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Short Version of the Guideline: Early Detection of Breast Cancer in Germany

An evidence-, consensus-, and outcome-based guideline according to the German Association of the Scientific Medical Societies (AWMF) and the German Agency for Quality in Medicine (AeZQ)

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Abstract The goal of the Guideline “Early Detection of Breast Cancer in Germany” is to assist physicians, healthy women, and patients in the decision-making process in favour of appropriate health care regarding early detection and diagnosis of breast cancer. The principle of early detection of breast cancer embraces the detection of non-invasive stages of breast cancer (UICC stage 0, carcinoma in situ), reducing the frequency of invasive breast cancer development, as well as the identification of breast cancer at an early stage (UICC stage I) having a chance of cure of more than 90%, as shown by a large number of trials. The Guideline summarized in the following paper is a precondition to establishing a nation-wide, comprehensive, quality-assurance program for the early detection and diagnosis of breast cancer. The resulting consequence should be a timely mortality reduction of breast cancer. The cure of early stage disease will additionally be achieved by less intensive treatment methods while largely maintaining the quality of life of breast cancer patients. Implementing the Guideline offers the possibility of a significant improvement in women’s health care.

Keywords Guideline · Evidence-based · Breast cancer · Early detection

Introduction

The goal of the Guideline is to assist physicians and women with a relevant risk of developing breast cancer in the medical decision-making process involving effective and qualified methods about the appropriate health care for the early detection of breast cancer. The content of the Guideline is not limited to the performance and quality assurance of mammography examination alone, but also includes all parts of the complete diagnostic chain necessary to find and clear up definitely suspicious breast lesions. In the case of testing positive for breast cancer, quality findings are the precondition for the establishment of individually tailored treatment plans.

The Guideline “*Early Detection of Breast Cancer*” therefore represents a set of recommendations with respect to the rules of guideline development in Germany as published previously [9]. When required by individual circumstances it is not only possible, but also necessary, to deviate from the recommendations. The Guideline in no way releases the physicians from the professional obligation of separately considering the particular medical situation and the individual psychological, physical, and social circumstances within the scope of the medical decision-making process. At the same time, the Guideline may not restrict the right of self-determination of women; her autonomy to decide for herself on the basis of informed consent. Instead, this results in the additional responsibility of providing support and transparency for a decision-making in partnership with the women based on information sufficient to empower and to allow active participation. When making use of the Guideline in clinical routine, it must be clear that the Guideline could never embody all possible details, methods, and procedures. Moreover, it does not exclude any medical procedures and

The names and affiliations of the Guideline Steering Committee and the Task Force Groups can be found in the Appendix

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approaches that individually can lead to an equally good clinical result.

The Guideline reflects the evidence-based state of knowledge of medical science at the time of its publishing. It is subject to continuous updating and revision. The publication of a revised version is planned for the year 2005. New evolving knowledge requiring inclusion in the Guideline in the interim will be published in the form of an addendum.

The short version of the Guideline is intended for the routine use of physicians. The decision regarding its use lies in the hands of the physicians responsible. It in no way releases physicians from the obligation to inform women and patients about relevant clinical trials and offer them the opportunity to participate in such studies. However, these should be only peer-reviewed studies which obey the principles of good clinical practice within the goal of investigating the causes of the disease, the introduction of innovative methods for their diagnosis, therapy and follow-up care, and analysing the benefit and side effects of these methods. This also applies to methods and approaches for the further development of primary and secondary prevention of breast cancer. The impact on quality of life, the psychological, physical, and social consequences of new developments must be taken into consideration within the scope of such studies.

The Guideline is intended to help establish methods of total quality management and to quantify and qualify these by the use of quality indicators. The Guideline is a prerequisite for the development and implementation of new concepts in health care (e.g., national breast cancer programs, breast centres and units, and disease management programs).

The short version of the Guideline presented has the aim of providing interested physicians in ambulatory care and physicians in hospitals with an overview of the entire complex of the chain of diagnosis for the early detection of breast cancer, but is not intended as a substitute for the detailed presentation of the long Guideline version “*Stufe-3-Leitlinie Brustkrebs-Früherkennung in Deutschland*” (Clinical Practice Guideline for the Early Detection of Breast Cancer in Germany) [17].

The short version of the Guideline contains the consensus guideline statements (paragraphs in italic) and summarizes the most important decision-making steps in the form of a clinical algorithm (Fig. 1). It also describes the instruments for assessing and measuring the quality management by the consensus-based quality indicators (marked by –symbol) [15, 16]. Quality indicators identical with the key performance indicators of the “*European Guidelines for Quality Assurance in Mammographic Screening*” are especially labelled thus; *EG [13]. In order to make the underlying evidence level and grade of recommendation of the guideline statements transparent to those persons interested, these are appended and denoted to the guideline statements in parentheses. Table 1 gives the prerequisites for the rating system used to define the level of evidence and grade

of recommendation [5]. Table 2 lists the professional associations and organisations, scientific and medical societies and non-medical organisations contributing to the development and the drafting of the Guideline. The complex methodological development of the Guideline including the financial, temporal, and personnel aspects has been described in a separate guideline report [1, 2].

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The special layout of the text provides assistance in identifying the most important aspects. The guideline statements are indicated by the use of italic text and the quality indicators are indicated by the –symbol. The explanation to procedures and recommendations provide assistance for the practical use.

1. Guideline statement: italic text.
 2. Explanation to procedures and recommendations: standard text
 3. Quality indicators: –symbol.
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Introduction

Based on new knowledge of tumour biology and recent therapeutic developments, no significant reduction in the mortality rate of breast cancer can be expected in the immediate future (IIA). Only a quality-assured multidisciplinary program for the early detection and diagnosis of breast cancer offers the promise of a significant mortality reduction. Quality assurance for the early detection of breast cancer is a multidisciplinary- and multi-professional responsibility. This requires the quality-assured, multidisciplinary combination of clinical breast examination, diagnostic imaging, minimal invasive tissue sampling, open biopsy, pathological breast tissue evaluation, and medical documentation, as parts of the diagnostic chain of health care to be mentioned and supervised by total quality management.

Recommendations for action in case of nonsuspicious normal findings and results

Age-specific repetition of preventive investigations and procedures according to the clinical algorithm Fig. 1 (recommended continuation related to the Guideline).



Fig. 1 The diagnostic chain: clinical algorithm for the early detection of breast cancer

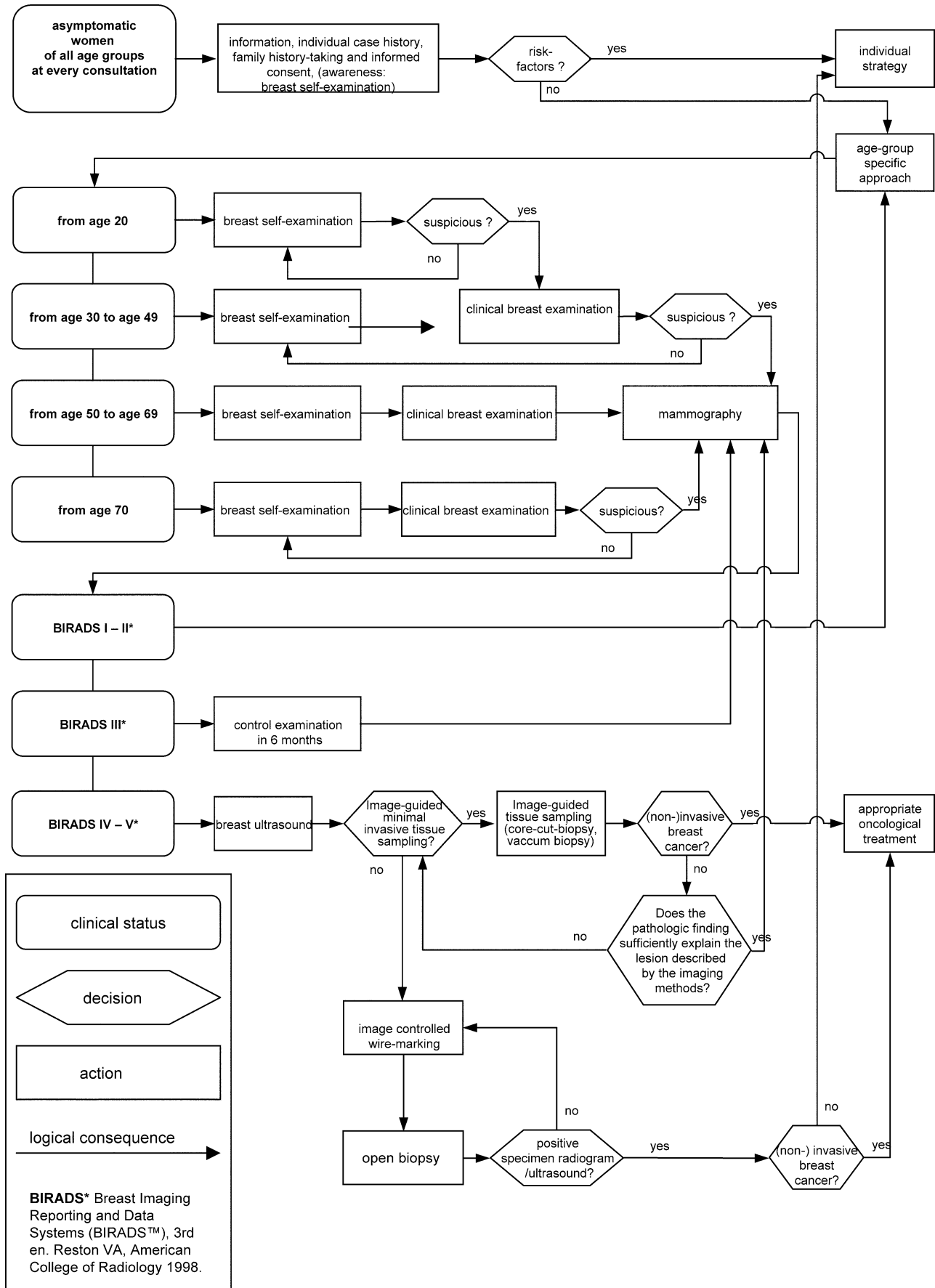


Table 1 Level of evidence and grade of recommendation according to [5]

Level	Prerequisite for the level of evidence
I	Meta-analysis of multiple, well-planned, controlled studies. Randomised study with low false positive and low false negative errors (high power)
II	At least one well-planned, controlled experimental study or randomised studies with high false positive and/or high false negative errors (low power)
III	Well-planned, non-randomised, controlled individual groups, pre-post cohorts, time or case control studies.
IV	Well-planned, comparative or correlative, descriptive or case studies
V	Case reports and clinical examples
Grade	Prerequisite for the grade of recommendation
A	Evidence level I or agreement of results from studies of evidence level II, III or IV
B	Evidence level II, III, or IV, predominantly with agreement of results
C	Evidence level II, III or IV, but with inconsistent results
D	Little or no empirical evidence

Recommendation for action in case of diagnosing non-invasive or invasive breast cancer, proved by breast specimen pathology

Adequate oncological care and consultation according to the *Guideline treatment and surveillance of breast cancer* (current recommendation, see [10, 11]).

–Percentage of complete data registration being necessary for total quality management of the complete diagnostic chain: $\geq 90\%$

Informed consent and shared decision-making

Medical examinations and diagnostic procedures involved in the early detection of breast cancer can cause psychological stress. Immediate and thorough information is therefore necessary in order to counteract this situation (IIB). The “Guideline Women’s Information” recommends the corridor in which the generation of qualified and competent specialized information material and the evaluation thereof is required regardless of the medium of its presentation.

Making clear to the patient the procedures and methods, their benefit, side effects, and risks is obligatory for all medical assessments recommended by physicians, including the required data collection. The written consent for data transfer (for clinical register and for cancer register) must always be obtained after a shared decision-making process via a physician-patient contact based on suitable information. The information has to take into account the variable needs of women in different age groups and of women in different social and cultural environments. A serious, competent, specialized, and

appropriate presentation must be chosen, which especially takes proper account of the psychological and also the physical stresses within the scope of early detection and diagnosis of breast cancer. The right of self-determination of the patient to decide for or against medical intervention after obtaining suitable information must always be ensured (*Guideline Women’s information*, [2, 17]). Information brochures have to include the:

- Examination intervals recommended
- Scheduling of the examinations and the related methods
- Type and effects of procedures
- Benefits, side effects, and risks of early detection procedures and methods
- Reliability and quality of recommended and used procedures and methods
- Physiology and pathology of the breast
- Suspicious breast symptoms (on inspection, on palpation, including functional aspects)
- Personal responsibility and patient’s rights
- Questions women may ask
- Counselling for women

–Percentage of women receiving adequate information material according to the clinical algorithm for the age-specific procedure: $> 90\%$

Personal case history and family history

According to the German law, the legal-based program for early detection and diagnosis of cancer (paragraph 25, Section 2 of the German Law: SGB V) medical case history taking, personal risk analyses, medical information, and counselling will be offered to women from the age of 20 years on [3]. The most important risk factor for the development of breast cancer is age. Quality-assured breast cancer detection methods and examinations are useful for every woman especially when the age of the woman indicates that a higher mortality rate can be expected, regardless of the different additional risks of developing the disease (IIB).

The individual case history taking should consider:

- Age
- Age of menarche
- Age of menopause
- Body mass index (BMI)
- Phase of menstrual cycle
- First full-term pregnancy
- Frequency and duration of breast feeding
- Previous oncological disease and radiation treatment
- Benign breast disease and non-invasive breast cancer
- Breast surgery
- Hormone therapy (composition, duration, dosage)
- Socio-economic status
- Family history of cancer, especially breast and ovarian carcinoma (i.e., risk of genetic constellation)

Table 2 Contributors to the drafting of the guideline according to [1]

Professional associations and organisations, scientific and medical societies	1	Working Group for Gynaecological Oncology
	2	German Association of the Scientific Medical Societies
	3	Berlin Cancer Society
	4	German Professional Association of Radiologists
	5	German Professional Association of Gynaecologists
	6	German Professional Association of Pathologists
	7	German Society of Female Physicians
	8	German Society of Surgery
	9	German Society of Gynaecology and Obstetrics
	10	German Society of Haematology and Oncology
	11	Germany Society of Medical Informatics, Biometry and Epidemiology
	12	Institute of Innovative Health Care Concepts
	13	German Society for Ultrasound in Medicine
	14	German Society of Senology
	15	German Society of Social Medicine and Prevention
	16	German Cancer Society
	17	German Cancer Aid
	18	German Menopause Society
	19	German Society of Radiology
	20	Association for Quality Management in Health Care
	21	Hessian Cancer Society
	22	Austrian Cancer Society / Austrian Cancer Aid
	23	Austrian Society of Radiology
	24	Austrian Society of Senology
	25	Swiss Society of Senology
	26	Association of German Plastic Surgeons
	27	World Society for Breast Health
Non-medical organisations	1	Campaign: Awareness of Breast Cancer
	2	German Federal Self-help Organisation for Women after Cancer
Other non-medical organisations supporting the implementation of the “Guideline Women’s Information” [2]	3	The Susan G. Komen Breast Cancer Foundation
	4	Women’s Health Coalition
	5	Breast Cancer Initiative
	6	Parent Society for Women’s Health Centers in Germany
	7	German Society for Insured Persons and Patients
	8	EUROPA DONNA European Coalition Against Breast Cancer, National Forum for Germany
	9	Women’s Health Forum
	10	Women’s Health Centre, Heidelberg
	11	Institute of Epidemiology: GSF Research Centre for Environment and Health
	12	Institute of Mammary Diagnostics Prof Barth/Dr Herrmann
	13	MEDEA
	14	MUT
	15	“Onco-Gyn” Patient Initiative
	16	Pro Sina
	17	Consumers’ Centre of Baden Württemberg
	18	German Federal Self-Help Organisation for Patients with Lymphedema

Individual and special risk constellation

In the presence of special risk factors, an individual early detection strategy must be discussed and recommended. For carriers of BRCA1/BRCA2 mutations, screening strategies are currently offered in clinical trials and studies (IIB).

Individual risk consultation

Individual risk consultation considers the absolute risk and the genetic risk constellation (the use of the GAIL

model is possible [7]). Primary individual risk reduction is based on diet, lifestyle recommendations, information about breast health, and the demonstration of breast self-examination. In the case of a special risk profile, an individual strategy for early detection and diagnosis is indicated, providing information, support, and counselling. This includes the offer of participation in clinical trials and studies following testing for hereditary breast cancer, modified approaches using breast diagnostic imaging methods for early detection of breast cancer (e.g., magnetic resonance imaging, breast ultrasound, mammography) and modified time intervals for performing the examinations.

Breast self-examination

The breast self-examination is an important contribution to individual motivation, enhancing awareness for preventive approaches. Properly performed breast self-examination on a trained regular basis helps to detect breast tumours. However, the effectiveness of breast self-examination (in lowering the breast cancer mortality rate) should not be overestimated. Nevertheless, breast self-examination must be and remains an important component of an early breast cancer detection program. Breast self-examination cannot be learned and begun early enough, and in any case regular practice should be recommended beginning at the age of 30. A program on early detection of breast cancer should inform women about the advantages and disadvantages of breast self-examination and explain the limited effect it has for the program (IIC).

Inspection and palpation include both breasts, the mamillary and areolar complex, and the local lymphatic drainage areas. Symptoms and signs to denote: pain, skin alterations, asymmetry of breasts, mamillary secretion, tissue density alterations, lumps, and tumour formation.

The instruction of breast self-examination can be supplemented by training on tactile models and by appropriate information material.

—Percentage of women who receive a risk consultation, instruction in breast self-examination, and a clinical breast examination by their physician: $\geq 97\%$

Clinical breast examination

The clinical breast examination includes the inspection and palpation of the mammary gland and local lymphatic drainage areas and must be a component of an early breast cancer detection program and should be started from at least the age of 30 years on in regular intervals over the entire lifetime. The results of studies show that, in particular, from the age of 40 the clinical breast examination with inspection and palpation of the mammary gland and the lymphatic drainage areas by the physician in combination with mammography contributes to the greater effectiveness of breast cancer screening (IIB).

Inspection and palpation

Inspection and palpation: breast, mamilla-areolar complex, and local lymphatic drainage areas (in standing and recumbent position denote: pain, skin alterations, breast asymmetry, mamillary secretion, tissue density, lump, and tumour formation).

A positive result at the clinical breast examination indicates the need for an appropriate individual strategy according to the symptoms presented. It includes the indications for the use of special diagnostic imaging methods and techniques.

Mammography

Mammography is currently the only method generally regarded as effective for the detection of early stages of breast cancer (IA). Evidence from prospective randomized trials indicated that with the introduction of a screening mammography in the form of serial X-ray examinations it is possible to reduce the age-dependent breast cancer mortality rate by 20–40%. The randomized studies furnish proof of the effectiveness of screening mammography for women between the ages of 50 and 70, and more recently also between the ages of 40 and 50, as well as after the age of 70 (IB). From the age of 40, the individual benefit of mammography outweighs the incumbent risks due to radiation exposure. The optimal relation of benefit to risks is found between the ages of 50 and 70 (IIB).

—Percentage of women under the age of 40 without increased risk for breast cancer who receive a mammogram: $\leq 0.1\%$

The following requirements must be taken into account for the introduction of an early breast cancer detection program: the regularly performed mammography examination is intended as a diagnostic tool to find non-palpable, suspicious lesions in asymptomatic women:

- Between the ages of 50 and 70, since the greatest benefit results in this age group
- In two planes, combined with a clinical breast examination
- In examination intervals of no longer than 24 months
- With a guaranteed quality assurance of equipment and personnel

The effects of endogenous and exogenous hormones must be considered for the approaches, performance, and methods used for diagnostic imaging (IIB).

Indication for mammography

The indication applies for asymptomatic women aged between 50 and 70. Before the mammography examination, case history taking, clinical breast examination, and informed consent must take place. The two-plane mammography has to be performed in the postmenstrual phase in pre- or peri-menopausal women. In postmenopausal women a discontinuation of current hormone substitute treatment might be considered to lower breast density to improve transparency. The qualification of personnel should be in accordance with the European Reference Organisation for Quality assured Breast Screening and Diagnostic Services (EUREF) [12]. It includes the practical performance of X-ray investigation and the data collection, the standardized recording of reading the mammogram according to P(perfect), G (good), M (moderate), I (unacceptable)—criteria for image quality and BIRADS (Breast Imaging and Data Reporting Systems) classification [4]—and the use of double reading (at least for BIRADS III-V). Directly following the

examination, the findings and results must be explained to the woman. BIRADS III findings indicate the need for a mammography control after 6 months. Lesions classified as BIRADS IV and V indicate further diagnostic imaging and tissue diagnosis by pathological clarification, preferentially by image-guided and minimally invasive tissue sampling.

Quality assurance in mammography

The technical quality assurance of mammography is based on the requirements of the "European Guidelines for quality assurance in mammography screening" [12, 13]. Specialised qualification and training of skills must be ensured for the physicians and medical-technical assistants, with continuous specialised training of the medical staff (step-wise concept). For the at least selectively indicated double reading of mammograms (BIRADS III-V), the second reading must be also performed by a certified expert. The meticulous data documentation and evaluation of the results must be ensured. The time interval between the first imaging result requiring further clarification and the invasive diagnostic procedures performed must be reduced to a minimum (IIIB).

- Percentage of women obtaining a mammogram with an acceptable image quality according to PGMI criteria (P, G, M): $\geq 97\%$ *EG
- Percentage of mammograms classified as BIRADS V found to be benign following pathological evaluation (false positive): $< 10\%$
- Percentage of women obtaining a mammogram and have given informed consent with respect to the method: $\geq 97\%$
- Percentage of women having been explained the results of their mammogram directly after the examination by a physician: $\geq 97\%$
- Percentage of women after mammography being satisfied with the service during and after the examination: $\geq 97\%$ *EG

Extended breast diagnostic imaging: ultrasound and magnetic resonance imaging (MRI)

Breast ultrasound is a supplementary examination for the further clarification of ambiguous lesions. It is not suitable alone as a screening method (IIIB). Magnetic resonance imaging is a supplementary breast examination method too, for specific indications. It is not suitable alone as a screening method. The value of magnetic resonance imaging as a part of an early detection program has not been evaluated within the scope of prospectively randomised trials (IIIB).

Indication for breast ultrasound

Indications for breast ultrasound are BIRADS IV and V mammographic lesions: standardized examination

procedure in the supine position, for recording the results the five stage classification (I–V) applies, obligatory documentation follows standardized requirements for localisation, size and ultrasound-morphology, including recommendations for further investigation or follow-up. The Guideline requires the quality assurance of breast ultrasound according to the German Society of Ultrasound in Medicine (DEGUM) [17].

- Percentage of women with a mammogram result of BIRADS IV and V obtaining a breast ultrasound: $\geq 97\%$
- Percentage of women with a waiting time of ≤ 5 work days between the mammographic result and the offered further assessment: $\geq 90\%$ *EG
- Percentage of women with a waiting time of ≤ 15 work days between the decision for treatment intervention and admission: $\geq 90\%$ *EG

Interventional guided minimal invasive diagnostic techniques

The pathological tissue diagnosis of ambiguous breast lesions is performed by core needle biopsy, vacuum biopsy or open biopsy. Percutaneous interventions must be performed in accordance with quality recommendations. The biopsy side and direction of minimal invasive procedures must be chosen and documented in order to excise the biopsy canal by the operation to follow (IIB).

Indication

The indication for interventional guided tissue sampling of mammography BIRADS IV and V and/or class IV and V ultrasound findings is the first step of the pathological clarification of diagnosis required as the precondition for further treatment planning. The choice of the method to be used (interventional guidance techniques: core needle biopsy or vacuum biopsy) depends on the particular individual lesion. The breast lesion must be clearly identifiable with the selected method; the biopsy canal chosen should correspond to the access path planned for a future operation. For solid lesions: ≥ 5 core needle samples are recommended, for microcalcification: 5–20 core needle biopsy samples with specimen radiography are recommended. Vacuum biopsy is preferably recommended for BIRADS IV lesions. The performance of a stereotactic vacuum biopsy has to be in accordance with the consensus recommendations recently published [8]. After breast tissue removal by interventional techniques, a mammogram in two planes is required. The control of results involves the correlation of the results obtained by diagnostic imaging with the pathological results of the breast tissue specimens taken. For cases that prove to be benign, follow-up imaging examinations after 6 months and 24 months are recommended.

–Percentage of non-palpable malignant lesions which have been pathologically clarified pre-operatively by image-guided interventional techniques (core needle biopsy or vacuum biopsy): $> 70\%$ *EG,

–The false negative rate of mammographically or sonographically image-guided interventional techniques (core needle biopsy, vacuum biopsy): $< 5\%$

–The false positive rate of mammographically or sonographically image-guided interventional techniques (core needle biopsy, vacuum biopsy): $< 1\%$

Open biopsy of non-palpable lesion

The quality assurance for open biopsies for the removal of non-palpable mammographically detected lesions is based on the guidelines of the European Commission. Before performing an open biopsy, a pre-operative breast tissue pathological clarification of the lesion can be performed using interventional techniques. The pre-operative wire marking of non-palpable lesions is always necessary if an open biopsy has to be performed. The verification of the correct excision of breast tissue specimen is performed by specimen radiography; if required, supplemented by specimen ultrasound. The place of incision must be adapted to the localization of the lesion (no tissue tunnelling). At operation, cutting of the specimens and frozen sectioning of non-palpable lesions is inappropriate (IVB).

Indication

Open biopsy with pre-operative wire marking must be performed for non-palpable BIRADS IV and V diagnoses if image-guided interventional tissue sampling cannot be performed or if there is a discrepancy between the result of diagnostic imaging and the pathological finding of a previously performed minimally invasive diagnostic procedure.

Image-controlled wire marking

The lesion is penetrated or the wire marking is placed within 1 cm of the lesion; mammography in two orthogonal planes after wire placement accompanied with a report, explaining the exact wire position (sketch if required) for the surgeon; intra-operative specimen radiography (with compression and, if required, magnification) if necessary and possible specimen ultrasound; intra-operative verbal communication confirming the correct excision of the lesion to the surgeon prior to skin suture. Followed by a written report from the surgeon: accurate description of the diagnostic and invasive procedures performed, including topographically marking of the specimen for the pathologist. The final evaluation and the definite report of the results include a written opinion statement.

–Percentage of wire marking, placed within a distance of 1 cm (≤ 1 cm) from an impalpable lesion prior to excision: $\geq 90\%$ *EG

–Percentage of non-palpable lesions with a positive specimen radiogram (specimen ultrasound) which have been primarily successful completely removed: $\geq 95\%$ *EG

Open biopsy

The incision (arched) is made close to the lesion, no tissue tunnelling, and onco-plastic techniques if required. There should be no cutting and frozen sectioning of breast tissue specimens. In exceptional cases, it is only justified for palpable lesions bigger than 1 cm and with consecutive intra-operative surgical consequences. The unequivocal topographic marking of the tissue samples according to a local interdisciplinary protocol defined by the surgeons and the pathologists involved is obligatory. A perioperative antibiotic prophylaxis is recommended.

- Percentage of topographically unequivocally marked breast tissue specimens from open biopsy: $\geq 97\%$
- Percentage of specimen radiography (specimen ultrasound) sent to the pathologist of preoperatively marked non-palpable lesions: $\geq 90\%$
- Percentage of women satisfied with the cosmetic results following open biopsy which subsequently pathologically prove to be a benign disease: $\geq 90\%$
- The rate of benign to malignant operations performed for diagnostic open biopsies (with reference to the guideline statement: image-guided interventional techniques): $< 1:1$ *EG

Pathology

The quality assurance for breast pathology is mainly based on the guidelines of the European Commission. Reference centres of pathology with centralised documentation, offering training and certification have to be established. In difficult and or ambiguous cases, double specimen evaluation by an expert panel is recommended (IIB).

Percutaneous biopsies

Complete embedding of breast tissue specimens.

Excisional biopsies

Surface marking for judging the excision boundary before cutting the tissue specimen.

Macroscopic and microscopic tissue processing

The processing of breast tissue examination, the evaluation, and the data documentation must be in

accordance with the *Manual of Mammary Pathology* of the Guideline [17].

Obligatory quality requirements of the pathology report

Metric tumour size descriptions, metric descriptions of the minimal resection distance, pathology of tumour type according to the WHO classification [14], pTNM classification (UICC TNM, [18]), grading according to Elston and Ellis [7], and immunohistochemistry of the estrogen and progesterone receptors for invasive carcinomas. The final evaluation should summarize the correlation of the pathological results with the findings of the imaging diagnostic procedures.

–Percentage of full pathology reports with description of tumour size (DCIS and invasive carcinomas) in metric units (mm/cm), histological tumour type (modified WHO classification [4]) and pTNM classification (UICC, TNM classification of malignant tumours [18]): $\geq 95\%$

–Percentage of pathology reports of DCIS and invasive carcinomas with references to the nearest resection margin in metric units (mm/cm): $\geq 95\%$

–Percentage of pathology reports of invasive carcinomas with details concerning the grading according to Elston and Ellis (1991) [6]: $\geq 95\%$

–Percentage of pathology reports of invasive carcinomas with details concerning the hormone receptor status (immunohistochemistry estrogen and progesterone receptors): $\geq 95\%$

Data documentation and quality requirements

The resulting health care outcomes and quality of life must be recorded and evaluated. Only those clinical parameters should be used for the evaluation of the quality of care for early detection and diagnosis of breast cancer which are sufficient to meet the recognized quality requirements in Germany given in the consensus paper of the Federal Chamber of Physicians (BÄK), the Union of Public Health Service Physicians (KBV) and the German Association of the Scientific Medical Societies (AWMF).

The results and findings obtained along the diagnostic chain of early detection of breast cancer in the individual case must be documented in a standardized, interdisciplinary form, including all local regulations with regard to a total quality management: i.e., data feedback concerning the permanent improvement of process quality and outcomes measured and evaluated by the use of quality indicators. Multidisciplinary case conferences and quality circles should be contractually defined, if necessary. The data transfer to clinical and epidemiological cancer registers must be regulated regionally and locally.

Quality indicators reflecting the functionality of the complete diagnostic chain within an established early detection program for breast cancer

- Percentage of ductal carcinoma in situ: $\geq 10\%$ *EG
- Percentage of invasive breast carcinoma with ≤ 5 mm: $\geq 10\%$
- Percentage of invasive breast carcinoma with ≤ 10 mm: $\geq 20\%$ *EG
- Percentage of invasive breast carcinoma with ≤ 20 mm: $\geq 65\%$
- Percentage of lymph node-negative invasive breast carcinoma: $> 75\%$ *EG
- Percentage of women stating that they were well informed within the breast cancer early detection program and have been involved in the medical decision-making process additionally to the written declaration of informed consent: $> 90\%$
- Percentage of breast cancer cases occurring following a previous BIRADS I-III mammogram within a period of 24 months (interval carcinomas/false negative): $\leq 50\%$ *EG
- Percentage of interval carcinomas referred and subjected to an interdisciplinary detailed analysis: $\geq 95\%$
- The detection rate is greater than the observed rate of incidence: $> 50\%$

Implementation

Implementation is not automatically successful as a result of existing guidelines, rather it is due to scientifically founded strategies for change in health care. The "Guideline Women's Information" is embedded in the Guideline "Early Detection of Breast Cancer in Germany" and is an important instrument of implementation [2].

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