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ORIGINAL ARTICLE

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Factors associated with adjuvant systemic anti-cancer treatment discontinuation for early breast cancer during the COVID-19 pandemic

Elinor R. Gatfield[1] | Adam Bataineh[2] | Bara El Kurdi[3] | Mukesh B. Mukesh[1] | Suat W. Loo[1]

[1]Department of Oncology, Colchester General Hospital, East Suffolk and North Essex Foundation Trust, Colchester, UK

[2]Department of Oncology, University College London Hospitals NHS Foundation Trust, London, UK

[3]Division of Gastroenterology, University of Texas Health Science Centre at San Antonio, San Antonio, Texas, USA

Correspondence
Elinor Gatfield, Department of Oncology, Colchester General Hospital, East Suffolk and North Essex Foundation Trust, Turner Road, Mile End, Colchester CO4 5JL, UK.
Email: elinor.gatfield@nhs.net

Abstract

Objective: The Covid-19 pandemic led to challenging discussions between oncology clinicians and patients regarding additional risks posed by SARS-CoV-2 infection whilst receiving systemic anti-cancer therapies (SACT). We assess the potential factors affecting discontinuation of adjuvant early breast cancer treatment during the pandemic.

Methods: Data were collected on all patients with early breast cancer undergoing adjuvant SACT, between 16 March and 17 April 2020 at a single UK cancer centre. Univariate binary logistic regression analysis was performed on variables including age, recurrence risk, Index of Multiple Deprivation decile, presence of physical comorbidities, modality of treatment (neoadjuvant or adjuvant), type of treatment (cytotoxic chemotherapy or monoclonal antibodies), percentage of cycles completed and availability of alternative treatments, with a binary dependent variable on treatment discontinuation.

Results: Sixty-two patients with early breast cancer were identified: 18 receiving neoadjuvant and 44 adjuvant therapies. Median age was 57.5 years (range 31–75 years). Age ($P = 0.02$), percentage of treatment cycles completed ($P = 0.014$) and presence of alternative treatment options ($P = 0.019$) were significant factors for SACT discontinuation during the height of the Covid-19 pandemic.

Conclusion: Factors affecting patients' decisions to discontinue SACT for early breast cancer during the Covid-19 pandemic were elucidated, which may help identify patients requiring additional support.

KEYWORDS
adjuvant treatment, breast cancer, Covid-19, discontinuation factors

1 | INTRODUCTION

The Covid-19 pandemic has had an immense impact on the delivery of cancer services within the National Health Service in the UK. Screening services were suspended, and according to Cancer Research UK, there was a 75% drop in the number of urgent '2-week wait' referrals for suspected cancer in England in April 2020 (Cancer Research UK, 2020). Moreover, preliminary published data from Wuhan in China suggested that patients with a cancer diagnosis are at a higher risk of contracting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, partly due to the need for multiple hospital visits for treatment (Yu et al., 2020).

In addition, patients with cancer who developed Covid-19 as a result of SARS-CoV-2 infection reportedly have worse clinical outcomes with an increased risk of serious complications or death compared to the general population, especially if they have received anti-cancer treatment within 14 days of presentation (Zhang et al., 2020). Consequently, the National Institute for Health and Care Excellence (NICE) published a document on interim systemic anti-cancer therapies (SACT), endorsed by NHS England, to allow oncology clinicians greater flexibility in the management of their patients during the Covid-19 pandemic (NICE, 2020). For early breast cancer, these included suspending adjuvant therapies for low risk patients and reducing the course of adjuvant trastuzumab from 12 to 6 months as per the results of the PERSEPHONE trial (Earl et al., 2019). These interventions aimed to reduce hospital visits and admissions, thereby limiting patients' exposure to SARS-CoV-2. Nonetheless, both clinicians and patients are still faced with difficult decisions regarding whether to alter SACT based on the risk posed by SARS-CoV-2 infection and that of cancer relapse and progression. We have recently reported significant differences in the perception of treatment risks and benefits between clinicians and patients with early breast cancer, with a significant proportion of patients reluctant to accept a therapeutic pause as they feared cancer relapse more than the risks posed by SAR-CoV-2 infection (Gatfield et al., 2020). In this paper, we analysed the decisions made by patients with early breast cancer regarding their adjuvant SACT during the Covid-19 pandemic and explore the clinical factors associated with their decisions to discontinue treatment.

2 | METHODS

2.1 | Patient population and study design

The study included all patients with early breast cancer who were receiving neoadjuvant or adjuvant SACT except endocrine treatment, at a single UK cancer centre during the height of the Covid-19 pandemic in March to April 2020. We contacted each patient prior to their scheduled SACT appointment over the telephone, due to assumed risks of patients attending hospital appointments, for an in-depth discussion regarding the benefits of treatment continuation and the potential risks posed by Covid-19. An informed decision was then made by each patient regarding whether to proceed or discontinue treatment. The data were then analysed retrospectively.

Telephone consultations with patients were conducted either by the breast oncology consultant in charge of their care or the breast oncology registrar. Shared decision-making is an integral component for the NHS to offer personalised care to patients (NHS, 2022), and these consultations were based on this theory. Patients were able to discuss the options with their families following the consult before making a final decision with regards to treatment continuation.

2.2 | Ethical considerations

Prior ethical approval was not obtained for this study, as patients had telephone consultations conducted as part of routine clinical practice at the beginning of the Covid-19 pandemic, in order to ascertain their decisions with regards to continuation of treatment. All patient information was anonymised for the purposes of the data analysis.

2.3 | Clinical parameters explored

We explored a number of clinical parameters to determine whether they were significantly associated with patients' decisions to discontinue treatment. These included age, risk status for breast cancer relapse, socioeconomic deprivation as measured by the Index of Multiple Deprivation (IMD) decile, presence of physical comorbidities, treatment modality (neoadjuvant or adjuvant), type of treatment (cytotoxic chemotherapy or monoclonal antibodies), number of treatment cycles completed as a percentage of the total number of cycles prescribed for neoadjuvant or adjuvant treatment and whether alternative options such as endocrine treatment were available. IMD decile is the official measure of relative deprivation in England and considers a wide range of factors influencing an individual's living conditions, with people being regarded as deprived if they lack any kind of resources, not solely financial (GOV.UK, 2019).

Patients were assigned to low, intermediate or high risk status based on the factors described in Table 1. A list of all 62 patients, their clinical parameters and decision regarding the discontinuation of treatment can be found in Table S1.

We hypothesised that advancing age, low risk status for breast cancer relapse, deprivation, presence of physical comorbidities, adjuvant as opposed to neoadjuvant therapy (where the tumour is still in-situ),

TABLE 1 Risk status for breast cancer recurrence

Low risk	Breast predict score[a] of <5% for adjuvant treatment
Intermediate risk	Breast predict score of 5–10% for adjuvant treatment **OR** HER2+ or TNBC with negative axillary lymph nodes **OR** ER+ with positive axillary lymph nodes
High risk	Breast predict score of >10% for adjuvant treatment **OR** HER2+ or TNBC with positive axillary lymph nodes **OR** BRCA mutation

Note: Definitions for low, intermediate and high risk categories as used in this study.

Abbreviations: BRCA, BReast CAncer gene; HER2+, patients with breast cancer over-expressing HER2 receptor proteins; TNBC, triple negative breast cancer, no expression of hormone receptors or overexpression of HER2 receptors.

[a]Breast Predict score calculated for patients receiving adjuvant therapies to determine absolute benefit at 10 years, at https://breast.predict.nhs.uk/. The Breast Predict score was not calculated for patients receiving neoadjuvant therapies. This score determined the risk category over other clinical features, as more prognostic factors are being taken into account when calculating. If a patient had a germline BRCA mutation, they were automatically placed into the high risk category.

monoclonal antibodies (PERSEPHONE trial), a higher percentage of treatment cycles completed and the presence of alternative treatment options would be associated with patients' decisions to discontinue SACT.

2.4 | Statistical analysis

To determine which clinical parameters might influence patient decision-making, binary logistic regression was performed using SPSS version 22.0 (IBM, Inc.). A univariate binary logistic regression was first performed on each clinical variable with a binary dependent variable (decision to discontinue or continue treatment). If patients were receiving both cytotoxic chemotherapy and monoclonal antibody therapies, they were categorised as being on chemotherapy treatment. $P < 0.05$ was regarded as statistically significant. All clinical variables were tested for co-dependency by performing a simple spearman correlation between the available variables. Those which were found to have a statistically significant correlation were considered co-dependent, and these variables were eliminated. As age and the presence of comorbidities were found to be co-dependent, presence of comorbidities was eliminated. A multivariate logistic regression was subsequently performed on variables that showed a significant relationship with the decision to discontinue treatment. Due to the small sample size, parameters that approached statistical significance were also included in the multivariate logistic regression analysis, as a bigger sample size may have shown them to be significant (Serdar et al., 2021).

3 | RESULTS

3.1 | Patient population

Between 16 March and 17 April 2020, 62 patients were identified as receiving neo-adjuvant or adjuvant SACT for early breast cancer at Colchester General Hospital, UK. The median age of the patients was 57.5 years, range 31–75 years. Eighteen patients were receiving neoadjuvant therapy, and 44 patients were receiving adjuvant therapy. Eleven patients were deemed to have low risk disease, 33 had intermediate risk disease and 18 had high risk disease. Table 1 presents the risk status definitions of the study population.

3.2 | Predictors of treatment discontinuation

Overall, 10 patients decided to discontinue treatment. Age, percentage of treatment cycles completed and the presence of alternative treatment options with endocrine therapy were found to be significant factors associated with patients' decisions to discontinue SACT ($P = 0.02$, $P = 0.014$, $P = 0.019$, respectively), as per Table 2. The older the patient and the higher the percentage of treatment cycles completed, the more likely the patient was to make a decision to discontinue SACT. Other clinical parameters were found not to be associated with patients' decisions to discontinue SACT; these included risk status for breast cancer relapse ($P = 0.352$), Index of Multiple Deprivation decile ($P = 0.917$), modality of treatment (neoadjuvant vs. adjuvant, $P = 0.178$) and the type of treatment (cytotoxic chemotherapy versus antibodies, $P = 0.492$), as per Table 2.

4 | DISCUSSION

This study assesses factors that may influence patients' perceptions and decision-making regarding SACT for early breast cancer during the current Covid-19 pandemic. We hypothesised that the additional risks associated with Covid-19 may affect patients' decision-making due to concerns about their perceived vulnerability and that certain clinical parameters may identify those who are more likely to want to discontinue treatment. This is important as patients' decision to discontinue SACT can have an adverse impact on their long-term oncological outcome.

TABLE 2 Statistical analysis of clinical parameters

	Univariate analysis OR	95% confidence interval	*P* value	Multivariate analysis OR	95% confidence interval	*P* value
Age	1.092	1.003–1.189	0.041	1.124	1.014–1.247	0.027
Risk status	0.479	0.101–2.259	0.352	-	-	-
IMD decile	0.986	0.757–1.284	0.917	-	-	-
Physical comorbidities	4.804	1.103–20.922	0.037	-	-	-
Neoadjuvant	0.229	0.027–1.955	0.178	-	-	-
Adjuvant	4.371	0.511–37.367	0.178	-	-	-
Chemotherapy	0.617	0.156–2.447	0.492	-	-	-
Antibodies	1.620	0.409–6.421	0.492	-	-	-
Percentage of cycles completed	1.027	0.998–1.058	0.072	1.051	1.010–1.094	0.014
Alternative treatment options available	4.029	0.784–20.703	0.095	18.081	1.605–203.698	0.019

Note: Odds ratio calculations to determine significance of associations between clinical parameters and patients' decisions to discontinue treatment.
Abbreviations: OR, odds ratio; IMD, Index of Multiple Deprivation.

It is reassuring to know that a recent analysis from the UK Coronavirus Cancer Monitoring Project (UKCCMP) identified no evidence to suggest that cancer patients on SACT are at an increased risk of mortality from Covid-19 compared with those not on active treatment, with risk of death being largely attributed to by the patients age, gender and comorbidities instead (Lee et al., 2020). In this small patient cohort, we identified advancing age, a higher percentage of treatment cycles completed and the availability of alternative treatment options with endocrine therapy as significant factors associated with patients' decision-making to discontinue neoadjuvant or adjuvant SACT for early breast cancer. The long-term impact of such decisions remains to be determined.

The effect of advancing age on patients' decision-making to discontinue SACT may be partly explained by the extensive press coverage of the Covid-19 pandemic, in particular the increased risk of severe complications and mortality posed by Covid-19 for the older population (GOV.UK, 2020). Mortality rates from Covid-19 appear to rise sharply with advancing age and this association was also found among cancer patients in the UKCCMP analysis. In addition, at the height of the Covid-19 pandemic in the UK, those over the age of 70 were advised to take extra precautions to minimise their risk of contracting SARS-CoV-2 infection. A systematic review by Puts et al. (2015) found physician recommendation and the fear of side effects and treatment-related complications to be important factors influencing older adults' decision to decline cancer treatment. Thus, older cancer patients may require greater reassurances and support when making treatment-related decisions during the current Covid-19 pandemic.

Patients with advancing age are more likely to have physical comorbidities, which is another independent risk factor for mortality from Covid-19 among the general population and patients with cancer. There has been extensive press coverage on physical comorbidities and its association with a higher risk of serious complications and death from Covid-19 and those with chronic respiratory, heart, kidney and liver diseases, chronic neurological conditions and diabetes as well as immunosuppressed individuals were advised to 'shield' during the height of the UK Covid-19 pandemic (NHS, 2022). We found co-dependency between advancing age and the presence of physical comorbidities among our patient cohort with early breast cancer when analysing their decisions to discontinue SACT. The knowledge that they were considered at 'high risk' of serious complications from Covid-19 may have led some to decide to discontinue SACT.

The study also found 'percentage of treatment cycles completed' and 'presence of alternative treatment options' as other significant factors associated with patients' decisions to discontinue SACT during the height of the Covid-19 pandemic. Patients who have completed a higher percentage of their planned treatment may feel that they have had 'sufficient' cycles of SACT and that the small potential additional benefit of treatment continuation may not justify the increased risk of contracting Covid-19 through further hospital visits. Where applicable, they may have been reassured by the results of the PERSEPHONE trial, and they may feel that they have already derived most of the oncological benefit from the treatment cycles they have received so far (Earl et al., 2019). For patients with hormone receptor positive early breast cancer, they may feel more comfortable with their decision to discontinue SACT in the knowledge that there is a 'less risky' oral alternative in the form of endocrine treatment that requires significantly less hospital visits, and does not cause myelosuppression.

Unlike age, percentage of treatment cycles completed and presence of alternative treatment options, IMD decile was not found to be a statistically significant factor influencing treatment decision-making among patients with early breast cancer in our study. Patients living in socioeconomically deprived areas are more likely to suffer with physical health comorbidities such as cardiovascular disease (Foster et al., 2018). Although there has been press coverage highlighting the link between deprivation and risk of adverse outcomes from Covid-19, with mortality rates more than twice higher among those living in the most deprived areas compared with the least deprived (Office for National Statistics, 2020), this association was not widely reported until after we had completed data collection for our present study. Moreover, patients from socioeconomically deprived areas may be more dependent on physician's guidance and recommendation when it comes to treatment decision-making due to lack of educational opportunities, as there is an established link between socioeconomic deprivation and educational attainment (Thomson, 2018). Patient decision-making did not appear to be influenced by the individual's modality and type of treatment, including if treatment was being given with neoadjuvant or adjuvant intent. This suggests that patients were able to consider their prognosis as a whole rather than decisions being based on whether their tumour remained in situ or not.

Breast cancer recurrence risk status was also not shown to be a statistically significant factor influencing patient decision-making. As part of informed consent for treatment, patients were aware of their risk of breast cancer recurrence prior to agreeing to proceed with neoadjuvant or adjuvant treatments. Patients receiving adjuvant treatment were routinely informed of the potential benefits as per the Breast Predict tool (https://breast.predict.nhs.uk/tool). Risk status was discussed during the telephone consultations again to support patients to make informed decisions regarding treatment continuation. As this variable was not shown to influence patient decision-making, it suggests that patients were more concerned by the potential more immediate consequences from contracting SARS-CoV-2 rather than the potential delayed implications of breast cancer relapse.

There are some limitations of this study including that it analyses a small patient cohort from a single UK cancer centre. Moreover, it was confined to patients with early breast cancer; the results are thus not applicable to those with metastatic disease or other tumour types where the balance between treatment benefit and Covid-19 risks are different. It is also possible that patient anxiety played a role in decision-making, but this was not assessed at the time of patient discussions. In retrospect, assessing the Hospital Anxiety and Depression Scale (HADS) for each patient may have given further insight into the possible reasons as to why patients decided to discontinue treatment, although as the majority of discussions were conducted over the

telephone, this would have been difficult in terms of practicalities, and posting out a HADS scoring sheet after the conversation may have led to recall bias. Furthermore, patient decision-making may have been based on their perception of risk of contracting Covid-19, which depends on many factors, including their behaviour and compliance to public health advice as well as their cancer diagnosis. It was not possible to assess this formally. Patient decision-making may also have been affected by their social support network. We did not collect data on social or marital status, which is a limitation. The power within the patient-clinician relationship was not assessed for this study. As the consultations were conducted as part of routine clinical practice via telephone during the height of the first wave of the Covid-19 pandemic in the UK, it would have been difficult for an independent reviewer to assess the power relationship, and if clinicians had done as assessment, this would have led to bias. We acknowledge that sharing power within a consultation is integral to patient-centred care, but the way that clinicians perceive and redress power in a relationship is complex and beyond the scope of this study (Nimmon & Stenfors-Hayes, 2016). As different clinicians had the conversations with patients, there may have been differing power dynamics and this could lead to bias. However, differing clinicians conducting the appointments at the time was a pragmatic approach, taken in a real-life situation at the beginning of the pandemic. Moreover, it was felt that patients were more likely to feel more able to make a decision regarding treatment continuation with the guidance of a clinician that they already knew and had a relationship with.

Clinical teams have also gained more experience and confidence in managing patients on SACT since the Covid-19 pandemic began and they are now more likely to encourage their patients to continue treatment, especially following the publication of the UKCCMP analyses. Patients' and clinicians' perceptions of the risks posed by Covid-19 are likely to alter over time as further data on case numbers, overall mortality rates and the impact of SACT on Covid-19 fatality emerges. Clinicians' treatment recommendations, patients' decision-making regarding case management and the factors influencing such decisions are therefore likely to change as the Covid-19 pandemic develops. Nonetheless, knowledge of the clinical factors that may lead patients to opt for treatment discontinuation is important as it allows the wider multi-disciplinary team to support their patients during complex discussions around treatment planning and to address their fears and concerns surrounding Covid-19 and SACT. Ultimately, the patient needs to feel comfortable with the decisions they make regarding their treatment, as disagreements between patients and their clinicians can lead to difficult therapeutic relationships and a loss of trust, particularly if the breast cancer subsequently recurs.

We have identified advancing age, a higher percentage of treatment cycles completed and the presence of alternative options in the form of endocrine treatment as significant factors predicting patients' decisions to discontinue SACT for early breast cancer during the current Covid-19 pandemic. Knowledge of these factors will allow clinicians to identify patient cohorts with early breast cancer who may benefit from increased guidance and support in the decision-making process regarding SACT.

CONFLICT OF INTEREST

The authors have declared no conflict of interest.

DATA AVAILABILITY STATEMENT

Data are available in the supporting information.

ORCID

Elinor R. Gatfield https://orcid.org/0000-0003-3240-757X

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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