

From New Challenges in the Emergency Phase to Different Opportunities in the Coexistence Phase of Covid-19: An Experience in Breast Cancer Care

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Abstract

Introduction: The COVID-19 pandemic has required a significant re-allocation of healthcare resources. The aim of this article is to report our experience with the management of breast cancer in the COVID-19 era in order to share our experience and provide information useful to develop possible organization model.

Methods: In our study, we retrospectively analysed the data collected in the DataBreast™ database of all patients undergoing breast surgery in 2020 and compared them with those of the previous year.

Results: In 2020, due to the suspension of BC screening programs from March to May, we observed a progressive decline in surgery. The proportion between breast conserving surgeries and mastectomies remained constant. Among the mastectomies the rate of reconstruction remained stable at 60%. Breast reconstruction techniques remained unchanged compared to 2019. The rate of TN cancers undergoing NACT remained stable at 40% and all patients underwent surgery in adequate time. The safety measures applied have allowed to avoid outbreaks of infection among both patients and healthcare workers. ICG fluorescence technique for SLNB, Breast Care Nurse's re-call service and online psychological interviews have allowed to reduce hospital access for patients. We continued to guarantee multidisciplinary assessments through online modalities.

Conclusions: The implementation of new practices, such as the ICG fluorescence technique for preoperative mapping of the sentinel lymph node, multidisciplinary online meetings, telemedicine, psychological and nursing support service allow to implement the patient's sense of safety and continue to offer high standards of care according to breast guidelines without compromising the safety of patients and healthcare professionals.

Keywords: COVID-19; SARS-CoV-2; Breast Cancer

Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has spread dramatically worldwide since the beginning of 2020 [1]. On February 21st the first Italian patients with severe coronavirus disease 2019 (COVID-19) was diagnosed in Italy. Due to rapid human-to-human transmission and in order to limit the viral spread, on March 10th, the government has implemented extraordinary restrictions [2]. The COVID-19

pandemic has required a sudden and significant re-allocation of healthcare resources posing great present and future challenges to maintain breast surgery services. Especially at the beginning of the lockdown, only urgent medical services were guaranteed while oncological diagnostic procedures and treatments suffered a significant slowdown [3]. The challenge is to maintain operative capacity but also to protect both patients and healthcare workers from the risk of exposure to SARS-CoV-2. Stopping the service for cancer patients could not be an option. Healthcare facilities had

to strive to keep normal service in the safest conditions possible. The following safety measures were established: 1) Triage procedures were applied each patient prior to hospital admission: administration of an ad hoc questionnaire focused on the recent onset of symptoms most related to COVID-19 and contacts with COVID-19 patients or suspected ones and detection of patients' body temperature prior to their admittance to the hospital building, 2) patients staying in hospital rooms wearing face masks, 3) limited access to the outpatients area 4) access to the hospital allowed only by appointment or through the emergency room 5) no relatives admitted to the ward, 6) nasopharyngeal swab 48h before the scheduled surgery, 7) adequate personal protective equipment 8) in the event of confirmed infection, patients are transferred to a dedicated COVID-19 unit or elective surgery is postponed until healing with negative swab.

The hospital activity, in the most severe phase of the emergency, has been reconsidered by have imposed to postponing non-urgent surgeries, but to keep surgeries for malignancies within the priority limits (30 days) as far as possible. Normally the clinician's action is based on the guidelines, but in this situation the goal was to find a balance between the need to reduce the spread of the epidemic, continue anticancer treatments and rationalize the use of health resources to ensure best clinical practice.

In our country the reorganization of healthcare resources has been entrusted to the individual regions. This has created very heterogeneous realities with inevitable repercussions on organizational and welfare models, including Breast Care. At the beginning of the emergency the Italian National Association of Breast Surgeons (A.N.I.S.C.) tried to highlight what was acceptable to all realities [4]:

- To undergo surgery within the deadlines set by all recommendations, patients with histologically-proven malignant breast cancer discussed at the preoperative multidisciplinary meeting and neoadjuvant patients finishing treatment;
- To initiate patients with HER2 positive or triple negative neoplasia on neoadjuvant chemotherapy (NACT);
- To delay dubious or suspected diagnoses (B3);
- To delay the time necessary to exit the emergency and reschedule the reconstructive interventions, except for immediate reconstructions;

- To continue to guarantee multidisciplinary assessments by favoring online sessions;
- To guarantee medications, clinic and diagnostic activity and communication session of the definitive diagnosis.

In the months of major health emergency, breast cancer screening programs were temporary suspended [5]. According to the data reported by the National Screening Observatory [6], over 600,000 fewer women underwent mammography screening compared to the same period of 2019, equal to a reduction of 43.5% (-53.6% in the period January-May and -28.1% from June to September). At the end of September, the standard months of delay were 3.9. There are large swings between regions. The number of undiagnosed carcinomas is estimated to be 2793, of which 297 in Veneto.

Extensive database studies demonstrated the effect of delayed breast resection on survival [7-9].

Never as during this period has it been essential, due to the variations in clinical-assistance pathways compared to the standard, to maintain multidisciplinary consultation of the cancer patient. However, having to limit in-person meetings, the use of videoconferencing meetings was strongly recommended.

Postponing or changing treatment due to the pandemic may cause patients to feel they are not receiving optimal care. To deal with the increased risk of distress and psychological disorders and the obligation to adhere to social distancing, telemedicine has been used also by psychologists and psychiatrists to guarantee psychological individual and group support for patients while limiting visits to the cancer center.

The aim of this article was to report our experience with the management of breast cancer in the COVID-19 era in order to share our experience and provide information useful to develop possible organization model.

Methods

In our study, we retrospectively analysed the data collected in the DataBreast™ database of all patients undergoing breast surgery in 2020 and compared them with those of the previous year.

DataBreast™ is software for quality monitoring of breast cancer diagnosis, treatment and follow-up. It is a data warehouse of prospectively collected information that includes individual records of primary breast cancer cases diagnosed and treated in our Breast Centre. It collects in excess of 170 variables by patient record, including patient and cancer characteristics, information about preoperative workup, multidisciplinary approach, type of surgery, type of medical therapy and follow up data.

The data collected in the DataBreast™ database that we have considered for this article is mainly concerns surgery, in particular about number and type of breast surgery operation (conserving or mastectomy), reconstructive technique (prosthesis and non-synthetic dermal matrix or expander), identification technique of sentinel lymph node (radioactive isotope or indocyanine green) and triple negative carcinomas treated with neoadjuvant chemotherapy.

Categorical variables are expressed as numbers and percentages. Continuous data were reported as median. Demographic and clinical data were compared between groups with χ^2 test for categorical variables. All statistical analyses were performed with Microsoft Office Excel.

Written informed consent was obtained from all patients.

Results

In 2020, 558 breast surgery operations were performed in our Centre, compared to 669 in the previous year. An overall annual decline of 16.6% was observed (Figure 1).

Figure 1: Monthly comparison of the number of breast surgeries between 2019 and 2020.

In 2020 we performed 339 breast surgical operations for malignant tumors versus 431 in 2019.

The monthly trend points out that the difference is not constant over the course of the year: there was a progressive decline in surgeries from March to June 2020. The difference was more marked between surgeries for malignant neoplasms than for all types of surgeries (Figure 2). The number of surgeries performed between August and September 2020 was comparable to the previous year, only to drop again in the last quarter of the year but less marked than in the period of the first epidemic wave.

Figure 2: Monthly comparison of the number of breast cancer surgeries between 2019 and 2020.

All patients undergoing breast surgery from mid-March onwards underwent nasopharyngeal swab for SARS-Cov-2 48 hours prior to surgery. Only 3 patients had a positive nasopharyngeal swab; their surgery was postponed and performed a few weeks later. No patient had a positive nasopharyngeal swab for SARS-Cov-2 within two weeks of hospital discharge. Even among the Breast Surgery staff there were no intra-hospital infections.

In 2020 155 of the breast cancer patients (46%) underwent conserving-breast surgery and 184 (54%) had a mastectomy. In the previous year 213 patients (49%) had performed breast-conserving surgery and 218 (51%) had a mastectomy (p 0.34).

Among patients who underwent mastectomy in 2020, 37.5% were over 70 years old compared to 37.1% in 2019 (p 0.97).

Taking into account the type of mastectomy performed, we did not notice a statistically significant difference between total

mastectomies and conservative mastectomies in the two years (71 and 113 cases respectively in 2020 versus 82 and 136 cases in 2019, p 0.94).

In the year of the pandemic, the reconstructive technique with breast implants and non-synthetic dermal matrix was used more frequently than breast reconstruction with expander, reflecting the same percentages of the previous year (65 vs 35% and 57 vs 43%, p 0.19) (Figure 3).

Figure 3: Comparison of the type of breast reconstruction between 2019.

In our series sentinel lymphnode biopsy (SNLB) was performed in 233 (76%) cases in the 2020 group and in 296 (75%) cases in 2019 group (p 0.75). 73 (24%) patients presented ipsilateral node involvement in 2020 group versus 97 (25%) patients in 2019 group, (p 0.71).

In our centre, the sentinel lymph node is identified by radioactive isotope technique or by indocyanine green (ICG) florescence technique.

In 2019 the sentinel lymph node had been identified with the ICG technique in 50 (17%) cases, with the radioactive isotope technique in 240 (81%) and with the mixed technique in 6 (2%). In 2020, on the contrary, the lymph node was identified by the

ICG technique in 189 (81%) cases, with the radioactive isotope technique in 41 (18%) and with the mixed technique in 3 (1%) (p < 0.00001).

In 2020 there were 22 cases of triple negative breast cancer compared to 27 in the previous year. Comparing the two years, the percentage of triple negative carcinomas treated with neoadjuvant chemotherapy was 50% in 2020 and 41% in 2019, the difference was statistically not significant (p 0.719275).

In 2019, all patients undergoing NACT for triple negative breast cancer underwent breast surgery; the same trend is assumed for the patients in 2020 as 82% of the patients have already undergone breast surgery, while for the others it will be necessary to wait for the end of neoadjuvant chemotherapy.

Length of hospital stay was comparable between the groups; median hospitalization time was 2 days in 2020 and 1.8 days in 2019.

Discussion

During the pandemic, we have tried to continue providing high-profile services, in appropriate times and following traditional Breast Cancer Guidelines.

In our case series, we observed a progressive decline in surgeries from March to June 2020, more marked among surgeries for malignant neoplasms. This reduction was due to the suspension of the breast cancer screening programs from March to May 2020 with a consequent reduction in the diagnosis of early cancers. The second epidemic wave, in the last quarter of the year, resulted in a less marked reduction in breast cancer surgeries compared to the period of the lockdown, probably because after the lockdown the screening programs resumed their activity which was reorganized in terms of safety to continue even during new epidemic waves.

Some guidelines issued at the outbreak of the pandemic proposed to limit to the I level the oncological procedures in the case of breast conservative surgery and as regards mastectomy, consider simple mastectomies and avoid immediate reconstructions, both on implant and autologous [10]. American College of Surgeons recommended discouraging elective mastectomy in patients eligible for breast conservative surgery. For patients requiring mastectomy, immediate reconstruction

with implant or tissue expander, it's recommended to perform it only if the hospital resources permitted [11]. In our case series, the percentage of patients undergoing mastectomy with reconstruction in 2020 compared to 2019 remained stable at 61-62%. Breast reconstruction techniques also remained unchanged in 2020 compared to the previous year and the main reconstructive technique remains breast reconstruction with definitive implant and non-synthetic dermal matrix.

In our case series comparing the two years it is observed that the percentage of triple negative carcinomas treated with neoadjuvant chemotherapy does not change.

Breast surgery after NACT was also performed at an appropriate time in 2020, according to traditional guidelines for breast cancer.

For some years in our breast surgery, we have started to use the ICG florescence technique for the preoperative mapping of the sentinel lymph node, developing a high level of expertise and demonstrating its safety in terms of efficacy.

The standard for axillary lymph node staging in breast cancer patients with a clinically and radiologically normal axilla is sentinel lymph node biopsy (SLNB) with a radioisotope. This method provides for the access and stay of the patient for several hours in Nuclear Medicine the day before the surgery to perform a lymphoscintigraphy. These problems can all be addressed by the surgeon who takes control of the injection procedure using tracers without radioisotopes. The use of indocyanine green (ICG) which provides the visualization with a photodynamics camera has been widely used and evaluated in systematic tests and reviews [12,13]. As already some years in our breast surgery, we had started to use the ICG fluorescence technique for the preoperative mapping of the sentinel lymph node, developing a high level of competence and demonstrating its safety in terms of efficacy, it was easy to adopt this solution.

In order to reduce unnecessary access of patients to the hospital and to improve their sense of security, we have set up a post-discharge telemonitoring (re-call service at 24-hour). This was organized and supervised by dedicated Breast Care Nurse. The patients undergoing breast surgery are contacted by Breast Nurse 24 hours after discharge to assess how they experienced the return home and offer further support in pain and drainage management.

Cancer patients may be worried about whether their treatments will be delayed and what the implications might be on their outcomes. It is important to recognize the increased level of distress that breast cancer patients and their families might face during this time, over and above the distress already experienced in relation to their diagnosis and treatment and the pandemic itself. As a result, it is important that psychosocial staff will be more utilized to assess distress and available to address the ongoing needs of patients and families during this pandemic [14].

Psychological support for breast cancer patients also continued throughout 2020, with adequate safety measures. In order to facilitate access to this service, for patients wishing to minimize access to the hospital for fear of contagion, the possibility of online psychological interviews was offered.

Another important point, in order to maintain high quality standards of care even during the pandemic, was that we continued to guarantee multidisciplinary assessments. Multidisciplinary meeting might involve a general surgeon, an oncologist, a radiotherapist, a radiologist and a pathologist while maintaining an adequate social distance and wearing masks, other team members could follow the meeting online.

The data management activity was maintained during the pandemic period by the breast data manager [15], a dedicated person responsible for data collection and analysis using the DataBreast™. It's important that the data are collected during the patient management process, because the data manager must inform the breast centre team about performance quality according to indicators and about any emerging criticality. During the pandemic in our centre, data management was maintained and therefore allowed to make the quality indicators, calculated in 2019, available to the Eusoma Commission during the First Audit, on November 26 2020. In the following months, the Non-Conformities (NC) and Recommendations (R) detected by the Audit Team were fixed and corrected, obtaining 19 February 2021 the Eusoma Breast Centres Certification. In November 2021, there will be the second inspection during the Surveillance Audit. A lot of data collected allows, in addition to the qualitative assessment of the standards, the research through the publication of scientific articles. Cancer control plans must include high-quality population and clinical cancer registries for breast cancer to inform both research and improve quality of care [16].

Conclusions

- The spread of COVID-19 has required a rapid reorganization of health service delivery in face of the pandemic.
- The challenge is to reorganize the health care services, in particular by taking adequate safety measures and strategies to reduce unnecessary hospital access, to continue to offer high standards of care according to breast guidelines without compromising the safety of patients and health professionals.
- The implementation of new practices, such as the ICG fluorescence technique for the preoperative mapping of the sentinel lymph node, allows for no delay in surgery and ensures the safety of patients and health professionals.
- The pandemic can also lead to an improvement in our activity; the organization of multidisciplinary meetings, for example, favors the participation of a greater number of professionals.
- In this difficult situation, moreover, our attention must also be focused on the implementation, also through telemedicine, of the psychological support and nursing support service (Breast Care Nurse's re-call service) in order to accompany patients, support them during their treatment and implement their sense of security.
- These changes in our activity, necessitated by the pandemic, have been an opportunity for improvement in the Breast Unit's activity so we intend to maintain them in the future after the end of the pandemic.

Conflict of Interest

The authors declare no conflict of interest related to the publication.

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Ethical Approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study ethical approval from the Committee on Health Research Ethics is not required.

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