

Proposals for the modification of diagnostics and combination treatment of breast cancer during the COVID-19 pandemic

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Introduction

These recommendations focus on potential limitations in the availability of combined treatment for breast cancer due to the COVID-19 pandemic and indicate the options for therapy postponement and/or the correct selection of patients for modified treatment. They were prepared with the aim of preventing negative health consequences for patients due to treatment priorities, and to indicate admissible alternative procedures adapted to the epidemiological situation and the resources available to a given oncological clinic.

General rules of conduct during the COVID-19 pandemic

The team drafting these guidelines offers the following recommendations:

- In centres where it is possible, combined treatment of tumours should be consolidated and offered in a 'virus-free' space, i.e. at a place free of COVID-19.
- A decision on the treatment method and its modification related to the general epidemiological situation in the country because of the pandemic, its prospects, and the available resources (materials, drugs and staff) required

for combined treatment, should be made each time by a council of specialists in many fields.

- A decision on the treatment method should be made together with the patient and take into account the patient's wishes, the potential advantages of anticancer treatment and its risks, including the risk related to SARS-CoV-2 infection during therapy, and its consequences (also with regard to the course of oncological treatment).
- The fundamental requirement that ensures treatment for cancer patients is the need to secure oncological clinics against SARS-CoV-2 infection by adequate *triage* of patients, the provision of personal protective equipment and its appropriate use by staff and patients, access to tests confirming the infection for patients and staff, and the monitoring of the epidemiological situation in a given clinic. It is recommended that, if possible, the medical staff works only at one clinic.
- Before the patient arrives at the oncological clinic, it is recommended that the patient be contacted on the phone in order to obtain the patient's epidemiological history with the emphasis on the symptoms and risk of infection, and inform the patient about the ways of reducing

How to cite:

Łacko A, Maciejczyk A, Kasprzak P, Dupla D, Senkus E, Wysocki W, Nowecki ZI, Matkowski R. *Proposals for the modification of diagnostics and combination treatment of breast cancer during the COVID-19 pandemic.* NOWOTWORY J Oncol 2020; 70: 77–84.

the risk of infection (including self-isolation, i.e. a regime close to quarantine lasting 7-14 days before admission to the hospital).

- Before admission to an oncological clinic, in particular if invasive procedures or treatment involving the risk of immunosuppression is planned, patients should be tested for the SARS-CoV-2 infection.
- It is necessary to ensure sufficient space so that it is possible to maintain the recommended distance between patients at oncological clinics (the current recommendation is 2 metres) where necessary and where there are more people (e.g. waiting rooms or the rooms where infusions are administered).
- During oncological diagnostics it is recommended patients be informed about the general rules reducing the risk of infection, emphasising the negative impact of possible SARS-CoV-2 infection on the possibilities and therapeutic effectiveness of anticancer therapy.
- **If SARS-CoV-2 infection has been confirmed or is suspected, the patient's oncological treatment should be postponed.**
- The risk of serious complications in COVID-19 is more than 3 times higher for oncological patients than for the general population.
- It is necessary to make every effort to maintain the continuity of oncological treatment during the pandemic because its duration cannot be defined, while excessive postponement of treatment, both radical and palliative, may reduce the chances for its success and cause the deterioration of the cancer patient's quality of life.

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Minimally invasive image diagnostics of breast diseases during the COVID-19 pandemic

As regards image diagnostics and breast lesion biopsies, the team drafting these guidelines offers the following recommendations:

- Do not postpone image diagnostics for patients with clinical symptoms of breast cancer.
- Do not postpone needle biopsies of lesions qualified as BIRADS 4 or 5.
- Consider image diagnostics according to schedule in young patients (up to 45 years of age) whose treatment ended no more than 4 years ago or in patients up to 55 years of age – in the case of malignancies with a high risk of early recurrence (i.e. TNBC and HER2+).
- Consider check-ups for the carriers of a *BRCA1/2* mutation under the age of 40 if the envisaged postponement of planned check-ups is more than 6 months.
- If the patient's lesions are qualified as BIRADS 3, consider observing following the protocol employed so far (i.e. 6–6–12 months) or the simplified protocol (i.e. 12–12 months) if the pandemic continues.
- Reschedule/postpone planned screening mammography examinations.

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Systemic treatment of breast cancer patients during COVID-19 pandemics

As regards the systemic treatment of breast cancer patients, the team drafting these guidelines offers the following recommendations:

- In particular for the patients **in radical treatment**, the therapy should be conducted if only it is possible, following the standards in force. The modification of treatment regimens (e.g. selecting oral instead of intravenous drugs or a regimen with longer breaks between cycles) aims to reduce the number of visits to the oncological clinic to a minimum, which is rational, but it may not result in offering sub-optimal therapy.
- The treatment offered at an outpatient clinic or at a day ward at the centre which is the closest to the patient's residence reduces the risk of infection.

The definition of systemic treatment urgency

To ensure the most optimal access to oncological care during the SARS-CoV-2 pandemic, cancer patients have been divided into two groups:

- **Group A** – patients who are not being treated at present, who have completed treatment, or whose disease is under full control, e.g. those who are receiving auxiliary hormone treatment.

- **Group B** – patients who are undergoing treatment because of an early or advanced tumour; patients in this group qualify for active anticancer treatment including surgery, radiotherapy and systemic treatment.

The treatment selection process should take into account the factors related to the tumour (progression level and phenotype) and the patient (general condition and comorbidities) as well as the individual SARS-CoV-2 infection risk associated with the treatment offered and the need to visit the oncological clinic. This is especially important in the case of older patients (>60 years of age) with cardiovascular and respiratory diseases who smoke and require transport to the clinic (remote place of residence). If the risk of infection exceeds any potential benefits of standard therapy in this group, it seems justified to modify it, e.g. offer pre-surgical hormone therapy, even in the case of operative luminal tumours, shorten Trastuzumab therapy to 6 months or administer individual hormone treatment instead of hormone therapy combined with CDK 4/6 inhibitors (table I).

The rules for the systemic treatment of breast cancer patients during the COVID-19 pandemic according to the cancer phenotype and progression

As regards the treatment of patients according to the progression and phenotype of breast cancer, the team drafting these guidelines offers the following recommendations:

- Recommendations for patients with a local-regional stage of breast cancer without metastases can be found in table II a.
- Recommendations for patients with metastatic breast cancer can be found in table II b.

Treatment monitoring

As regards the monitoring of breast cancer patients' systemic treatment, the team drafting these recommendations emphasises the following:

- The number of tests performed should be reduced, in particular for clinically stable patients.
- Laboratory tests of patients who live far away from the oncological clinic should be performed locally.
- Complications may be monitored by phone or online contact.

Auxiliary treatment

As regards auxiliary treatment for breast cancer patients, the team drafting these recommendations emphasises the following:

- Because of the additional infection risk related to neutropenia as well as the potential difficulty with distinguishing the COVID-19 infection from other pathogens, patients on chemotherapy with a medium or high risk of neutropenic

Table I. The division of patients into groups according to the cancer treatment stage and recommended strategies

Patient group	Strategy	Means
Currently not under treatment	<ul style="list-style-type: none"> – Infection prevention – Postponing check-ups if there are no symptoms of an active disease – Phone or online consultations 	<ul style="list-style-type: none"> – Education on the pandemic and infection prevention methods – Dissemination of information on protective measures
With a diagnosis of early stage cancer, radical treatment (preoperative, auxiliary, surgical)	<ul style="list-style-type: none"> – Infection prevention – Optimal treatment available at SARS-CoV-2-free hospitals – Treatment modification if needed with the lowest possible risk of its effectiveness 	<ul style="list-style-type: none"> – All the above-mentioned measures – Severe restrictions of direct contact – Adequate use of personal protection equipment by staff – Monitoring of complications and potential infection symptoms – Clinical pathway secured against the SARS-CoV-2 infection – If oral medications are used, patients are prescribed drugs for 2–3 months of therapy – Treatment regimen modification if needed (extension of the break between cycles) – Phone or online consultations in the case of complications
With metastatic stage cancer	<ul style="list-style-type: none"> – Infection prevention – Optimal treatment available at SARS-CoV-2-free hospitals – Treatment modification if needed with the lowest possible risk of its reduction in effectiveness 	<ul style="list-style-type: none"> – All the above-mentioned measures – Treatment postponement or a temporary break in treatment if no risk of unacceptable progression is involved – Treatment with the use of oral medications of the lowest myelotoxicity level if the clinical situation allows it – If oral medications are used, patients are prescribed drugs for 2–3 months of therapy – Postponement of the use of CDK4/6 inhibitors (this option remains available in the second line of treatment) in patients with luminal HER2-positive breast cancer if the clinical situation allows it – Optimum auxiliary treatment, routine use of growth factors in patients with the medium and high risk of neutropenic fever, reduced use of corticosteroids, oral instead of intravenous bisphosphonates, extension of the period between administration if it is justified – Rational monitoring of the therapy effectiveness, postponement of imaging tests in patients in a stable clinical condition

Table II a. Rules for the systemic treatment of patients with an early and locally advanced stage of the disease during the COVID-19 pandemic

Subtype (local progression, without M1)	Treatment	Remarks
Early tumour	Luminal HER2-negative	Surgery or preoperative HTH if surgery entails high risk
	HER2-positive – non-luminal subtype or – triple-negative luminal subtype	Preoperative chemotherapy (\pm anti-HER2 treatment) or surgery
Locally advanced tumour	Luminal HER2-negative	Preoperative chemotherapy or hormone therapy according to standards
	HER2-positive – non-luminal subtype or – triple-negative luminal subtype	Preoperative chemotherapy (\pm anti-HER2 treatment)

Table II b. Rules for the systemic treatment of patients with metastatic cancer during the COVID-19 pandemic

Subtype (metastatic, M1)	Treatment	Comments
Luminal HER2-negative	Individual hormone therapy or in combination with molecular drugs	It is recommended to use oral drugs (e.g. aromatase inhibitors or Tamoxifen instead of Fulvestrant) and exercise caution when starting the CDK4/6 inhibitor therapy if it can be employed in the second line treatment
HER2-positive – non-luminal or – luminal	Chemotherapy or hormone therapy + anti-HER2 treatment	
'Triple-negative'	Oral chemotherapy if possible and/or of the lowest myelotoxicity	

fever should be administered granulocyte colony-stimulating factor.

- Exercise caution when administering corticosteroids.
- Due to the limited access to GPs/primary care, including laboratory tests performed locally, it seems justified to use empirical antibiotic therapy when such tests cannot be performed for patients with infection symptoms.
- In patients with stable bone metastases, it is possible to extend the breaks between the administration of parenteral drugs modifying bone metabolism (bisphosphonates and denosumab). It is also recommended that the possibilities of offering this therapy outside oncological clinics, e.g. in home hospices, be created.

The observation of patients after radical treatment

As regards the rules for the observation of breast cancer patients after radical treatment, the team drafting these recommendations emphasises the following:

- It is recommended that the number of visits during the observation period be reduced, but it is necessary to avoid exposing patients to the risk of the failure to detect recurrence that might potentially qualify for radical treatment.
- Optimum imaging tests (e.g. control MMG) should be performed depending on the disease recurrence risk. They should be postponed for low risk patients.

- It is recommended that consultations be carried out on the phone instead of check-ups; check-ups in person should be reserved for patients with concerning symptoms.

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Radiotherapy of breast cancer patients during the COVID-19 pandemic

Breast cancer patient categorisation for radiotherapy

As regards the rules for breast cancer patients' radiotherapy, the team drafting these recommendations proposes the following categorisation of patients according to the rules defined in table III.

Table IV presents the way of modifying treatment fractionation during the COVID-19 pandemic.

Moreover, the authors of these recommendations propose the following regimen modifications as regards radical surgical treatment:

- Each time, consider whether the extension of margins after breast-conserving therapy with a microscopically positive focal margin should be abandoned. Patients with microscopically positive focal margin may be qualified for

Table III. The method of breast cancer patient categorisation for radiotherapy during the COVID-19 pandemic

Category	Procedure	Clinical situation
A	The highest priority; it is necessary to begin radiotherapy up to 8 weeks after the completion of surgical or systemic treatment	<ul style="list-style-type: none"> – Inflammatory breast cancer – Massive metastases to ≥ 4 lymph nodes – Massive LVI – TNBC with N+ – ypN+ – Regional recurrence
B	It is necessary to begin radiotherapy up to 16 weeks after the completion of surgical or systemic treatment	<ul style="list-style-type: none"> – T4 (other than inflammatory breast cancer) – TNBC, N0 – ypT+ and ypN0 – LVI (NOS) – Invasive cancer in patients below 40 years of age – ER+ with 1–3 positive lymph nodes and other unfavourable prognostic factors (G3, LVI)
C	It is possible to postpone radiotherapy up to 20 weeks after the completion of surgical or systemic treatment	<ul style="list-style-type: none"> – Tumour T1, T2, N0 hormonosensitive – HER2-negative – Patients above 40 years of age – Patients on hormone therapy – Unfavourable prognostic factors (close margins, G3)
D	It is possible to abandon radiotherapy	<ul style="list-style-type: none"> – Patients above 65 years of age – Tumours up to 30 mm, N0 – ER+, HER2-negative, G1-2, margins ≥ 2 mm; please note – radiotherapy reduces the 5-year risk of local recurrence by 3% – DCIS, especially with ER+ – Patients on hormone therapy

Table IV. Modifications of fractionation method during the COVID-19 pandemic

Indications	Fractionation
APBI <ul style="list-style-type: none"> – Age > 50 years old; tumour ≤ 2 cm T1, negative margin width min. 2 mm without LVI, ER+, BRCA negative, or – DCIS of low and medium differentiation level, detected using screening MMG, size ≤ 2 cm with negative margins ≥ 3 mm, located especially on the left side 	<ul style="list-style-type: none"> – 5 fractions of 6 Gy each every 2nd day up to the total dose of 30 Gy – IMRT technique or: <ul style="list-style-type: none"> – According to FAST Forward: 5 fractions of 5.2 Gy each up to the total dose of 26 Gy within a week
WBI <ul style="list-style-type: none"> – Resignation from BOOST: patients T1-2N0 at the age of 50 or older with negative margins ≥ 2 mm, without unfavourable prognostic factors (G3, DCIS component) – Resignation from the radiation of lymph nodes: Post-menopausal patients T1, ER+, HER-, G1-2, SLND up to 2 lymph nodes affected (level I together with the place left after the incorrect resection of the sentinel node are affected) 	<ul style="list-style-type: none"> – According to UK FAST: 5 fractions of 5.7 Gy each once a week up to the total dose of 28.5 Gy or: <ul style="list-style-type: none"> – According to FAST Forward: 5 fractions of 5.2 Gy each up to the total dose of 26 Gy within a week
WBI + BOOST \pm RNI	SIB 15 fractions of 2.66 Gy per breast and 3.2 Gy per boost up to a total dose of 40 Gy per breast/ 48 Gy per boost SIB 16 fractions of 2.66 Gy per breast + 3 Gy per boost up to a total dose of 42.56 Gy per breast/ 48 Gy per boost
WBI + RNI	15 fractions of 2.66 Gy up to a total dose of 40 Gy
Patients after mastectomy with breast reconstruction	Options to consider: <ul style="list-style-type: none"> – 15 fractions of 2.66 Gy up to a total dose of 40 Gy – or 20 fractions of 2.25 Gy up to a total dose of 45 Gy

a boost of teletherapy (the dose and the technique depend on the current possibilities of the radiotherapy centre).

- The decision to abandon lymphadenectomy if metastases to sentinel lymph nodes are confirmed and replace it with radiotherapy should be made individually for each patient by a council of specialists in many disciplines. It is necessary to take into account the current possibilities of the surgical ward and the radiotherapy centre.

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Surgical treatment of breast cancer patients during the COVID-19 pandemic

As regards the rules for the surgical treatment of breast cancer patients, the team drafting these recommendations proposes the following categorisation of patients according to surgery urgency as defined in Table V.

Depending on the intensity and activity of the pandemic and the availability of equipment and staff, a decision may be

made to postpone all surgeries except for emergency clinical situations only, such as the incision and draining of breast abscess, the securing of haemorrhage and/or haematoma, the revision of ischaemic lobes after mastectomy or breast-conserving surgeries, etc.

Recommendations for surgery qualification

The team drafting these recommendations proposes the following categorisation of surgery types according to the surgery urgency category as defined in table V.

- Patients diagnosed with malignant breast cancer (Category 1) should be operated on as planned. If the patient's oncological condition allows it and all the standards are maintained, single-stage mastectomy with breast reconstruction should be preferred to delayed reconstruction.
- Such surgeries as: incision and draining of breast abscess, removal of haematoma, revision of ischaemic breast lobes after mastectomy or breast-conserving surgeries (Category 1) should be performed as planned.

In selected clinical situations, combined therapy should begin with preoperative systemic treatment, both as a result of classical indications in the case of patients with locally advanced tumours, patients with HER2 positive or triple-negative breast cancer (chemotherapy and, optionally, immunotherapy) and patients with early, luminal HER2 negative breast cancer (hormone therapy). Detailed recommendations can be found in the chapter entitled *Rules for the systemic treatment of breast cancer patients during the COVID-19 pandemic according to the cancer phenotype and progression*.

- In the case of the absence of the radiological and pathological correlation and the need for the diagnostic resection of lesions with a high cancer risk (>10%), surgical treatment should not be postponed by more than a few weeks. At the same time, patients awaiting surgery should be selected on the basis of the following order (starting with the most urgent cases), taking into account their age and comorbidities: BIRADS 5, 4C, 4B (Category 2). In the case of B3 lesions with a high risk of cancer diagnosis (>10%), surgical treatment should be planned taking into account the potential risk of cancer confirmation, the patient's age, and comorbidities (Category 2–3). There is

Table V. Categories of breast cancer surgery urgency during the COVID-19 pandemic

Category 1	<ul style="list-style-type: none"> – New diagnosis of malignant cancer (unless preoperative systemic treatment is planned) – Incision and draining of breast abscess, removal of haematoma, revision of ischaemic lobes after mastectomy or breast-conserving surgery 	Operate as planned, without delays
Category 2	<ul style="list-style-type: none"> – No radiological and pathological correlation and necessary diagnostic resection of lesions with a high risk of cancer (>10%) 	Do not postpone by more than 6–12 weeks
Category 3	<ul style="list-style-type: none"> – B3 lesions with a risk of cancer diagnosis not exceeding 10% – Surgeries reducing the risk of breast cancer development – Postponed breast reconstruction surgeries – Benign breast cancer surgeries 	Postpone until the COVID-19 epidemic ends in Poland or until the epidemiological situation stabilises and the oncological clinic is secured in terms of optimum staff and equipment

data indicating that B3 lesions (e.g. ADH and LN with ER expression) may be treated using tamoxifen or aromatase inhibitors. Also, DCIS with ER expression may be subjected to hormone therapy lasting 6 months. For this reason, the urgency of surgeries in such cases should be qualified as Category 3 and, while awaiting surgery, the patient should undergo local treatment preceded by hormone therapy (if possible, it is recommended to fix a clip marking the lesion).

- In the case of B3 lesions with the risk of cancer diagnosis not exceeding 10% (the analysis of the biopsy result combined with the radiological image), surgery may be abandoned/postponed until the COVID-19 epidemic ends in Poland (Category 3).
- Most experts recommend that radical surgery (extension of margins) after breast-conserving therapy should be abandoned in the case of a low risk of residual cancer.
- Most experts recommend that additional surgeries in the axilla (e.g. SLB after cancer diagnosis following the removal of B3 lesions or auxiliary lymphadenectomy after the biopsies of metastatic sentinel lymph nodes) should be abandoned in the case of a low risk of residual cancer.
- Surgeries reducing the risk of breast cancer should be abandoned/postponed until the COVID-19 epidemic ends in Poland (Category 3).
- Breast reconstruction surgeries should be abandoned/postponed until the COVID-19 epidemic ends in Poland (Category 3).
- Surgeries of benign breast tumours should be abandoned/postponed until the COVID-19 epidemic ends in Poland (Category 3).

Remarks related to surgical treatment

It needs to be emphasised that:

- The qualification of patients for mastectomy instead of breast-conserving therapy is not recommended because of better quality of life and long-term results (survival) following breast-conserving therapy as compared with mastectomy.
- Single-stage mastectomy with direct-to-implant breast reconstruction (DTI) are optimal procedures in the case of mastectomies performed due to malignant breast tumours (Category 1). Reconstructions with the patient's own tissue should be postponed, but in the situations when they are performed the revision/revascularisation of an ischaemic lobe using the patient's own tissue should be performed as an emergency procedure.

Planned admissions to breast cancer surgeries

The authors of this document propose that the admission procedure to a surgical ward for breast cancer patients during the COVID-19 pandemic include the following elements:

- It is recommended to determine the potential risk of SARS-CoV-2 infection in patients about 48 hours before the

surgery (which includes obtaining the history of B and C symptoms – table VI – and the possibilities of potential contact with persons infected with SARS-CoV-2 from patients on the phone or in person).

- It is recommended that patients undergo self-isolation (self-isolation criteria are identical to the quarantine criteria) for 7–14 days before admission to a surgical ward.
- It is recommended that:
 - Patients express consent to self-isolation at the moment they are enrolled in the list of patients qualified for surgery as well as to the RT-PCR test before their admission to the hospital.
 - Patients sign a declaration that they are aware of the risk of SARS-CoV-2 infection despite the precautions and care exercised by the hospital with regard to prophylaxis and the protection measures used,
 - Only patients with no symptoms suggestive of SARS-CoV-2 infection or other upper respiratory tract infection who have a negative result on the PCR test for SARS-CoV-2 infection and who have undergone self-isolation for 7-14 days may be admitted to surgeries.

Please note!

In the case of each patient with the symptoms of cancer who has a positive result on the COVID-19 test, it needs to be determined when the patient may qualify for oncological treatment. Patients with positive results in emergency and urgent situations (e.g. abscess, haematoma, lobe necrosis) must be operated on in a hospital dedicated to the treatment of patients with SARS-CoV-2 infection.

Admissions to urgent breast and lymph node surgeries

It is recommended to divide surgeries that require immediate intervention in the following way:

- **EMERGENCY** surgeries, e.g. severe haemorrhage, revascularisation using a lobe of the patient's own tissue.
- **URGENT** surgeries, e.g. haematoma, abscess, revision of an ischaemic lobe after mastectomy/breast-conserving therapy.

Testing before the admission of an emergency patient to a surgical ward involves obtaining the patient's epidemiological history and, if preoperative RT-PCR is impossible, a chest CT scan (the majority of patients with indications for emergency surgery have a higher temperature and often non-specific pain; they should be checked for type B or C of symptoms – table IV).

The chest CT scan and RT-PCR recommendations do not apply to the patients with haemorrhage that occurred during hospitalisation at a given centre before which RT-PCR was performed. This recommendation applies to patients with severe haemorrhage admitted to hospital from home or other centres, only if it can be performed considering the patient's clinical condition.

Table VI. Categories and definitions of SARS-CoV-2 infection symptoms

Category of symptoms	Definition
Symptoms B (mild symptoms suggestive of COVID-19)	<ul style="list-style-type: none">– temperature of 37–37.9°C or possible fever symptoms such as interchangeable shivering and sweating– shivering– muscle pain– sore throat– diarrhoea– loss of sense of smell and taste or change of taste– non-specific pain– upper respiratory tract infection
Symptoms C (SARS)	<ul style="list-style-type: none">– cough– dyspnoea– fever of 38°C and higher

Conflict of interest: none declared

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Received and accepted: 9 May 2020

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