

# Surgical site infections in patients undergoing breast oncological surgery during the lockdown

## An unexpected lesson from the COVID-19 pandemic

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### Abstract

**Background:** The present study aims to evaluate how the measures to contain the SARS-CoV-2 spreading affected the surgical site infections (SSIs) rate in patients who underwent nondeferrable breast cancer surgery (BCS).

**Methods:** This study is a retrospective analysis of prospectively collected data from a consecutive series of patients underwent nondeferrable BCS in a regional Italian Covid-free hub during two different period: March to April 2020 (pandemic cohort [PC]) and March till April 2019 (control cohort [CC]). SSIs were defined according to the criteria established by the Center for disease control and prevention (CDC) and additional treatment, serous discharge, erythema, purulent exudate, separation of deep tissues, isolation of bacteria, and stay (ASEPSIS) scoring systems.

**Results:** One hundred ninety-nine patients were included in the present study: 100 and 99 patients who underwent nondeferrable BCS from March to April 2020 (PC) and from March to April 2019 (CC), respectively. The overall SSIs rate in this series was 9.1% according to CDC criteria and 6.5% according to ASEPSIS criteria. The SSIs incidence decreased during the pandemic period. Moreover, the SSIs rate according to ASEPSIS criteria was statistically lower in the PC than in the CC. We observed significant evidence of higher SSIs, both in terms of CDC and ASEPSIS score, in patients having undergone breast reconstruction compared with patients not undergoing immediate reconstruction.

**Conclusions:** The restrictive measures issued during the lockdown period seemed to lower the SSIs rates in patients undergoing nondeferrable BCS.

**Keywords:** Covid-19 pandemic, Breast cancer, Surgical site infections, Center for Disease Control and Prevention (CDC), Additional treatment, Serous discharge, Erythema, Purulent exudate, Separation of deep tissues, Isolation of bacteria, and Stay (ASEPSIS)

### Introduction

From February 9, 2020, global data reported that more than 100 million people had become infected with “Severe Acute Respiratory Syndrome Corona Virus 2” (SARS-CoV-2) and more than 2 million had died for Corona Virus Disease 2019 (COVID-19) [1–3]. On February 21, 2020, the first case of COVID-19 was diagnosed in Italy. The increasingly restrictive measures adopted to contain SARS-CoV-2 pandemic have

culminated into the national lockdown issued in March 2020. To lower the risk of SARS-Cov-2 infection in cancer patients, while guaranteeing continuity of care in this setting, a sudden reorganization of the hospital structures was implemented by National and Regional Health System and each Italian Region has identified dedicated COVID-19 hubs. The Regina Elena National Cancer Institute (IRE) has been identified by the Lazio Region as one of these. Our Unit of Breast Surgery is a high volume surgical center, which includes breast and plastic and

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The authors declare that they have no conflicts of interest with regard to the content of this report.

Ethics approval and consent to participate: approval was waived by the Institutional Review Board of the Regina Elena National Cancer Institute on the 21st July 2020 (Protocol# RS N.1382/20). Informed consent was obtained from all patients participating in the study. This research was conducted according to

the principles established by the Declaration of Helsinki. Data will be provided from the corresponding author on reasonable request.

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reconstructive surgery. Specific internal protocols to preserve cancer patients from SARS-CoV-2 infection and disease have been adopted by the institutional risk management team, in full agreement with the guidelines released from the Italian Minister of Health (MoH) and Regional Health Department [4,5].

The challenge for public health system was to reallocate resources and operators to face the virus emergency assuring at the same the continuity of standard care nononcologic and oncologic patients. In order to properly address to this smaller and extremely heterogeneous group of patients needs, new therapeutic priorities have been established. Therefore, guidelines informing the selection of nondeferrable cancer patients have been published [6,7]. In specific referral to breast cancer patients, priorities for outpatient, diagnostic and surgical activities have been identified [8,9].

Surgical site infections (SSIs) represent the most common and expensive hospital-acquired infections, accounting for 20% of such infections. The annual cost of SSI in the United States is estimated to be about US\$3.5 to US\$10 billion, stemming from the associated increased length of stay, emergency department visits, and readmissions [10]. The Center for Disease Control and Prevention (CDC) and additional treatment, serous discharge, erythema, purulent exudate, separation of deep tissues, isolation of bacteria, and stay (ASEPSIS) are two of the most common SSI scoring systems [11–13].

SSIs following breast cancer surgery (BCS) are dreaded complications which occur at a frequency approximately varying within a 0.8% to 26% range [14–19]. These latter events have a negative impact on important patients' outcomes, including the timing of adjuvant treatment delivery and disease free survival [14–19].

The aim of the present study is to compare the surgical outcomes of consecutive patients who underwent nondeferrable BCS during the pandemic period (March–May 2020) with consecutive patients who underwent nondeferrable BCS during the same time frame but one year earlier, in order to assess the impact of the extraordinary measures issued by the Italian MoH to reduce the SARS-CoV-2 spread on the SSIs rate.

## Material and Methods

### Patient population

This study is a retrospective analysis of prospectively collected data, approved by our Institutional review board. Informed consent was obtained from all participants. The research was conducted according to the principles established by the Declaration of Helsinki.

The indication for “non-deferrable breast surgery” was defined by the American College of Surgeons Surgical Care Guidelines [6]. We also found breast cancer patients diagnosed more than a month earlier to be eligible for inclusion.

All patients were evaluated before surgery with ultrasound, mammography, or magnetic resonance imaging. Breast cancer was diagnosed by core needle biopsy. Pre and postoperative images were taken to show the aesthetic results. An *ad hoc* multidisciplinary team handled the selection of patients undergoing BCS according to the previously mentioned criteria. To this aim, weekly meetings were organized. One single representative member for each of the following professional figures was involved: general and plastic surgeon, oncologist, radiotherapist, radiologist, and psychologist. The perioperative measures in place at our Surgical Division for the prevention of SSIs include the recommendations of the World Health Organization (WHO) [20]. During the pandemic, in addition to routine clinical practices, extraordinary measures were adopted, which can be summarized as follows: major control and limitation of hospital access, use of personal protective equipment, standard and hydrogen peroxide in the vaporized form disinfection of the

operating room, social distancing, and self-monitoring of fever and respiratory symptoms by healthcare professionals [4]. The additional measures taken in our Covid-free hub included also the use of single hospital rooms.

### Enrollment process and definition of comparative groups

A first subset of consecutive patients was selected from patients undergoing BCS during pandemic period (March–May 2020, Pandemic Cohort, PC). A second subset of consecutive patients was selected from patients undergoing BCS during the same time frame but one year earlier (March–May 2019, Control cohort, CC). Based on the possible risk factors for SSIs mostly described in the literature [21–23], patients aged 80 years or older, diagnosed with autoimmune disorders, in course of therapy with steroids or within the past 6 months, American Society of Anesthesiologists (ASA) score equal to/greater than 4, body mass index (BMI) equal to/greater than 35, kidney/liver/bone marrow failure, were excluded from the present study. Data extraction was performed by specifically trained personnel and focused on demographic features, comorbidities neoadjuvant therapy, relevant clinical and pathological characteristics, ASA score, surgical procedures, operative time, type of breast reconstruction, drainage use, SSIs classified according to CDC and ASEPSIS score, time between surgery and infection onset, the need of rehospitalization, and delay to the start of adjuvant therapy. All data were collected in a Microsoft Excel program (Microsoft Corporation, Redmond, Washington, USA). From March 2019 to May 2020, 633 patients underwent nondeferrable BCS in the Division of Breast Surgery at IRE, Rome, Italy. All patients followed the same treatment protocol and used an identical surgical approach performed by the same team. 130 patients underwent nondeferrable BCS from March 15, 2020 to June 15, 2020, and 121 patients underwent nondeferrable BCS from March 15, 2019, to June 15, 2019. Forty-six patients did not meet the above-mentioned inclusion criteria, so they were excluded from the present study (18.3%) and 6 patients (2.4%) were lost during the follow-up period, leaving 199 patients to be included in the study: 100 patients entered in the PC (50.3%) and 99 in the CC (49.8%). The flow-chart of the patients selection was illustrated in Figure 1.

### Surgical procedure

For conservative and radical surgery, we used a standard technique and the procedures were performed by breast surgeons without plastic surgeons. All quadrantectomies were followed by oncoplastic surgery through volume replacement and volume displacement techniques. In case of reconstructive surgery the procedures were performed by breast and plastic surgeons. Reconstructive options included simplex mastectomy (SM), nipple-sparing mastectomy (NSM), and skin-reducing mastectomy (SRM) followed by one stage breast reconstruction implant or tissue expanders as a safe bridge to definitive reconstruction. The implant placement was subcutaneous or submuscular after careful evaluation of each patient. Sentinel lymph node biopsy with indocyanine green was performed in all cases. In case of neoadjuvant chemotherapy, sentinel lymph node biopsy was performed using a dual staining technique (indocyanine green and radioisotope). Axillary lymph node dissection was performed in case of intraoperative finding of metastatic sentinel lymph node. Surgery is performed under general anesthesia. All patients received prophylactic intravenous antibiotics. Patients were placed in the standard supine position with both arms abducted at 90°. In case of mastectomy a surgical drain was always placed, while in case of conservative surgery, it was evaluated intraoperatively on a case-by-case basis.

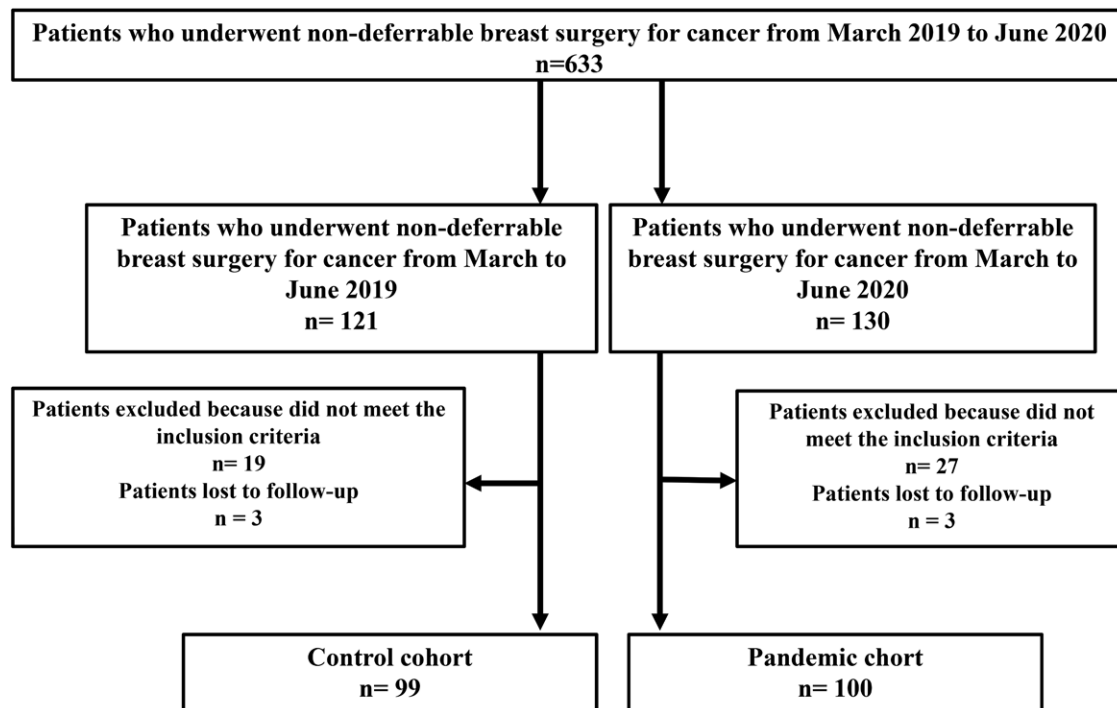


Figure 1. The flow-chart of the patients selection.

### Outcomes measures

Postsurgical controls were performed regularly for a minimum of 12 months in all patients. In case of breast reconstruction controls were set biweekly over the first 3 months and every 2 weeks for two additional months. Conversely, if no implants were placed, controls were scheduled twice per week for a minimum of 30 days. Regarding the time of drain use, we adopted a volume-controlled removal method in all patients. A culture specimen was collected when an infected wound was suspected by the surgeon or in case of pain or tissue tenderness, swelling, redness or heat, purulent drainage, or body temperature  $> 38^{\circ}\text{C}$ . SSIs were defined according to the CDC and ASEPSIS score [12,13]. SSI was defined by CDC criteria as follows: purulent drainage (CDC#1), positive aseptically collected culture (CDC#2), signs of inflammation with opening of incision and absence of negative culture (CDC#3), or physician diagnosis of infection (CDC#4) [10]. The ASEPSIS score is calculated based on the percentage of the wound affected by serous exudate, erythema, purulent exudate, and separation of deep tissues. Additional points are awarded for antibiotic treatment, drainage of pus under local anesthesia, debridement of the wound under general anesthesia, isolation of bacteria, and stay as inpatient prolonged over 14 days. Scores are grouped into four categories: satisfactory healing (0–10), disturbance of healing (11–20), minor SSI (21–30), moderate SSI (31–40), and severe SSI ( $>40$ ) [11].

### Statistical analysis

Continuous variables are expressed as mean  $\pm$  standard deviation (SD) while categorical variables as frequencies and percentages. Associations were estimated throughout chi-square or Fisher exact test. For quantitative variables, groups were compared by Mann-Whitney test. A  $P$  value lower than 0.05 was considered statistically significant. Statistical analyses were carried out with SPSS software 22.0 (SPSS Inc., Chicago, Illinois).

### Results

Out of 199 patients included in the present study, 75 (37.7%), 59 (29.6%), 50 (25.1%), and 15 (7.5%) underwent quadrantectomy, SM, NSM, and SRM, respectively. Eighty-five patients (42.7%) underwent breast reconstruction: in 38 cases (19.1%) a tissue expander was placed and in 47 cases (23.6%) a breast implant was placed. In 41 patients (20.6%), a subcutaneous implant was placed and in 44 patients (22.1%) a submuscular implant was placed. Patients' characteristics and surgical outcomes of the entire series are shown in Table 1.

No statistically significant differences were observed between the CC and the PC related to demographic features, comorbidities, neoadjuvant therapy, smoking habit, ASA score, surgical procedures, type of breast reconstruction, number of bilateral procedures and operative time. The mean CDC score was lower in the PC, but without reaching statistical significance. In contrast, the mean ASEPSIS score was statistically lower in the PC than in the CC ( $P < 0.0001$ ).

The impact of key patient- and breast surgery-related features on the outcome of interest, that is, SSIs, as defined by the CDC and the ASEPSIS criteria is summarized in Tables 2 and 3.

Overall, the SSIs rate in this series was 9.1% according to CDC criteria and 6.5% according to ASEPSIS criteria.

We observed significant evidence of higher SSIs, both in terms of CDC and ASEPSIS score, in groups of patients having undergone breast reconstruction with submuscular breast implant, especially in the case of SRM.

The overall number of SSIs according to CDC criteria was 18, classified as follows: CDC#1: 5 cases; CDC#2: 1 case; CDC#3: 4 cases, and CDC#4: 8 cases. The mean time to the occurrence of SSIs was 17.1 days, within 7- to 42-day range.

In the CC, the number of SSIs according to CDC criteria was 12 (66.7%), with the related distribution being: CDC#1: 5 cases; CDC#3: 3 cases, CDC#4: 4 cases. The mean time to the occurrence of surgical site infection was 18.2 days, within a 7- to 42-day range. In the PC, the number of SSIs according to CDC criteria was 6 (33.3%), with the following

**Table 1****Patients' characteristics and surgical outcomes of the entire case-series (N = 199)**

	<b>Control cohort n = 99 (49.75%)</b>	<b>Pandemic cohort n = 100 (50.25%)</b>	<b>P</b>
Sex ratio (M:F)	0:99	2:98	0.4975
Mean age ± SD, years (range)	56.31 ± 11.18 (35–78)	53.72 ± 11.74 (34–79)	0.3840
Mean BMI ± SD, kg/m <sup>2</sup> (range)	24.87 ± 3.37 (19–33)	23.79 ± 4.11 (18–34)	0.0630
Neoadjuvant therapy, n (%)	8 (8.08)	11 (11)	0.6306
Comorbidities, n (%):	29 (29.29)	32 (32)	0.7589
- Diabetes	9 (9.09)	8 (8)	0.8056
- COPD	6 (6.06)	7 (7)	1.0000
- Heart diseases	14 (14.14)	17 (17)	0.6965
Smoking, n (%)	18 (18.18)	26 (26)	0.2319
Mean ASA score ± SD (range)	1.94 ± 0.4 (1–3)	2.1 ± 0.4 (1–3)	0.0845
Surgical procedures, n (%)			
- Quadrantectomy	41 (41.41)	34 (34)	0.3078
- Simplex mastectomy	27 (27.27)	32 (32)	0.5353
- Nipple-sparing mastectomy	25 (25.25)	25 (25)	1.0000
- Skin-reducing mastectomy	6 (6.06)	9 (9)	0.5928
Breast reconstruction, n (%)	43 (43.43)	42 (42)	0.8865
- Breast implant	21 (21.21)	26 (26)	0.5050
- Tissue expander	22 (22.22)	16 (16)	0.2842
Implant placement, n (%)			
- Subcutaneous	21 (21.21)	20 (20)	0.8624
- Submuscular	22 (22.22)	22 (22)	1.0000
Surgical drainage, n (%)	67 (67.68)	57 (57)	0.1439
Mean timing of drainage use ± SD, days (range)	8.06 ± 6.13 (7–15)	8.85 ± 6.33 (7–15)	0.3944
Bilateral procedures, n (%)	14 (14.14)	19 (19)	0.4464
Mean CDC score ± SD (range)	0.30 ± 0.94 (0–4)	0.20 ± 0.84 (0–4)	0.1510
Mean ASEPSIS score ± SD (range)	12.91 ± 14.41 (0–70)	5.75 ± 7.46 (0–65)	<0.0001

ASA, American Society of Anesthesiologists; ASEPSIS, additional treatment, serous discharge, erythema, purulent exudate, separation of deep tissues, isolation of bacteria and stay; BMI, body mass index; CDC, center for disease control; COPD, chronic obstructive pulmonary disease; SD, standard deviation.

**Table 2****The impact of key patient-and breast surgery-related features on the outcome of SSIs as defined by the criteria established by the CDC (N = 199)**

	<b>SSIs according to CDC criteria</b>		<b>P</b>
	<b>NO n = 181 (90.95%)</b>	<b>YES n = 18 (9.05%)</b>	
Control cohort/Pandemic cohort	87(48.07)/94 (51.93)	12(66.67)/6(33.33)	0.1464
Sex ratio (M:F)	2 (1.1):179 (98.89)	0 (0):18 (100)	1.0000
Mean age ± SD, years (range)	56.25 ± 11.8 (34–79)	51.39 ± 10.6 (37–72)	0.0790
Mean BMI ± SD, kg/m <sup>2</sup> (range)	24.07 ± 3.88 (18–34)	26.75 ± 1.75 (25–30)	0.0554
Neoadjuvant therapy, n (%)	18 (9.94)	1 (5.56)	1.0000
Comorbidities, n (%):	48 (48.49)	3 (16.67)	0.5713
- Diabetes	16 (16.16)	1 (5.56)	1.0000
- COPD	13 (13.13)	–	0.6124
- Heart diseases	19 (19.20)	2 (11.11)	1.0000
Smoking, n (%)	41 (22.65)	3 (16.67)	0.7680
Mean ASA score ± SD (range)	2.02 ± 0.39 (1–3)	2.13 ± 0.35 (2–3)	0.1132
Surgical procedures, n (%)			
- Quadrantectomy	71 (39.23)	4 (22.22)	0.2050
- Simplex mastectomy	56 (30.94)	3 (16.67)	0.2826
- Nipple-sparing mastectomy	47 (25.97)	3 (16.67)	0.5701
- Skin-reducing mastectomy	7 (3.87)	8 (44.44)	0.0001
Breast reconstruction, n (%)	73 (40.33)	12 (66.67)	0.0442
- Breast implant	36 (19.89)	11 (61.11)	0.0004
- Tissue expander	37 (20.44)	1 (5.56)	0.2056
Implant placement, n (%)			
- Subcutaneous	29 (16.02)	3 (16.67)	1.0000
- Submuscular	44 (24.31)	9 (50.0)	0.0259
Surgical drainage, n (%)	111 (61.33)	13 (72.22)	0.4500
Mean timing of drainage use ± SD, days (range)	7.43 ± 6.35 (7–15)	8.89 ± 6.08 (10–15)	0.3505
Bilateral procedures, n (%)	33 (18.23)	5 (27.78)	0.3472

ASA, American Society of Anesthesiologists; BMI, body mass index; CDC, center for disease control; COPD, chronic obstructive pulmonary disease.; SD, standard deviation; SSIs, surgical site infections.

**Table 3****The impact of key patient-and breast surgery-related features on the outcome of SSIs according to ASEPSIS score (N = 199)**

	SSIs according to ASEPSIS criteria		P
	Satisfactory or mild disturbance of healing (score 0–20) n = 186 (93.47%)	Wound infection (score 21–70) N = 13 (6.53%)	
Control cohort/Pandemic cohort	88 (47.31)/98 (52.69)	11 (84.62)/2 (15.38)	0.0101
Sex ratio (M:F)	2 (1.08):184 (98.92)	0 (0):13 (100)	1.0000
Mean age ± SD, years (range)	56.03 ± 11.8 (34–80)	52.69 ± 11.8 (41–72)	0.2920
Mean BMI ± SD, kg/m <sup>2</sup> (range)	24.19 ± 3.88 (18–34)	25.71 ± 3.88(23–28)	0.2294
Neoadjuvant therapy, n (%)	19 (10.22)	–	0.6180
Comorbidities, n (%)	59 (31.72)	2 (15.38)	0.3513
-Diabetes	16 (8.60)	1 (7.69)	1.0000
- COPD	13 (6.99)	–	1.0000
-Heart diseases	30 (16.13)	1 (7.69)	0.6962
Smoking, n (%)	44 (23.66)	–	0.0761
Mean ASA score ± SD (range)	2.73 ± 0.39 (1–3)	2.46 ± 0.35 (2–3)	0.1131
Surgical procedures, n (%)			
-Quadrantectomy	73 (39.25)	2 (15.38)	0.1368
-Simplex mastectomy	57(30.65)	2 (15.38)	0.3519
-Nipple-sparing mastectomy	48 (25.81)	2 (15.38)	0.5235
-Skin-reducing mastectomy	8 (4.30)	7 (53.85)	0.0001
Breast reconstruction, n (%)	75 (40.32)	10 (76.92)	0.0172
- Breast implant	37 (19.89)	10 (76.92)	0.0001
-Tissue expander	38 (20.43)	–	0.1350
Implant placement, n (%)			
-Subcutaneous	29 (15.59)	3 (23.08)	0.4432
-Submuscular	46 (24.73)	7 (53.85)	0.0446
Surgical drainage, n (%)	113 (60.8)	11 (84.62)	0.1368
Mean timing of drainage use ± SD, days (range)	7.36 ± 6.36(7–15)	10.38 ± 5.19 (10–15)	0.0956
Bilateral procedures, n (%)	30 (16.83)	3 (23.08)	0.4558

ASA, American Society of Anesthesiologists; ASEPSIS, Additional treatment, Serous discharge, Erythema, Purulent exudate, Separation of deep tissues, Isolation of bacteria, and Stay; BMI, Body Mass Index; CDC, Center for Disease Control; COPD, chronic obstructive pulmonary disease; SD, standard deviation; SSIs, surgical site infections.

distribution: CDC#2: 1 case; CDC#3: 1 case, and CDC#4: 4 cases. The mean time to the occurrence of SSIs was 14.3 days, within a 7- to 21-day range. The overall number of SSIs according to ASEPSIS criteria was 13, classified as follows: 5 cases of minor wound infection (ASEPSIS score 21–30); 2 cases of moderate wound infection (ASEPSIS score 31–40); 6 cases of severe wound infection (ASEPSIS score >40). The mean time to the occurrence of SSIs was 15.3 days, within 6- to 42-day range.

In the CC, the number of SSIs according to ASEPSIS criteria was 11 (84.6%), with the related distribution being: 4 cases of minor wound infection; 2 cases of moderate wound infection, and 5 cases of severe wound infection. The mean time to the occurrence of SSIs was 13.6 days, within a 6- to 42-day range.

In the PC, the number of SSIs according to ASEPSIS criteria was 2 (15.4%): a minor and a severe wound infection. The mean time to the occurrence of SSIs was 14.3 days, within a 7- to 21-day range.

Three patients of the CC with a severe wound infection (CDC#1), who had undergone reconstructive surgery, were then newly hospitalized for implant or expander removal after 7, 11, and 15 days from the first breast surgery. In these latter cases, the short interval between the two consecutive surgeries did not delay the administration of the adjuvant treatment. In other two patients of the CC, successfully treated with medical therapy, adjuvant therapy was postponed till a 4-week delay was configured. Need of rehospitalization and delay to the start of adjuvant therapy did not occur in the PC.

## Discussion

This study was conducted with the aim to investigate the impact of the extraordinary measures issued by the Italian MoH to

reduce the SARS-CoV-2 spread on the SSIs rate. For this purpose, the surgical outcomes of patients who underwent nondeferrable BCS during the pandemic period (March–May 2020) were compared with those of the patients who underwent nondeferrable BCS during the same time frame 1 year earlier.

The overall SSIs rate observed in this series was 9.1% according to CDC criteria and 6.5% according to ASEPSIS criteria, which is in line with the range reported in the literature (from 0.8% to 26%) [14–19,24]. As expected, and as reported in literature [25–29], the SSIs rate observed in this study decreased during the pandemic period. Moreover, the SSIs rate according to ASEPSIS criteria was statistically lower in the PC than in the CC ( $P < 0.0001$ ). These data could be explained as the ASEPSIS scoring system has shown to have a more accurate predictive value than the CDC score for breast reconstruction SSIs [11].

Patient-related risk factors associated with higher rates of SSIs, along with potentially successful prevention strategies, have been widely described in literature [14,21–23]. Autoimmune disorders, steroid therapy, high ASA score, old age, obesity, and kidney/liver/bone marrow failure are all independent risk factors and at least partly predictable risk factors of SSI [14,21–23], therefore they were excluded from the present study. Other potential risk factors are comorbidities (e.g., diabetes, hypertension), smoking habit, neoadjuvant therapy, immediate breast reconstruction and prolonged indwelling drain, but whether and how much each of them participates in the onset of SSIs is still debated in the literature [21–23,29]. To minimize the role of potential risk factors, we compared two homogeneous groups of patients. From our findings, none of the potential risk factors mentioned above, except for immediate breast reconstruction, appear to play a significant role in the onset of SSI. Overall, we observed significant evidence of higher SSIs, both in terms of CDC and ASEPSIS score, in patients having undergone breast

reconstruction Although there is a meta-analysis by Xue et al. [21], which includes 681 SSI cases and 2064 controls, that states that breast reconstructive surgery is not a risk factor for SSIs, there is a general and univocal consensus about the increased SSIs rate after immediate breast reconstruction, probably also due to longer operative time and larger breast volume [30–34]. However, reported SSI rates vary widely depending on the definition used for the infection, the surveillance method to identify infections and the length of follow-up period [30–32].

We also found evidence of a significantly higher number of SSIs cases in patients who had performed SRM. These data are consistent with the finding from Pechevy et al. [35]. In addition, we noticed a qualitative difference between the two cohorts compared. Indeed, in the CC, two patients needed rehospitalization and implant/expander removal and two further patients were forced to prolonged medical therapy, with a consequent delay longer than 4 weeks in the administration of adjuvant treatment. Conversely, none of the breast cancer patients from the PC required rehospitalization and there were no delays in adjuvant therapy initiation.

Since no updates have been recently provided for the prevention of SSIs and no significant differences emerged when comparing the two cohorts by relevant patient- and disease characteristics, it is our opinion that the measures adopted at the Institutional level in full accordance with the policy issued by the Italian MoH and that we can define cost-less or with affordable costs, have contributed to lower the frequency of occurrence of SSIs in patients undergoing nondeferrable BCS.

The restrictive measures adopted during the lockdown period described above [4] limited hospital access for trainees, students and family members, guaranteeing assistance with the minimum necessary staff. Furthermore, as previously described, the footfall in the operating room was limited and, at the same time, the intermediate cleaning procedures have been intensified. The patients themselves, more sensitized about the importance of hand hygiene, masks, and social distancing played an important role. To summarize, the physical contact between the healthcare personnel and patients, between patients and visitors and between patients and doctors among themselves has been reduced to an absolute minimum.

As reported in the literature, this sort of “forced patient isolation” could result in a reduction in the SSI rate and this is in line with our study [36].

However, we must consider that the consequences of COVID-19 pandemic and its related isolation are many more: although the actions taken during the lockdown period seem to reduce the incidence of SSIs, they have caused an unprecedented destruction in medical education and training [37] and an increase in the stress of both medical staff and patients forced to live the period of hospitalization in complete solitude [38].

We have tried to investigate this aspect in our patients: in an *ad hoc* questionnaire addressing the quality of care during the lockdown period, our patients seemed to consistently appreciate the quality of the assistance provided and were overall favorable to the adoptions of such restrictions. The containment measures were all perceived as “necessary and protective” and not “unnecessarily oppressive” by our patients. On this basis, we may hypothesize that most of these actions would be accepted on a stable basis by our patients if associated with a significant reduction in SSIs rates.

Prevention of SSIs is a mainstay not only in breast surgery but more generally in oncologic surgery. SSIs may lead to prolonged hospital stay and, consequently, to increased costs. Additional related consequences may include poor cosmetic results, and higher chances of reconstruction failure. All of these may significantly contribute to patients’ distress. Furthermore, SSI, occasionally, may impact the oncologic care of cancer patients due to a delay in adjuvant therapies’ administration and impaired postoperative surveillance, that potentially increases local and systemic cancer recurrence rates [3,15]. To the best of our

knowledge, although several authors have described their surgical experience in the COVID-19 era [39,40], limited evidence is available on the effects of such restriction measures on the occurrence of SSIs in patients undergoing nondeferrable BCS.

The main limitations of the present study are its retrospective nature and the quite restricted number of patients included in the two cohorts that may affect the statistical analysis and does not allow for any firm conclusions.

## Conclusions

In conclusion, our data seem to support the role of the restrictive measures adopted during the pandemic in lowering the rates of SSIs in patients undergoing nondeferrable BCS. The SSIs rate according to ASEPSIS criteria was statistically lower in the PC than in the CC. We observed significant evidence of higher SSIs in patients having undergone immediate breast reconstruction.

The submuscular placement of the breast implant, especially after SRM, appears to be a potential risk factor for SSIs. Extending these low-cost interventions in the postpandemic era could decrease morbidity associated with SSIs in BCS. Further studies with a larger number of patients from other Covid-19 free hubs are required to draw more definitive conclusions.

## Conflict of interest statement

The authors declare that they have no financial conflict of interest with regard to the content of this report.

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SC, MC, DC, CB: article writing and conception, data collection and analysis. MB, PV, SG, MC critical revision for important intellectual contents. IP, FP study design. IS statistical analysis. SC, DC, MC: article drafting. The authors read and approved the final article.

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