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PERSPECTIVE

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Learning from organisational changes in the management of breast cancer patients during the COVID-19 pandemic: Preparing for a second wave at a breast unit in northern Italy

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Abstract

Italy was the first western country to be hit by the initial wave of severe adult respiratory syndrome coronavirus 2 pandemic, which has been more widespread in the country's northern regions. Early reports showing that cancer patients are more susceptible to the infection posed a particular challenge that has guided our Breast Unit at Hub Hospital in Trento to making a number of stepwise operational changes. New internal guidelines and treatment selection criteria were drawn up by a virtual multidisciplinary tumour board that took into account the risks and benefits of treatment, and distinguished the patients requiring immediate treatment from those whose treatment could be delayed. A second wave of the pandemic is expected in the autumn as gatherings in closed places increase. We will take advantage of the gained experience and organisational changes implemented during the first wave in order to improve further, and continue to offer breast cancer management and treatment to our vulnerable patient population.

KEYWORDS
breast cancer, COVID-19, treatment of breast cancer during COVID-19

1 | INTRODUCTION

Coronavirus disease 2019 (COVID-19), which is caused by severe adult respiratory syndrome coronavirus 2 (SARS-CoV-2), quickly spread from China to the rest of the world and, as of 22 May 2020, had led to 5,168,433 confirmed cases and 335,936 deaths (www.worldometers.info/coronavirus).[1,2]

Italy was the first western country to be hit by the initial wave of SARSCoV-2 infection and, by 22 May 2020, it was the country with the sixth highest number of cases and deaths (respectively 228,658 and 32,616). The local spread of the disease was heterogeneous, with the northern regions of the country recording 80.4% of the cases and 86.7% of the deaths. In the province of Trento, which has a population of 540,000 inhabitants, 5444 cases and 541 deaths had been recorded as of 22 May 2020.

Initial epidemiological data showed that COVID-19 related mortality was highest among the elderly and subjects with co-morbid hypertension, diabetes, and cancer. Cancer patients are more susceptible to the infection because of the immunosuppression caused by anti-cancer medical and surgical treatments, and various studies have shown that such patients are at higher risk of the complications of the COVID-19 than subjects without cancer. This meant that there was an urgent need to reduce their risk of exposure and make organisational changes in order to adapt the allocation of healthcare resources appropriately.[3–4]

What follows is a description of the stepwise operational changes adopted by the Breast Unit of Ospedale Santa Chiara, the principal hospital in the province of Trento.

1.1 | Screening for infected cases

All of the patients who had access to the hospital's diagnostic and therapeutic services were pre-screened by telephone some days before their appointment in order to identify those with symptoms giving rise to a suspicion of SARS-CoV-2 infection. These were then tested and, if positive, managed at home by means of telemedicine or in an area of the hospital dedicated to COVID-19.

All patients were instructed to respect social distancing, regularly wash their hands thoroughly, and wear a mask inside the hospital.[5]

1.2 | Diagnosis

- About 600 new breast cancer cases are diagnosed every year at the Breast Centre in Trento (611 in 2019; 38% by means of screening, and 62% symptomatic patients).
- On 11 March 2020, mammography-based population screening and risk-adapted breast screening programmes for asymptomatic subjects (BRCA carriers) were suspended in accordance with the recommendations issued by the American Society of Breast Surgeons (ASBrS) and American College of Radiology (ACR) on 2 March.[6]
- In order to avoid a delayed diagnosis, subjects with lesions giving rise to the suspicion of breast cancer underwent ultrasound-guided and stereotactic vacuum-assisted breast biopsies (VABs)
- Between 11 March and 6 April 2020, 51 cases of breast cancer were diagnosed: 19 in situ and 32 invasive lesions (one with distant metastases).

1.3 | Therapeutic strategy

- Our internal guidelines and treatment selection criteria were adapted by redefining clinical priorities on the basis of multidisciplinary discussions in early March. This was subsequently supported by the published literature

concerning cancer care and risk/benefit ratios,[7] and the Breast Cancer Consortium[8] and ESMO recommendations.[13]

- On-line multidisciplinary tumour board meetings were regularly held by means of teleconferencing. Treatments and their timing were defined on the basis of tumour biology with the aim of distinguishing the patients requiring immediate treatment from those whose treatment could be delayed.
- Two main scenarios were considered for operable cases:
  - Patients requiring up-front surgery, with three different priority levels (see below)
  - Patients requiring neo-adjuvant treatment (aggressive tumour biology such as triple-negative or HER2-positive lesions, or locally advanced luminal tumours).

1.4 | Surgery

- In 2019, 525 patients with new breast cancers underwent surgery at our Breast Unit
- On 18 March, scheduled surgical interventions were suspended in order to expand the number of critical care beds with artificial ventilation.
- On 2 April, breast surgery was resumed at an alternative facility usually dedicated to outpatient surgery, thus allowing operations to be carried out for half of the time usually allocated to them before the pandemic.
- Complex breast reconstructive surgery (autologous tissue flaps) was reduced in order to decrease the risk of complications.
- Outpatient surgery was introduced whenever possible, with the patients being discharged in the afternoon or evening, and then followed up by telephone and scheduled appointments for wound care.
- These activities were coordinated by a nursing case manager, who was present at all times.
- When discharge was not feasible on the day of surgery, the patients were admitted to the Breast Unit at the main hospital.
- Efforts were made to keep outpatient planning and surgical activities at the main hospital to a minimum (emergency procedures for hematoma/abscess drainage, and complex cases).
- Selection criteria based on tumour type and biology were weighed against the risks of anaesthesia and infection.
- Since April, all patients scheduled for surgery have undergone nasopharyngeal swab testing for SARS-CoV-2; in addition, operating theatre staff have been periodically tested.
- The surgical priorities defined after multidisciplinary discussions are shown on Tables 1 and 2. We usually treat 200 priority A cases (Table 1) and 300 priority B cases (Table 2) a year.
- Most of the operations involved high-risk patients; 25 received adjuvant chemotherapy.
- No patient at low/medium risk and/or with small ductal carcinoma in situ or benign lesions (fibro-adenoma, probably benign nodules) underwent surgery during the study period.
- No woman carrying the BRCA mutation underwent prophylactic contralateral surgery (in the case of cancer) or bilateral mastectomy (in the absence of cancer)
- All of the candidates for surgery from April onwards were asymptomatic and had a negative nasopharyngeal swab test for SARS-CoV-2.

1.5 | Systemic therapy

- Activities in the Medical Oncology Department remained unchanged, with protective measures being taken by all patients and healthcare staff (surgical masks, social distancing, hand washing and surface cleaning and disinfection).

TABLE 1 Selection criteria for urgent cases (priority A <4–5 weeks)

Selection criteria	Patients operated from Mar 24 to May 25
End of neoadjuvant treatment[a]	6
High-risk cases with aggressive tumour biology for whom chemotherapy is contraindicated or was refused	4
Patients <70 years with luminal type B lesions where final pathology report is needed for further treatment decisions	25
Triple negative disease or HER2 positive <1.5 cm (T1N0)	5
Patients with extended or comedonic G3 in situ carcinoma with higher probability of invasive disease	12
Short interval (<48 months) locoregional recurrences	4

[a]Treatment of choice in triple negative or HER2 positive lesions >1.5 cm or Luminal type B > 2 cm and/or N1 associated to high proliferation index (>20%).

TABLE 2 Delayed procedures (priority B < 8–12 weeks) with the possibility of alternative systemic upfront treatment

Selection criteria	Patients operated from Mar 24 to May 25
Patients <70 years with cT1N0 luminal A disease[a]	10
Patients >70 years with luminal A and B disease (<T3 N0)[a]	2
Luminal disease in patients with important comorbidities who may require postoperative critical care[a]	3
Long interval (>48 months) locoregional recurrences (<rT3 N0)[a]	

[a]Postmenopausal women can receive hormonal therapy and further delay surgical time.

- Systemic treatments continued as usual:
  - Neo-adjuvant or adjuvant treatments were guaranteed adequate timing (2-3 weeks after diagnosis and 4-5 weeks after surgery respectively), including the continuation of adjuvant trastuzumab.
  - Haematopoietic growth factors were administered to decrease the risk of neutropenia and febrile neutropenia due to chemotherapy regimens that induce an intermediate/high risk of immunosuppression (i.e. anthracyclines, 3-weekly docetaxel).
  - Steroid use was limited or reduced.
  - In accordance with the international guidelines, adjuvant endocrine therapies in pre- and post-menopausal women remained unchanged as they do not increase the risk of immunosuppression.
- Preoperative hormonal treatment was proposed to 46 patients with hormone responsive tumours awaiting priority B surgery, and was accepted by 30.[10]
  - Carbon-track landmarking was used for all lesions in order to allow their localisation at the time of surgery.
  - In the case of frail patients, their general practitioner was contacted in order to coordinate therapy, monitor side effects, and avoid hospital admission.
  - Twenty-two very frail patients aged >80 years received hormonal treatment alone, with adequately long-lasting responses and few side effects.

- No case of disease progression, toxicity or intolerance was observed in this group during therapy, thus obviating the need to schedule immediate surgery.
- Agents administered for osteoporosis prophylaxis were delayed in 64 cases.
- Ports were flushed every 12 weeks rather than monthly
- Two patients developed COVID-19 during neoadjuvant chemotherapy; their anti-cancer treatment was suspended in both cases and resumed after their full recovery.

2 | RADIOTHERAPY

2.1 | Radiotherapy was guaranteed:

- For patients who had already started treatment.
- For patients with symptomatic disease (brain, bone or lymph node metastases, bone marrow compression, painful/bleeding tumour mass, etc.). Hypofractionation was used when clinically appropriate in order to reduce hospital admissions.
- Hypofractionation was also preferred in patients with an indication for post-operative radiotherapy after breast conservation (e.g. 40 Gy in 15 fractions over three weeks)[9,11,12]
- Radiotherapy could be delayed in the case of patients at low or very low risk (luminal A, DCIS)
  - For 3–4 months after surgery in low-risk patients.
  - Elderly patients at low risk of recurrence were advised to avoid radiotherapy.

2.2 | Follow-up

- Six- and 12-month follow-up examinations were carried out in the form of an electronic medical record-assisted phone call.[14]
- Patients were contacted by phone and, after they had been told the reasons for the call, their consent was requested.
- Disease-related symptoms and/or side effects attributed to hormonal therapy were investigated. The patients were reassured and given a new appointment with instructions as to the tests to undergo in the meantime.
- Hospital admission was guaranteed if disease progression was suspected on the basis of reported symptoms or altered diagnostic test results (mammography and ultrasonography examinations were carried out on a regular basis in the case of follow-up patients).
- Nineteen patients requested a standard visit for symptoms related to hormonal therapy.

2.3 | Other services/departments

- On-site psychology and nutritional counselling services were suspended. However, given the significant psychological impact that awareness of their cancer and the greater risk of serious complications of COVID-19 can have on patients, and the fact that they may be exposed to even greater emotional distress in addition to the loneliness and isolation imposed by the lockdown, telemedicine was used to ensure psychological support while limiting visits to the cancer centre.
- Preservation of fertility services were temporarily suspended, but the patients receiving chemotherapy who wished to maintain their fertility were treated with the addition of LHRH analogues in order to reduce gonadal damage.

2.4 | Possible strategies to be undertaken in case of second wave

We reported the main organisational changes made in the different activities of our Breast Unit (diagnosis, surgery, medical treatment, radiotherapy and other services) on the basis of tumour biology, disease stage, and the presence of co-morbidities.

These changes were not free of errors but represented new opportunities to work as a team in order to achieve the usual goals in a continuously changing scenario. Treatment decisions have been made by a virtual multidisciplinary tumour board that took into account the risks and benefits of treatment, and distinguished the patients requiring immediate treatment from those whose treatment could be delayed.

We will take advantage of the organizational changes implemented during the first wave in order to improve our response further and allow us to withstand a second wave while continuing to offer breast cancer management.

For this reason we resumed the screening mammography activity in June ensuring a greater distance between women (wider waiting spaces).

We will continue to take advantage of outpatient surgery and implement it if necessary.

If the volume of Covid-19 patients and ICU should increase in second wave we will consider moving the activity of breast surgery to a spoke hospital.

We will continue to propose preoperative hormonal therapy to patients with hormone responsive tumours awaiting priority B surgery (see Table 2).

This therapy can become exclusive in very fragile patients and/or aged >80 years. This alternative strategy will be promoted to continue in regular clinical practice except in the onset of ulceration or local progression.

An secondary problem we feel compelled to report was our lack to release official anticipated communication to the community and patients about our organizational changes. An omission that could be easily solved by publishing official short communications on their smartphone (i.e. via mobile application). Patients on our waiting list for surgery would follow could thus follow the news and be aware of the emergent situation evolving in the hospital.

2.5 | Future projects

We will continue to use telemedicine as a means of carrying out pre-screening assessments for symptoms of COVID-19 before allowing access to any hospital service, and for monitoring treatments and side effects.

An app is being developed that will:

- Remind patients about their appointments; - Coordinate appointments in such a way as to avoid large gatherings;
- Provide reminders to maintain social distancing, wear a mask, and wash hands frequently; - Collect feedback from patients in order to monitor for COVID-19 symptoms;
- Provide tutorials on:
- post-surgical wound care at home; - rehabilitation/exercises to reduce the risk of arm lymphedema.
- Monitor potential patient-reported toxicities and side effects.
- Provide urgent information, or contact via chat.

3 | CONCLUSIONS

Managing breast cancer patients in the context of the SARS-CoV-2 outbreak has been an enormous challenge as ensuring the safety of patients and healthcare staff has required special attention in addition to the usual activities of cancer care.

Cancer patients are at increased risk of developing COVID-19 related complications, which probably worsens outcomes in comparison with non-cancer patients. During an acute pandemic and lockdown, it is necessary to balance the risk of cancer progression against the risk of becoming infected, and establish measures to reduce the risk of transmission to a vulnerable population.

This paper summarises the main organisational changes made in the different activities of our Breast Centre (diagnosis, surgery, medical treatment, radiotherapy and other services) on the basis of tumour biology, disease stage, and the presence of co-morbidities. These changes were not free of errors but represented new opportunities to work as a team in order to achieve the usual goals in a continuously changing scenario. Treatment decisions have been made by a virtual multidisciplinary tumour board that took into account the risks and benefits of treatment, and distinguished the patients requiring immediate treatment from those whose treatment could be delayed.

The first wave of the pandemic took northern Italy by surprise, and has led to a high death toll among the general population and healthcare personnel. However, this devastating experience has also taught us lessons that will help us to confront future events with greater confidence. Italy is now gradually reducing lockdown measures as the number of new COVID-19 cases and the mortality rate continue to decline. However, a second wave is expected in the autumn as the likelihood of gatherings in closed places increases.

We will take advantage of the organisational changes implemented during the first wave in order to improve our response further and allow us to withstand a second wave while continuing to offer breast cancer management and treatment to our vulnerable patient population.

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ETHICS STATEMENT

The research has been carried out within an appropriate ethical framework and according to internationally accepted standards for research practice. Patient informed consent was acquired for the treatments carried out but not for organizational changes related to the particular emergency situation.

AUTHOR CONTRIBUTIONS

Antonella Ferro, Paolo Cristofolini and GMG significantly contributed to the study conception and design. Antonella Ferro, Marco Pellegrini, Carmine Fantò, Paolo Cristofolini, Salvatore Mussari, Silvia Lazzeri, Sara Cantarelli and Monica Campregher analysed and contributed to the interpretation of data. Carlos A. Garcia-Etienne, Orazio Caffo and Giovanni Maria Guarrera significantly contributed to critical revision of the manuscript for important intellectual content.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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