Breast Cancer Research and Treatment
https://doi.org/10.1007/s10549-022-06694-1

CLINICAL TRIAL

Highly specialized Breast Centers did not experience delay of care during COVID-19 pandemic in Italy: the Senonetwork experience

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Received: 7 June 2022 / Accepted: 24 July 2022
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Abstract

Aim of the study The study aims to evaluate the performance of selected, high-volume, highly specialized, Italian Breast Centers at the time of COVID-19 pandemic (year 2020), compared to pre-pandemic time (year 2019), highlighting differences in terms of clinical presentation of breast cancer (BC) and therapeutic strategies.

Methods Patients' data were provided by the Senonetwork data warehouse Senonet. In order to examine changes in the surgical and oncological management of BC patients during different phases of COVID-19 pandemic, we took advantage of a selection quality indicators (QIs). We performed the analyses in two time-frames, from July to September (Jul-Sep) (2019 versus 2020) and from October to December (Oct-Dec) (2019 versus 2020).

Results Our analysis did not show any statistically significant difference in terms of diagnosis, surgical, oncological and radiation therapy procedures between the two trimesters 2019 and 2020. Nevertheless, we observed statistically significant differences, favoring 2020, when analyzing time-to surgery and time-to radiotherapy. On the other hand, we observed a significant reduction of neoadjuvant chemotherapy and we did not recollect any data on a major use of neoadjuvant endocrine therapy.

Conclusions In Italian Breast Centers, partners of Senonetwork, we could not observe any treatment delay or change in standard clinical practice for BC care during the 2020 pandemic year, compared to 2019 pre-pandemic year. This finding is in contrast with the globally reported decrease in the performance of the Italian Breast Centers due to the COVID-19 pandemic, and has to be linked to the sharp selection of Senonetwork Breast Centers.

Keywords Covid-19 · Breast cancer · Delay in breast cancer treatment · Breast centers

Introduction

Breast cancer (BC) is a common disease affecting one in eight Western women and is potentially lethal. For the majority of patients with early stage BC, surgery remains the primary treatment and standard guidelines recommend to limit delay from diagnosis to start of treatment, because time-to-surgery, varying from greater than 30–60 days from diagnosis in different studies, has been reported to adversely affect BC prognosis [1–3]. The impact of COVID-19 pandemic on BC oncological surgery worldwide was considerable, and was determined not only by the reduction in surgical procedures, but also by postponement of screening procedures, clinical visits, exams and chemotherapy administration [4]. Early in the COVID-19 pandemic course, both US and European medical societies provided expert opinion regarding how best to manage and prioritize BC patients, issuing recommendations based on individual patient disease risk and hospital resources. For example, surgery delay in clinical stage I, postmenopausal, hormone receptors positive (HR +), HER2 negative tumors, considering neo-adjuvant endocrine therapy, or chemotherapy scheduling modification (switching, when appropriate, from weekly dosing to 2- or 3-weekly dosing) in order to reduce accesses to hospital, was proposed [5].

Aiming to accommodate the many changes brought about by COVID-19, BC care multidisciplinary Italian

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The members of Senonetwork Working group are listed in the acknowledgement section.

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Published online: 26 August 2022

associations (composed of oncology, surgery, radiotherapy and radiology experts) collaborated to address recommended treatment strategies. These recommendations had three main goals: (1) to continue safe and effective oncological care for all new and known patients; (2) to decrease the risk of infection for patients and staff; and (3) to ensure the availability of protective materials, staff, and intensive care unit capacity for critically ill patients with COVID-19. Moreover, in line with efforts to prioritize care for COVID-19, national screening programs, including that for BC, were halted from March 2020 to approximately the end of April 2020, with differences in timing and implementational modalities varying across different Italian Regions.

Senonetwork Italia, a non-profit organization devoted to support the quality of multidisciplinary BC care, promoted a national survey to evaluate the impact of COVID-19 pandemic on clinical care of women with BC among Italian Breast Centers [6]. The survey showed how the majority of Italian Breast Centers were operating within hospitals involved in the treatment of COVID-19 patients [6]. Routine activities underwent a major decrease (more than 50%) especially in radiology, surgery, medical oncology and radiotherapy (in 38%, 22%, 11% and 5% of Breast Centers, respectively); in 38% of Breast Centers, the number of weekly procedures was reduced to 38% or more [6]. In addition, a decreased availability of operating room time was reported by the majority of Breast Centers (78%), equally distributed among low- and high-volume centers [6].

The present work aims to evaluate selected, high-volume, highly specialized, Italian Breast Centers performance and clinical presentation of BC at the time of COVID-19 pandemic (year 2020), compared to pre-pandemic time (year 2019), taking advantage of the Senonet electronic database, a data warehouse conceived to perform quality assessment and improvement of BC care in Italian Centers.

Patients and methods

Patients' selection and quality indicators

Patients' data were provided by the Senonetwork data warehouse Senonet, which collects data sent by all Centers adhering to the project; Italian Centers involved in the analyses are listed in Table 1. Of note, in order to be part of Senonetwork, Italian Centers should count at least 150 BC cases per year, treated by a dedicated multidisciplinary team of a minimum of one breast surgeon, breast radiologist, breast radiation oncologist, breast medical oncologist and breast pathologist, as per European guidelines [7]. Each single Center provided anonymized patients clinic-pathological data to Senonet, which is protected and managed by a team of dedicated statisticians.

Table 1 List of Centers participating in Senonet data warehouse

Breast Centers participating in Senonet
AOUI Azienda Ospedaliera Universitaria Integrata—Verona
AST Lanciano Vasto Chieti—Ortona
ASUITS Ospedale Cattinara—Trieste
Azienda Ospedaliero Universitaria del Policlinico di Modena
Azienda Ospedaliera Universitaria Pisana
Azienda Ospedliera S. Giovanni Addolorata—Roma
Breast Unit Multimedica—Milano
Centro di Senologia Rimini-Sant'Arcangelo di Romagna
Fondazione IRCCS Policlinico San Matteo—Pavia
Fondazione Poliambulanza—Brescia
Humanitas Cancer Center Catania
Humanitas Clinical and Research Center IRCCS, Rozzano—Milan
Istituto Europeo di Oncologia IEO—Milan
Istituti Clinici Scientifici Maugeri—Pavia
Nuovo Ospedale di Prato
Ospedale Cardinal Massaia di Asti
Ospedale di Bellaria AUSL di Bologna
Ospedale di Bolzano
Ospedale Mater Sautis Legnago AULSS 9 Veneto—Verona
Policlinico di S. Orsola—Bologna

In order to monitor the quality of breast care, Senonet provided a set of benchmark quality indicators (QIs) [8], a selection of which was used in the present work to examine changes in the surgical and oncological management of patients with BC during the different phases of COVID-19 pandemic. The complete list of the Senonet QIs is shown in Table 2.

With the aim of analyzing specific differences in BC care between the pandemic year 2020 and the pre-pandemic year 2019, highlighting the specific effect of the different COVID-19 waves in Italy, we performed the analyses in two time-frames, considering the third and the fourth trimester of each year, from July to September (Jul–Sep) (2019 versus 2020) and from October to December (Oct–Dec) (2019 versus 2020). The choice of the study periods was based on specific epidemiological data for COVID-19 pandemic waves in Italy during 2019 and 2020 [9, 10].

Statistical methods

Quantitative and qualitative variables were described using medians and frequencies/percentages, respectively, as a total and in the four periods. For all the variables, proportion of missing cases was separately documented as proportions and not included in the calculation of distributions.

Differences in the indicators, all defined as proportions, were tested using the chi-squared test for trend in proportions; statistical significance was set at the 0.05 level. For

Table 2 List of Senonet Quality Indicators

List of Senonet Quality Indicators
Record of histological type, grading, hormonal status, HER2 status, margins, vascular invasion & size for invasive forms
Record of histological type, grading, hormonal status, margins & size for non-invasive forms
MRI before surgery for invasive cases
X-ray of surgical specimen in cases treated with conservative surgery with microcalcification only
Surgery within 30 days from indication to treatment
Surgery within 42 days from the first diagnostic exam
Surgery within 60 days from screening mammography
Only one surgical operation for invasive cancer treatment
Only one surgical operation for non-invasive cancer treatment
At least 10 lymph nodes removed for axillary dissection (sampling excluded)
Only sentinel lymph nodes examination in pN0 cases
No axillary dissection for non-invasive cases
Maximum 3 lymph nodes removed as sentinel lymph nodes
Conservative surgery for invasive cases up to 3 cm (non-invasive component included)
Conservative surgery for non-invasive cases up to 2 cm
Radiotherapy after conservative surgical treatment
Post-mastectomy radiotherapy for pN2a cases
Radiotherapy within 12 weeks from surgical intervention (if adjuvant chemotherapy not indicated)
Endocrine therapy indication for endocrine-sensitive invasive cases
Chemotherapy indication for invasive, hormone receptor negative cases if pT > 1 cm or pN +
Chemotherapy and trastuzumab indication for invasive HER2 + cases
Primary chemotherapy indication for inflammatory cancer

each indicator, the denominator includes only eligible cases with information available; patients from Centers with more than 25% of missing information were removed from the denominator and the number of units involved in the calculation were documented for each indicator. All the analyses were performed using R version 4.0.5.

Results

A total of 6287 invasive lesions were analyzed, median age was 62, most of the patients underwent breast conserving surgery (BCS) (67.4%) and less than a quarter of patients performed neo-adjuvant chemotherapy (12.3%). Most of the patients presented with 1 to 2 cm lesions (pT1c) (38.8%) and had node-negative disease (pN0) (64.3%). The great majority of patients had estrogen and progesterone receptor (ER and PgR) positive disease (88.6% and 77.5%, respectively) and were HER2 negative (score 0–1 + or 2 + and FISH negative; 74.7% and 12.4%, respectively); median Ki-67 was 15%, with around half of the population presenting with Ki-67 < 15% and the other half with Ki-67 ≥ 15% (53.2% and 46.8%, respectively). Patients' characteristics are depicted in Table 3, together with their subdivision into trimesters from both 2019 and 2020. No statistically significant differences were observed across the different time-frames in terms of disease stage at presentation, considering both the size of the primary tumor and the extent of lymph nodes involvement (data not shown). Analyzing differences in terms of pathological characteristics among the time-frames under investigation, we could observe a statistically significant major ER and PgR positive expression in 2020 compared to 2019 (ER + Trend Test p-value = 0.006; PgR + Trend Test p-value = 0.006), and higher number of HER2 + cases (HER2 Trend Test p-value = 0.038), while no significant differences in terms of Ki-67 percentage (Ki-67 Trend Test p-value = 0.999) were observed. Indeed, when looking at BC biological subtypes, triple negative (TN) BC was less prevalent in 2020 compared to 2019, while luminal-A like subtype seemed more prevalent in 2020 compared to 2019 (TNBC Trend Test p-value = 0.002; luminal-A like Trend Test p-value = < 0.001); no statistically significant differences were observed in the differential prevalence of luminal-B like/luminal-B HER2 + and HER2 enriched-like subtypes between 2019 and 2020 (data not shown). We further analyzed specific differences in terms of diagnosis and surgical treatment timing. Nearly all the surgically treated invasive BC cases had a proper radiological (Birads 5) and/or cytological (C5) confirmed pre-surgical diagnosis, across the two years-time considered (Trend Test p-value = 0.836), and a similar proportion of patients underwent a magnetic resonance imaging (MRI) before surgery (Trend Test

Table 3 Patients' characteristics

		Total		Jul-Sep 2019		Oct-Dec 2019		Jul-Sep 2020		Oct-Dec 2020	
		N	%	N	%	N	%	N	%	N	%
	Total	7032	100	1730	100	1791	100	1661	100	1850	100
Diagnosis	In situ	745	10.6	187	10.8	211	11.8	153	9.2	194	10.5
	Invasive	6287	89.4	1543	89.2	1580	88.2	1508	90.8	1656	89.5
Invasive											
	Total	6287	100	1543	100	1580	100	1508	100	1656	100
	Median age (range)			61 (25–100)		62 (22–95)		63 (27–98)		62.5 (22–95)	
	Missing	1406	22.4	50	3.2	224	14.2	548	36.3	584	35.3
Neoadj CT	No	4090	87.7	1046	86.4	988	84.1	945	87.7	1111	92.4
	Yes	575	12.3	164	13.6	187	15.9	133	12.3	91	7.6
	Missing	1622	25.8	333	21.6	405	25.6	430	28.5	454	27.4
Surgery type	BCS	3919	67.4	956	65.0	1045	66.1	888	58.9	1030	62.2
	Mastectomy	1893	32.6	514	35.0	469	29.7	461	30.6	449	27.1
	Missing	475	7.6	73	4.7	66	4.2	159	10.5	177	10.7
pT	yT0-yTis-yTmic	205	3.5	58	4.0	70	4.7	48	3.4	29	1.9
	yT1a-yT1b-yT1c	231	3.9	63	4.3	79	5.3	58	4.1	31	2.0
	yT2	68	1.2	24	1.7	26	1.7	10	0.7	8	0.5
	yT3-4	20	0.3	9	0.6	5	0.3	5	0.4	1	0.1
	T1mic	67	1.1	21	1.4	13	0.9	14	1.0	19	1.2
	T1a	334	5.7	77	5.3	86	5.7	84	6.0	87	5.6
	T1b	1170	19.9	285	19.7	275	18.4	266	18.9	344	22.3
	T1c	2288	38.8	537	37.1	580	38.8	549	39.0	622	40.4
	T2	1324	22.5	337	23.3	319	21.3	322	22.9	346	22.5
	T3-4	187	3.2	38	2.6	43	2.9	53	3.8	53	3.4
	Missing	393	6.3	94	6.1	84	5.3	99	6.6	116	7
pN	yN0	333	5.9	98	7.0	110	7.7	77	5.7	48	3.2
	N0	3650	64.3	898	63.9	898	62.6	868	64.1	986	66.5
	yN1	125	2.2	38	2.7	38	2.6	34	2.5	15	1
	N1	1093	19.3	261	18.6	259	18.1	260	19.2	313	21.1
	yN2-3	71	1.3	23	1.6	26	1.8	15	1.1	7	0.5
	N2	200	3.5	41	2.9	49	3.4	54	4.0	56	3.8
	N3	181	3.2	43	3.1	47	3.3	44	3.2	47	3.2
	Nmi(sn)	24	0.4	4	0.3	7	0.5	3	0.2	10	0.7
	Missing	610	9.7	137	8.9	146	9.2	153	10.1	174	10.5
ER	Negative	598	11.4	175	13	167	12.2	132	11.1	124	9.4
	Positive	4629	88.6	1170	87	1207	87.8	1057	88.9	1195	90.6
	Missing	1060	16.9	198	12.8	206	13	319	21.1	337	20.4
PgR	Negative	1173	22.5	314	23.5	337	24.6	254	21.5	268	20.2
	Positive	4037	77.5	1021	76.5	1031	75.4	929	78.5	1056	79.8
	Missing	1077	17.1	208	13.5	212	13.4	325	21.6	332	20
Her2	0/1 +	4130	74.7	1037	75	1031	72.5	961	74.6	1101	76.8
	2 + (FISH -)	688	12.4	159	11.5	197	13.8	169	13.1	163	11.4
	2 + (FISH +)	193	3.5	52	3.8	49	3.4	54	4.2	38	2.6
	2 + (FISH missing)	107	1.9	15	1.1	31	2.2	31	2.4	30	2.1
	3 +	410	7.4	120	8.7	115	8.1	73	5.7	102	7.1
	Missing	759	12.1	160	10.4	157	9.9	220	14.6	222	13.4
Ki-67	0–14%	2936	53.2	740	53.4	757	53.0	673	52.7	766	53.8
	≥ 15%	2579	46.8	645	46.6	672	47.0	605	47.3	657	46.2
	Missing	772	12.3	158	10.2	151	9.6	230	15.3	233	14.1

Table 3 (continued)

		Total		Jul-Sep 2019		Oct-Dec 2019		Jul-Sep 2020		Oct-Dec 2020	
		N	%	N	%	N	%	N	%	N	%
Grade	I	830	14.6	200	14.3	199	14.0	183	13.5	248	16.5
	II	3300	58.1	784	56.2	822	57.7	791	58.3	903	59.9
	III	1552	27.3	411	29.5	403	28.3	382	28.2	356	23.6
	Missing	605	9.6	148	9.6	156	9.9	152	10.1	149	9

p-value = 0.529) (Fig. 1A, B). Interestingly, in 2020 the time-to-surgery appeared to be shorter than in 2019, with surgery being performed more frequently in ≤ 30 days from clinical indication or in ≤ 42 days from the first test positive for invasive BC (Trend Test *p*-value = < 0.001 for both QIs) (Fig. 1C, D). Considering surgical indication, there were no statistically significant differences in terms of choice of adequate surgical procedure, with the great majority of patients, across all the time-frames in both 2019 and 2020, undergoing a single surgical procedure for both in situ and invasive lesions (Fig. 2A, B). Nevertheless, we observed a higher preference for BCS for treatment of invasive lesions ≤ 3 cm in 2020 compared to 2019, while no differences were seen in the rate of choice of BCS for non-invasive lesions ≤ 2 cm across the two years considered (Fig. 2C, D). Taking into account the management of the axilla, a statistically significant trend was observed, with more pN0 patients in 2020 treated with sentinel lymph node biopsy (SLNB), without axillary dissection (Trend Test *p*-value = < 0.001) (Fig. 2E). Lastly, we sought to analyze possible differences, between the considered time-frames in 2019 and 2020, also in non-surgical procedures, such as radiotherapy and oncological treatments. No statistically significant difference was observed in terms of radiotherapy indication, both after BCS (Trend Test *p*-value = 0.11) and after mastectomy in pN2a cases (Trend Test *p*-value = 0.7), while, in accordance

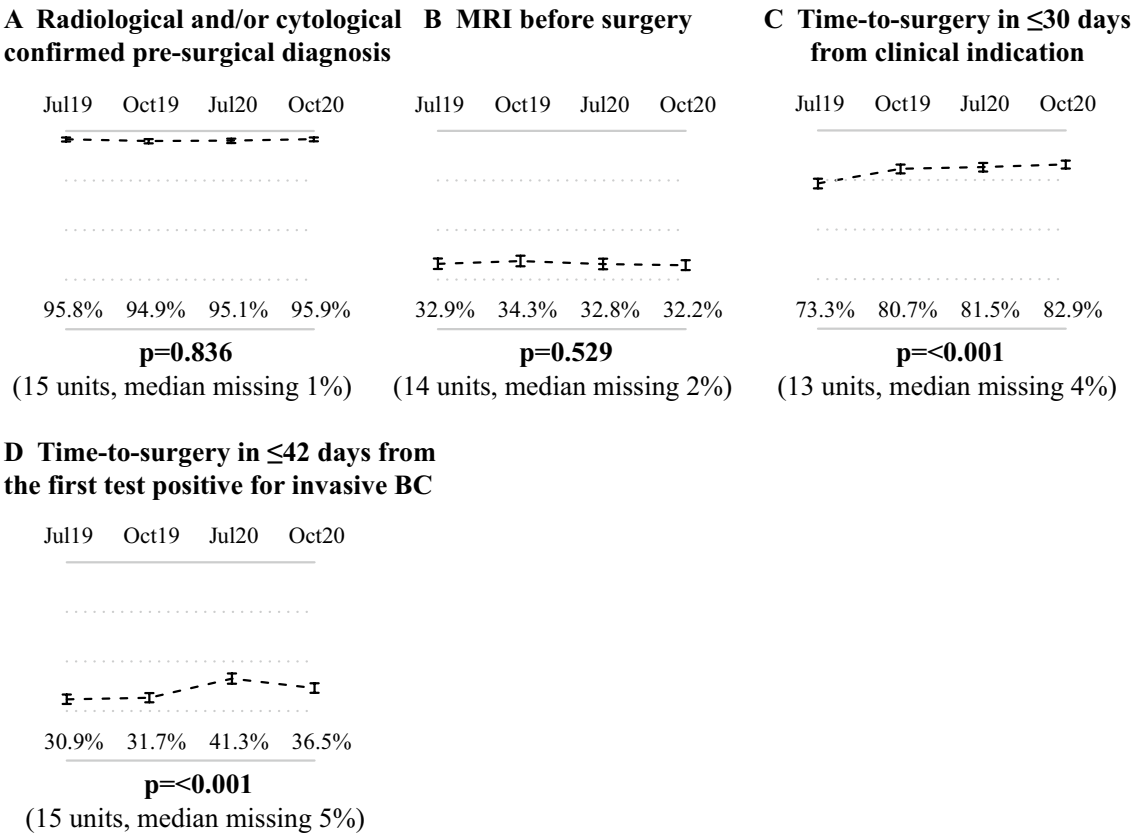

Fig. 1 **A** Radiological and/or cytological confirmed pre-surgical diagnosis. **B** MRI before surgery. **C** Time-to-surgery in ≤ 30 days from clinical indication. **D** Time-to-surgery in ≤ 42 days from the first test positive for invasive BC

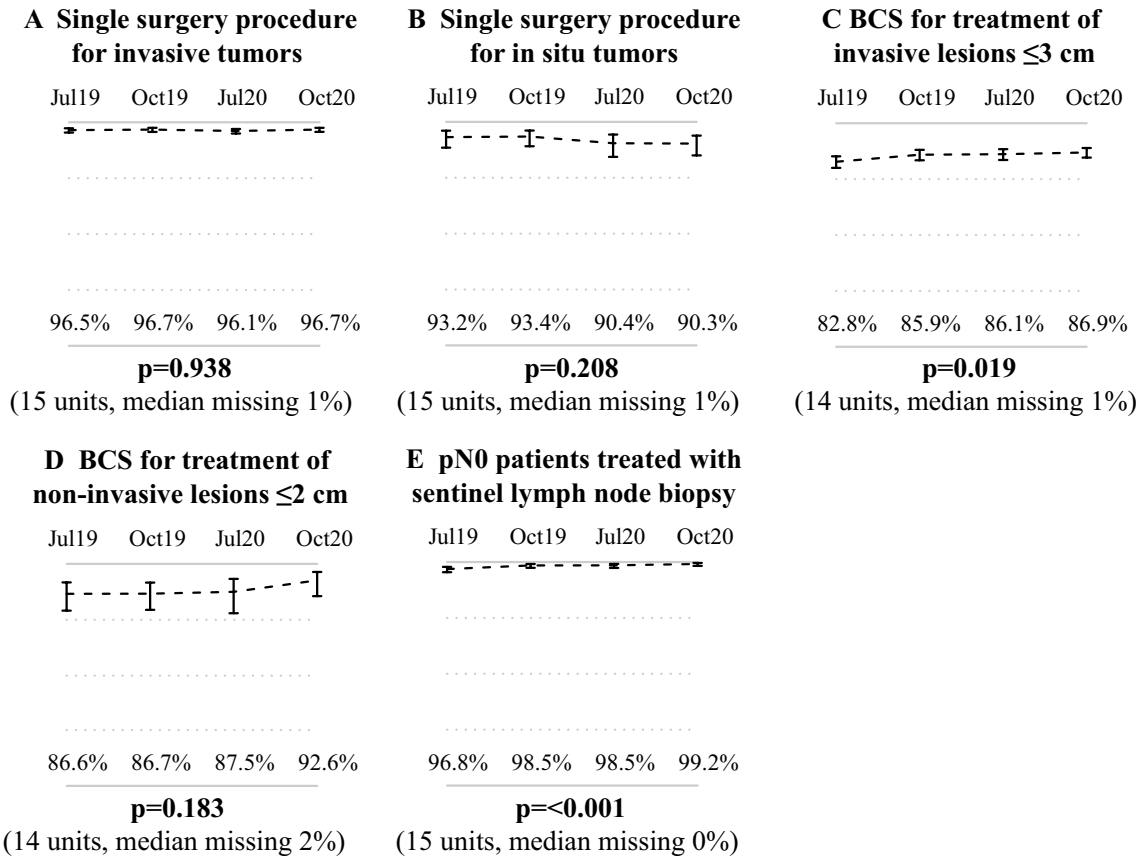

Fig. 2 **A** Single surgery procedure for invasive tumors. **B** Single surgery procedure for in situ tumors. **C** BCS for treatment of invasive lesions ≤ 3 cm. **D** BCS for treatment of non-invasive lesions ≤ 2 cm. **E** pN0 patients treated with sentinel lymph node biopsy

to what was observed for time-to-surgery, we observed a better outcome in 2020 compared to 2019 in terms of time-to-radiotherapy, when the latter was clinically indicated (Trend Test p-value = < 0.001) (Fig. 3A–C). When analyzing oncological treatment indication, we could not find any statistically significant difference in terms of adjuvant treatments decision between the two years-time considered (Trend Test p-value = 0.478, 0.392 and 0.162 for endocrine therapy in hormone receptor positive case, chemotherapy for high risk hormone receptor negative cases and trastuzumab for HER2 + cases, respectively) (Fig. 3D–F). On the other hand, we observed a statistically significant reduction in neoadjuvant chemotherapy indication in 2020 compared to 2019 (Trend Test p-value = < 0.001).

Discussion

The present study, conducted among Senonetwork Italian Breast Centers, focused on the management of BC care during 2020 COVID-19 pandemic. Comparing patients' clinic-pathological characteristics, diagnosis, surgical and medical treatment variables between 2019 and 2020 time-frames, we sought to investigate if, in this selected, high-volume network of Breast Centers, any change in standard practice occurred due to the onset of the pandemic. To do so, we took advantage of data collected in Senonet, the Senonetwok data warehouse, and used a set of QIs, configured to monitor quality and commitment of Breast Centers in BC care, to describe changes in specific BC treatment areas.

Our analysis did not show any statistically significant difference in terms of diagnosis, surgical, oncological and radiation therapy procedures when comparing the two trimesters of the years considered. Nevertheless, we observed statistically significant differences, favoring the 2020 pandemic year, when analyzing time-to surgery and time-to radiotherapy (when indicated). This could be explained by an improvement in treatment strategies and even more strict collaboration between different Breast Centers. Indeed, since the first onset of the pandemic, Italian Breast Centers' activities have been promptly reorganized, in response to the need of balancing the emergency of COVID-19 patients with the urgency of continuum of care for oncological patients, bearing in mind the potential exposure to SARS-CoV-2 infection of these frail patients. As cited before, many international guidelines

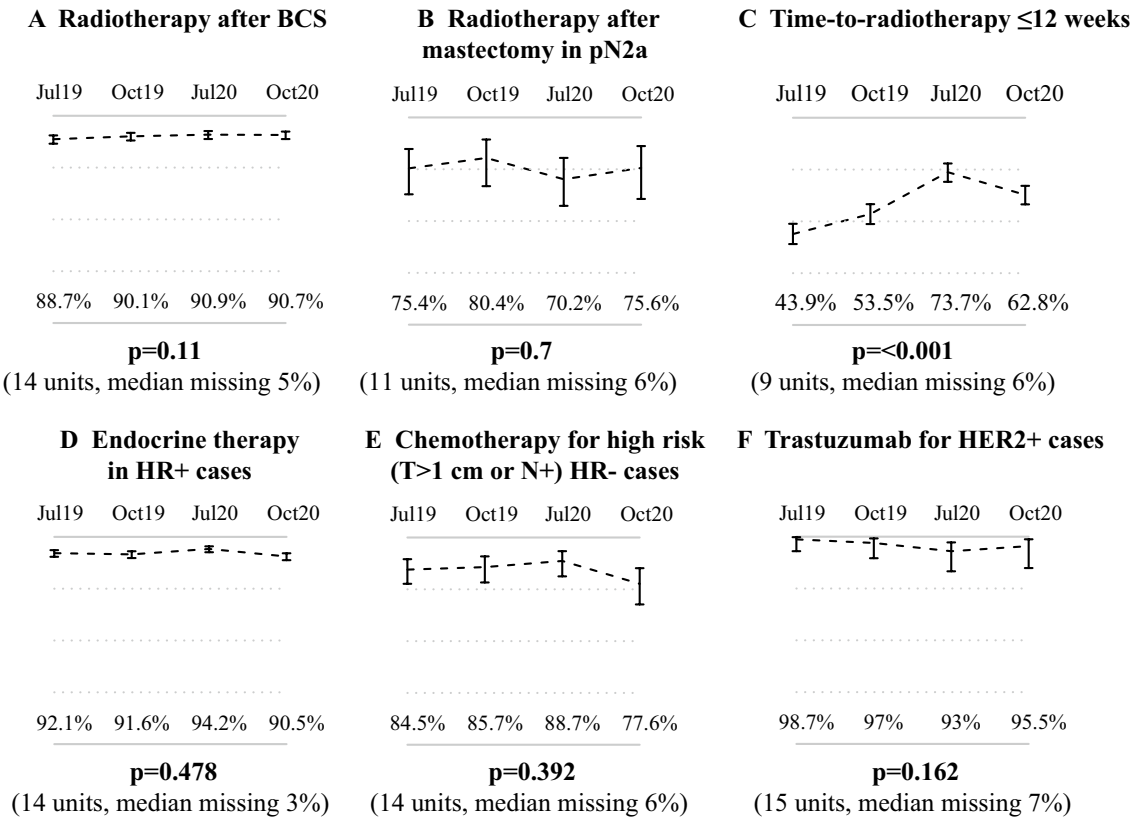

Fig. 3 **A** Radiotherapy after BCS. **B** Radiotherapy after mastectomy in pN2a. **C** Time-to-radiotherapy ≤ 12 weeks. **D** Endocrine therapy in HR + cases. **E** Chemotherapy for high risk (T > 1 cm or N +) HR- cases. **F** Trastuzumab for HER2 + case

recommended postponing surgery in low to medium risk BC patients, favoring neoadjuvant approaches, with many studies reporting a five-fold increment in the choice for neoadjuvant endocrine therapy in HR positive, HER2 negative tumors [11, 12]. In our dataset, we observed a significant reduction in the use of neoadjuvant chemotherapy and we did not recollect any data on a major use of neoadjuvant endocrine therapy. This might be due to the fact that our high-volume, highly selected, Breast Centers were restructured to serve as BC care hubs for other low volume Hospitals and were organized to be able to perform upfront surgery (mainly BCS, as encouraged by International Guidelines) to the majority of ≤ 3 cm, HR positive, HER2 negative patients.

Moreover, a major implement of SLNB, without axillary lymph node dissection (ALND), was observed in our case series in 2020 compared to 2019. This might be explained by the elevated number of small, cN0 tumors selected for upfront surgery, as previously explained, but it might also reflect the gradual paradigm shift that the surgical management of the axilla have been encompassing through the last years, due to the wide acceptance of Z0011 trial findings on the possibility of omitting ALND in selected low-risk tumors [13].

Regarding radiation therapy, moderate-hypofractionated schedules were strongly recommended during the COVID-19 pandemic, reducing treatment duration and patients' risk exposure [14], and in case of clinical indication for a boost, a further dose to the tumor bed, was preferably a simultaneous integrated one [15]. These management indications, together with the possibility of addressing BC patients to dedicated Breast Centers hubs for adjuvant radiotherapy and the lowering of indications for palliative radiation treatments, might explain the shorter time-to radiotherapy observed in our case series in 2020 compared to 2019.

Immediate breast reconstruction was offered also during COVID-19 pandemic in order to maintain therapeutic standards, nevertheless some degree of variation in the clinical protocol was adopted by many centers to face the pandemic outbreak [16].

In conclusion, even if we globally observed a decrease in the performance of the Italian Breast Centers due to the COVID-19 pandemic, with major issues regarding an adequate and prompt access to treatment [6], in our study, providing data from a highly selected network of high-volume Breast Centers, we could not notice any treatment delay or radical change in standard clinical practice. These findings probably reflect the Senonetwork selection

of Breast Centers fulfilling high-standard requirements of multidisciplinary organization and the capability of this network of Brest Centers to cooperate, joining forces also to serve as surgical and radiation therapy hubs for the nearest territorial area.

Due to the persistence of pandemic waves after 2020 and the unceasing need for COVID-19 inpatient care, which might lead to an increased number of women with advanced BC at diagnosis in the future, we still need to accurately monitor the performance of Italian Breast Centers through the years and take in place appropriate actions to prevent disfunction in the health care of oncologic patients.

Acknowledgements Francesca Pellini (Azienda Ospedaliera Universitaria Integrata, Verona, Italy), Simona Grossi (Breast Centre Ortona - ASL2 Abruzzo, Italy), Marina Bortul (Breast Unit Trieste, Azienda Sanitaria Universitaria Giuliano Isontina, Trieste, Italy), Alfredo Tafà AUSL di Bologna (IRCCS Scienze Neurologiche, Ospedale Bellaria, Italy), Giovanni Tazzioli (Breast Unit Azienda Ospedaliero-Universitaria Policlinico di Modena, Italy), Matteo Ghilli (Centro Senologico Multidisciplinare, AOUP, Pisa, Italy), Tiziana Mastropietro (Centro di Senologia, Azienda Ospedaliera San Giovanni Addolorata, Rome, Italy), Francesco Caruso (Breast Centre Humanitas Catania, Misterbianco, Catania, Italy), Andrea Bonetti (Breast Centre Azienda ULSS9 Scaligera, Ospedale Mater Sautis Legnago, Verona, Italy), Angelica Della Valle (Breast Surgery Department, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy), Alessandra Huscher (Fondazione Poliambulanza, Brescia, Italy), Corrado Tinterri (Breast Unit, Humanitas Research Hospital, IRCCS, Rozzano, Milan, Italy), Armando Santoro (UO of Medical Oncology, Department of Oncology and Hematology, Humanitas Research Hospital, IRCCS, Rozzano, Milan, Italy; Department of Biomedical Sciences, Humanitas University, Pieve Emanuele, Milan, Italy), Marco Klinger (Reconstructive and Aesthetic Plastic Surgery School, Department of Medical Biotechnology and Translational Medicine BIOMETRA - Plastic Surgery Unit, University of Milan, Humanitas Research Hospital, IRCCS, Rozzano, Milan, Italy), Mario Taffurelli (IRCCS Azienda Ospedaliero-Universitaria di Bologna, Policlinico di S. Orsola, Bologna, Italy), Fabio Corsi (Breast Unit, Department of Surgery, Istituti Clinici Scientifici Maugeri IRCCS, Pavia, Italy; Department of Biomedical and Clinical Sciences "Luigi Sacco", Università di Milano, Milan, Italy), Paolo Veronesi (IRCCS Istituto Europeo di Oncologia, Milan; Università degli Studi di Milano, Dipartimento di Oncologia ed Ematologia, Milan, Italy), Bettina Ballardini (Breast Division, Multimedica Breast Unit, Multimedica IRCCS, Milan, Italy), Laura Biganzoli (Oncologia Medica Sandro Pitigliani, Nuovo Ospedale di Prato, Prato, Italy), Maggiorino Barbero (Breast Unit, Ospedale Cardinal Massaia, Asti, Italy), Romano Polato (Ospedale Centrale di Bolzano, Azienda Sanitaria dell'Alto Adige, Comprensorio Sanitario di Bolzano, Italy) Sonia Santicchia (Ospedale Infermi di Rimini-Sant'Arcangelo di Romagna, Italy)

Funding The authors have not disclosed any funding.

Data availability Enquiries about data availability should be directed to the authors.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

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