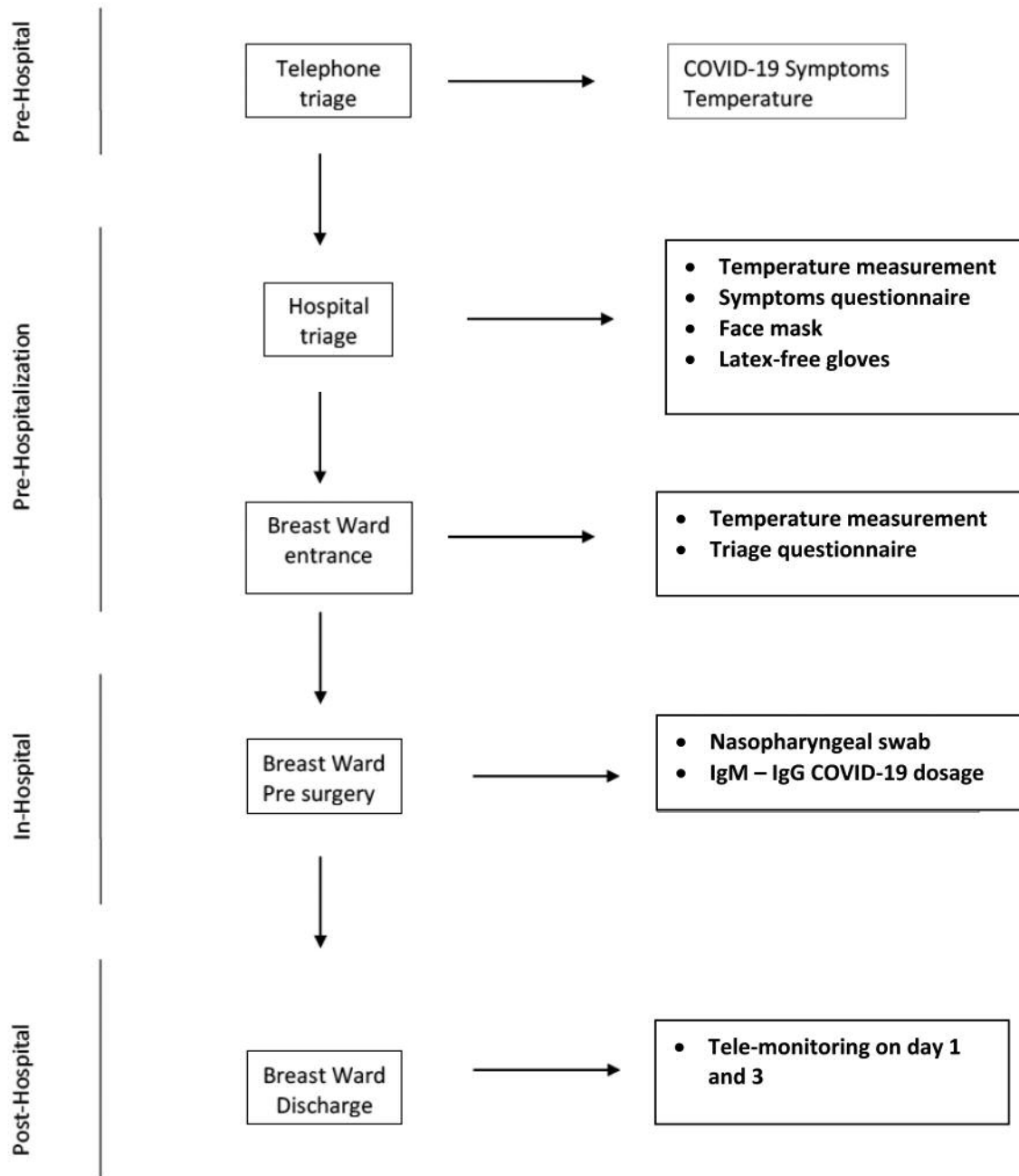


Figure 1. Flowchart outlining pre-hospitalization, in-hospital, and post-hospital procedures.

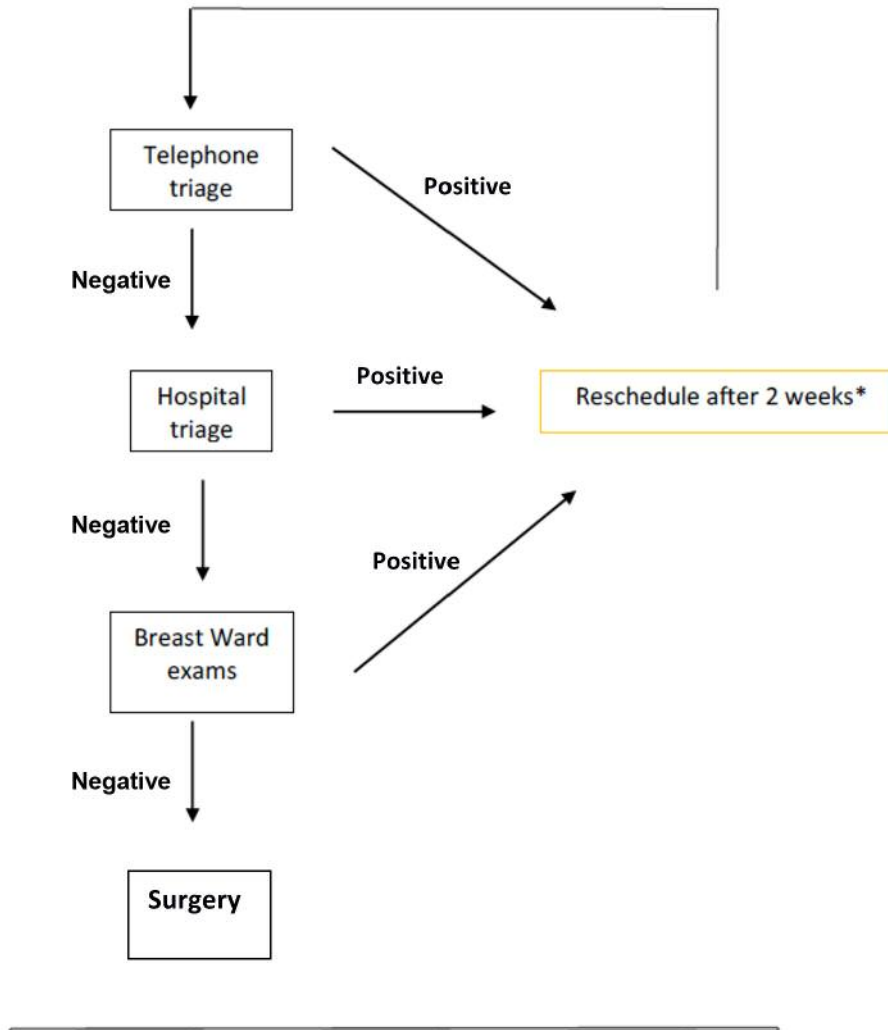
Patients and Methods

The study protocol was submitted to the Regional Ethics Committee; no specific consent was required since all clinical information was already mentioned in the standard Privacy Module that each patient signed at hospitalization.

Patient screening flowchart. From March 9th to April 9th 2020, case-tailored flowcharts were developed to screen our patients for COVID-

19 symptoms (fever, cough and respiratory symptoms) covering three distinct settings: Home, hospitalization, and post-discharge triage (Figures 1 and 2) (5-8). In-hospital and post-discharge triages were developed according to the recommendations of national legislation ISS COVID-19 n. 1/2020 (9-11) and WHO recommendations of February 27th 2020 (12), and properly adapted to our local requirements.

Telephone triage. This was performed 7 days before the hospitalization by a dedicated Breast Care Nurse who was



* Rescheduled after 2 weeks from first asymptomatic day

Figure 2. Flowchart of triage-based selection of patients.

properly trained by our Infectious Disease Team as regards suspicious COVID-19 symptoms; the patient was kindly asked to contact the Breast Unit if symptoms of infection developed thereafter. The pool of questions is shown in Table I, and COVID-19 symptoms were classified according to major and minor criteria shown in Table II. When the patient tested positive for one major or at least two minor criteria, the Public Health Office was alerted for home monitoring and the surgical program was temporarily suspended; a new telephone triage was performed 2 weeks later. Patients who tested negative had a confirmatory telephone triage repeated on the day before hospitalization.

In-hospital triage. As soon as the patient got to the Breast Unit, she followed a three-steps procedure before any interface with HCWs, that is: i) she used an automatic hand sanitizer dispenser, and ii) she took a disposable face mask from an automatic dispenser, and iii) she

wore disposable latex-free gloves (12-15). The nurse dedicated to the in-hospital triage was properly equipped with Personal Protective Equipment (PPE), that is: gloves, face mask, goggles, and gown (12-15). A COVID-19 questionnaire developed by the Hospital Department of Public Health Epidemiology was given to the patient, including health clinical data such as body temperature and any COVID-19 symptoms occurring during the past 2 weeks. The patient's body temperature was then detected by means of a telethermometer and only negative patients were permitted access to our Breast Unit; of note, the patient was introduced into the Breast Unit alone, with no family members; elderly patients and those with motor impairments were assisted by a dedicated HCW properly equipped with PPE until completion of all logistic procedures.

Hence, the patient submitted the certifications of these two triages (telephone and in-hospital triage) in the anteroom of the Breast Unit, and a second body temperature detection was

Table I. Clinical assessment checklist.

Symptoms	Medical history
Fever	<ul style="list-style-type: none"> • Do you live with a patient confirmed as having COVID-19? • Did you have physical contact with a patient confirmed as having COVID-19? • Did you have physical non-protected contact with secretion from a person with COVID-19? • Did you have any prolonged contact (face to face, more than 15 min and less than 2 m distance) with a confirmed patient? • Did you have any prolonged contact in closed spaces (elevator, meeting room, more than 15 min and less than 2 m distance) with a patient with COVID-19? • If you are a Healthcare Worker: did you have any contact without proper PPE with a confirmed patient or with infected biological fluid? • Have you traveled in the past 2 weeks with a person with COVID-19?
Cough	
Dyspnea	

acquired, always maintaining the correct interpersonal distance. After admission, the patient was immediately subjected to nasopharyngeal (NP) swab and humoral tests for IgM and IgG COVID-19 antibodies and, while waiting for the definitive results, she was isolated in a single room. Surgery was definitively scheduled as soon as the NP swab tested negative, while the COVID-19 serology test was performed only for investigational purpose and did not affect the surgical program. Whenever sentinel lymph-node biopsy (SLNB) was scheduled, the patient underwent lymphoscintigraphy at the Nuclear Medicine Department; surgery was re-scheduled if any logistic delay that precluded a timely lymphoscintigraphy occurred.

After completion of the operation, the surgeon contacted the patient's family members as indicated by the patient in order to clarify the immediate surgical outcome since no visitor was permitted into the ward. The patients were discharged as soon as they were clinically stable in order to minimize the risk of re-admission.

Post-discharge triage. A dedicated well-trained Breast Care nurse made a video-call to the patient at home on the first and third day after discharge in order to verify her clinical status (body temperature, pain level by means of Visual Analogue Scale, drainage volume and macroscopic appearance, etc.) while waiting for the first visit on the seventh post-operative day at the Outpatient Clinic, post-discharge visits being reduced to the minimum required (16). Whenever a patient developed COVID-19 related symptoms, Public Health Officers and Family Doctors were informed in order to monitor her clinical course.

Patient selection. The re-allocation to our Breast Unit of all patients with breast cancer coming from our Region required urgent and well-defined criteria to prioritize surgical timing without impairing the prognostic outcome or increasing the risk of infection among patients and HCWs. According to the American College of Surgeons guidelines, patients were divided into two groups: The treated group of patients, that is patients with an actual risk of impaired survival when surgery is delayed for more than 3 months; and secondly, the deferred group, that is patients for whom the surgical procedure might be delayed until resolution or mitigation of the COVID-19 pandemic (17).
Treated group:

Table II. Major and minor criteria for the assessment of COVID-19-related symptoms.

Major criteria	Minor criteria
<ul style="list-style-type: none"> • Fever • Cough • Myalgia or fatigue • Expectoration • Dyspnea 	<ul style="list-style-type: none"> • Headache or dizziness • Diarrhea • Nausea and vomiting

Table III. Patient selection based on pathological diagnosis.

	Genoa Breast Clinic, n (%)	Regional Breast Units, n (%)	Total, n (%)
Invasive breast cancer	62 (81.6%)	9 (100.0%)	71 (83.5%)
DCIS	6 (7.9%)	-	6 (7.1%)
B4	8 (10.5%)	-	8 (9.4%)
Total	76 (100.0%)	9 (100.0%)	85 (100.0%)

DCIS: Ductal carcinoma *in situ*; B4: highly suspicious tru-cut biopsy.

Table IV. Preoperative criteria for the selection of the treated group.

Preoperative breast diagnosis	Patients, n (%)
Completed neoadjuvant chemotherapy regimen	5 (5.9%)
cT1/2N0, ER+/PR+/HER2- <50 years old	54 (63.5%)
cT1N0 Triple-negative or HER2+	9 (10.6%)
Highly suspicious tru-cut biopsy (B4)	8 (9.4%)
Local recurrence	1 (1.2%)
Re-excision surgery	2 (2.4%)
cTisN0, ER+/ER-	6 (7.0%)
Total	85 (100.0%)

ER: Estrogen receptor; PR: progesterone receptor; HER2: human epidermal growth factor receptor 2.

Table V. Type of surgical procedure stratified by preoperative histology.

Procedure	Invasive breast cancer, n	DCIS, n	B4, n	Total, n (%)
BCS + SLNB	39	-	-	39 (45.9%)
Lumpectomy	-	5	8	13 (15.3%)
NSM + SLNB + reconstruction*	10	1	-	11 (12.9%)
Simple mastectomy	11	-	-	11 (12.9%)
BCS + SLNB + ALND	6	-	-	6 (7.1%)
BCS + ALND	3	-	-	3 (3.5%)
Bilateral NSM + SLNB + reconstruction	2	-	-	2 (2.4%)
Total	71	6	8	85 (100.0%)

BCS: Breast-conserving surgery; DCIS: ductal carcinoma *in situ*; B4: highly suspicious tru-cut biopsy; SLNB: sentinel lymph-node biopsy; NSM: nipple-sparing mastectomy; ALND: axillary lymph node dissection; *homolateral reconstruction.

- Patients who had completed neoadjuvant chemotherapy, regardless of T or N stages;
- Patients with clinical (c) T₁₋₂N₀, estrogen receptor-/progesterone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer less than 50 years of age;
- Patients with cT₁N₀ triple-negative or HER2-positive disease;
- Patients with highly suspicious (B4) tru-cut biopsy;
- Patients with local recurrence;
- Those who underwent re-excision surgery;
- Patients with cTisN₀ breast cancer, especially with nodule/mass lesion, histological grade 3, or with extensive area of microcalcifications.

Deferred group:

- Patients who underwent excision of benign lesions (*e.g.* fibroadenoma or other benign nodules);
- Those with duct excision (*i.e.* suspected intraductal papilloma);
- Patients with likely-benign (B3) tru-cut biopsy;
- Patients who underwent prophylactic mastectomy for BRCA1/2 DNA repair associated gene-positive disease;
- Patients with cT₁₋₂N₀ estrogen receptor-/progesterone receptor-positive, and HER2-negative breast cancer over 50 years of age undergoing neoadjuvant hormonal treatment;
- Those with complete response after neoadjuvant chemotherapy;
- Patients with cN positive regardless of cT stage re-directed to neoadjuvant chemotherapy.

Whenever possible, breast-conserving surgery was the preferred surgical option. Definitive mastectomy, either nipple-sparing mastectomy or simple mastectomy, with reconstruction performed when indicated to couple an oncological safe procedure with the best cosmetic outcome. All these clinical aspects were discussed weekly by means of video-conferencing within the Multidisciplinary Breast Cancer meetings, including patients coming from other Regional Breast Units.

Results

Overall, from March 9th to April 9th 2020, 91 patients underwent telephone triage by a dedicated Breast Care Nurse of the Breast Surgery Clinic at Ospedale Policlinico San Martino in Genoa; 85 patients (93.4%) were deemed fit for surgery, while five patients (5.5%) were temporarily excluded from the operative schedule because of fever (n=3)

or hospitalization for COVID-19 infection (n=2). Another patient was excluded after in-hospital triage due to NP swab positivity, although she was completely asymptomatic, without fever and with IgM-negative antibody test; she was referred to the Infectious Diseases Clinic for daily tele-monitoring and surgery was re-scheduled 2 weeks later, following the same selection procedure, according to WHO recommendations (18). Another asymptomatic patient had a slight increase of IgM antibody with negative NP swab; she was assessed by the Infectious Diseases Team, and surgery was re-scheduled 2 weeks later after obtaining a second negative NP swab (19). As regards the Referral Centre, 76 out of 85 patients (89.4%) were selected at our Breast Surgery Clinic, while the remaining nine patients came from other regional Breast Units.

The pathological diagnosis of patients scheduled for surgery stratified by the Referral Centre is reported in Table III; most patients had a preoperative diagnosis of invasive breast cancer (71 out of 85 patients, 83.5%). The preoperative criteria used for the selection of the treated group of patients is reported in Table IV. Surgical procedures are described in Table V. Most patients underwent breast-conserving surgery (61 out of 85 patients, 71.8%); 13 patients (15.3%) had nipple-sparing mastectomy with breast reconstruction; and the remaining 11 patients (12.9%) underwent simple mastectomy. Three (3.5%) patients, who had completed the neoadjuvant chemotherapy regimen and had achieved partial response on axillary nodes underwent breast-conserving surgery with immediate axillary lymph node dissection. The mean in-hospital stay was 2.2 days (SD=0.7 days). After hospital discharge, none of the patients needed re-admission due to post-operative complications, and they were all managed in the Outpatient Clinic.

Discussion

Re-allocation of healthcare resources as well as re-organization of clinical activities became an urgent necessity due to the COVID-19 pandemic, including those at Breast

Units. For this reason, a specific algorithm was developed according to national and international recommendations with the aim of performing strict COVID-19 screening before, during, and after the hospitalization of patients undergoing surgery at our Breast Surgery Clinic. The main goal was to avoid any impairment of survival of patients with breast cancer, as well as to preserve our clinical and surgical work-force.

By means of our patient screening flowchart, five out of 91 patients (5.5%) were temporarily suspended from the surgical schedule because of fever or previous hospitalization due to COVID-19 infection; another patient was excluded after in-hospital triage. As for the remaining patients, the least patient-to-HCW interface was guaranteed until a negative NP swab was obtained. This greatly reduced the risk of COVID-19 infection, a serious risk especially for HCWs, both from the individual and efficiency perspective because an increased COVID-19 infection rate among healthcare personnel would necessarily reduce healthcare provision.

Notwithstanding the reduced availability of operating theatres and Anaesthetists, due to their re-assignment to Intensive Care Units, a more than relevant set of patients were able to undergo safe surgical procedures with no added post-operative morbidity and, most noteworthy, no demonstrated COVID-19 infection among patients and HCWs. As a matter of fact, approximately 65 patients with a definitive preoperative diagnosis of breast cancer are operated on monthly at our Breast Unit, and another set of approximately 20 patients are treated for suspicious or benign breast lesions; this represents almost half of the overall population of patients with breast diseases in our Region (3). Certainly, the number of patients reported in this preliminary experience has a rather low representation of women coming from other Regional Breast Units (nine out of 85=10.5%). This may be well explained by: i) The recruitment of patients from other Regional Breast Units, with some delay from the actual start of this observational study; ii) the hesitation of some patients to undergo treatment with another surgical team, far from home, whilst still hoping for a rather quick resolution of COVID-19 pandemic; iii) the fear of logistic difficulties related to post-operative multidisciplinary treatments (such as medical or radiation therapy) and, last but not least, fear of becoming infected during hospitalization.

Regarding the in-hospital stay, it was restricted to the absolute minimum in order to avoid any unnecessary overload of healthcare structures, with a mean length of stay of almost one day more as compared to the pre-COVID era, and this was mainly due to the specific preventative measures required before patient's admission. In the post-operative course, patients were regularly discharged with breast/axillary drainage whenever clinical conditions were

more than suitable, and well-structured post-discharge tele-monitoring was organized and supervised by dedicated Breast Care Nurses.

A critical bias of this preventative program was due to the possibility of unfaithful statements by some patients psychologically stressed and threatened by their breast cancer diagnosis, wishing to expedite their operation; this may have biased some details regarding their own or parental clinical status, thus impairing the reliability of the telephone triage. However, the in-hospital triage and the meticulous respect of interpersonal distance, use of PPE, and isolation of patients while waiting for the definitive results of NP swabs allowed proper selection of patients for their scheduled operation while preventing spread of COVID-19 infection. As a matter of fact, no COVID-19 infection was detected in patients undergoing surgery nor in HCWs during this month of dedicated surgical activity.

Conclusion

Planning and proper timing of multimodal treatments are key aspects in management of patients with breast cancer as in other oncological settings; this new infectious disease, with no clear perspectives in the very near future, may seriously hamper the clinical management of oncological patients. This preliminary clinical experience clearly shows that elective breast cancer surgery can be safely pursued with careful preservation of both patient and HCWs health status.

Our protocol represents an operative strategy that can easily be transferred to other surgical specialties in order to avoid any undue delay of cancer treatment, although further assessment is still required in the mid- to long-term in order to verify its effectiveness. These healthcare screening measures are easily applicable in high-volume Breast Units, they may support clinical decision-making and re-allocation of healthcare resources, thus it may be useful in implementing European Community recommendations for prevention of COVID-19 infection.

Conflicts of Interest

This study received no grant and all Authors declare that they have no conflicts of interest.

Authors' Contributions

Piero Fregatti and Marco Gipponi: Study planning, surgical treatment, manuscript editing; Maria Giacchino and Marco Sparavigna: follow-up and data management; Federica Murelli: surgical treatment, follow-up and data management; Maria Luisa Ton, Maria Teresa Calabrò, and Lina Orsino: dedicated nurse assistance and data management; Daniele Friedman: study planning, surgical treatment, manuscript editing.

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