

VIA MEDICA

# Surgical management of breast malignancies

Consensus of the Polish Society of Surgical Oncology under the substantive auspices of the National Consultant in surgical oncology

#### Editors: Zbigniew I. Nowecki Arkadiusz Jeziorski

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#### **Abbreviations**

AGO — Arbeitsgemeinschaft Gynäkologische Onkologie ALND — axillary lymphadenectomy AS — angiosarcoma BCS — breast-conserving surgery BCT - breast-conserving treatment BCU - Breast Cancer Unit CB — core-needle biopsy CT — computed tomography DCIS - ductal carcinoma in situ EUSOMA — European Society of Mastology FNA — fine-needle aspiration IBTR — ipsilateral breast tumour recurrences IHC --- immunohistochemistry LCIS - lobular carcinoma in situ MC - microcalcification MDT — multidisciplinary team: radiologist, pathologist, surgical oncologist, clinical oncologist, radiotherapist, physiotherapist, etc. MMG — mammography MRI — magnetic resonance imaging MRM - modified radical mastectomy NAC — systemic preoperative (neoadjuvant) treatment (mainly relevant to neoadjuvant chemotherapy, less often to endocrine therapy) NCCN - National Comprehensive Cancer Network NSM - nipple-skin-sparing mastectomy OBS — oncoplastic breast surgery PET — positron emission tomography PPV — prospective predictive value for malignancy in resection PSSO — Polish Society of Surgical Oncology; PTChO — Polskie Towarzystwo Chirurgii Onkologicznej PTP — Polskie Towarzystwo Patologów (Polish Pathology Association) R0 — radical surgery excision margin ("no ink on tumour") R1 — microscopically non-radical surgery excision margin RRBM — mastectomy reducing risk of breast cancer ("prophylactic mastectomy") SIS — Senologic International Society SLN — sentinel lymph nodes SLNB — sentinel lymph nodes biopsy SSM — skin-sparing mastectomy TNBC — triple-negative breast cancer USG — ultrasonography VAB — vacuum-assisted biopsy VNPI — Van Nuys Prognostic Index WBRT — whole-breast radiation therapy XRT/RT - radiotherapy

#### Introduction

#### Zbigniew I. Nowecki, Arkadiusz Jeziorski

During the last few decades there has been a trend in breast cancer treatment toward limitation of operation extensity together with higher individualisation of systemic treatment and radiotherapy. Breast cancer treatment has evolved into a separate therapeutic area requiring specialised knowledge. According to the European Society of Mastology (EUSOMA), breast cancer patients should have access to multidisciplinary care, including: radiologist, oncology surgeon with ability in breast reconstruction, in close cooperation with clinical oncologist, radiotherapist, nuclear medicine specialist, specialist in rehabilitation, clinical geneticist, psycho-oncologist, psychiatrist, palliative treatment specialist, specialised nurse, administrative assistant, and social worker. However, the crucial role in diagnosis, treatment, follow-up, and outline of treatment strategy is played by the oncology surgeon.

In May 2015 during the 21<sup>st</sup> Conference of the Polish Society of Surgical Oncology, the Section of Breast Cancer and Reconstructive Surgery was initiated, established by the Polish Society of Surgical Oncology (PSSO) (Polskie Towarzystwo Chirurgii Onkologicznej, PTChO) Management Board on 3rd October 2014. One of the main postulates of the Section members was the development of uniform, common recommendations, which could guide oncology surgeons treating breast cancer in Poland. It was proposed that a discussion platform be created, allowing achievement of agreement regarding all subjects of interest for surgeons. These actions were supported by the PSSO Management Board and the National Consultant in surgical oncology.

The consensus should comprise diagnosis, surgery treatment, and breast reconstruction. As previously mentioned, breast cancer patients should be treated with team management; however, the oncology surgeon remains a central member of the multi-disciplinary team (MDT) qualifying to the treatment and defining the type and extension of therapy. According to this, the guidelines also included the problems of loco-regional conservative treatment and some aspects of systemic therapy. Of note, the developed Consensus was not aimed at verifying the recommendations in clinical oncology, radiotherapy, or other oncological specialities, but to give substantive suggestions to the oncology surgeon regarding which therapeutic option should be supported in discussions during MDT meetings. In these situations the information was always implemented: "MDT decision, suggested standpoint of surgical oncologist:...", which highlights the importance of team consensus in each individual therapeutic decision.

The Consensus was prepared based on international recommendations, mainly developed by German AGO

(der Arbeitsgemeinschaft Gynäkologische Onkologie e. V. in der Deutschen Gesellschaft für Gynäkologie und Geburtshilfe e. V. sowie in der Deutschen Krebsgesellschaft e. V.) (http://www.ago-online.de/en/guidelines-mamma/march-2016/) and american NCCN (National Cancer Comprehensive Network) (https://www.nccn.org/professionals/physician\_gls/f\_guidelines.asp#site).

The Recommendations "Surgical management of breast malignancies — Consensus of the Polish Society of Surgical Oncology" were developed after the collective discussion of nearly 60 members of the Section of Breast Cancer and Reconstructive Surgery of the Polish Society of Surgical Oncology and many other specialists who were giving lectures. The vast majority of the Consensus, including basic problems of breast cancer surgery, was then publicly discussed and verified upon voting during the Section's meeting on 16th June 2016 in the Maria Skłodowska Curie Memorial Cancer Centre and Institute of Oncology in Warsaw. The remaining topics were verified during electronically conducted voting.

During preparation of the Consensus the value of each single topic was assessed based on:

- Oxford Score evidence level (Tab. 1), Oxford Score recommendation grade (Tab. 2), AGO recommendation criteria (Tab. 3), and NCCN guidelines (recommendations above 2A),
- Polish Society of Surgical Oncology recommendation criteria modelled on AGO score and presenting the consensus percentage within Consensus Authors regarding each discussed issue (Tab. 4).

During discussion of this Consensus all the aforementioned recommendation criteria were available. However, for clarity this publication presents only PTChO recommendation criteria.

The aim of the presented team publication is the outline of substantive frames of our management, as well as defining essential conditions for qualification, surgical treatment, and perioperative management. We would like to have this Consensus as a true "guide" for all surgeons treating breast cancer patients. At the same time, we highlight that our Consensus is like a "frame", indicating some directions of management. It is worth mentioning that sometimes we are forced to treat patients who need highly individualised treatment, beyond this Consensus. In this group of patients, the decisions about tailored treatment, giving some benefits, are made by a multidisciplinary team.

The development of the guidelines "Consensus of the Polish Society of Surgical Oncology under the substantive auspices of the National Consultant in surgical oncology" is an essential strategy of the Polish oncology surgeon community because they have achieved, as a community, surgical skills and oncological knowledge as well as diagnostic-therapeutic possibilities, allowing patient treatment in all Polish centres according to the most optimal procedures.

| Level | Publication on the topic: therapy/prevention, aetiology/harm:  | Publication on the topic: prognosis   |
|-------|--|---|
| 1a    | Systematic reviews (with homogeneity) of randomised controlled trials  | Systematic review (with homogeneity) of inception cohort studies; clinical rule validated on a test set   |
| 1b    | Individual randomised controlled trials (with narrow confidence interval)  | Individual inception cohort study with $\ge$ 80% follow-up; clinical rule not validated on a second set of patients                                       |
| 1c    | All or none randomised controlled trials   | All or none case-series   |
| 2a    | Systematic reviews (with homogeneity) of cohort studies  | Systematic review (with homogeneity) of either<br>retrospective cohort studies or untreated control groups in<br>randomised controlled trials             |
| 2b    | Individual cohort study (including low quality randomised controlled trials e.g. < 80% follow-up)                | Retrospective cohort study or follow-up of untreated<br>control patients in randomised controlled trials; or clinical<br>rule not validated in a test set |
| 2c    | "Outcomes Research" or ecological studies  | "Outcomes research"   |
| 3a    | Systematic review (with homogeneity) of case-control studies   | -   |
| 3b    | Individual case-control study  | _   |
| 4     | Case-series (and poor quality cohort and case-control studies)   | Case-series (and poor quality prognostic cohort studies)  |
| 5     | Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" | Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"  |

#### Table 1. Oxford Score of levels of evidence (edited by lek. M. Maczkiewicz)

#### Table 2. Oxford Score of recommendation grade (edited by lek. M. Maczkiewicz)

| Grade A | Consistent results directly based on Level 1 evidence  |
|---------|--|
| Grade B | Consistent results directly based on Level 2 or 3 evidence or extrapolated recommendations from Level 1 evidence |
| Grade C | Directly based on Level 3 or 4   |
| Grade D | Directly based on Level 5 or problematic/inconsistent/unequivocal Level 2, 3, or 4 evidence                      |

#### Table 3. AGO recommendation criteria (edited by lek. M. Maczkiewicz)

| Recommendation level | Recommendation criteria   |
|----------------------|---|
| ++                   | This investigation or therapeutic intervention is highly beneficial for patients, can be recommended without restriction, and should be performed   |
| +                    | This investigation or therapeutic intervention is of limited benefit for patients and can be performed  |
| +/-                  | This investigation or therapeutic intervention has not shown benefit for patients and may be performed only in individual cases. According to current knowledge, a general recommendation cannot be given |
| -                    | This investigation or therapeutic intervention can be disadvantageous for patients and might not be performed   |
| 2-                   | This investigation or therapeutic intervention is clearly disadvantageous for patients and should be avoided or omitted in any case   |

| Recommendation Recommendation criteria*<br>level |   | Consensus level among<br>Consensus authors |  |
|--|---|--|--|
| 2+   | This investigation or therapeutic intervention is highly beneficial for patients, can be recommended without restriction, and should be performed | 81–100%                                    |  |
| 1+   | This investigation or therapeutic intervention is of limited benefit for patients and is recommended to be performed                              | 61–80%                                     |  |
| 0  | This investigation or therapeutic intervention has not shown benefit for patients and may be performed only in individual cases                   | 41–60%                                     |  |
| 1–   | This investigation or therapeutic intervention can be disadvantageous for patients and is not recommended to be performed                         | 21–40%                                     |  |
| 2-   | This investigation or therapeutic intervention is disadvantageous for patients and should be avoided  | 0–20%                                      |  |

Table 4. Polish Society of Surgical Oncology (PSSO) recommendation criteria, used during assessment of particular diagnostic and therapeutic problems in breast cancer patients

\*In individual cases, the therapeutic decision is based on criteria of the patient's clinical state and cancer stage, and is finally developed during an MDT meeting

### A. PREOPERATIVE DIAGNOSIS AND QUALIFICATION TO SURGICAL OPERATION

#### A.1. Multidisciplinary treatment of breast cancer. Organisational basis for a centre of breast cancer diagnosis and treatment — Breast Cancer Unit in Poland

#### Arkadiusz Jeziorski, Zbigniew I. Nowecki

Decreasing the extensity of radical operations, together with improvement of breast cancer patients survival from 45-50% at the end of the nineteenth century to 80-90% currently, result from early diagnosis, better understanding of tumour biology as well as complexity, and multidisciplinary approach to the therapy. Currently, breast cancer patients are under the supervision of a multidisciplinary team involving: surgical oncologist (with competency in breast reconstruction), radiologist, pathologist, molecular biologist, medical oncologist, radiotherapist, specialist in nuclear medicine, specialist in rehabilitation, clinical geneticist, psycho-oncologist, psychiatrist, specialist in palliative care, specialised nurse working in a Breast Cancer Unit (BCU), administrative assistant, and social worker. A crucial role in this team is still played by a surgical oncologist, who coordinates the diagnostic process and treatment, and often continues the patient's follow-up for many years.

At the end of the twentieth century, groups of experts started make their best efforts to establish BCUs, being highly specialised centres, taking complex and modern care of breast cancer patients, starting from screening, through diagnosis and treatment, to follow-up, together with palliative care. EUSOMA (European Society of Mastology; 2000, 2013) developed the principles and organisational requirements for effective functioning of BCUs.

BCU activity includes four stages of intervention: 1. Diagnosis:

- confirmation of cancer exclusion,
- assessment of cancer stage,
- histological assessment.
- 2. Outline of treatment program.
- 3. Treatment.
- 4. Follow-up after treatment cessation.

In Polish conditions, BCUs should have the privileged to perform without quantitative limits of health services; however, their activities should be in line with different regulations according to:

- health services, according to the oncology treatment cart (DiLO cart),
- reimbursement lists and drug programmes,

- reports and settlements with the National Health Fund (NFZ),
- waiting lists.
- BCUs have the following obligations:
- authorisation to obtain BCU status (according to EUSOMA requirements),
- adherence to guidelines of management and participation in periodic evaluations,
- maintenance of accurate registration of medical documentation to monitor quality,
- participation in an assessment process regarding medial quality and patient satisfaction,
- performance of periodic audits.

Establishing a BCU in Poland should be conducted in three steps:

- step I establish pilotage BCU,
- step II assess pilot BCU performance,
- step III establish full-profile BCU.

During each step, clear criteria of the centre's accreditation should be adopted (Appendix 1).

The BCU should be accredited by an authority (agenda of Ministry of Health) in cooperation with scientific societies and national consultants. Because in Poland there is no such entire organisation at this time, accreditation is possible through EUSOMA and SIS. The Polish Society of Surgical Oncology should consider appointing the Committee of Alignment of Breast Cancer management with procedures recommended by the PSSO (so-called small PSSO accreditation — "Certificate of Compatibility with PSSO procedures").

#### A.2. Detection, and clinical and imaging diagnosis of breast cancer

#### Monika Nagadowska, Ewa Wesołowska

#### I. Detection

- Screening based on mammography according to American Cancer Society (ACS) guidelines and U.S. Preventive Services Task Force (USPFT) is recommended in women with no clinical signs and symptoms.
- Contrary to previous guidelines, ACS recommends decreasing the age of the screened population (after 40 years), and in women ranging between 40 and 50 years to change the time intervals (every 12 months).
- Genetic-based screening is not justified in women at overage risk of morbidity, and ACS recommends it

#### Appendix 1. Proposed criteria of accreditation for Breast Cancer Units (BCUs) in Poland\*

| Stage   | I   | II  | III |
|---|-----|-----|-----|
| General assumptions   |     |     |     |
| Number of newly diagnosed patients treated in the centre  | 100 | 100 | 150 |
| Main BCU departments: outpatients, diagnostic radiology, pathology in place, surgery,           | х   | х   | х   |
| chemotherapy, radiotherapy (in place or contracted), data management centre, conference         |     |     |     |
| room equipped with multimedia (for app. 20 persons)   |     |     |     |
| Paper or electronic protocols made at each step of diagnosis and treatment                      | х   | х   | х   |
| (medical secretaries)   | _   |     |     |
| Diagnostic radiology  |     |     |     |
| Equipment not older than five years: digital mammography, USG with line                         | х   | х   | х   |
| transducer $\geq$ 14 MHz, Mammotome biopsy, stereotactic biopsy, MRI with attachment for breast |     |     |     |
| (in place or contracted)  |     |     |     |
| Two radiologists specialised in breast diseases   | x   | X   | х   |
| Each radiologist should assess a minimum of 1000 diagnostic imaging every year                  | _   |     | Х   |
| Descriptions according to the BIRADS system are mandatory                                       | x   | X   | х   |
| Collaboration with screening centre   |     | x   | х   |
| Training according to EUSOMA criteria   |     |     | х   |
| At least two radiology technicians, performing a minimum of 20 diagnostic images weekly         |     | x   | х   |
| Surgical treatment  |     |     |     |
| At least two specialists in oncology surgery, operating on a minimum of 50 women every year     | х   | х   | х   |
| (each)  |     |     |     |
| Ability in breast reconstruction and oncology plastic surgery                                   | х   | х   |     |
| Bank of prostheses for reconstruction   |     | х   | х   |
| Possibility of SNB in place   | х   | х   | х   |
| Uniform and validated protocols for every procedure   |     | х   | х   |
| Possibility to perform intraoperative mammography and histological examination                  | х   | х   | х   |
| Uniform template of referral and signage of preparations  | х   | х   |     |
| Percentage of BCT   | 25  | 40  | 50  |
| Possibility to remove non-palpable lesions  | х   | x   | Х   |
| Scientific photography documentation  | x   | x   | х   |
| Separated emplacement to take scientific pictures   |     | x   | Х   |
| Pathological diagnosis  |     |     |     |
| Agreed systems for signage of preparations  | x   | x   | х   |
| Equipment and apparatus not older than 10 years   | x   | x   | х   |
| ER, PR, HER2, and Ki67 assessment   | x   | x   | х   |
| Weekly interdisciplinary team meetings  | x   | x   | х   |
| Analysis of failures  |     | х   | х   |
| Unified form of test descriptions   | x   | x   | х   |
| Two pathologists assessing yearly at least 50 newly diagnosed cancers                           | x   | x   | х   |
| Possibility to store paraffin-embedded blocks for 10 years; collaboration with tissue bank      |     | x   | х   |
| Molecular assessment; genetics  |     |     |     |
| Possibility to perform assessment of BRCA status (contracted)                                   | x   | x   | х   |
| Established protocol for definition of positive family history                                  |     | x   | х   |
| Ensured consultancy of oncology geneticist  |     | x   | х   |
| Chemotherapy  |     |     |     |
| Outpatient chemotherapy (five beds) and stationary chemotherapy (three beds)                    | x   | x   | Х   |
| Equipment not older five years  |     | х   | х   |

| Stage  | I       | II   | Ш    |
|--|---------|------|------|
| Pharmacy preparing cytotoxic drugs in place  | х       | х    | х    |
| Two clinical oncologists   | х       | х    | х    |
| Two oncology nurses administering cytotoxic drugs  |         | х    | х    |
| Radiotherapy   |         |      |      |
| In place or contracted   | х       | х    | х    |
| Own equipment: brachytherapy   | х       | х    | х    |
| Intraoperative radiotherapy  |         |      | х    |
| Irradiation quality control  |         | х    | х    |
| Palliative care  |         |      |      |
| In place or contracted   |         | х    | х    |
| Medical supplies point   |         |      |      |
| Possibility to provide with prostheses, wigs, and other equipment                              |         | х    | х    |
| Clinical trials centre   |         |      |      |
| At least 10% of patients enrolled to clinical trials   |         |      | х    |
| Rehabilitation   |         |      |      |
| Developed own program of prophylaxis and treatment of extremity oedema                         | х       | х    | х    |
| Own physiotherapy centre   |         |      | х    |
| Protocols, photography documentation   | х       | х    | х    |
| Registry and epidemiology  |         |      |      |
| Own  | х       | х    | х    |
| Trainings  |         |      |      |
| Organisation once per year of either a regional or national conference                         |         | х    | х    |
| Active participation of physicians in two national and two foreign conferences                 |         |      | х    |
| Training in Polish or foreign BCU once per year  |         |      | х    |
| Work quality control in BCU  |         |      |      |
| Comprehensive external audit EUSOMA once per year  |         | х    | х    |
| Use of treatment quality measures  | Minimal | Full | Full |
| Minimum weekly interdisciplinary meetings including full team                                  |         | х    | х    |
| Written treatment plan for each patient  |         | х    | х    |
| More than 90% of patients discussed  |         | x    | х    |
| Verification of treatment plan based on pathological evaluation — including full team          |         | х    | х    |
| Time since diagnosis until treatment commencement (weeks)                                      | 5       | 4    | 3    |
| During the first visit, it should be possible to perform BAG, BAC, USG, MMR                    | х       | х    | х    |
| Information about diagnosis and treatment steps available for the patient either in written or |         | x    | х    |
| electronic form  |         |      |      |
| Patients with advanced cancer should have visits according to different time schemes than for  |         | x    | х    |
| the first time (different management and treatment protocols)                                  |         |      |      |
| An established protocol, available for the patient, regarding the extent and frequency of      |         | x    | х    |
| follow-ups after treatment cessation   |         |      |      |

\*The presented organisational principles were based on an unpublished Report of the Committee for BCU, appointed by the Ministry of Health in 2012, of which Prof. A. Jeziorski was a member

in populations at significantly higher risk (e.g. Jewish Ashkenazi population).

II. Diagnosis

 Screening with Magnetic Resonance Imagining (MRI of breast) mammography is not justified in women at overage risk of morbidity, and is recommended in women with confirmed mutation *BRCA1/2*. — In preclinical stages, diagnosed during screening programmes, further diagnosis is conducted in centres prepared for intensified diagnosis and coordinated by radiologists.  In preclinical stages, diagnosed outside mammography-based screening, further diagnosis is conducted in oncological centres.

#### **Presumptive diagnosis**

**Clinical evaluation** includes: medical history, general health assessment, menopausal status, and possibly biochemistry panel.

**Primary tumour assessment** includes: physical evaluation, mammography (preferably digital) with supplemental USG, and breast MRI in special cases.

#### **Detailed diagnosis**

After imaging evaluations a decision regarding the way and sequence of test verifying imaging lesions in breasts is made.

**Tissue sample taking (core-needle biopsy and its variations)** from primary lesion and possible satellite lesions/sites is essential during planning of BCT.

Assessment of regional lymph nodes includes: physical examination, USG, and possible biopsy (either PCI or CB with setting of a marker, when neoadjuvant chemotherapy followed by SLNB is planned).

After diagnosis of breast cancer is confirmed, clinical-pathological-mammography correlation is recommended in order to make a decision regarding optimal loco-regional treatment. **TNM classification** — in every case, a physical examination and tests are needed during preparation for surgery.

- In early stages (I–IIA) tests for distant metastases are not recommended (so-called "spread tests"), unless there are clinical concerns indicating the possibility of such lesions.
- In stage IIB and IIIA "spread tests" should be considered, especially when neoadjuvant treatment is planned.
- In stage IIIB "spread tests" are recommended.

After completing the diagnosis process the decision should be made in cooperation with the patient about psycho-oncology consultancy and consultancy regarding fertility prevention.

Also, after completing the diagnosis a decision should be made regarding genetic consultancy, depending on the patient's age and family history.

- 1. ACS, http://www.cancer.org/breastcancerearlydetection.
- 2. NCCN Guidelines: Breast cancer diagnosis, treatment. Version 2.2016.
- Peccatori FA, Azim HA, Orecchia R et al. Rak piersi diagnostyka w ciąży. ESMO clinical practice guidelines. Ann Oncol 2013; 24 (suppl 6).
- Senkus E, Kyriakides S, Ohno S et al. Primary breast cancer: ESMO guidelines for diagnosis, treatment and follow up. Ann Oncol 2015; 26 (suppl 5).
- 5. USPSTF, http://www.uspreventiveservicestaskforce.org.

| Subject  | Clinical and imaging<br>diagnosis |
|--|-----------------------------------|
| Analysed problems  | PSSO recommendation               |
| Mammography screening according to ACS/USPFT 2015/2016 guidelines (screening since 40 years of | 0                                 |
| age, and between 40 and 50 years of age every 12 months)                                       |                                   |
| Genetic screening  | 1–                                |
| MRI screening  | 1–                                |
| Medical history, physical examination  | 2+                                |
| Diagnostic mammography with USG of breast and regional lymph nodes                             | 2+                                |
| Diagnostic breast MRI  | 0                                 |
| Tumour biopsy after imaging completion   | 2+                                |
| Primary lesion biopsy (tissue sample for assessment; full panel of tests: ER/PR, HER2, Ki67)   | 2+                                |
| Fine-needle aspiration of primary lesion in case of suspected cancer                           | 1–                                |
| Biopsy of second/next lesion in breast, especially considering BCT                             | 2+                                |
| CB biopsy — tissue sample from clinically suspected lymph nodes                                | 0                                 |
| PCI biopsy — cytological material from clinically suspected lymph nodes                        | 2+                                |
| Fine-needle biopsy — only to verify possible metastases  | 1+                                |
| Fine-needle aspiration (FNA) of primary lesions when cancer is suspected                       | 1–                                |
| Setting a marker to primary lesion and lymph node  | 2+                                |
| Clinical, imaging, and pathological correlation before making therapeutic decision             | 2+                                |
| Genetic test < 35 years of age and/or familial history   | 1+                                |
| Genetic test > 50 years of age and/or familial history   | 0                                 |
| Consultancy of psycho-oncologist   | 0                                 |
|  | cont.                             |

| Analysed problems  | PSSO recommendation |
|--|---------------------|
| Consultancy regarding fertility prevention   | 1+                  |
| Screening toward metastases in stage I–II  | 0                   |
| Screening toward metastases in stage III   | 1+                  |
| Test for operation and/or depending of patient's complaints  | 2+                  |
| Additional tests depending on abnormalities, e.g. AP   | 1+                  |
| Pregnant patients  |                     |
| USG as a preferred test for assessment of breast, abdomen, and pelvis                              | 2+                  |
| Chest X-ray and mammography — with use of cover, as safe management                                | 1+                  |
| MRI (without gadolinium), if other tests are inconclusive (unequivocal) or there is a suspicion of | 1+                  |
| bone or brain metastases   |                     |
| Performing CT, PET, bone scintigraphy — is contraindicated   | 2+                  |
| Assessment of markers: Ca 125, Ca 15-3 is contraindicated  | 2+                  |

#### A.3. Pathological diagnosis

#### Jacek Piechocki, Wojciech P. Olszewski

Appropriate preoperative histological diagnosis, e.g. core-needle biopsy of primary lesion in breast and cytology of regional lymph nodes, is a basis for therapeutic decision-making regarding initiation of the treatment of patients with breast cancer. However, appropriate postoperative diagnostics allow optimal choice of adjuvant treatment.

Diagnostic standards of invasive and pre-invasive breast cancer were developed by the Polish Pathology Association (Polskie Towarzystwo Patologów, PTP) and are available on the PTP website: www.pol-pat. pl/pl/strony/standardy-129.

| Table 1. Basic elements of synoptic histological assessment | Table | 1. Basic | elements | of s | synoptic | histol | ogical | assessment |
|---|-------|----------|----------|------|----------|--------|--------|------------|
|---|-------|----------|----------|------|----------|--------|--------|------------|

| Pathology Breast Cancer Report                                       |   |
|--|---|
| Infiltrating breast cancer   |   |
| Patient's personal data  | First name, surname; PESEL, etc.  |
| Referring physician's personal data                                  | First name and surname; PWZ (physician's licence number)                      |
| Date of ordering assessment  |   |
| Date of sending result to the referring physician                    |   |
| 1. Operational material type   |   |
| — Breast gland sample  |   |
| — Whole breast gland   |   |
| — Other  |   |
| 2. Surgical procedure  |   |
| For example, excision with localisation (hook); total                | mastectomy; others  |
| 3. Macroscopic assessment  |   |
| — Tumour localisation  |   |
| — Sample size (cm); tumour size (cm)                                 |   |
| — Number of primary tumour lesions (concernin                        | g invasive cancer)  |
| • single   |   |
| <ul> <li>multiple number of lesions, size of the greater</li> </ul>  | test lesion   |
| undefined  |   |
| — Margins (ink marking and sampling)                                 |   |
| <ul> <li>after partial excision: anterior, posterior, sup</li> </ul> | perior, inferior, medial, and lateral margin without/with cancer infiltration |
| after mastectomy: deep margin on fascia w                            | ithout/with cancer infiltration   |
| — Other organ-specific macroscopic features (co                      | nditional assessment):  |
| · fear annual a china al constant ann ann infilmeat                  |   |

• for example, skin ulceration, cancer infiltration of pectoral muscle

| <ul> <li>Histological type of cancer according WHO</li> </ul>                       | NST; lobular; others  |
|---|---|
| 2012 classification:  |   |
| — Cancer grade  | G:  |
| Histological grade (SBR/Nottingham)   |   |
| <ul> <li>The largest size of infiltrating component</li> </ul>                      | mm  |
| — DCIS component  |   |
| — Surgical margins  | The most narrow (localisation) mm   |
| — Radicality of excision  | R0, R1  |
| <ul> <li>Number of lymph nodes assessed and with metastases</li> </ul>              | Number of sentinel lymph nodes assessed   |
|   | Number of all lymph nodes assessed  |
|   | Number of lymph nodes with macrometastases  |
|   | Number of lymph nodes with micrometastases  |
|   | Number of lymph nodes with isolated cancer cells  |
|   | Size of the largest metastatic deposit (if present)   |
|   | Extra-capsular cancer infiltrations and/or in fat tissue                                    |
| n case of sentinel lymph nodes:   | pN0(i-)(sn) with no isolated cancer cells in sentinel lymph nodes                           |
| (sn) — indicates that below six lymph nodes were assessed:                          | pN0(i+)(sn) isolated cancer cells in sentinel lymph nodes                                   |
|   | pN1mi(sn) micrometastases in sentinel lymph nodes   |
| <ul> <li>Other organ-specific microscopic features</li> </ul>                       | — Embolus from cancer cells in lymphatic vessels or blood                                   |
| (conditional assessment)  | vessels   |
|   | <ul> <li>Invasion of cancer cell surrounding nerves truncus</li> </ul>                      |
|   | - Assessment of lesions after preoperative treatment pCR, pPR,                              |
|   | pNR   |
| — Clinical stage (S)  | pTNM stage:   |
| <ul> <li>Differential diagnosis — minimal immunohistochemistry<br/>panel</li> </ul> | <ul> <li>For diagnosis of myoepithelial cells: CK5/6, CK14, CK17, p63,<br/>SMMHC</li> </ul> |
|   | — For differentiating between lobular and ductal cancer:                                    |
|   | E-cadherin  |
|   | — For confirmation of neuroendocrine differentiation:                                       |
|   | chromogranin, synaptophysin, CD56   |
|   | — For confirmation of presence of isolated cancer cells in                                  |
|   | sentinel lymph node: CK19   |
| <ul> <li>Markers of predictive and prognostic factors</li> </ul>                    | — Oestrogen receptor (ER):%   |
|   | — Progesterone receptors (PgR):%  |
|   | — HER2/Neu IHC; HER2/Neu FISH: (0–3) +  |
|   | — Кіб7%   |
| <ul> <li>Biological subtypes of infiltrating breast cancer</li> </ul>               | Luminal A   |
| (for cancer without special type and lobular type)                                  | Luminal B (HER2-negative)   |
|   | Luminal B (HER2-positive)   |
|   | HER2-positive (non-luminal)   |
|   | Triple negative (ductal)  |
|   |   |
| — Biological subtypes of infiltrating breast cancer                                 | Hormone-dependent   |

### B. PRIMARY SURGICAL TREATMENT OF INVASIVE BREAST CANCER

# **B.1. Primary breast conserving treatment with no neoadjuvant systemic treatment**

#### Janusz Piekarski, Arkadiusz Jeziorski

- In patients with breast cancer in stage I and II (TNM UICC/AJCC 2010), conserving treatment (tumour excision and radiotherapy) is as efficient as mastectomy.
- Breast conserving treatment (BCT) is the recommended method of the treatment of breast cancer patients in stage I and II (TNM UICC/AJCC 2010).
- Conserving treatment is possible in patients, in which conserving operation still allow performing a radical mastectomy.

 Conserving treatment is possible in patients in whom primary tumour volume to breast volume ratio allows good cosmetic effect.

- Gentilini O, Botteri E, Rotmensz N et al. Conservative surgery in patients with multifocal/multicentric breast cancer. Breast Cancer Res Treat 2009; 113: 577–583.
- Tan MP, Sitoh NY, Sim AS. Breast conservation treatment for multifocal and multicentric breast cancers in womenwith small-volume breast tissue. ANZ J Surg 2014; doi: 10.1111/ans.12942. [Epub ahead of print].
- Wolters R, Wöckel A, Janni W et al; BRENDA Study Group. Comparing the outcome between multicentric and multifocal breast cancer: what is the impact on survival, and is there a role for guideline-adherent adjuvant therapy? Aretrospective multicenter cohort study of 8,935 patients. Breast Cancer Res Treat 2013; 142: 579–590.

| Subject   | Primary breast       |
|---|----------------------|
|   | conserving treatment |
|   | (BCT)                |
| Analysed problems   | PSSO recommendation  |
| Indications to BCT  |                      |
| Patients with breast cancer in stage I and II are qualified to BCT (TNM UICC/AJCC 2010)                   | 2+                   |
| Conserving treatment (tumour excision and radiotherapy) is as efficient as mastectomy, so BCT is          | 2+                   |
| recommended as primary surgical treatment in stage I and II (TNM UICC/AJCC 2010)                          |                      |
| Breast cancer patients in whom radical mastectomy will be performed are qualified to BCT                  | 2+                   |
| BCT is performed in patients in whom the volume of primary tumour to volume of breast ratio allows        | 2+                   |
| a good cosmetic effect  |                      |
| Patients with multifocal cancer are qualified to conserving treatment, if radical excision, postoperative | 2+                   |
| radiotherapy, as well as good cosmetic effect is possible   |                      |
| Patients with multicentric cancer are qualified to conserving treatment, if radical excision,             | 2+                   |
| postoperative radiotherapy, as well as good cosmetic effect is possible                                   |                      |
| Absolute contraindications to BCT   |                      |
| Lack of patient consent for conserving treatment  | 2+                   |
| Lack of possibility of radical excision of breast cancer  | 2+                   |
| Lack of possibility of using supplemental radiotherapy  | 2+                   |
| Local recurrence after BCT is not a contraindication to repeated conserving treatment                     | 0                    |
| Technical aspects of surgical operation   |                      |
| Radical excision of primary tumour is essential (R0 — this is an efficient surgical margin,               | 2+                   |
| so-called "no ink on the tumour")   |                      |
| When excision is not radical, excision margin should be widened or mastectomy performed                   | 2+                   |
| In cases when intraoperative imaging shows that the lesion was not removed or not removed                 | 2+                   |
| radically, excision of the appropriate lesion or its lacking part during the same operation is needed,    |                      |
| as well as repeated intraoperative imaging  |                      |
| In patients with non-palpable during physical examination cancer preoperative tumour localisation         | 2+                   |
| should be marked (metal marker, radioactive marker, "hook"). Optionally, excision under                   |                      |
| intraoperative USG control could be performed   |                      |

| Analysed problems   | PSSO recommendation |
|---|---------------------|
| Intraoperative marking of excised preparation directions is essential (e.g. with strands, metal markers, etc.). It enables precise indication of places/locations of lack of radical operations (lack of R0 margin) | 2+                  |
| It is recommended that intraoperative imaging (mammography/USG) excised preparation is performed in order to confirm radical excision of appropriate lesion   | 2+                  |
| Intraoperative imaging is performed with the same method, which was used for preoperative lesion identification   | 2+                  |
| Site after excised tumour must be marked with metal "clips" in order to improve accuracy of<br>supplemental adjuvant radiotherapy ("clips" made of material enabling performance of MRI in<br>the future)           | 2+                  |
| It is recommended to set five "clips" on the site wall (from lateral, medial, distal, and proximal sides) and its fundus (in the deepest place)   | 2+                  |
| Intraoperative histological analysis of excision margins is not a standard in BCT   | 2+                  |
| In each case BCT of invasive cancer in step II irradiation of whole breast is performed   | 2+                  |
| Each patient after mastectomy needs the assessment of MDT to establish optimal adjuvant therapy   | 2+                  |

#### **B.2. Primary mastectomy**

#### Arkadiusz Jeziorski, Janusz Piekarski

- According to its efficacy and results (loco-regional control and survival) BCT replaced mastectomy in the vast majority of breast cancer patients; however, some patients still have the indications to perform this operation, and some of them would prefer this way of treatment.
- Mastectomy remains the standard of breast cancer treatment in a selected group of patients.
- Patients with infiltrating breast cancer stage I and II, who are ineligible to conserving treatment or who do not consent, are qualified to mastectomy.
- Depending on clinical indications the are following types of mastectomy:

Nipple sparing mastectomy (NSM) — amputation covers breast gland together with fascia of pectoral major muscle; skin covering of breast gland, nipple-areola complex (NAC), and pectoral muscles: major and minor are left.

Skin sparing mastectomy (SSM) — amputation covers breast gland, part of the skin covering gland together with nipple-areola complex together with fascia of pectoral major muscle; significant part of skin covering breast gland and pectoral muscles; major and minor are left.

**Simple mastectomy** — removal of whole breast together with skin covering the gland, nipple-areola

complex, and fascia of muscle pectoral major, without axillary lymph nodes.

**Madden modified radical mastectomy** — removing the whole breast together with the skin covering the gland, nipple-areola complex, and fascia of pectoral major muscle and excision of axillary lymph nodes.

**Patey modified radical mastectomy** — removal of whole breast together with the skin covering the gland, nipple-areola complex, and fascia of pectoral major muscle and excision of pectoral muscle minor together with axillary lymphadenectomy.

**Radical mastectomy** — removal of whole breast together with the skin covering the gland, nipple-areola complex, and both pectoral muscles and axillary lymphadenectomy, with lymph nodes level I–III.

- Fisher B, Anderson S, Bryant J et al. Twenty-year followup of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. N Engl J Med 2002; 347: 1233–1241.
- Veronesi U, Cascinelli N, Mariani L et al. Twenty-year follow-up of a randomized study comparing breast-conserving surgery with radical mastectomy for early breast cancer. N Engl J Med 2002; 347: 1227–1232.
- Blichert-Toft M, Nielsen M, Düring M. Long-term results of breast conserving surgery vs. Mastectomy for early stage invasive breast cancer: 20-year follow-up of the Danish randomized DBCG-82TM protocol. Acta Oncol 2008; 47: 672–681.
- Johansen H, Kaae S, Jensen MB, Mouridsen HAT. Extended radical mastectomy versus simple mastectomy followed by radiotherapy in primary breast cancer. A fifty-year follow-up to the Copenhagen Breast Cancer randomised study. Acta Oncol 2008; 47: 633–638.

| Subject  | Primary mastectomy  |
|--|---------------------|
| Analysed problems  | PSSO recommendation |
| As efficacy and treatment result (loco-regional disease control, and survival) of BCT are comparable,    | 2+                  |
| it could replace mastectomy in the vast majority of breast cancer patients                               |                     |
| Diagnosis  |                     |
| Similarly to all cases qualified to surgical operation, according to the standard, it includes: physical | 2+                  |
| examination, imaging (MMR, USG), and histological evaluation (CB)  |                     |
| Indications to mastectomy  |                     |
| Patient's choice and decision  | 2+                  |
| Each cancer in stage I and II ineligible to BCT  |                     |
| Radical cancer excision margins impossible to achieve (lack of R0 margins), also after re-operation      | 2+                  |
| Too large tumour in relation to breast and poor cosmetic effect expected (tumour/breast ratio)           | 2+                  |
| Inflammatory breast cancer as an option after NAC  | 2+                  |
| Early period of pregnancy (I trimester)  | 1+                  |
| No response to systemic neoadjuvant treatment  | 2+                  |
| In patients with DCIS:   |                     |
| — extensive, palpable tumour (unfavourable tumour/breast ratio)  | 2+                  |
| — high VNPI index (≥ 10)   | 2+                  |
| In case of contraindications to postoperative radiotherapy after BCT (or BCT impossible to perform)      | 2+                  |
| Palliative, salvage mastectomy   | 2+                  |
| Patients at high and very high risk with confirmed genetic changes or with positive family history of    | 0                   |
| breast cancer  |                     |
| Indications to particular types of mastectomy  |                     |
| NSM/SSM  |                     |
| Patients at high and very high risk with confirmed genetic changes or with positive family history of    | 1+                  |
| breast cancer, qualified to surgical procedures, reducing the risk of morbidity                          |                     |
| Patients with preoperatively diagnosed DCIS, ineligible to BCT   | 2+                  |
| In case of extensive ductal hyperplasia or lobular hyperplasia with atypical cells                       | 0                   |
| Simple mastectomy  |                     |
| Patients with DCIS, ineligible to BCT  | 2+                  |
| Patients with invasive breast cancer, ineligible to BCT, without axillar lymphadenectomy                 | 2+                  |
| (SLN without metastases)   |                     |
| Patients who have undergone palliative mastectomy due to locally advanced breast cancer                  | 2+                  |
| Patey modified radical mastectomy  |                     |
| In patients with intraoperative diagnosed Rotter's lymph node infiltration into pectoral minor           | 2+                  |
| muscle   |                     |
| Radical mastectomy   |                     |
| In patients with cancer infiltration of pectoral major muscle, with partial or radical excision of       | 2+                  |
| pectoral major muscle, also after systemic neoadjuvant treatment   |                     |
| Madden modified radical mastectomy   |                     |
| In remaining, not aforementioned cases, with no contraindications to BCT                                 | 2+                  |
| Each patient after mastectomy requires MDT assessment to determine optimal adjuvant treatment            | 2+                  |
| — indications to XRT and systemic treatment  |                     |
| Each patient qualified to mastectomy should receive a comprehensive information regarding                | 2+                  |
| possibility of reconstructive operation as well as to receive breast prosthesis                          |                     |
| Each patient after mastectomy requires rehabilitation to prevent extremity oedema and recover            | 2+                  |
|  | = -                 |

#### **B.3. Sentinel lymph node biopsy** in primary breast cancer (with no neoadjuvant systemic treatment)

### Zbigniew I. Nowecki, Arkadiusz Jeziorski, Dawid Murawa

- Sentinel lymph node biopsy (SLNB) in breast cancer is a reliable method to assess cancer stage in regional lymph nodes.
- Indications to SLNB include clinically unchanged lymph nodes (cN0), confirmed in USG and cytological analysis after PCI (in case of indications to biopsy).

- To identify SLN an isotope-based technique is used +/- SLN staining. Sampling  $\geq$  4 SLN does not improve the accuracy of this method.
- Intraoperative SLN is not a standard of care during SLNB.
- Clinics (operational wards) that do not perform SLNB in breast cancer should not treat this type of patient.

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016/.
- 2. https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.
- Jeziorski A (ed). Węzeł chłonny wartowniczy. Via Medica, Gdańsk 2014.
   Lyman GH, Temin S, Edge SB et al. Sentinel lymph node biopsy for
- A. Eynan Gr., terinin S, Euge SB et al. Sentime infinit node biopsy for patients with early-stage breast cancer: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol 2014; 32: 1365–1383. Doi: 10.1200/JCO.2013.54.1177.

| Subject  | Indications to sentinel<br>lymph node biopsy<br>in early stage breast<br>cancer (with no systemic<br>neoadjuvant treatment) |
|--|---|
| Analysed problems  | PSSO recommendation   |
| SLNB is performed according to PSSO recommendation   | 2+  |
| SLNB is performed to make appropriate assessment of breast cancer stage in regional lymph nodes      | 2+  |
| Indications to SLNB  |   |
| Clinically unchanged lymph nodes (cN0) confirmed in USG and (in case of indications to biopsy)       | 2+  |
| Cancer cT 1-2  | 2+  |
| Cancer cT 3  | 1+  |
| Cancer cT4 a-c   | 0   |
| Multifocal/multicentre cancer  | 2+  |
| Inflammatory breast cancer   | 2-  |
| Breast sarcoma   | 2-  |
| Breast lymphoma  | 2-  |
| Phyllodes tumour   | 2-  |
| Metastases of malignant cancer from localisation other than breast                                   | 2-  |
| In DCIS  |   |
| Palpable tumour  | 2+  |
| Microcalcifications $\geq$ 5 cm; microcalcifications $\geq$ 2 cm with poor risk factors              | 2+  |
| Suspicious for microinvasion   | 2+  |
| Eligible to mastectomy   | 2+  |
| After previous excision of invasive and/or preinvasive cancer (together with excision of cancer site | 2+  |
| without widening the surgical margins — depending on surgical margins during primary excision)       |   |
| After previous plastic surgery of breast (e.g. reduction mammoplasty)                                | 1+  |
| Cancer recurrence after BCT from SLNB  | 2+  |
| SLNB in area of internal mammary artery confluence   | 2-  |
| During "prophylactic mastectomy"   | 2–  |
| Pregnant women (administration of isotope and biopsy on the same day),                               | 1+  |
| SLNB without dye deposition  |   |
| Breastfeeding women  | 2+  |

| Analysed problems   | PSSO recommendation |
|---|---------------------|
| Elderly patients  | 2+                  |
| Male patients with breast cancer  | 2+                  |
| Method of SLNB according to PSSO recommendations  |                     |
| SLNB performed in standard way by all — surgical team members                                   | 2+                  |
| Radiocolloid administered the day before or on the day of operation (minimally four hours       | 2+                  |
| before operation)   |                     |
| Isotope: colloid <sup>99m</sup> Tc  | 2+                  |
| Dye: PatentBlau   | 2-                  |
| Triple method   | 2+                  |
| Method with ferromagnetism  | 1+                  |
| Method with indocyanine green   | 0                   |
| Clinical intraoperative assessment of axilla after — SLN biopsy                                 | 2+                  |
| Localisation of marker (isotope +/- dye)  |                     |
| SLNB performed according to PSSO recommendations  |                     |
| Standardised method, performed by all members of the surgical team                              | 2+                  |
| (possible injection of isotope or dye: peritumoural, into tumour, intracutaneous, subcutaneous) |                     |
| Number of sampled SLN   |                     |
| Sampling $\ge$ 4 SLN does not improve test accuracy   | 2+                  |
| Level of SLN identification should be at the level $\ge$ 95%                                    | 2+                  |
| Intraoperative assessment of SLN:   |                     |
| in BCT (meeting the criteria of Z0011 Trial)  | 2-                  |
| in BCT (not meeting the criteria of Z0011 Trial)  | 1-                  |
| in mastectomy   | 1–                  |
| Each patient with diagnosed metastasis (each metastasis) to regional                            | 2+                  |
| lymph nodes should be discussed by MDT to identify optimal adjuvant treatment                   |                     |

#### **B.4. Lymphadenectomy in primary** breast cancer (with no neoadjuvant systemic treatment)

#### Zbigniew I. Nowecki, Arkadiusz Jeziorski

- Patients qualified to initial surgical treatment of breast cancer with confirmed metastases to lymph nodes (pN+) require lymphadenectomy in area of regional lymphatic confluence (axillary lymph node dissection, ALND).
- ALND enables the assessment of breast cancer stage and regional disease control. This surgical procedure does not influence patient's survival.
- Each patient qualified initially to ALND requires preoperative USG of regional confluence with confirmation of metastases to lymph nodes by using fine-needle biopsy (FNB) (NCCN2.2016).
- In case of negative verification of FNB the patients should be qualified to SLNB (unless there are clear contraindications: very early pregnancy, no patient's consent, etc.).

- Each patient initially qualified to ALND, should be presented to MDT after receiving postoperative pathology report to qualify to appropriate adjuvant treatment.
- Each patient after ALND requires rehabilitation and prevention of oedemas.

- Giuliano AE, McCall L, Beitsch P et al. Locoregional recurrence after sentinel lymph node dissection with or without axillary dissection in patients with sentinel lymph node metastases: the American College of Surgeons Oncology Group Z0011 randomized trial. Ann Surg 2010; 252: 426–432; discussion 432–433. Doi: 10.1097/SLA .0b013e3181f08f32.
- 2. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.
- 4. Jeziorski A (ed). Węzeł chłonny wartowniczy. Via Medica, Gdańsk 2014.
- Lyman GH, Temin S, Edge SB et al. Sentinel lymph node biopsy for patients with early-stage breast cancer: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol 2014; 32: 1365–1383. Doi: 10.1200/JCO.2013.54.1177.

| Subject  | Indications to axillar<br>lymphadenectomy in early stage<br>breast cancer (with no systemic<br>neoadjuvant treatment) |
|--|---|
| Analysed problems  | PSSO recommendation   |
| ALND is performed to improve patient survival  | 2-  |
| ALND is one of the options to achieve appropriate regional disease control   | 1+  |
| Lymphadenectomy should be limited to ALND  | 2+  |
| ALND includes dissection of lymph nodes from level I/II  | 2+  |
| ALND includes dissection of lymph nodes from level III only in the case of clinically suspicious<br>lymph nodes of level II                        | 2+  |
| Indications to ALND  |   |
| Metastases to regional lymph nodes, when systemic neoadjuvant treatment is not expected  |   |
| cN1 (confirmed by using USG + PCI)   | 2+  |
| cN2 (confirmed by using USG + PCI)   | 2+  |
| cN3 (confirmed by using USG + PCI)   | 2–  |
| "Occult" breast cancer   | 2+  |
| Surgical operation of breast with DCIS diagnosed   | 2–  |
| Lymph nodes recurrence after previous treatment of breast cancer   | 2+  |
| In breast sarcomas, lymphomas, and tumour phyllodes (with exclusion of cases with  | 2–  |
| confirmed metastases)  |   |
| Inadequate ALND in cases of suspected lack of radicality (e.g. $<$ 10 lymph nodes in   | 2-  |
| preoperative histological preparation, others)   |   |
| Even if possible SLNB  | 2-  |
| Indications to ALND after SLNB   |   |
| Lack of SLN identification during SLNB (level I of axillary lymph nodes is dissected)  | 2+  |
| SLN + with extracapsular lymph node infiltration   | 1+  |
| SLN (i+) and BCT   | 2–  |
| SLN (mic+) and BCT   | 2–  |
| SLN+ (met criteria of Z0011 Trial)   | 1–  |
| SLN+ and mastectomy (without chest wall irradiation)   | 2+  |
| SLN+ and mastectomy (with chest wall irradiation) and only in cases: T1/2, SLN 1–2(+), without infiltration of lymph node capsule                  | 0   |
| Each patient with diagnosed metastasis (each metastasis) to regional lymph nodes should be discussed by MDT to identify optimal adjuvant treatment | 2+  |
| Each patient after ALND requires rehabilitation to prevent oedemas and recover appropriate   | 2+  |

#### **B.5. Intraoperative radiotherapy**

#### Dawid Murawa, Bartosz Urbański

- Radiotherapy is used in breast conserving treatment and during mastectomy with coexisting specific risk factors. Individualisation of radiotherapy during planning and delivery of the beam should be highlighted.
- Irradiation boost of tumour site during BCT could be also performed using electrons, photons, and brachytherapy.

- Whole-breast irradiation changes recurrence risk and influences patients' overall survival.
- The doses during whole-breast irradiation should range between 46 and 50 Gy in 23–25 fractions or 40 and 42.5 Gy in 15–16 fractions (hypofractionation). In patients with high recurrence risk, irradiation boost of the tumour site is recommended. The usual recommended dose ranges between 10 and 16 Gy in 4–8 fractions.
- In case of accelerated partial breast irradiation, (APBI) patient participation in clinical trials is recommended.

- Preliminary studies with APBI show that local control of early breast cancer (with specific inclusion criteria) is comparable with standard treatment using whole-breast irradiation.
- In case of unavailable clinical trials, use of APBI could be based on ASTRO/GEC-ESTRO guidelines; patient's age > 50 years, with no *BRCA1/BRCA2* mutations, T1N0 ER positive breast cancer, infiltrating ductal with no extensive intraductal component and LCIS, negative surgical margins.

#### References

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- 2. https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.
- SedImayer F, Sautter-Bihl M-L, Budach W et al. and Breast Cancer Expert Panel of the German Society of Radiation Oncology (DEGRO). DEGRO practical guidelines: radiotherapy of breast cancer IDEGRO practical guidelines: radiotherapy of breast cancer I. Radiotherapy following breast conserving therapy for invasive breast cancer. Strahlenther Onkol 2013; 189: 825–833.
- Wenz F, Sedlmayer F, Herskind C et al. Accelerated Partial Breast Irradiation in clinical practice. Breast Care (Basel) 2015; 10: 247–252.

| Subject  | Intraoperative<br>radiotherapy |
|--|--------------------------------|
| Analysed problems  | PSSO recommendation            |
| MDT decision, suggested standpoint of surgical oncologist                                    |                                |
| Irradiation boost of tumour site (local control improvement, without influence of survival): |                                |
| Age < 40 years   | 2+                             |
| Age 40–60 years  | 1+                             |
| Age > 60 years, G3, or > $pT1$   | 0                              |
| Intraoperative radiotherapy (including APBI)*:   |                                |
| As irradiation boost before whole-breast irradiation   | 2+                             |
| As the only method of breast irradiation (IORT 50kV, IOERT)**                                |                                |
| — > 50 years**   | 0                              |
| — > 70 years**   | 0                              |
| Postoperative partial breast irradiation as the only method of radiotherapy:                 |                                |
| Intra-tissue brachytherapy   | 0                              |
| — > 70 years**   | 0                              |
| Intra-cavity brachytherapy (balloon brachytherapy)   | 1–                             |

\*Recommended participation on available clinical trials; \*\*only tumours pT1, pN0, R0, G1-G2, HR+, non-lobular, age > 50 years, with no extensive intraductal component, IORT during initial surgical operation

### C. PRIMARY NEOADJUVANT TREATMENT

#### C.1. Breast conserving treatment after systemic neoadjuvant treatment

#### Wojciech M. Wysocki, Wojciech Połkowski, Andrzej Kurylcio

- Method of choice of surgical treatment of breast cancer patients should be wide local excision WLE); it concerns also the patients in whom baseline primary cancer stage excluded BCT, providing satisfactory response to systemic neoadjuvant treatment.
- In patients with breast cancer of size > 2 cm (according to ESMO 2015 recommendation), especially in biological cancer subtypes of poor prognosis (HER2-positive, triple negative), systemic preopera-

tive treatment could be used, improving the conditions to local operation and prognosis.

 If patients could undergo BCT and express a wish to do so, and given that the centre has no capacity, the patient should be referred to a centre where this kind of treatment is possible.

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- 2. https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.
- http://onkologia.zalecenia.med.pl/pdf/PTOK\_2013\_05\_Rak%20 piersi\_internet2014.pdf.
- Senkus E, Kyriakides S, Ohno S et al. ESMO Guidelines Committee. Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol 2015; 26 (suppl 5): v8–30.

| Subject   | Indications to breast<br>conserving treatment after<br>systemic neoadjuvant<br>treatment<br>PSSO recommendation |  |
|---|---|--|
| Analysed problems   |   |  |
| In cases of primary large operable breast cancer, and the need to perform mastectomy together   | 2+  |  |
| with anterograde and adjuvant treatment, if the patient expresses the wish to conserve the  |   |  |
| breast, systemic neoadjuvant treatment should be considered   |   |  |
| Before systemic neoadjuvant treatment, the marker should be placed in the localisation of the primary tumour  | 2+  |  |
| Assessment of response to systemic neoadjuvant treatment should involve physical examination and radiological imaging   | 2+  |  |
| To assess the response to systemic neoadjuvant treatment mammography and/or magnetic resonance imaging should be used   | 2+  |  |
| The imaging method should be selected by MDT (considering, in the first place, the method that was used to assess the cancer size before systemic neoadjuvant treatment)  | 2+  |  |
| Breast conserving surgical operation after systemic neoadjuvant treatment should be performed with dissection of the area indicated in controlled preoperative imaging  | 2+  |  |
| Breast conserving surgical operation after systemic neoadjuvant treatment should be performed with achievement of cancer-free microscopic surgical excision margins (R0)  | 2+  |  |
| Breast conserving surgical operation after systemic neoadjuvant treatment should be performed app. 2–4 weeks after the last cycle of this therapy (after nadir period)  | 2+  |  |
| Indications   |   |  |
| Confirmed patient's consent for breast conserving treatment   | 2+  |  |
| Achieving complete response after systemic neoadjuvant treatment  | 2+  |  |
| Achieving partial response after systemic neoadjuvant treatment — enabling a therapy meeting criteria of conservative treatment and achieving good cosmetic effect  | 2+  |  |
| Achieving partial response (with complete recovery of skin changes, in case of T4a-c tumour;<br>after careful MDT assessment with individual recurrence risk analysis), conducting a therapy<br>meeting criteria of conservative treatment and achieving good cosmetic effect | 0   |  |

# **C.2. Mastectomy after primary neoadjuvant treatment**

Wojciech M. Wysocki, Wojciech Polkowski, Andrzej Kurylcio

#### References

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- 2. https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.
- http://onkologia.zalecenia.med.pl/pdf/PTOK\_2013\_05\_Rak%20 piersi\_internet2014.pdf.
- Senkus E, Kyriakides S, Ohno S et al. ESMO Guidelines Committee. Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol 2015; 26 (suppl 5): v8–30.

| Subject  | Indications for<br>mastectomy after<br>primary neoadjuvant<br>treatment |
|--|---|
| Analysed problems  | PSSO recommendation   |
| Mastectomy after systemic neoadjuvant treatment should be performed approximately 2–4 weeks after the last cycle of this therapy (after nadir period)  | 2+  |
| Indications  |   |
| Withdrawal of patient's consent for attempted breast conserving treatment  | 2+  |
| Diagnosis of disease progression during systemic neoadjuvant treatment   | 2+  |
| Achieving partial response after systemic neoadjuvant treatment with decreasing of tumour size, which DOES NOT ENABLE its wide dissection (despite possibly meeting other, usual criteria for BCS) | 2+  |
| Presence of cancer cells in surgical operation margins after attempt of repeated local dissection  | 2+  |
| No possibility of using adjuvant radiotherapy  | 2+  |
| In the case of achieving response to systemic neoadjuvant treatment, if <b>inflammatory cancer</b> was initially diagnosed   | 2+  |
| In the case of achieving response to systemic neoadjuvant treatment, if <b>multicentre lesions</b> were initially diagnosed  | 2+  |
| In the case of achieving response to systemic neoadjuvant treatment, if <b>cT4a-c cancer*</b> was initially diagnosed  | 2+  |

\*Except reservation according to NCCN 2.2016 presented in the table of indications to breast conserving treatment after systemic neoadjuvant treatment

#### **C.3. Sentinel lymph node biopsy** in breast cancer patients after neoadjuvant treatment

#### Zbigniew I. Nowecki, Arkadiusz Jeziorski

- Use of systemic neoadjuvant treatment (neoadjuvant chemotherapy, NAC, or endocrine therapy) enables downstaging of regional lymph nodes from pN+ to pN0 in 20–40% of treated patients.
- Sentinel lymph node biopsy in breast cancer patients eligible to NAC replaces standard method ALND.
- Indications to perform SLNB include clinically unchanged lymph nodes (cN0) confirmed by USG.
- Isotope and staining methods are used in identification of SLN.
- Intraoperative assessment of SLN is recommended during SLNB after NAC.

 It is recommended that SLNB after NAC is performed by centres/teams with extensive experience of SLNB.

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.
- Caudle AS, Yang WT, Krishnamurthy S et al. Improved Axillary Evaluation Following Neoadjuvant Therapy for Patients With Node-Positive Breast Cancer Using Selective Evaluation of Clipped Nodes: Implementation of Targeted Axillary Dissection. J Clin Oncol 2016; 34: 1072–1078. Doi: 10.1200/JCO.2015.64.0094.
- Kuehn T, Bauerfeind I, Fehm T et al. Sentinel-lymph-node biopsy in patients with breast cancer before and after neoadjuvant chemotherapy (SENTINA): a prospective, multicentre cohort study. Lancet Oncol 2013; 14: 609–618. Doi: 10.1016/S1470-2045(13)70166-9.
- Mamounas E. Impact of neoadjuvant chemotherapy on locoregional surgical treatment of breast cancer. Ann Surg Oncol 2015; 22: 1425–1433. Doi: 10.1245/s10434-015-4406-6.

| Subject  | Indications to sentinel lymp<br>after systemic neoadjuvant |    |
|--|--|----|
| Analysed problems  | PSSO recommendation  |    |
| SLNB is performed to appropriately assess cancer stage in regional lymph         | 2+   |    |
| nodes  |  |    |
| A. Regional lymph node states before NAC — cN0                                   |  |    |
| Indications to SLNB in patients initially with cN0                               |  |    |
| SLNB before NAC  | 1+   |    |
| SLNB after NAC   | 0  |    |
| Repeat SLNB after NAC, if SLNB before NAC detected metastases to SLN             | 2-   |    |
| Methods of SLN assessment in patients initially with cN0                         |  |    |
| SLNB before NAC:   |  |    |
| Standard method for the centre, according to PSSO recommendations for SLNB       | 2+   |    |
| SLNB after NAC:  |  |    |
| Standard method for the centre, according to PSSO recommendations for            | 2+   |    |
| SLNB, but methods with the use of isotope and dye                                | 2 1  |    |
| Localisation of marker placing (isotope +/- dye) in patients initially with cN0: |  |    |
| According to PSSO recommendations for SLNB, standard method for the centre       | 2+   |    |
| Number of sampled SLNs in patients initially with cN0                            |  |    |
| According to PSSO recommendations for SLNB, standard method for the centre       | 2+   |    |
| Intraoperative assessment of SLN in patients initially with cN0                  | Δ.Τ  |    |
| SLNB before NAC — not required   | 2+   |    |
| -  |  |    |
| SLNB after NAC — indicated   | 1+   |    |
| After NAC, postoperative assessment of SLN is recommended in order to            | 2+   |    |
| identify each metastasis (including ITC and micrometastasis)                     |  |    |
| Recommended surgical procedures in patients initially with cN0 after             |  |    |
| performing SLNB before NAC   |  |    |
| Below are mentioned the situations with pN0 before NAC:                          |  | 2. |
| pN0 (SLN) before NAC, after NAC  | Proceeding — observation                                   | 2+ |
| Below are mentioned the situations with pN+ before NAC:                          |  |    |
| pN+ (SLN) before NAC   | Proceeding — ALND  | 2+ |
| ycN0 after NAC   | Proceeding — observation                                   | 1– |
| (qualification similar to Z0011 Trial)   | Proceeding — repeat SLNB                                   | 2– |
| pN+ (SLN) before NAC   | Proceeding — ALND#   | 2+ |
|  | Proceeding — radiotherapy                                  | 2– |
| — ycN0 after NAC   | of lymphatic confluence                                    |    |
| (qualification does not meet criteria to Z0011 Trial)                            | Proceeding — repeat SLNB                                   | 2– |
| Recommended surgical procedures in patients after performed SLNB                 |  |    |
| after NAC  |  |    |
| Surgical procedures in patients initially with cN0 and ycN0                      |  |    |
| ypN0 (SLN) — proceeding: observation (only SLNB performed)                       | 1+   |    |
| ypN+ (SLN) — proceeding: ALND  | 2+   |    |
| B. Regional lymph node states before NAC — cN+                                   |  |    |
| Surgical procedures in patients initially with cN+ before NAC                    |  |    |
| Administration of "marker" into metastatic lymph node is indicated when          | 2+   |    |
| SLNB is considered after NAC in patients with pN+ before NAC                     |  |    |
|  |  |    |
| Methods of indicate of SLN:  |  |    |

| Analysed problems   | PSSO recommendation |
|---|---------------------|
| Injection of isotope + dye:   |                     |
| Standard method for the centre  | 2+                  |
| Number of sampled SLN:  |                     |
| Sampling of $\geq$ 3 SLN, if requirement not met, ALND should be performed    | 2+                  |
| Number of sampled SLN:  |                     |
| Sampling of $\geq$ 3 SLN and "marker", if requirement not met, ALND should be | 2+                  |
| performed   |                     |
| Intraoperative assessment of SLN in patients initially with cN+               |                     |
| before NAC:   |                     |
| Indicated   | 2–                  |
| Each patient with diagnosed metastasis (each metastasis) to regional lymph    | 2+                  |
| nodes should be discussed by MDT to identify optimal adjuvant treatment       |                     |
| Surgical procedures in patients initially with cN+ and ycN0 after NAC         |                     |
| Criteria of Z1071 Trial met: proceeding — only SLNB                           | 0                   |
| Criteria of Z1071 Trial not met: proceeding — ALND                            | 1+                  |
| Surgical procedures in patients initially with cN+ and ycN+ after NAC         |                     |
| Proceeding — ALND   | 2+                  |

#### C.4. Lymphadenectomy in breast cancer after systemic neoadjuvant treatment

#### Zbigniew I. Nowecki, Dawid Murawa

- The patients after neoadjuvant chemotherapy qualified for surgical treatment of breast cancer in cases of metastases to regional lymph nodes (pN+) require ALND.
- Using of neoadjuvant chemotherapy in patients with locally advanced breast cancer enables radical operation. ALND is a method making it possible to achieve regional disease control. This type of operation has no influence on survival.
- Achieving complete pathology regression (yp-T0ypN0) after neoadjuvant chemotherapy improves survival in some of the biological subtypes of breast cancer (TNBC, HER2+). Thus, in patients who will require postoperative systemic chemotherapy, that treatment should be considered before operation. This also applies to the patients who require tumour "shrinkage" to perform BCT, as well as in patients

with biological subtypes of poor prognosis, regardless of extension of planned operation.

- Each patient after neoadjuvant chemotherapy eligible to ALND, after receiving a postoperative pathology report, should be discussed by the MDT regarding qualification to possible adjuvant treatment.
- Each patient after ALND requires rehabilitation and prevention of oedemas.

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- https://www.nccn.org/professionals/physician\_gls/f\_guidelines.asp#site.
   Caudle AS, Yang WT, Krishnamurthy S et al. Improved Axillary Evaluation Following Neoadjuvant Therapy for Patients With Node--Positive Breast Cancer Using Selective Evaluation of Clipped Nodes: Implementation of Targeted Axillary Dissection. J Clin Oncol 2016; 34: 1072–1078. Doi: 10.1200/JCQ.2015.64.0094.
- Coates AS, Winer EP, Goldhirsch A et a. Tailoring therapies improving the management of early breast cancer: St Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2015. Ann Oncol 2015; 26: 1533–1546. Doi: 10.1093/annonc/mdv221.
- Mamounas EP. Impact of neoadjuvant chemotherapy on locoregional surgical treatment of breast cancer. Ann Surg Oncol 2015; 22: 1425–1433. Doi: 10.1245/s10434-015-4406-6.

| Subject  | Indications to axillar<br>lymphadenectomy afte<br>systemic neoadjuvant<br>treatment |
|--|---|
| Analysed problems  | PSSO recommendation   |
| If patients need systemic therapy (chemotherapy) based on preoperative MDT, initiation of such   | 2+  |
| treatment should be considered before surgery  |   |
| Administration of entire systemic neoadjuvant treatment before operation is standard   | 2+  |
| Standard methods of assessing the response to NAC include:   |   |
| Physical examination   | 2+  |
| USG  | 2+  |
| MRI  | 1+  |
| Disease progression during NAC is an indication to "salvage" surgery or radiotherapy   | 2+  |
| Surgical treatment is planned for the period 2–4 weeks after NAC completion (in order to avoid complications after chemotherapy)                     | 2+  |
| pN+ after NAC is an indication to ALND   | 2+  |
| Each metastasis to SLN after NAC (including ITC and micrometastasis) is an indication to ALND  | 2+  |
| In case of pN+ before NAC, the preferred method of surgical treatment is still ALND after NAC completion   | 1+  |
| Acceptable method of surgical treatment (unless assessed HP before NAC regional lymph nodes status) is ALND after NAC completion                     | 1+  |
| Lack of SLN identification after SLNB in patients treated with NAC is an indication to ALND  | 2+  |
| Lack of identification of $\geq$ 3 SLN and/or lack of "clip" in sampled SLN after NAC in case of conversion from cN+ to cN0 is an indication to ALND | 2+  |
| Each patient with diagnosed metastasis to regional lymph nodes (each metastasis) should be discussed by MDT to identify optimal adjuvant treatment   | 2+  |
| Each patient after ALND requires rehabilitation in order to prevent extremity of oedema and to recover appropriate physical function                 | 2+  |

### Editor's notes to parts B.3, B.4, C.1, C.2, C.3, C.4

#### Systemic preoperative treatment

Systemic preoperative treatment of breast cancer patients could be an initial method in the following situations:

- locally advanced, primary inoperable (including inflammatory) breast cancer. Use of cytotoxic drugs alone or in combination with targeted therapy could downstage a tumour and make operation possible, decreasing the risk of micrometastases and improving long-term results,
- downstaging is a decrease of loco-regional advancement of primary inoperable breast cancer, to perform breast conserving surgical operation,
- in breast cancer subtypes with especially poor prognosis [e.g. TNBC and HER2(+)], regardless of initial advancement and the extension of planned surgical operations (especially in tumours > 2 cm). Achieving pCR (ypT0ypN0) in those subtypes improves long-term results and prolongs OS.

In patients who possibly require systemic preoperative treatment MDT, based on breast cancer subtype and its advancement, should consider introducing this therapy before operation. It concerns the aforementioned situations regardless of the extension of planned surgical operations.

#### References

 Senkus E, Kyriakides S, Ohno S et al. ESMO Guidelines Committee. Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol 2015; 26 (suppl 5): v8–30.

#### **Clinical Trial ACOSOG Z0011**

Inclusion criteria:

- female patients diagnosed with breast cancer cT1-2cN0 M0,
- detection of macrometastases of breast cancer to ≤ 2 SLN, excluding patients with extranodal infiltrations ("gross extranodal disease"),
- after BCT (radical conserving surgical operations and radiotherapy from tangential fields),
- systemic adjuvant treatment according to postoperative indications.

#### References

 Giuliano AE, Hunt KK, Ballman KV et al. Axillary dissection vs no axillary dissection in women with invasive breast cancer and sentinel node metastasis: a randomized clinical trial. JAMA 2011; 305: 56–75. doi: 10.1001/jama.2011.90.

#### **Clinical Trial ACOSOG Z1071 (Alliance)**

Inclusion criteria:

- female patients with verified diagnosis of breast cancer and metastasis in lymph nodes verified after biopsy PCI/CB,
- clinical stage cT1-2cN0 M0,
- after neoadjuvant chemotherapy with effect cN0,
- recommended triple method of SLNB (isotope and dye) with sampling of > 2 SLN.

#### **References**

 Boughey JC, Suman VJ, Mittendorf E et al. Sentinel lymph node surgery after neoadjuvant chemotherapy in patients with node-positive breast cancer: the ACOSOG Z1071 (Alliance) clinical trial. JAMA 2013; 310: 1455–1461. doi: 10.1001/jama.2013.278932.

### **D. OTHER RECOMMENDATIONS**

#### **D.1. Breast cysts**

#### Janusz Piekarski, Arkadiusz Jeziorski

- Breast cysts could be divided into:
- **simple/uncomplicated** cysts, with thin wall and no echoes in USG,
- **complicated**, with thin wall and homogenous hypoechoic content in USG,
- **complex**, consisting of cystic and solid (thickened cyst walls, septa, and solid intracystic structures).
- The method of choice during diagnosis of simple and complicated cysts (homogenous hypoechoic) as well as groups of microcysts is ultrasonography.

| Subject   | Breast cysts   |
|---|----------------|
| Analysed problems   | PSSO           |
|   | recommendation |
| The method of choice for cyst diagnosis is USG  | 2+             |
| Simple cysts are classified as BIRADS 2 (benign lesion). In cases without clinical symptoms there are no  | 2+             |
| indications for biopsy of simple cysts  |                |
| Aspiration biopsy of a simple cyst could be performed in the case of clinical signs and symptoms          | 1+             |
| After aspiration biopsy of a simple cyst there are no indications for cytological assessment of aspirated | 1+             |
| mass due to the extremely low possibility of diagnosing cancer in this cyst. Exceptional situations       |                |
| include cases when the aspirated mass is bloody coloured  |                |
| Complicated cysts and groups of microcysts are classified as BIRADS 3 (possibly benign lesions).          | 2+             |
| Ultrasound follow-up or fine-needle aspiration (FNA) is recommended in six months                         |                |
| When a complex cyst is visible in ultrasound — <b>BIRADS 4</b> (suspicious lesion) — possible diagnosis   | 2+             |
| should be confirmed after biopsy with histological evaluation. Whenever possible, histological            |                |
| assessment of a sample from a solid part of the complex cyst should be performed                          |                |

#### **D.2. Fibroadenoma**

#### Janusz Piekarski, Arkadiusz Jeziorski

 Fibroadenomas are the most commonly diagnosed benign breast tumours, most prevalent in young women, usually with size 2–3 cm. There are mainly single lesions; however, in some patients the tendency is observed toward multiple lesions of different sizes.

 Once diagnosis of fibroadenoma is established, there is no need for excision of the lesion or for further diagnostics workup.

| Subject  | Fibroadenomas       |
|--|---------------------|
| Analysed problems  | PSSO recommendation |
| Considerable diagnosis of fibroadenoma based on ultrasound is possible only if the lesion    |                     |
| meets the following criteria:  |                     |
| — is homogenous  |                     |
| — is solid   |                     |
| — is oval  |                     |
| <ul> <li>its long axis is parallel to the surface of the skin</li> </ul>                     |                     |
| Such lesions are assigned with BIRADS 3 category (possibly benign lesion), and additionally: | 2+                  |
| <ul> <li>either underwent observation (follow-up USG in six months)</li> </ul>               |                     |
| — or biopsy  |                     |
| Fibroadenomas not changed during observation are re-classified from BIRADS 3                 | 2+                  |
| (possibly benign lesion) to BIRADS 2 category (benign lesion)                                |                     |
|  | cont.               |

| Analysed problems   | PSSO recommendation |
|---|---------------------|
| When a lesion that is visible in USG does not show all features of fibroadenoma it should be          | 2+                  |
| assigned with BIRADS 4 category (suspicious lesion). In this case core-needle biopsy is needed        |                     |
| In patients with multiple fibroadenomas sufficient procedures include a biopsy (fine- or core-needle) | 1+                  |
| of one of the lesions and follow-up ultrasound of the remaining lesions in six months                 |                     |
| If a diagnosed lesion:  | 2+                  |
| <ul> <li>— has the largest dimension greater than 3 cm</li> </ul>                                     |                     |
| <ul> <li>has a cystic component</li> </ul>  |                     |
| <ul> <li>or during six months its size increases by more than 1 cm</li> </ul>                         |                     |
| - phyllodes tumour (PT) should be suspected. Histological assessment should be performed              |                     |
| (core-needle biopsy)  |                     |
| Diagnostic and therapeutic processes should be conducted regardless of whether the lesion             | 2+                  |
| is palpable or not  |                     |
| If during the diagnostics procedure fibroadenoma is confirmed, there is no need for excision          | 1+                  |
| of the lesion   |                     |

#### **D.3. Atypical ductal hyperplasia**

#### Piotr Gierej

- Atypical ductal hyperplasia (ADH)/atypical intraductal epithelial proliferation (AIDEP) is a factor increasing the risk of cancer development (3–5-fold) in the same or opposite breast and is considered as a *precancerous* condition. The risk of cancer development as higher as number of ADH-type lesions is higher and younger patient's age. The prospective predictive value for malignancy in resection (PPV) for ADH is 20–30%.
- During histological diagnosis core-needle biopsy/Mammotome vacuum-assisted biopsy is recommended.
- In the case of ADH diagnosis, surgical biopsy procedure (excisional biopsy) is basically recommended. Extensive/multifocal ADH is also a possible indication to mastectomy. The risk of cancer diagnosis after ADH excisional biopsy is higher when histological evaluation reveals high levels of atypical cytology,

necrosis, or/and the terminal ductal-lobular unit (TDLU) is more than 2.

- When ADH is diagnosed within histological surgical margins after excision of invasive or pre-invasive cancer, radical surgical treatment (additional margins excision) could be retreated, especially when radiotherapy is planned. ADH does not increase the risk of local recurrence after radiotherapy.
- When ADH is diagnosed within margins of a histological sample after excision a radical surgical procedure (additional margins excision) is recommended; the only observation could be allowed if there is complete excision in radiological evaluation.

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016/.
- https://www.nccn.org/professionals/physician\_gls/f\_guidelines.asp#site.
   Visvanathan K, Chlebowski RT, Hurley P et al. American Society of
- Clinical Oncology clinical practice guideline update on the use of pharmacologic interventions including tamoxifen, raloxifene, and aromatase inhibition for breast cancer risk reduction. J Clin Oncol. 2009; 27: 3235–3258.

| Subject   | Atypical ductal<br>hyperplasia |
|---|--------------------------------|
| Analysed problems   | PSSO recommendation            |
| Diagnosis of ADH in core-needle biopsy/Mammotome vacuum-assisted biopsy is a recommendation to open biopsy (excisional) | 2+                             |
| Surgical treatment after diagnosis of ADH in core-needle biopsy/Mammotome vacuum-assisted                               | 0                              |
| biopsy could be exceptionally retreated when the following criteria are met:  |                                |
| <ul> <li>lack of tumour features in radiological imaging</li> </ul>   |                                |
| — small size ( $\leq$ 2 TDLU in Mammotome vacuum-assisted biopsy)   |                                |
| <ul> <li>complete lesion excision during biopsy detected in follow-up radiological evaluation</li> </ul>                |                                |
| When ADH is diagnosed within histological surgical margins after excision of invasive or pre-invasive                   | 1+                             |
| cancer a radical surgical treatment is not needed   |                                |
|   | cont                           |

| When ADH is diagnosed within margins of a histological sample after excision a radical surgical   | 0  |
|---|----|
| procedure (additional margins excision) is recommended; the only observation could be             | Ū  |
| exceptionally allowed if there is complete excision in radiological evaluation                    |    |
| Women with ADH should be informed about increased risk of breast cancer morbidity                 | 2+ |
| Mammography once per year is recommended as a follow-up   | 2+ |
| MDT decision, the suggested standpoint of the surgical oncologist                                 |    |
| Preventive endocrine therapy could be considered in female patients diagnosed with ADH, with high | 1+ |
| risk of breast cancer morbidity, but without a higher risk of thromboembolic complications        |    |
| Tamoxiphen given preventively in women with ADH at age over 35 years decreases the risk of breast | 1+ |
| cancer and DCIS morbidity   |    |
| Preventive administration of aromatase inhibitors (exemestane, anastrozole) in postmenopausal     | 0  |
| women is not recommended  |    |

#### **D.4. Flat epithelial atypia**

#### **Piotr Gierej**

- Flat epithelial atypia (FEA)/columnar cell hyperplasia with atypia in radiological imaging most commonly co-exists with microcalcifications. FEA increases approximately five-fold the risk of breast cancer development. The predictive value for malignancy in resection for FEA is 0–10%.
- During histological diagnosis core-needle biopsy/Mammotome vacuum-assisted biopsy is recommended.
- When FEA is diagnosed in biopsy, surgical treatment (excisional biopsy) is recommended.

- When FEA is diagnosed within histological surgical margins after excision of invasive or pre-invasive cancer radical surgical treatment (additional margins excision) could be retreated, especially when supplemental radiotherapy is planned.
- When FEA is diagnosed within margins of a histological sample after excisional biopsy a radical surgical procedure is not needed, when microcalcifications have been completely dissected.

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- 2. https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.

| Subject   | Flat epithelial atypia |
|---|------------------------|
| Analysed problems   | PSSO recommendation    |
| Surgical treatment after diagnosis of FEA in core-needle biopsy/Mammotome vacuum-assisted biopsy                | 1+                     |
| could be retreated when the following criteria are met:   |                        |
| — small size of FEA ( $\leq$ 2 TDLU in Mammotome vacuum-assisted biopsy)  |                        |
| <ul> <li>complete excision of the lesion during biopsy detected in follow-up radiological evaluation</li> </ul> |                        |
| When FEA is diagnosed within histological surgical margins after excision of invasive or pre-invasive           | 0                      |
| cancer, radical surgical treatment is not needed  |                        |
| When FEA is diagnosed within margins of histological sample after excisional biopsy, a radical surgical         | 1+                     |
| procedure is not recommended, when microcalcifications have been completely dissected                           |                        |
| Mammography once per year as population-based screening is recommended as a follow-up after                     | 2+                     |
| FEA excision  |                        |

# **D.5. Radial scar/complex sclerosing lesion (CSL)**

#### Piotr Gierej

- Radial scar/complex sclerosing lesion (CSL) is a benign lesion; however, the prospective predictive value for malignancy in resection is 8.3% (0–10%).
- For histological diagnosis core-needle biopsy/Mammotome vacuum-assisted biopsy is recommended.
- In case of radial scar/complex sclerosing lesion diagnosed in core-needle biopsy an open surgical biopsy procedure (excisional biopsy) is recom-

mended. Excisional biopsy could be retreated in the case of small lesions after excision in radiological follow-up after core-needle biopsy/Mammotome vacuum-assisted biopsy.

 When radial scar/CSL is diagnosed within histological surgical margins after excision, radical surgical treatment is not needed.

#### References

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.

| Subject  | Radial scar/complex<br>sclerosing lesion (CSL) |
|--|--|
| Analysed problems  | PSSO recommendation                            |
| In the case of small lesions and their completed dissection during core-needle biopsy/           | 1+   |
| /Mammotome vacuum-assisted biopsy, an open surgical biopsy procedure could be retreated          |  |
| When radial scar/CSL is diagnosed within histological surgical margins after excision, a radical | 2+   |
| surgical treatment is not needed   |  |
| The follow-up after dissection of radial scar/CSL could be performed within screening tests      | 1+   |

#### **D.6.** Papilloma

#### Piotr Gierej

- Papilloma could co-exist with preinvasive and invasive cancer (0–10%; for atypical papilloma up to 20%). Diagnosis atypical papilloma increases the risk of cancer development in the same breast (4.6–13%).
- Core-needle biopsy/Mammotome vacuum-assisted biopsy is recommended for histological diagnosis.
- Papilloma without atypical features in representative biopsy sample and correlation with imaging tests could undergo observation.
- When atypical papilloma is diagnosed, a surgical treatment (excisional biopsy) is required. When atypical papilloma is diagnosed within histological surgical margins after excision, a radical surgical procedure is recommended, unless the lesion was completely dissected in radiological imaging.

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.

| Subject   | Papilloma           |
|---|---------------------|
| Analysed problems   | PSSO recommendation |
| Diagnosis of atypical papilloma in core-needle biopsy/Mammotome vacuum-assisted biopsy is an indication to open (excisional) biopsy   | 2+                  |
| When atypical papilloma is diagnosed within histological surgical margins after excision, a radical surgical procedure is recommended, unless the lesion was completely dissected in radiological imaging | 2+                  |
| Multifocal papilloma requires open biopsy   | 2+                  |
| In patients with atypical papilloma, mammography once per year is recommended as a follow-up, and after excision of papilloma without atypical features — only screening tests                            | 2+                  |

# **D.7. Diagnosis and treatment of ductal carcinoma** *in situ* (DCIS) in the breast

#### Jacek Piechocki

- Surgical treatment (BCT or mastectomy) is the basis of therapy of ductal carcinoma *in situ* (DCIS) in the breast.
- Adjuvant treatment (radiotherapy, endocrine therapy) is discussed within MDT and together with the patient, to limit the recurrence risk.
- Prognosis of relapses of invasive cancer after treatment of DCIS is approximately 50% for all relapses after DCIS treatment.

| Subject   | DCIS                |
|---|---------------------|
| Analysed problems   | PSSO recommendation |
| Diagnosis   |                     |
| Physical examination  | 2+                  |
| Mammography   | 2+                  |
| MMG targeted to MC  | 2+                  |
| Advantage of digital over analogue MMG  | 2+                  |
| Marker/clip inserted during core-needle biopsy  | 2+                  |
| USG of the breast   | 2+                  |
| MRI of breast for analysis of DCIS extension  | 0                   |
| Stereotactic biopsy/VAB   | 2+                  |
| PCI   | 2-                  |
| Surgical management   |                     |
| Surgical dissection after localisation  | 2+                  |
| Surgical dissection after "buckle" <sup>#</sup> localisation of extensive lesions                   | 1+                  |
| Intraoperative MMG/RTG of preparation   | 2+                  |
| Intraoperative USG  | 0                   |
| Parallel extension of margins with their absence after MMG/RTG of preparation                       | 2+                  |
| Intraoperative histological evaluation  | 2-                  |
| Excision with margin — R0 ("clear margin")  | 2+                  |
| In multifocal DCIS — BCS possible to perform  | 0                   |
| Additional excision of margins, if in HP < 2 mm   | 1-                  |
| Mastectomy, if lack of negative margins after additional excision                                   | 2+                  |
| Mastectomy, if microcalcifications > 5 cm, even if possible to perform BCS                          | 0                   |
| Indications to SLNB in DCIS after CB  |                     |
| BCS + SLNB (SLNB to consider in case of "poor prognosis factors"                                    | 2+                  |
| SLNB + mastectomy   | 2+                  |
| SLNB, when DCIS diagnosed in male patients  | 1+                  |
| ALND  | 2-                  |
| DCIS and microcalcifications > 5 cm, microcalcifications > 2 cm with poor prognosis factors         | 2+                  |
| Recurrences management  |                     |
| After radiotherapy — local dissection + SLNB  | 1+                  |
| Without radiotherapy — treatment like during initial diagnosis                                      | 2+                  |
| Adjuvant treatment after surgical management of DCIS  |                     |
| Adjuvant treatment is MDT decision, after analysis of recurrence risk; suggested standpoint o       | of                  |
| surgery oncologist in this situation:   |                     |
| DCIS with microinvasion in postoperative preparation evaluation — treatment like in invasive cancer | r 2+                |
| Recommended radiotherapy  |                     |
| In every situation after BCS  | 0                   |

| Analysed problems                                     | PSSO recommendation |
|---|---------------------|
| After BCS in case of Van Nuys Prognostic Index 7–9    | 1+                  |
| After mastectomy                                      | 2-                  |
| Recommended endocrine therapy                         |                     |
| Tamoxifen (when ER not tested in the sample)          | 0                   |
| Tamoxifen, only if ER-positive                        | 0                   |
| Aromatase inhibitors (postmenopausal), if ER-positive | 0                   |
| Trastuzumab, only if HER2-positive                    | 2-                  |

Prognostic factors for local and regional recurrence in the case of DCIS considered during the decision regarding possible adjuvant treatment ("poor prognosis factors")

Age, size of cancer lesion, clinically palpable tumour,  $\geq$  NG2, comedo necrosis, margins of cancer resection, residual tumour or microcalcifications after dissection, focused cancer, architecture of lesion

#A few markers inserted around the tumour before operation

# **D.8. Diagnosis and treatment of lobular carcinoma** *in situ*

#### Leszek Kozłowski

- Diagnosis of lesions in breast in patients with suspected lobular carcinoma *in situ* (LCIS) should be based on histological evaluation after core-needle biopsy/Mammotome vacuum-assisted biopsy.
- Histological diagnosis of LCIS should include histological subtypes according to tumour biology [lobular intraepithelial neoplasia (LIN)]: 1 — classical type, 2 — comedo necrosis type, 3 — floryd LIN, 4 — pleomorphic type.

- Diagnosis of LCIS increases the risk of breast cancer morbidity (at least 3.5-fold).
- Extension of surgical operation in LCIS depends on the size of lesion in the breast and histological subtype.
- Management in the case of diagnosis of concomitant DCIS of infiltrating cancer in material removed from the breast should be the same as in ductal cancer (DCIS or invasive).

#### References

1. http://www.ago-online.de/en/guidelines-mamma/march-2016.

 https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.

| Subject  | Indications to surgical<br>treatment of lobular<br>carcinoma <i>in situ</i> (LCIS) |
|--|--|
| Analysed problems  | <b>PSSO</b> recommendation   |
| Diagnosis of lesions in the breast in patients with suspected lobular carcinoma in situ (LCIS)           | 2+   |
| should be based on histological evaluation with consideration of histological subtype LIN (after         |  |
| core-needle biopsy/Mammotome vacuum-assisted biopsy)   |  |
| Patients with diagnosed LCIS require precise diagnosis based on physical examination and imaging         | 2+   |
| tests (mammography, USG of breast, MRI), enabling exact assessment of disease advancement                |  |
| Diagnosis in all young women (below 40 years of age) with LCIS should be based on                        | 1+   |
| mammography and MRI of the breast  |  |
| Open/excisional biopsy should always be performed in cases of pleomorphic, floryd, and                   | 2+   |
| comedo necrosis LIN subtype in histological evaluation, regardless of the lesion diameter                |  |
| Extension of surgical operation depends on the size of the pathological lesion in the breast.            | 1+   |
| Lesions of LIN classical type:   |  |
| • below 2.0 cm   |  |
| <ul> <li>completely resected, confirmed in imaging test</li> </ul>                                       |  |
| <ul> <li>do not require more radical operation</li> </ul>  |  |
| In the case of diagnosis within margins of histological preparation, the features of LIN are as follows: | 2+   |
| — classical type   |  |
| more radical operation (with margins extension) is not required  |  |

| Analysed problems  | PSSO recommendation |
|--|---------------------|
| In the case of diagnosis within margins of histological preparation, the features of LIN are as follows: | 2+                  |
| — pleomorphic  |                     |
| — floryd   |                     |
| — comedo necrosis  |                     |
| more radical operation (with margins extension) is required  |                     |
| In the case of detection of glandular breast tissue (lesions difficult for diagnosis), the following     | 1+                  |
| are impossible:  |                     |
| <ul> <li>precise diagnosis</li> </ul>  |                     |
| <ul> <li>radical excision with good cosmetic effect according to lesion size</li> </ul>                  |                     |
| <ul> <li>detection in sample lesions with ADH features</li> </ul>  |                     |
| <ul> <li>indicating positive family history of breast cancer</li> </ul>                                  |                     |
| — detecting mutations, increasing the risk of breast cancer morbidity (BRCA1, BRCA2, CHEK, etc.)         |                     |
| NMS with reconstruction at the same time is recommended  |                     |
| Each patient with concomitant DCIS and LCIS lesions requires optimal therapy and further                 | 2+                  |
| management, as in DCIS   |                     |
| Each patient with concomitant invasive cancer and LCIS requires optimal therapy and further              | 2+                  |
| management, as in invasive cancer, depending on the clinical stage                                       |                     |
| The aim of surgical treatment of LCIS is prevention of overlooking concomitant types of breast           | 1+                  |
| infiltrating cancer  |                     |

#### **D.9. Breast cancer in young women**

#### Sylwia Grodecka-Gazdecka

- Breast cancer patients below 35 years of age account for a small group of patients (7% of patients in developed countries are below 40 years of age), but therapeutic decisions should be made by MDT, with consideration of young age specificity, including:
  - different cancer biology at young age,
  - · different endocrine status of young women,
  - maintenance of fertility after breast cancer treatment,
  - problems regarding treatment of the breast cancer during pregnancy,
  - indications to surgical operations decreasing the risk of breast cancer morbidity (there are no indications to surgical treatment of opposite breast except in carriers of *BRCA1* gene mutations).
- Performing a quick test of *BRCA1* gene mutation allows a more precise therapeutic decision to be made.
- Young age is an independent factor of the risk of local recurrence after breast cancer treatment, which needs carefully decision-making regarding local treatment.
- There is no evidence supporting routine performing of MRI before operation in young breast cancer patients (indications to MRI are the same as in older women).
   MRI during follow-up after treatment of breast cancer patients below 35 years of age is reasonable.

- Surgical treatment should not be fundamentally different than in the group of older patients, in favour of conserving treatment of the breast as well as lymph nodes.
- Breast reconstruction at the same time ensured comparable benefits as regard to overall survival as mastectomy without reconstruction; however, indications should be discussed within MDT, especially considering postoperative radiotherapy.
- In *BRCA1/2* genes mutation carriers:
  - breast cancer treatment should be led in highly specialised centres (tertiary care services),
  - there is no evidence regarding the advantage of mastectomy over BCT, but the decision about BCT should be made more carefully, considering the patient's motivation to conserve the breast,
  - radiotherapy does not increase the toxicity of treatment of mutation carriers.

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- 2. https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.
- Paluch-Shimon S, Pagani O, Partridge AH et al. Second international consensus guidelines for breast cancer in young women (BCY2). Breast 2016; 26: 87–99. Doi: 10.1016/j.breast.2015.12.010.
- Recio-Saucedo A, Gerty S, Foster C, Eccles D, Cutress RI. Information requirements of young women with breast cancer treated with mastectomy or breast conserving surgery: A systematic review. Breast 2016; 25: 1–13.
- Rosenberg SM, Partridge AH. Management of breast cancer in very young women. Breast 2015; 24 (suppl 2): 154–158.

| Subject  | Breast cancer      |
|--|--------------------|
|  | in young women     |
| Analysed problems  | PSSO recommendatio |
| All treatment plans should be discussed during an MDT meeting before therapy initiation, with                    | 2+                 |
| consideration to genetic predispositions, ensuring fertility and addressing problems of breast cancer            |                    |
| treatment during pregnancy   |                    |
| Young age as an independent decision-making factor is not an indication to more aggressive loco-                 | 2+                 |
| regional as well as systemic treatment   |                    |
| Decision-making regarding extension of loco-regional treatment needs psychological support                       | 1+                 |
| Performing a quick test of BRCA1 gene mutation allows making a more precise therapeutic decision                 | 1+                 |
| Young age is not an indication to mastectomy reducing a risk (except BRCA1 gene mutation                         | 1+                 |
| carriers) because it does not prolong overall survival   |                    |
| In BRCA1 gene mutation carriers:   |                    |
| <ul> <li>breast cancer treatment should be led in highly specialised centres (tertiary care services)</li> </ul> | 2+                 |
| - there is no evidence regarding the advantage of mastectomy over BCT, but the decision about                    | 2+                 |
| BCT should be made more carefully, considering the patient's motivation to conserve the breast                   |                    |
| <ul> <li>radiotherapy does not increase the toxicity of treatment of mutation carriers</li> </ul>                | 2+                 |
| Diagnosis  |                    |
| Standard diagnosis considering cancer clinical stage   | 2+                 |
| Indications to preoperative mammography magnetic resonance are similar to those for elderly                      | 1+                 |
| patients, but it is reasonable to perform this test in high-risk patients as well as patients after              |                    |
| radiotherapy of the chest wall   |                    |
| Surgical treatment   |                    |
| Surgical treatment should not differ fundamentally from that used in elderly patients, preferring                | 1+                 |
| conserving therapy   |                    |
| The choice of surgical treatment method of invasive cancer stage I and II should be based on the                 | 1+                 |
| individual patient's decision (after exclusion contraindications) with agreement from the MDT                    |                    |
| Breast reconstruction at the same time ensures the same benefits according to survival time as                   | 1+                 |
| mastectomy without reconstruction, but the indications should be discussed during the MDT                        |                    |
| meeting, specifically considering postoperative radiotherapy   |                    |
| The surgery of axillar lymph nodes should not differ from the same procedures in elderly patients                | 2+                 |
| SLNB is a standard procedure for cNO cancer  | 2+                 |
|  | 21                 |
| Neo- and adjuvant treatment is a decision of the MDT, suggested standpoint of the<br>surgical oncologist:        |                    |
|  | 2+                 |
| Each patient ineligible to primary conserving treatment should be proposed neoadjuvant                           | 2+                 |
| chemotherapy, and the treatment should be led in a highly specialised centre or within clinical trials           | 2 -                |
| Indications to radiotherapy are the same as in elderly patients, with consideration of RT after                  | 2+                 |
| mastectomy in young patients with high recurrence risk   | <b>A</b> .         |
| Patients should receive information about genetics and fertility ensuring counselling                            | 1+                 |
| Patients should be informed that endocrine contraceptive drugs are contraindicated after breast                  | 2+                 |
| cancer treatment   |                    |
| Patients should be informed that premature menopause increases the risk of bone density loss,                    | 2+                 |
| which requires monitoring and treatment  |                    |
| Post-therapy observation and management  |                    |
| Post-therapy observation is the same as in elderly patients  | 2+                 |

#### **D.10. Breast cancer in pregnant and breastfeeding women**

#### Agnieszka Jagiełło-Gruszfeld, Piotr Gierej

- Diagnosis in pregnant women with suspicion of breast cancer should be done depending on indications, as in non-pregnant women — with a special covering during the X-ray imaging, and with core-needle biopsy in order to make histology analysis of lesions in the breast.
- Premature pregnancy termination does not change the women prognosis.
- Childbirth should be done with time, iatrogenic prematurity should be avoided.
- Surgical operations in pregnant women are performed as in non-pregnant women.
- After the first trimester, chemotherapy does not increase the number of defects in the foetus, but increases the risk of developmental delay, preterm labour, and intrauterine foetal death.

- There is no data on the increased risk of developing cancer during lifetime in children after chemotherapy in pregnancy
- There are some contraindications during pregnancy: radiotherapy, endocrine therapy, targeted therapy (anti-HER2), and administration of bisphosphonates and denosumab.
- The prognosis in pregnant women considering appropriate treatment is similar to the risk in non-pregnant women at the same clinical stage, but pregnant women more frequently have higher clinical stage (because of delayed diagnosis).
- All therapeutic decisions should be made within MDT.

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.
- 3. http://www.mdanderson.org.
- Wildiers H, Stordeur S, Vlayen J et al. Breast cancer in women: diagnosis, treatment and follow-up. Good Clinical Practice (GCP) Brussels: Belgian Health Care Knowledge Centre (KCE). 2013. KCE Reports 143 — 3rd EDITION. D/2013/10.273/38.

| Subject  | Breast cancer in                    |
|--|-------------------------------------|
|  | pregnant and<br>breastfeeding women |
|  |                                     |
| Diagnosis  |                                     |
| Diagnosis of breast and biopsy in pregnant women with suspicion of breast cancer should be the     | 2+                                  |
| same as in non-pregnant women  |                                     |
| During histological diagnosis core-needle biopsy is recommended. During biopsy, the pathologist    | 2+                                  |
| should be informed about pregnancy — physiological changes in the breast during pregnancy          |                                     |
| increase the number of false-positive results  |                                     |
| There is a lack of indications to replace classical mammography with MRI mammography               | 2+                                  |
| Diagnosis to establish clinical stage: abdominal USG, chest X-ray, if necessary (with foetus       | 2+                                  |
| protection), other imaging tests only if clearly indicated, bone scintigraphy — not recommended    |                                     |
| Panel of imaging tests in stage I — chest X-ray  | 1+                                  |
| Panel of imaging tests in stage II — chest X-ray and abdominal USG                                 | 1+                                  |
| Panel of imaging tests in stage II — spinal MRI due to suggestions of metastases, without clear    | 1–                                  |
| clinical signs and symptoms  |                                     |
| MRI (without gadolinium), if other imaging tests inconclusive (unambiguous) or there is a suspicio | n 1+                                |
| (clinical signs and symptoms) of bone or brain metastases  |                                     |
| Panel of imaging tests in stage III — chest X-ray and abdominal USG                                | 1+                                  |
| Ultrasound is the preferred test to assess breast, abdominal cavity, and pelvis                    | 2+                                  |
| Chest X-ray and mammography — with protective shield, is a safe management                         | 1+                                  |
| CT, PET, and bone scintigraphy are contraindicated   | 2+                                  |
| Tests of markers: Ca 125, Ca 15-3 is not recommended   | 2+                                  |
| Surgery treatment  |                                     |
| Surgical operations in pregnant women are performed as in non-pregnant women                       | 2+                                  |

| Analysed problems   | PSSO recommendation |
|---|---------------------|
| During the first trimester, mastectomy + SLNB/lymphadenectomy are recommended. Conserving           | 1+                  |
| treatment could be performed during the second and third trimester, when the expected time of       |                     |
| radiotherapy initiation is after delivery term  |                     |
| During pregnancy $\geq$ 23 weeks, surgical treatment should be performed in a centre with neonatal  | 2+                  |
| and obstetric protection  |                     |
| Safety of parallel reconstruction operations during pregnancy is not clearly established and cannot | 0                   |
| be routinely recommended  |                     |
| SLNB  |                     |
| Pregnant women (isotope administration and biopsy on the same day) SLNB without dye                 | 1+                  |
| administration  |                     |
| Breastfeeding women   | 2+                  |
| Neo- and adjuvant treatment is a decision of the MDT, suggested standpoint of the                   |                     |
| surgical oncologist:  |                     |
| During pregnancy contraindicated are as follows:  | 2+                  |
| — radiotherapy  |                     |
| — endocrine therapy   |                     |
| — targeted therapy (anti-HER2)  |                     |
| <ul> <li>bisphosphonates and denosumab</li> </ul>   |                     |
| Radiotherapy  |                     |
| Radiotherapy during pregnancy — contraindicated   | 2+                  |
| In pregnant women, planned radiotherapy postponement (if the patient does not receive               | 2+                  |
| chemotherapy) should not exceed 12 weeks  |                     |
| Systemic treatment  |                     |
| Endocrine therapy, targeted therapy (anti-HER2), and bisphosphonates and denosumab                  | 2+                  |
| — contraindicated   |                     |
| Chemotherapy during the first trimester is contraindicated. Chemotherapy could be used during       | 2+                  |
| the second and third trimesters, and indications are the same as in non-pregnant women (allowed     |                     |
| drugs: anthracyclines and taxanes)  |                     |
| Childbirth/pregnancy termination is a decision of the MDT, suggested standpoint of the              |                     |
| surgical oncologist   |                     |
| Childbirth should be done with time; iatrogenic prematurity should be avoided                       | 2+                  |
| Premature pregnancy termination does not change the mother's prognosis                              | 1+                  |
| Natural childbirth/caesarean section as in healthy women, childbirth $\leq$ 3 weeks after last      | 1+                  |
| chemotherapy administration should be avoided   |                     |
| The patient should be informed that breastfeeding is contraindicated during radiotherapy,           | 2+                  |
| chemotherapy, and endocrine therapy   |                     |
| DCIS in pregnant women  |                     |
| DCIS diagnosed in pregnant women requires surgical treatment, as in non-pregnant women              | 2+                  |
| The principles of surgical treatment of DCIS in pregnant women are the same as in non-pregnant      | 2+                  |
| women   |                     |
| Observation of DCIS is allowed only during the last trimester                                       | 2+                  |
| Radiotherapy after BCS performed due to DCIS could be postponed after childbirth                    | 1+                  |
|   |                     |

# **D.11. Surgical management decreasing** the risk of breast cancer morbidity

## Dawid Murawa, Zbigniew I. Nowecki, Arkadiusz Jeziorski

- Surgical management decreasing breast cancer morbidity could pertain to the patients with diagnosed breast cancer as well as non-cancer patients, with confirmed genetic changes or positive family history regarding breast cancer.
- Patients with breast cancer based on inherited mutations account for a few per cent of the whole group breast cancer patients. The risk of cancer development depends on penetrance of the mutated gene.
- Mutations in suppressive genes BRCA1 and BRCA2 are a syndrome of the highest genetic predisposition to breast cancer development, increasing the morbidity more than 10-fold (3–5% of breast cancer patients are the carriers of those mutations). Other genes with high penetration include: TP53 (Li-Fraumeni syndrome) and PTEN (Cowden syndrome). Syndrome of moderate predisposition to breast cancer morbidity is connected with mutations in the following genes: ATM, BRIP1, CHECK2, and PALB2 (2–3-fold higher risk compared to the general population).
- The group at high risk (with morbidity risk more than 10-fold higher than in the general population) include patients:
  - with confirmed BRCA1 or BRCA2 mutation,

- with family history indicating ≥ 3 cancers in firstor second-degree relatives,
- with first-degree relatives diagnosed with breast and ovarian cancer.
- The group at high risk (with morbidity risk less than 10-fold higher than in general population) includes patients:
  - without confirmed BRCA1 mutation,
  - with family history: three cancers in first- or second-degree relatives under 50 years of age, or three cancers regardless of age.
- Mastectomy in the age range 40–50 years in women at high and very high risk of breast and/or ovarian cancer development decreases this risk by 90–95%.
- Bilateral adnexectomy (at the age 35-40 years
   based on criterion of the youngest ovarian cancer patient in a family or end of reproductive period) in women at high and very high risk of breast and/or ovarian cancer development decreases this risk by 50%.

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| Subject   | Surgical management<br>decreasing the risk of<br>breast cancer morbidity |
|---|--|
| Analysed problems   | PSSO recommendation  |
| Women with confirmed genetic changes or with positive family history of breast cancer should be       | 2+   |
| under the control of an outpatient clinic for genetic counselling within the program of taking care   |  |
| of families at high, inherently conditioned risk of breast and ovarian cancer development — a part    |  |
| of the Ministry of Health National Programme for Combating Cancer                                     |  |
| Besides patients with confirmed genetic changes and strong positive family history according          | 2+   |
| breast cancer, the patients receiving during childhood irradiation of chest wall (e.g. with Hodgkin's |  |
| disease) should also be qualified to surgical management decreasing the risk of breast cancer         |  |
| development   |  |
| Surgical management in female patients at higher risk of breast cancer development,                   |  |
| without diagnosis   |  |
| Both, uni- and bilateral mastectomy is not indicated in women without clearly defined genetic         | 1+   |
| cancer risk factors   |  |
| The procedure of qualification to surgical operation decreasing the risk of breast cancer should be   | 2+   |
| initiated according to the patient's request  |  |
|   | cont   |

| Analysed problems   | PSSO recommendation |
|---|---------------------|
| Qualification to surgical treatment is performed after:   |                     |
| - consultancy of a clinical geneticist, based on the results of tests essential to assess the risk  | 2+                  |
| of breast cancer  |                     |
| <ul> <li>physical examination and imaging tests (mammography, USG, MRI)</li> </ul>                  | 2+                  |
| <ul> <li>consultancy and assessment by a psycho-oncologist, as well as sexologists and</li> </ul>   | 2+                  |
| gynaecologists if required  |                     |
| — MDT decision  | 2+                  |
| Mastectomy conserving the nipple-areola complex with reconstruction at the same time                | 1+                  |
| (or without reconstruction) is a recommended surgical management                                    |                     |
| There are no indications to routine verification of the lymphatic system using SLNB                 | 2+                  |
| ALND of regional confluence as a diagnostic procedure is not recommended                            | 2+                  |
| Surgical management in female patients at higher risk of breast cancer development, with            |                     |
| breast cancer diagnosed in one breast   |                     |
| Qualification to breast cancer treatment is based on standard diagnostic procedure and MDT          | 2+                  |
| decision  |                     |
| Mastectomy with verification of regional lymphatic confluence is a recommended surgical             | 2+                  |
| management, according to current standards  |                     |
| BCT with verification of regional lymphatic confluence is an acceptable surgical management,        | 1+                  |
| according to current standards  |                     |
| Adjuvant treatment is provided according to current standards of breast cancer patients, based on   | 2+                  |
| MDT decision*   |                     |
| Surgical management decreasing the risk of cancer development in the opposite breast in             |                     |
| female patients at higher risk of breast cancer, with breast cancer diagnosed in one breast         |                     |
| The procedure of qualification to surgical operation decreasing the risk of cancer in the opposite  | 1+                  |
| breast should be initiated according to the patient's request (mastectomy with reconstruction at    |                     |
| he same time is suggested) <sup>#</sup>   |                     |
| ndications to mastectomy decreasing the risk of cancer should consider age at breast cancer         | 2+                  |
| diagnosis and information regarding evaluated genetic abnormalities                                 |                     |
| Surgical management decreasing the risk of cancer development in the opposite breast in             |                     |
| female patients diagnosed with episodic breast cancer   |                     |
| According to current clinical trials, surgical management decreasing the risk of cancer development | 2+                  |
| n the opposite breast in female patients diagnosed with episodic breast cancer <b>is not</b>        |                     |
| oncologically justified because it does not lead to decreased cancer risk in the opposite breast    |                     |
| and does not impact breast cancer-dependent survival  |                     |

\*Participation in clinical trials is recommended. #Patient's prognosis should be analysed

## **D.12. Breast cancer in elderly patients**

#### Sylwia Grodecka-Gazdecka

- Patients at the age > 65 years are genetically very heterogeneous.
- Therapeutic approach should be based on biological patient's age, being a result of calendar age, performance state, concomitant diseases, nutritional state, general health, and life style. Patient's preferences and potential toxicities should also be taken into consideration.
- Comprehensive geriatric assessment (CGA) is the most complex tool to analyse independent predictive

factors of morbidity and mortality of elderly patients and their "functional reserve".

- The most commonly used tools for functional reserve include:
  - Charlson Comorbidity Index a good indicator of survival over 10 years,
  - 12-indicator test assessing four-year risk of death,
  - IADL Lawton scale, G8 test,
  - Geriatric Prognostic Index.
- PSSO recommends, for breast cancer patients, the use of a geriatric assessment chart for oncological patients over 65 years of age (Appendix 2), in which:
  - patients receiving the number of points ranging between 87 and 100 ("fit patients") are not

burdened with the risk of more intensified early complications than patients in other age groups,

- in patients receiving the number of points ranging between 74 and 86 ("vulnerable patients") complex geriatric assessment and treatment modification should be considered,
- patients receiving the number of points below 74 ("frail patients") are qualified to the group at very high complication risk and should be very carefully qualified to surgical operation and treated as "frail" patients.

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- 2. http://www.ago-online.de/en/guidelines-mamma/march-2016.
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- O'Donovan A, Mohile SG, Leech M. Expert consensus panel guidelines on geriatric assessment in oncology. Eur J Cancer Care 2015; 24: 574–589.
- Wildiers H, Heeren P, Puts M et al. International Society of Geriatric Oncology consensus on geriatric assessment in older patients with cancer. J Clin Oncol 2014; 32 (24): 2595–2603.

| Subject   | Breast cancer in elderly<br>patients |
|---|--------------------------------------|
| Analysed problems   | PSSO recommendation                  |
| Patient's health status should be assessed according to the recommendations of PSSO's GONG  | 2+                                   |
| section   |                                      |
| Patients aged > 65 years in good general state (expected survival time > 5 years and accep  | table concomitant diseases)          |
| Treatment according to the standards  | 2+                                   |
| Surgical treatment as in younger patients   | 2+                                   |
| For regional confluence assessment, SLNB is recommended                                     | 2+                                   |
| Neo- and adjuvant treatment should be based on MDT decision, suggested standpoint of t      | he surgical oncologist               |
| Endocrine therapy for hormone-dependent breast cancers                                      | 1+                                   |
| Standard chemotherapy protocols < 70 years  | 1+                                   |
| Standard chemotherapy protocols > 70 years  | 1+                                   |
| Anti-HER2 therapy (trastuzumab)   | 1+                                   |
| Radiotherapy  | 1+                                   |
| Patients aged > 65 years with poor general state ("frail") — expected survival time < 5 yea | rs and significant concomitan        |
| diseases  |                                      |
| Therapeutic decision of MDT based on assessment of patient's general state                  | 2+                                   |
| Reduction of standard treatment   | 1+                                   |

## Appendix 2. GONG



## GONG — Geriatric Oncology Group GERIATRIC ASSESSMENT CHART FOR ONCOLOGICAL PATIENTS OVER 65 YEARS OF AGE

| First name and surname                                |   |                 | Age  | PESEL          |               |
|---|---|-----------------|--|----------------|---------------|
|   |   |                 |  |                |               |
|   |   |                 |  |                |               |
| Address   |   |                 | Phone  |                |               |
| Diagnosis: clinical                                   |   |                 |  |                |               |
| HEALTH G  | xcellent (3 po<br>ood (2 point<br>ad (1 points) | s)              | PERFORMANCE STATE<br>"Stand up and go" test (3 poin<br>"Stand up from chair, go 3 m,<br>sit down"<br>7–10 sec. = 3 points; 10–20 se<br>> 20 sec. = 1 point | turn around, c | ome back, and |
| BODY<br>MASS<br>INDEXBMI =body mass in kggrowth in m2 | - =   |                 | Normal 18.5–25 (6 points)<br>< 18.5 underweight (2 points)<br>> 25 overweight (2 points)   | )              |               |
| CREATININE CONCENTRATION: r                           | normal (1 po                                    | ints), abnormal | (0 points)   |                |               |
| BASIC DAILY LIFE FUNCTIONS<br>(modified Katz Index)   |   | points          | <b>COMPLEX DAILY LIFE FUNCTI</b><br>(modified Lawton scale)  | ONS            | points        |
| 1. Taking a shower                                    |   |                 | 1. Shopping  |                |               |
| 2. Dressing up  |   |                 | 2. Preparing meals   |                |               |
| 3. Eating   |   |                 | 3. Washing   |                |               |
| 4. Using toilet                                       |   |                 | 4. Home repairs  |                |               |
| 5. Urination and defecation contr                     | ol  |                 | 5. Cleaning  |                |               |
| 6. Moving   |   |                 | 6. Calling   |                |               |
| 7. Bending  |   |                 | 7. Money management  |                |               |
| 8. Crouch   |   |                 | 8. Using public transportation   |                |               |
| 9. Raising arms                                       |   |                 | 9. The reach to 500 m  |                |               |
| 10. Wearing a weight of 5 kg                          |   |                 | 10. Taking drugs   |                |               |
| Yes — 3 points; With help — 2 po                      | oints; No — 1                                   | 1 point         | Yes — 3 points; With help — 2  | points; No — 1 | point         |

## **CONCOMITANT DISEASES** (underline)

Cardiac disease, hypertension, pulmonary diseases, breathing disorders, gastrointestinal diseases, hepatic diseases, urinary tract diseases, renal chronic insufficiency, diabetes, atherosclerosis, Parkinson's disease, Alzheimer's disease 3 diseases (1 point)

2 diseases (2 points)

1 disease (3 points)

No diseases (6 points)

| ELDERLY SYNDROMES (underline)<br>Dementia, depression, urinary incontinence, bowel incontinence, imbalance, sight, hearing, taste disturbance,<br>chronic constipation, taking many medications<br>3 syndromes (1 point)<br>2 syndromes (2 points)<br>1 syndrome (3 points)<br>No syndromes (6 points) |
|--|
| MENTAL STATUS (2 points-1 point)   |
| Orientation in time (year, month, day)   |
| Orientation in place (country, city, location)   |
| Please repeat and try to memorise the address I will give you: 42 Gruszkowa street   |
| SOCIOECONOMIC SITUATION  |
| Good living conditions (3 points); bad (1 point)   |
| Health insurance (yes — 3 points); (no — 1 point)  |
| Home care (yes — 3 points); (no — 1 point)   |
| SUM OF POINTS (max 100) 9%   |
| <b>INTERPRETATION OF RESULT'S</b> — for management please see PSSO Consensus for breast cancer management 87–100 points — patient without complications risk — "fit patient"   |

74-87 points — patient at higher risk — "vulnerable patient"

< 74 points — patient at very high risk — "frail patient"

Date of evaluation...... Signature of evaluated person.....

## **D.13. Breast cancer in male patients**

#### Dariusz Nejc

- Breast cancer in male patients is very rare, as in postmenopausal women. The most common is NST cancer, ER-positive, PR-positive.
- General factors of breast cancer development risk in male patients include mutations (especially *BRCA2*), Cowden syndrome, Klinefelter's syndrome, hyperoestrogenism (endogenous and exogenous), and previous chest radiotherapy. Gynaecomastia is not a risk factor for breast cancer development in male patients.
- Screening is not recommended in the general male population.

- Endocrine therapy is a basic supplemental systemic treatment (with tamoxifen preferred, and aromatase inhibitors not recommended).
- Prognosis in male and female breast cancer patients (at the same age and with the same clinical stage) is similar.

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
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- Ferzoco RM, Ruddy KJ. Optimal delivery of male breast cancer follow-up care: improving outcomes. Breast Cancer 2015; 7: 371–379.
- Ruddy KJ, Winer EP et al. Male breast cancer: risk factors, biology, diagnosis, treatment, and survivorship. Ann Oncol 2013; 3, 24: 1434–1443.

| Subject  | Breast cancer<br>in male patients |
|--|-----------------------------------|
| Analysed problems  | PSSO recommendation               |
| Diagnosis  |                                   |
| Standard diagnosis (regardless of gender)  | 2+                                |
| Diagnosis is based on histological evaluation  |                                   |
| Before treatment initiation, mammography, USG of both breasts and axillary lymph nodes, chest        |                                   |
| X-ray, as well as abdominal and pelvic USG should be performed                                       |                                   |
| Treatment  |                                   |
| Treatment is based on MDT decision   | 2+                                |
| The choice of surgical method is based on the same principles of breast cancer treatment, regardless | 2+                                |
| of gender  |                                   |
|  | cont.                             |

| Analysed problems   | PSSO recommendation |
|---|---------------------|
| SLNB — recommended during diagnosis of regional lymphatic basin                             | 2+                  |
| Neo- and adjuvant treatment should be based on MDT decision, suggested standpoint of the    |                     |
| surgical oncologist:  |                     |
| Radiotherapy — standard (regardless of gender) should be considered according to anatomical | 2+                  |
| conditions in men   |                     |
| Chemotherapy — standard (regardless of gender)  |                     |
| Endocrine therapy (tamoxiphen preferred)  |                     |

## **E. DETAILED INDICATIONS**

## E.1. Inflammatory breast cancer

## Arkadiusz Jeziorski

- Inflammatory breast cancer is a rare malignancy, accounting for 1–5% of all breast cancers.
- Inflammatory breast cancer develops in microfocal form, which gives massive metastases through lymphatic vessels, leading to their occlusion. According to metastases' features, there are very early specific clinical signs and symptoms:
  - · redness and excessive warming of breast,
  - breast enlargement resulting from lymphatic oedema,
  - breast painfulness,
  - skin takes the form of peau d'orange.
- Imaging diagnosis (mammography, USG, MRM) is inefficient in the majority of cases.

- Diagnosis of inflammatory breast cancer is based on clinical picture and histological evaluation of skin sample, with embolism in vessels from cancer cells.
- Therapy of inflammatory breast cancer is combined and based on MDT decision.
- Surgical treatment (never as initial treatment of inflammatory breast cancer, most commonly as second stage, after neoadjuvant chemotherapy) is based on Madden mastectomy.
- Sentinel lymph node biopsy is contraindicated in this cancer type.
- Clinical classification of inflammatory breast cancer is T4cN0-3.

## References

- 1. http://www.ago-online.de/en/guidelines-mamma/march-2016.
- 2. https://www.nccn.org/professionals/physician\_gls/f\_guidelines. asp#site.

| Subject  | Inflammatory breast<br>cancer |
|--|-------------------------------|
| Analysed problems  | PSSO recommendation           |
| Histological diagnosis after skin biopsy                                   | 1+                            |
| Clinical classification at diagnosis of inflammatory breast cancer is cT4d | 2+                            |
| Therapeutic approach   |                               |
| Multidisciplinary treatment:   | 2+                            |
| preoperative chemotherapy, surgery, radiotherapy                           |                               |
| Surgical treatment:  |                               |
| Madden mastectomy after preoperative chemotherapy                          | 2+                            |
| BCT  | 1–                            |
| SLNB   | 2-                            |
| Postoperative treatment is based on MDT decision                           | 2+                            |

# **E.2.** Paget's disease of nipple with concomitant breast cancer

### Janusz Piekarski, Arkadiusz Jeziorski

- Clinical symptoms of Paget's disease of nipple include ulcerations, erosions, scabs, redness, or eczema, on the top of the nipple, and very often itching, painfulness or leakage from the nipple; these symptoms can be accompanied by palpable breast tumour.
- Paget's disease of nipple could has an isolated form (Paget's disease of nipple alone) or together with concomitant breast cancer (DCIS or invasive cancer).
- Breast cancer accompanying Paget's disease of nipple could be located directly behind the nipple and/or peripherally. A high percentage of infiltrating cancers and/or DCIS concomitant with Paget's disease of nipple are multifocal and/or multicentre.

| Subject   | Paget's disease of nipple<br>with concomitant<br>breast cancer |
|---|--|
| Analysed problems   | PSSO recommendation  |
| Diagnosis   |  |
| Diagnosis of Paget's disease of nipple is confirmed by histological evaluation of excision sample               | 2+   |
| taken from pathological changes on the nipple. The sample should include the full thickness of the nipple skin  |  |
| When histological evaluation does not confirm Paget's disease, and changes on the top of the                    | 2+   |
| nipple do not recover after conservative treatment, taking a sample form a nipple top should be taken once more |  |
| Imaging diagnosis including mammography and USG of the breast   | 2+   |
| When mammography and USG do not indicate pathological changes in the breast, MRI should be considered           | 1+   |
| Diagnosis of concomitant breast cancer is based on histological evaluation of the tumour sample                 | 2+   |
| Treatment   |  |
| Surgical management depends on the type of Paget's disease  |  |
| In patients with isolated Paget's disease of nipple without concomitant breast cancer, surgical                 | 2+   |
| operation includes removal of the nipple-areola complex (R0 resection)  |  |
| In patients with isolated Paget's disease of nipple there are no indications to SLN biopsy or axillary          | 2+   |
| lymphadenectomy. Additionally, there are no indications to supplemental radiotherapy                            |  |
| If Paget's disease is accompanied by breast cancer (DCIS and/or invasive cancer), adjuvant treatment            | 2+   |
| is based on principles regarding the treatment of breast cancer patients  |  |
| If Paget's disease is accompanied by breast cancer:   | 2+   |
| - there is possible surgical conserving treatment with supplemental radiotherapy. Operation                     |  |
| include removal of the nipple-areola complex with margins of healthy tissues located behind                     |  |
| the nipple (R0 resection) together with concomitant breast cancer (there is no requirement to                   |  |
| dissect the tissues en block)   |  |
| — management with axillary lymph nodes is according to the principles of breast cancer patients                 |  |
| Mastectomy is a treatment of choice in patients with change in nipple accompanied by multiple                   | 2+   |
| focuses of breast cancer in different parts of the gland  |  |

## E.3. Occult breast cancer

## Arkadiusz Jeziorski, Janusz Piekarski

- Occult breast cancer (carcinoma occultum mammae) is diagnosed in patients with metastases to axillary lymph nodes, but physical examination as well as imaging tests: mammography (MMR), ultrasonography (USG) and magnetic resonance imagination (MRI) do not reveal a tumour in breast tissue.
- Diagnosis is directed towards excluding of metastasis of adenocarcinoma from other organs.
- In the case of lack of abnormalities in imaging test (MMR, USG, and MRI) in a breast, radiotherapy

is an alternative for mastectomy together with lymphadenectomy.

- Barton SR, Smith IE, Kirby AM, Ashley S, Walsh G, Parton M. The role of ipsilateral breast radiotherapy in management of occult primary breast cancer presenting as axillary lymphadenopathy. Eur J Cancer 2011; 47: 2099–2106.
- Greco FA, Pavlidis N. Treatment for patients with unknown primary carcinoma and unfavorable prognostic factors. Semin Oncol 2009; 36: 65–74.
- Pentheroudakis G, Lazaridis G, Parlidis N. Axillary node metastases from carcinoma of unknown primary (CUPax): a systematic review of published evidence. Breast Cancer Res. Treat. 2010; 119: 1–11.
- Steunebrink: Bilateral axillary metastases of occult breast carcinoma: report of a case with a review of the literature. Breast 2005; 14: 165–168.

| Subject   | Occult breast cancer |
|---|----------------------|
| Analysed problems   | PSSO recommendation  |
| Diagnosis   |                      |
| Mammography, USG  | 2+                   |
| MRI   | 2+                   |
| PET   | 1+                   |
| Clinical staging  | 2+                   |
| CB of lymph nodes (HP test)   | 2+                   |
| HP test: detection of metastasis of adenocarcinoma. IHC assessment: ER, PR, HER2, and other tests | 2+                   |
| excluding metastases from other organs  |                      |
| Treatment   |                      |
| Based on MDT decisions  | 2+                   |
| Axillary lymphadenectomy (level I/II/III)   | 2+                   |
| Systemic treatment depending on state of lymph nodes  | 2+                   |
| Axillary lymph nodes cN1:   | 2+                   |
| Treatment — lymphadenectomy   |                      |
| Axillary lymph nodes cN2:   | 2+                   |
| Treatment — systemic neoadjuvant treatment and then lymphadenectomy                               |                      |
| In the case of lack of cancer changes in breast MRI, mastectomy and breast irradiation are        | 1+                   |
| equivalent therapeutic methods  |                      |
| Lymph node irradiation  | 1+                   |

## E.4. Bilateral breast cancer

## Janusz Piekarski, Arkadiusz Jeziorski

- Bilateral breast cancer is diagnosed in patients with two primary cancers of both breasts. The term bilateral breast cancer does not include patients with unilateral breast cancer and its metastasis in the opposite breast.
- Primary cancer of the opposite breast has the following features:
  - histological type is different from histology of first cancer,
  - infiltrating cancer is accompanied by non-infiltrating component (*in situ*),

- in the case of the same histological cancer type in both beasts, there are no metastases in axillary lymph nodes (or they are few) and distant metastases (satellite metastases).
- Bilateral breast cancer is:
  - simultaneous cancer diagnosed at the same time in both breasts,
  - synchronic when the time period between diagnosis of both cancers is no longer than six months,
  - metachronic (asynchronic) when the time period between diagnosis of both cancers exceeds six months.

| Subject  | Bilateral breast cancer |
|--|-------------------------|
| Analysed problems  | PSSO recommendation     |
| Diagnosis  |                         |
| Imaging and histological diagnosis is performed according to the diagnostic and therapeutic            | 2+                      |
| principles for patients with unilateral breast cancer  |                         |
| Treatment  |                         |
| Treatment of patients with bilateral breast cancer is based on the general principles of breast cancer | 2+                      |
| treatment and MDT decisions  |                         |
| Therapeutic decisions are made separately for each breast cancer, taking into consideration the        | 2+                      |
| clinical stage in each breast, and the possibility of summation of adverse events (e.g. radiotherapy   |                         |
| administered for left and right chest side) as well as cosmetic issues (symmetry)                      |                         |
| Recommended surgical treatment is bilateral mastectomy with possible reconstruction                    | 1+                      |
| Conserving treatment of both breasts in patients with bilateral breast cancer should be treated as     | 2+                      |
| a therapeutic option, possible to perform in reference centres   |                         |

## E.5. Tumour phyllodes of breast

## Jerzy W. Mituś, Wojciech M. Wysocki

- Treatment of non-malignant tumour phyllodes, characterised by good prognosis (recurrences in 8% of patients) is based on wide dissection of tumour with a 1-cm margin.
- The ability of non-malignant and borderline tumour phyllodes (after initial excision) to recur and transform into malignant type has been documented.

#### References

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- Mituś JW, Blecharz P, Walasek T, Reinfuss M, Jakubowicz J, Kulpa J. Treatment of Patients with Distant Metastases from Phyllodes Tumor of the Breast. World J Surg 2015.
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| Subject   | Tumour phyllodes of<br>breast (borderline and<br>malignant type) |
|---|--|
| Analysed problems   | PSSO recommendation  |
| Treatment of primary tumour   |  |
| Treatment of tumour phyllodes is based on wide excision with $\geq$ 1 cm margin or simple mastectomy (when wide excision does not allow proper wide operation margin) | 2+   |
| Incomplete excision (R1 resection) requires repeat operation (repeat wide excision or simple mastectomy)  | 2+   |
| There are no indications to SLNB or ALND if clinically changed lymph nodes are absent   | 2+   |
| Systemic treatment and radiotherapy used in adjuvant therapy require MDT agreement  |  |
| Supplemental systemic treatment:  |  |
| MDT decision; suggested standpoint of surgical oncology   |  |
| Postoperative systemic treatment (chemotherapy) does not influence overall survival time and risk of  | 1+   |
| local recurrence  |  |
| Endocrine therapy is completely inefficient   | 1+   |
| Treatment of local recurrence   |  |
| Local recurrence should be completely dissected (R0 resection)  | 2+   |
| In case of incomplete dissection of local recurrence (R1 resection), radiotherapy and chemotherapy should be considered   | 0  |
| After dissection of local recurrence radiotherapy should be considered  | 1+   |
| Treatment of systemic dissemination:  |  |
| MDT decision; suggested standpoint of surgical oncology   |  |
| Surgical management of distant metastases is in accordance with recommendations for distant   | 2+   |
| metastases of soft tissue sarcomas  |  |
| Radiotherapy: MDT decision; suggested standpoint of surgical oncology   |  |
| Postoperative radiotherapy after R0 resection with $\geq$ 1 cm margin is not recommended  | 1+   |
| After resection R0 with $< 1$ cm margin supplemental radiotherapy should be considered  | 0  |

## E.6. Metaplastic breast cancer

## Janusz Piekarski, Arkadiusz Jeziorski

 Metaplastic breast cancer is diagnosed based on the presence of different tissues in NST histological structure. There are two groups of metaplastic breast cancers: epithelial-epithelial (e.g. adenosquamous carcinoma) and epithelialmesenchymal.

| Subject  | Management of<br>metaplastic breast cancer |
|--|--|
| Analysed problems  | PSSO recommendation                        |
| There are no specific clinical and radiological symptoms of metaplastic breast cancers. Based on | 2+   |
| those symptoms metaplastic breast cancer could not be clearly clinically diagnosed               |  |
| Diagnosis is established on histological evaluation  | 2+   |
| If the core-needle biopsy sample is not representative, then decisive meaning is given to the    | 2+   |
| excisional biopsy and histological evaluation of the tumour                                      |  |
| Essential during diagnosis of metaplastic cancers is differentiation with sarcomas as regards    | 2+   |
| distinctness in clinical course and treatment of both cancers                                    |  |
| The choice of surgical treatment is based on the same principles as in NST in the same clinical  | 2+   |
| stage  |  |
| Qualification to supplemental treatment has to be agreed during an MDT meeting                   | 2+   |
| Follow-up after treatment cessation is conducted according to the principles typical for other   | 2+   |
| breast malignancies  |  |

## E.7. Breast lymphoma

## Jacek Zieliński

- Breast lymphoma could be a primary disease or a symptom of generalised neoplastic process. Primary breast lymphomas are very rare and account for 0.04–0.5% of breast malignancies.
- The majority of primary breast lymphomas are B-cell non-Hodgkin's lymphomas.
- Diagnosis of breast lymphoma is based on the following criteria:
  - histological evaluation (open biopsy is recommended),
  - presence of lymphoma in breast gland tissue and/or in regional lymph nodes, if they appeared at the same time,
  - lack of lymphoma localised outside the breast.
- Treatment of breast lymphoma is analogous to the treatment of lymphomas in different localisations, and it is based on histological diagnosis and clinical stage.
- The main method of breast lymphoma treatment is chemotherapy and/or radiotherapy. Mastectomy is not recommended due to the lack of impact of

this method on survival time and prevalence of local recurrences.

- After breast reconstruction operations with use of implants, there is a possibility of T-cell lymphomas ALCL-ALK (-) (anaplastic large cell lymphoma). Of note, it is very rare — approximately 200 case were reported worldwide to date. The main clinical symptom of this type of lymphoma is the appearance of exudate inside the capsule surrounding the implant. Diagnosis is based on cytological assessment of the effusion sample and tissue biopsy in order to get an appropriate histological evaluation.
- When lymphoma is diagnosed after reconstruction breast operation capsulotomy is indicated.

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| Subject Analysed problems   | Breast's lymphoma  |  |
|---|--------------------|--|
|   | PSSO recommendatio |  |
| Diagnosis   |                    |  |
| Diagnosis of breast lymphoma is based on the following criteria:                                | 2+                 |  |
| <ul> <li>— histological evaluation (open biopsy recommended)</li> </ul>                         |                    |  |
| — presence of lymphoma in breast tissue and/or in regional lymph nodes, if they appeared at the |                    |  |
| same time   |                    |  |
| <ul> <li>lack of lymphoma localised outside the breast</li> </ul>                               |                    |  |
|   | cont.              |  |

| Analysed problems   | PSSO recommendation |
|---|---------------------|
| A recommended form of diagnosis is taking a histological sample during open biopsy                      | 2+                  |
| Each patient, after receiving a histological result, has to be presented to the MDT in order for        | 2+                  |
| qualification to appropriate treatment  |                     |
| Treatment   |                     |
| Treatment of breast's lymphoma is analogous to the treatment of lymphomas in different                  | 2+                  |
| localisations, and it is based on histological diagnosis and clinical stage                             |                     |
| The main method of breast lymphoma treatment is chemotherapy and/or radiotherapy                        | 2+                  |
| Mastectomy is not recommended due to lack of impact of this method on survival time and                 | 0                   |
| prevalence of local recurrences   |                     |
| After breast reconstruction operations with use of implants, there is a possibility of T-cell lymphomas | 2+                  |
| (anaplastic large cell lymphoma, ALCL). The main clinical symptom of this type of lymphoma is the       |                     |
| appearance of exudate inside the capsule surrounding the implant. Diagnosis is based on cytological     |                     |
| assessment of an effusion sample and tissue biopsy in order to obtain an appropriate histological       |                     |
| evaluation  |                     |
| When ALCL is diagnosed after reconstruction breast operation, capsulotomy is indicated as well as       | 2+                  |
| possible further treatment based on the MDT decision (radiotherapy +/– chemotherapy)                    |                     |

## E.8. Cancer metastases to the breast

## Janusz Piekarski, Arkadiusz Jeziorski

- Cancer metastases to the breast, especially single and being a first symptom of malignancy, are very rare. In approximately 1/3 of cases the primary location of cancer at diagnosis of metastases to the breast is unknown.
- The most important risk factor for cancer metastases to the breast is previously diagnosed other malignant disease.
- The malignancy, which is the most common source of distant metastases in the breast is cancer of the opposite breast. The frequency of metastases of breast

cancer to the opposite breast is definitely lower than the prevalence of bilateral breast cancer (e.g. two primary cancers in both breasts). The second most common are secondary sites of lymphatic malignancies and melanoma, followed by: lung cancer, ovarian cancer, prostate cancer, renal cell cancer, and gastric cancer.

- The most common clinical form of cancer metastases to the breast is tumour: painless, solid, circular or oval, and movable against surrounding tissues. Clinically it is similar to a fibroadenoma.
- Cancer metastases to the breast could be single or multiple changes. In more than 50% of patients there are also concomitant metastases to axillary lymph nodes detected.

| Subject   | Cancer metastases<br>to breast |
|---|--------------------------------|
| Analysed problems   | PSSO recommendation            |
| Diagnosis   | 2+                             |
| During clinical diagnosis detailed medical history is mandatory, especially toward previous other malignant diseases                        | 2+                             |
| Diagnosis is based on histological evaluation   | 2+                             |
| Each patient, after receiving a histological result, has to be presented to the MDT in order to qualify to appropriate treatment            | 2+                             |
| Treatment   | 2+                             |
| Treatment is relevant to primary cancer diagnosed and led by the MDT  | 2+                             |
| Surgical treatment of cancer metastases to the breast is limited to local tumour dissection for either diagnostic or cytoreductive purposes | 2+                             |
| Mastectomy is indicated in the case of bleeding from the tumour   | 2+                             |
| Follow-up schedule after treatment cessation depends on the primary tumour diagnosed  | 2+                             |

#### E.9. Primary stage IV breast cancer

#### Arkadiusz Jeziorski

- Advanced breast cancer means that at diagnosis of the disease there are already distant metastases present.
- Advanced breast cancer is incurable in almost all cases, and treatment is aimed to prolongation of survival time and symptoms relief.
- The choice of appropriate treatment strategy is based on the MDT decision and depends on the patient's general state, local cancer advancement, prognostic and predictive factors, as well as the presence and type of clinical symptoms.
- The main therapy method is systemic treatment.
- According to indications, surgical treatment is a palliative care.

| Subject  | Primary stage IV<br>breast cancer |  |
|--|-----------------------------------|--|
| Analysed problems  | PSSO recommendation               |  |
| The main therapy method is systemic treatment, according to the MDT decision                 | 2+                                |  |
| Surgical treatment is a palliative care, relieving the symptoms or protecting against        | 2+                                |  |
| haemorrhage  |                                   |  |
| Surgical treatment of the primary tumour could be considered in the case of stable bone      | 0                                 |  |
| metastases (if it is the only localisation of disease spread) after a few months of systemic |                                   |  |
| treatment, upon patient's request, and after MDT decision                                    |                                   |  |

## E.10. Angiosarcoma and other sarcomas of the breast

#### Piotr Rutkowski, Zbigniew I. Nowecki

- Due to the very low prevalence of breast sarcomas there is no treatment schedule specifically developed for this type of malignancy. Recommendations regarding treatment of sarcomas in other localisations should be implemented.
- Primary angiosarcoma (AS) accounts for only 0.05% of all breast malignancies. It is estimated that one case of primary AS is noted per 1700–2000 primary breast cancers. This comes to approximately seven cases per million women. Secondary AS is connected with chronic extremity oedema after mastectomy (Stewart-Treves syndrome) and previous radiotherapy.
- Taking into account the high aggressiveness of AS, the management of choice, giving the best results, is combined treatment with surgery and supplementary radiotherapy (even in patients with secondary angiosarcoma) +/– perioperative chemotherapy.

— By analogy to soft tissue sarcoma in different localisations, breast lymphoma is also very rarely connected with metastases in lymph nodes. Surgical treatment of choice should be simple mastectomy or radical local conserving dissection without axillary lymphadenectomy. Neo- and adjuvant radiotherapy (or possible chemotherapy) is recommended according to treatment principles, similarly to sarcomas in different localisations.

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| Subject                                      | Combined treatment of<br>angiosarcoma and other<br>sarcomas of the breast |
|--|---|
| Analysed problems                            | PSSO recommendations  |
| Diagnosis                                    |   |
| Standard imaging diagnosis: mammography, USG | 2+  |
| MRI of chest wall                            | 2+  |

| Analysed problems   | PSSO recommendations |
|---|----------------------|
| Exact clinical staging (CT of chest and abdomen, brain MRI)                                   | 2+                   |
| Fine-needle aspiration  | 2-                   |
| Core-needle biopsy  | 2+                   |
| Treatment of primary lesions  |                      |
| Radical surgical treatment (R0) with/without muscle pectoral major                            | 2+                   |
| BCT, if possible  | 0                    |
| ALND  | 1–                   |
| Neo-/adjuvant chemotherapy (after agreement in MDT)   | 0                    |
| Adjuvant radiotherapy, even in induced angiosarcoma, is a standard of postoperative treatment | 1+                   |
| Adjuvant radiotherapy (in sarcomas other than AS)   | 1+                   |
| In case of impossible operation and/or radical operation, neoadjuvant chemotherapy (NEC) is   | 1+                   |
| indicated as initial treatment  |                      |
| Treatment of local recurrence   |                      |
| R0 resection  | 2+                   |
| Radiotherapy, chemotherapy, especially after R1 resection                                     | 1+                   |
| NAC as initial treatment should be considered   | 1+                   |
| Treatment of metastases, inoperable local recurrence  |                      |
| Therapy based on MDT decisions, as for other sarcomas   | 2+                   |
|   |                      |

## F. LOCO-REGIONAL RECURRENCES OF BREAST CANCER

# F.1. Treatment of local recurrence after breast cancer therapy

## Rafał Matkowski, Anna Kulik, Sławomir Mazur

- Local ipsilateral breast tumour recurrence (IBTR) is a recurrence within the breast, chest wall, axillae, as well as supraclavicular, subclavicular, and retrosternal lymph nodes, after previous treatment performed with radical intention (definition of Union Internationale Contre le Cancer [UICC]).
- IBTR is diagnosed in approximately 2–20% of breast cancer patients, despite previous optimal treatment
   this results from potential biological aggressiveness of the tumour. In this group of patients the risk of general spreading of the disease is 3–5-fold higher than in patients without local recurrence.
- IBTR definition includes two different biological processes connected to the cancer: true recurrences (TR) and new primary tumours (NP). Primary lesion, from which TR comes, is characterised by a higher percentage of metastases to lymph nodes (37.8%), and short disease-free interval (DFI) on average 46.6 months. NP features include low percentage of metastases to lymph nodes (8.7%) and longer DFI (on average 62.1 months). Risk factors for TR are as follow: young age, positive margins, metastases to lymph nodes, and treatment without radiotherapy.

Risk factors for NP include: young age, treatment without radiotherapy, and cancer in opposite breast after initial surgical treatment. Furthermore, NP shows significantly better prognosis — five-year overall survival (OS) is 71.0% in TR and 94.7% in NP; P = 0.022, so less intense treatment schemes could be considered (e.g. re-BCT).

— Each patient, after receiving a pathology report confirming local recurrence, should undergo repeat staging (rTNM), analysis of expression of different receptors on cancer cells (ER, PR, HER2, and Ki67), and MDT discussion in order to qualify to individualised combined treatment.

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| Subject   | Treatment of local<br>recurrence after breast<br>cancer therapy |
|---|---|
| Analysed problems   | PSSO recommendation   |
| Treatment of local recurrence after conserving breast cancer therapy                                      |   |
| "Salvage mastectomy"  |   |
| Mastectomy with the intention to achieve R0   | 2+  |
| Skin-sparing mastectomy (SSM) with the intention to achieve R0  | 1+  |
| Nipple-skin-sparing-mastectomy (NSM) with the intention to achieve R0                                     | 0   |
| MDT decision, suggested standpoint of the surgical oncologist:  |   |
| The decision to repeat XRT in patients after primary BCT and then after "salvage mastectomy" sho          | uld be individualised:  |
| Radiotherapy including chest wall +/- regional lymph nodes  | 0   |
| Dose escalation in previously not irradiated fields (+10%)  | 1–  |
| "Salvage" re-BCT  |   |
| Repeat breast conserving treatment (re-BCT) with the intention to achieve R0                              | 0   |
| In patients after previous BCS, without radiotherapy, re-BCS requires supplemental radiotherapy<br>— WBRT | 2+  |
|   | cont.   |

| Analysed problems   | PSSO recommendation |
|---|---------------------|
| MDT decision, suggested standpoint of the surgical oncologist:                                    |                     |
| n patients after previous BCS with radiotherapy, re-BCS requires repeat supplemental radiotherapy | 1+                  |
| Surgical management in an axillary in patients with rcN0  |                     |
| 5LNB after previous SLNB in the case of rcN0; if nSLN could not be identified, axillary           | 1+                  |
| ymphadenectomy is recommended   |                     |
| SLNB after previous ALND in the case of rcN0  | 2-                  |
| Treatment of local recurrence after mastectomy  |                     |
| "Salvage surgery"   |                     |
| Radical treatment — R0 resection  | 2+                  |
| Palliative treatment — full-thickness chest wall resection  | 0                   |
| MDT decision, suggested standpoint of the surgical oncologist:                                    |                     |
| Radiotherapy  |                     |
| n patients without radiotherapy after previous mastectomy, supplemental radiotherapy should be    | 1+                  |
| used, including chest wall +/- regional lymph nodes (after recurrence dissection)                 |                     |
| Repeat irradiation (chest wall + hyperthermia)  | 0                   |
| Recurrence in axillary lymph nodes  |                     |
| RT of axillae after R0 resection in patients without previous RT of this area                     | 1+                  |
| Repeat radiotherapy of axillae after R0 resection in patients after previous RT of this area      | 0                   |
| Recurrence in supraclavicular lymph nodes   |                     |
| Surgical treatment  | 0                   |
| Radiotherapy  | 1+                  |
| Recurrence in internal mammary lymph nodes  |                     |
| Surgical treatment  | 0                   |
| Radiotherapy  | 1+                  |
| MDT decision, suggested standpoint of the surgical oncologist:                                    |                     |
| n the treatment of local recurrence after consideration of biological subtype of cancer (ER, PR,  |                     |
| HER2, and Ki67):  |                     |
| n patients after R0 resection:  |                     |
| Systemic treatment should be used, according to biological subtype                                | 2+                  |
| n patients in whom R0 resection is not possible:  |                     |
| Palliative systemic treatment should be used, according to biological subtype                     | 2+                  |

## G. RECONSTRUCTION AND PLASTIC SURGERY IN ONCOLOGY

## **G.1. Reconstruction management** in breast cancer patients — general indications

#### Piotr Pluta, Sławomir Cieśla

- In each case of breast-conserving therapy (BCT) oncoplastic breast surgery (OBS) should be used in order to achieve radical oncology operation as well as good aesthetic effect after surgery and radiotherapy (aesthetic and functional results of 20–40% BCT operations without OBS are poor).
- There are possible extensive resections of glandular breast tissue together with the tumour, including up to 50% of breast volume, with good aesthetic effect and adequately wide margins. The methods of oncoplastic level II (relocation of tissue within breast) or III (replacement of loss with the tissue moved from out of the breast) should be used.
- Comparing of traditional BCT and OBS techniques is in favour of OBS, including local recurrences, early complications, and aesthetic and functional results.
- In women after mastectomy, reconstruction at the same time should be recommended only if absolute contraindications are excluded.
- Radical dissection of glandular tissue with cancer together with skin-conserving or even nipple-areola complex should be supplemented with the reconstruction performed at the same time with use of implants or patient's own tissue, depending on

surgery experience. It allows potential surgical correction later on.

- Reconstruction of dissected breast influences not only the patient's mental status, but also prevents abnormalities of normal body posture.
- In each case of breast reconstruction, symmetrisation of healthy breast should be considered, either performed at the same time or delayed (enlargement or reduction with suspension).

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| reconstruction<br>The main situation in which indications to breast reconstruction are considered is the patient's<br>high motivation to undergo this surgical operation or sequential procedures  | PSSO recommendation<br>2+<br>s 2+ |
|--|-----------------------------------|
| Each female patient qualified to mastectomy should be informed about possible breast<br>reconstruction<br>The main situation in which indications to breast reconstruction are considered is the patient's<br>high motivation to undergo this surgical operation or sequential procedures<br>Qualification to reconstruction procedure is based on careful analysis of the patient's operlopic |                                   |
| high motivation to undergo this surgical operation or sequential procedures  | s 2+                              |
| Qualification to reconstruction procedure is based on careful analysis of the patient's oncologi   |                                   |
| as well as mental status   | ical 2+                           |
| Qualification to immediate reconstruction procedure is performed after comprehensive analysis<br>and the decision of the MDT   | is 2+                             |
| The choice of technique of breast reconstruction (operations with use of expanders/implants, autologous reconstructions) is based on site experience and the patient's preferences   | 2+                                |
| Immediate procedures are preferable, due to their beneficial impact on patients' life comfort a costs (despite higher risk of reconstruction failure)  | and 1+                            |
| There are no oncological contraindications to delayed reconstruction   | 0                                 |

| Analysed problems  | PSSO recommendation |
|--|---------------------|
| An absolute contraindication to immediate reconstruction is inflammatory breast cancer     | 2+                  |
| Scheduled radiotherapy is not a contraindication to immediate reconstruction               | 0                   |
| The following factors should be considered as increasing complication risk and potentially | 2+                  |

influencing qualification to breast reconstruction:

- BMI > 30
- current smoking
- diabetes
- previous radiotherapy of chest wall

- age - assessment of patient's state according to PSSO GONG section recommendations

## **G.2. Reconstruction management** in breast cancer patients — detailed indications

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Artur Bocian, Krzysztof Kurczych, Daniel Maliszewski

| Subject  | Reconstructions       |  |
|--|-----------------------|--|
|  | in breast cancer      |  |
|  | — detailed indication |  |
| Analysed problems  | PSSO recommendation   |  |
| Operation type   |                       |  |
| A. Oncoplastic conserving operations   |                       |  |
| Reduction mammoplasty adapted to the tumour  | 2+                    |  |
| Techniques of local flaps  | 2+                    |  |
| Partial mastectomy with tissue transfer  | 2+                    |  |
| B. Mastectomy conserving skin/nipple (SSM/NSM)   |                       |  |
| Mastectomy conserving skin (SSM/NSM) is:   |                       |  |
| safe (frequency of recurrence is the same as after radical mastectomy)                                 | 2+                    |  |
| nipple-areola complex could be preserved   | 2+                    |  |
| could be performed after breast plastic surgery with mastopexia/reduction                              | 2+                    |  |
| C. Types of bilateral mastectomy reducing risk of breast cancer (RRBM)                                 |                       |  |
| Simple mastectomy  | 1+                    |  |
| RRBM by SSM (skin sparing during mastectomy)   | 1+                    |  |
| RRBM by NSM (nipple-areola complex sparing)  | 1+                    |  |
| Prophylactic contralateral mastectomy  | 1+                    |  |
| Different reconstruction aspects   |                       |  |
| A. Reconstruction after mastectomy   |                       |  |
| Use of implants filled with silicone   | 1+                    |  |
| Reconstruction with autologous tissue  | 1+                    |  |
| Reconstruction with pediculated tissue   | 1+                    |  |
| Reconstruction with free transplant tissue   | 1+                    |  |
| Autologous tissue combined with implants   | 1+                    |  |
| B. Timing of reconstruction after mastectomy   |                       |  |
| Breast reconstruction at the same time — obligatory during SSM and NSM                                 | 1+                    |  |
| Advantages — avoiding a syndrome after mastectomy and disturbances of supplemental treatment (CTH, RT) |                       |  |

| Analysed problems  | PSSO recommendation |
|--|---------------------|
| Delayed breast reconstruction  | 1+                  |
| Disadvantages — lack of skin envelope  |                     |
| "Delayed-immediate" breast reconstruction  | 0                   |
| C. Breast reconstruction depending on timing of radiotherapy                                 |                     |
| C.1. Implant reconstruction (IR)   |                     |
| Implant reconstruction (IR) in case of expected adjuvant radiotherapy                        | 0                   |
| Primary reconstruction with expander and then with definitive prosthesis in case of expected | 0                   |
| adjuvant radiotherapy  |                     |
| IR without radiotherapy (XRT)  | 2+                  |
| IR after mastectomy before XRT   | 1+                  |
| IR after mastectomy and after XRT  | 0                   |
| Disadvantages — tissue fibrosis, problems with wound healing                                 |                     |
| IR after mastectomy due to recurrence after BCT  | 0                   |
| C.2. Breast reconstruction (BR) with autologous tissue TRAM or LD                            |                     |
| BR after XRT   | 2+                  |
| BR before XRT  | 1–                  |
| Disadvantages — tissue fibrosis, problems with wound healing, fat tissue necrosis            |                     |
| D. Methods of restorations of breast and tissues after radical operations                    |                     |
| D.1. Materials replacing tissue losses used during reconstructions (recommended              |                     |
| participation in clinical trials)  |                     |
| Autologous tissue (e.g. autodermal transplant, flap from latissimus dorsi muscle — LD)       | 1+                  |
| Acellular dermal matrix (ADM)  | 1+                  |
| Synthetic mesh to muscle repair  | 1+                  |
| D.2. Lipotransfer  |                     |
| Lipotransfer after mastectomy and breast reconstruction                                      | 1+                  |
| Lipotransfer after BCT   | 1+                  |
| Transplants enriched with autologous adipose-derived stem cells (ASC) (in clinical trials)   | 0                   |
| D.3. Pediculated flaps   |                     |
| Breast reconstruction with autologous tissue TRAM, LD (both could be performed as techniques | 1+                  |
| with muscle sparing)   |                     |
| Delayed TRAM in patients with risk factors   | 1+                  |
| Pediculated TRAM from the same side  | 1+                  |
| D.4. Free tissue transfers   |                     |
| DIEP flaps   | 1+                  |
| Free flap TRAM   | 1+                  |
| SIEA flap  | 1+                  |
| SGAP/IGAP flap   | 1+                  |
| Free lobular transplant with gracilis muscle (TMG)   | 1+                  |
| Free tissue transfers:   |                     |

Patients' satisfaction after use of free tissue transfers was not higher than for pediculated flaps.

Advantages:

- flaps: DIEP and free TRAM are the procedures that are potentially muscle sparing.
  - With the use of DIEP flaps, there was a lower proportion of abdominal hernias.

Disadvantages:

- time-consuming and absorbing staff procedure
- intensified preoperative monitoring
- higher percentage of re-operations and general failure
- RT before reconstruction increases the frequency of vascular complications

| Analysed problems  | PSSO recommendation |
|--|---------------------|
| D.5. Combined reconstruction technique: flap-implant   |                     |
| Flap from latissimus dorsi muscle — LD(LD) + implant   |                     |
| — reconstruction after RT  | 1+                  |
| — reconstruction before RT   | 1+                  |
| Other flaps + implant  | 0                   |
| Note:  |                     |
| Advantages: like for tissues after XRT; appropriate implant coverage; TRAM: preferred stepwise |                     |
| procedure  |                     |
| Disadvantages: muscle constructions (LD flap)  |                     |
| E. Other reconstruction aspects that should be considered in specific situations               |                     |
| Symmetrisation of opposite breast  | 2+                  |
| Re-operation to improve aesthetic effect in reconstructed breast                               | 2+                  |
| Reconstruction of nipple-areola complex  | 2+                  |

## H. FOLLOW-UP AFTER TREATMENT CESSATION

# H.1. Follow-up after breast cancer treatment

## Arkadiusz Jeziorski, Zbigniew I. Nowecki

During follow-up after radical treatment, the following are recommended:

- systematic monthly self-control,
- promoting healthy lifestyle, physical activity, and diet counselling in obese women,
- unlimited access to rehabilitation and services, allowing minimisation of physical, mental, and social consequences of breast cancer treatment.

| PSSO recommendation | Frequency                                    | Recommended tests                       |
|---------------------|--|---|
| 2+                  | Once per month                               | Self-control                            |
| 2+                  | First 2 years — every 3–6 months             | Physical examination                    |
| hs                  | During 3–5 years — every 6 months            |   |
|                     | After 5 years — every 12 months              |   |
|                     | Every 12 months                              | Mammography and breast USG              |
| ths after 2+        | After BCT — first imaging 6 months after     |   |
|                     | operation                                    |   |
| ion in 2+           | Every 12 months — special attention in       | Gynaecological examination              |
|                     | patients treated with tamoxifen              |   |
| ion in 1+           | Every 24 months — special attention in       | Densitometry in women during HTH        |
| nhibitors           | patients treated with aromatase inhibitors   |   |
| 1+                  | BMI within the range 20–25                   | Body weight assessment                  |
| dications 2+        | According to individual clinical indications | Additional laboratory and imaging tests |
| dications           | <b>U</b>                                     | Additional laboratory and imaging tests |

## **CONSENSUS COMMITTEE MEMBERS**

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