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Guidelines Breast
Version 2024.1E

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LEHREN
HEILEN

Diagnosis and Treatment of Patients with early and advanced Breast Cancer

Early Detection and Diagnosis



Early Detection and Diagnosis

- **Versions 2005–2023:**
Albert / Blohmer / Fallenberg / Fersis / Gerber / Junkermann / Kühn /
Maass / Müller-Schimpfle / Scharl / Schreer / Wöckel

- **Version 2024:**
Fallenberg / Heil

Screened data bases

Pubmed 2018 - 2023
Medline 2018 - 2023
Cochrane 2018 - 2023

Guidelines

S3 Diagnostik, Therapie und Nachsorge des Mammakarzinoms:

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2. Wöckel A, Festl J, Stüber T et al. Interdisciplinary Screening, Diagnosis, Therapy and Follow-up of Breast Cancer. Guideline of the DGGG and the DKG (S3-Level, AWMF Registry Number 032/045OL, December 2017) - Part 2 with Recommendations for the Therapy of Primary, Recurrent and Advanced Breast Cancer. Geburtshilfe Frauenheilkd. 2018 Nov;78(11):1056-1088. doi: 10.1055/a-0646-4630. Epub 2018 Nov 26.

European Commission Initiative on Breast Cancer (ECIBC)

European guidelines on breast cancer screening and diagnosis

<https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines>

2015 ACS Update Breast Cancer Screening for women at average risk

IARC Handbook 2016

European Commission 2016

(<http://ecibc.jrc.ec.europa.eu/recommendations/list/3;Update 24.11.2016, Abruf 20122016>)

Screened: Metaanalyses/ Systematic reviews / RCT / Cohort studies



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Early Detection with Mammography

| Age | Interval | Oxford | | AGO |
|--------|----------|--------|----|------------------|
| | | LOE | GR | |
| < 40 | na | - | - | -- |
| 40-44 | na | 1b | B | - |
| 45-49 | 24-36 | 1a | A | + [#] |
| 50-75* | 24 | 1a | A | ++ |
| > 75** | 24 | 4 | C | +/- [#] |

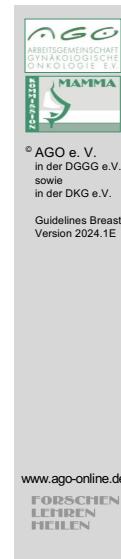
* National Mammography-Screening-Program

** health status + life expectancy more than 10 years

clear indication necessary, or indicated if screening age is adapted

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Early Detection in Asymptomatic Women
Digital Breast Tomosynthesis, Endpoint: cancer detection rate

| | Oxford | | |
|---|-----------|----------|----------|
| | LOE | GR | AGO |
| Digital Breast Tomosynthesis (DBT ± SM)* | 1a | A | + |

Replacing FFDM by synthetic MG in addition to DBT **1a** **A** **++**

The complete DBT dataset of images has to be available for judgment / reporting, the synthetic mammography only is not sufficient.

* Sign. higher sensitivity, heterogeneous specificity, and higher costs [machine, evaluation, archiving] of DBT in comparison to Full-Field Digital Mammography (FFDM)
Dose reduction due to calculated synthetic 2D mammography (SM) instead of additional FFDM, no significant reduction of interval cancers to date

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 - 11. Kleinknecht JH, Ciurea AI, Ciortea CA. Pros and cons for breast cancer screening with tomosynthesis - a review of the literature. *Med Pharm Rep.* 2020;93(4):335-41.
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AI for cancer detection

| | Oxford | | |
|---|---------------|-----------|------------|
| | LOE | GR | AGO |
| AI in screening | | | |
| Second reader of mammography | 1b | B | +/- |
| To reduce workload (AI only) | 2b | B | - |
| Tomosynthesis: stand alone or second reader | 2a | B | - |

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Workload-Reduktion:

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Breastcancer: incidence and mortality risk

Tabelle 3.17.2
Erkrankungs- und Sterberisiko in Deutschland nach Alter und Geschlecht, ICD-10 C50, Datenbasis 2019

| Frauen im Alter von | Erkrankungsrisiko | | Sterberisiko | |
|---------------------|---------------------------|---------------------|---------------------------|-----------------------|
| | in den nächsten 10 Jahren | jemals | in den nächsten 10 Jahren | jemals |
| 35 Jahren | 1,0 % (1 von 99) | 13,1 % (1 von 8) | 0,1 % (1 von 1.000) | 3,5 % (1 von 28) |
| 45 Jahren | 2,2 % (1 von 45) | 12,3 % (1 von 8) | 0,2 % (1 von 410) | 3,5 % (1 von 29) |
| 55 Jahren | 2,8 % (1 von 35) | 10,4 % (1 von 10) | 0,4 % (1 von 230) | 3,3 % (1 von 31) |
| 65 Jahren | 3,4 % (1 von 29) | 8,2 % (1 von 12) | 0,8 % (1 von 130) | 3,0 % (1 von 34) |
| 75 Jahren | 3,6 % (1 von 28) | 5,6 % (1 von 18) | 1,3 % (1 von 77) | 2,5 % (1 von 40) |
| Lebenszeitrisiko | | 13,2 % (1 von 8) | | 3,5 % (1 von 28) |
| Männer im Alter von | in den nächsten 10 Jahren | | jedemal | |
| 35 Jahren | < 0,1 % (1 von 29.250) | 0,1 % (1 von 750) | < 0,1 % (1 von 319.800) | < 0,1 % (1 von 2.500) |
| 45 Jahren | < 0,1 % (1 von 11.400) | 0,1 % (1 von 760) | < 0,1 % (1 von 44.700) | < 0,1 % (1 von 2.500) |
| 55 Jahren | < 0,1 % (1 von 4.000) | 0,1 % (1 von 790) | < 0,1 % (1 von 24.400) | < 0,1 % (1 von 2.500) |
| 65 Jahren | < 0,1 % (1 von 2.300) | 0,1 % (1 von 890) | < 0,1 % (1 von 8.400) | < 0,1 % (1 von 2.600) |
| 75 Jahren | 0,1 % (1 von 1.700) | 0,1 % (1 von 1.100) | < 0,1 % (1 von 5.650) | < 0,1 % (1 von 3.000) |
| Lebenszeitrisiko | | 0,1 % (1 von 750) | | < 0,1 % (1 von 2.500) |

From:https://www.krebsdaten.de/Krebs/DE/Content/Publikationen/Krebs_in_Deutschland/kid_2023/kid_2023_c50_brust.pdf?__blob=publicationFile



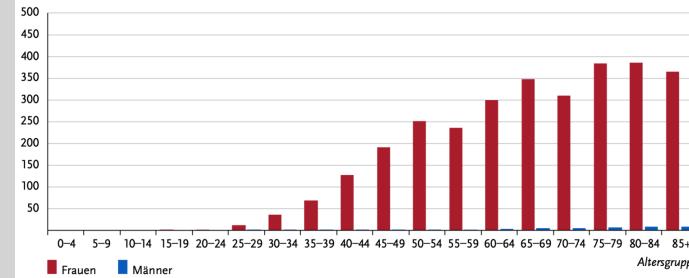
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Breastcancer: Age specific new Cancer cases

Abbildung 3.17.2
Altersspezifische Neuerkrankungsraten nach Geschlecht, ICD-10 C50, Deutschland 2019 – 2020
je 100.000



From:https://www.krebsdaten.de/Krebs/DE/Content/Publikationen/Krebs_in_Deutschland/kid_2023/kid_2023_c50_brust.pdf?__blob=publicationFile



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Mammography-Screening Benefit and Harm

**Data background: Breast Cancer Surveillance Consortium Registry Data
per 10.000 Women screened over 10 years**

| Age | 40-49 | 50-59 | 60-69 | 70-74 |
|--------------------------------------|---------|----------|------------|-----------|
| Breast cancer death avoided (CI 95%) | 3 (0-9) | 8 (2-17) | 21 (11-32) | 13 (0-32) |
| False-positive (n) | 1212 | 932 | 808 | 696 |
| Breast biopsies (n) | 164 | 159 | 165 | 175 |
| False-negative (n) | 10 | 11 | 12 | 13 |

Siu AL on behalf of the USPSTF 2016, 164:279-296

Siu AL, on behalf of the U.S. Preventive Services Task Force
Screening for Breast Cancer: U.S. Preventive Services Task Force
Recommendation Statement. Ann Internal Med 2016 vol 164: 279-296



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Early Detection (normal risk) Sonography / MRI

| Oxford | | |
|--------|----|-----|
| LoE | GR | AGO |
| 5 | D | -- |
| 3a | C | - |
| 2a | B | ++ |
| 1b | C | ++ |
| 2b | B | ++ |
| 2b | C | ++ |
| 1b | B | + |

■ Screening-Breast sonography alone

- Automated 3D-sonography

■ Breast sonography as an adjunct:

- Dense mammogram
(heterogeneously dense, extremely dense)
- Elevated risk
- Mammographic lesion
- Second-look US (MRI-only detected lesions)

■ MRI if screening MG is negative and breast composition: extremely dense* 45–75 LJ

* Definition of extremely dense corresponds to BI-RADS-density category D, heterogeneously dense to BI-RADS-category C according to ACR BI-RADS-Atlas 5th ed. 2013

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Recommendations International

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Early Detection (normal risk) Clinical Breast Examination (CBE)

| | Oxford | | |
|--|--------|----|-----|
| | LoE | GR | AGO |
| As stand alone procedure | | | |
| ▪ Self-examination | 1a | A | -* |
| ▪ Clinical breast examination (CBE) by health professionals outside checkup for cancer | 1a | C | -* |
| ▪ Clinical breast examination (CBE) by health professionals during checkup for cancer | 1a | B | ++ |
| ▪ Medical palpation by blind / visually impaired persons | 3b | C | - |
| CBE because of mammographic / sonographic lesion | 5 | D | ++ |
| CBE in combination with imaging | 1a | A | ++ |

* May increase breast awareness

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Assessment of Breast Symptoms or Lesions

| | Oxford | | |
|---|--------|----|-----|
| | LoE | GR | AGO |
| ▪ Clinical examination | 3b | B | ++ |
| ▪ Mammography | 1b | A | ++ |
| ▪ Tomosynthesis*** | 2a | B | + |
| ▪ Contrast-enhanced mammography (alone or as adjunct) | 2a | B | + |
| ▪ Sonography | 2b | B | ++ |
| ▪ Elastography (shear-wave) * | 2b | B | + |
| ▪ Automated 3D-sonography | 3b | B | +/- |
| ▪ MRI** | 2b | B | + |
| ▪ Minimally invasive biopsy | 1b | A | ++ |

* Adjunct assessment
** If clinical examination, mammography and sonography incl. needle biopsy do not allow a clear assessment
*** Replacement of additional FFDM with SM

Combined DM + DBT + US + MRI

1. Mariscotti G, Houssami N, Durando M, et al. Accuracy of mammography, digital breast tomosynthesis, ultrasound and MR imaging in preoperative assessment of breast cancer. Anticancer Res. 2014 Mar;34(3):1219-25.

US-Axilla +FNA/CNB

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Pre-therapeutic Assessment of Breast

| | Oxford | | |
|---|--------|----|-----|
| | LoE | GR | AGO |
| ▪ Clinical examination | 5 | D | ++ |
| ▪ Mammography (completion of the imaging) | 2b | B | ++ |
| ▪ + Tomosynthesis (DBT)*** | 2b | B | + |
| ▪ Contrast-enhanced mammography (alone) adjusted with regards of radiation sensitivity of patient and availability* | 2a | B | + |
| ▪ Sonography (breast) | 2b | B | ++ |
| ▪ MRI* | 1b | A | + |
| ▪ Minimally invasive biopsy** | 1b | A | ++ |
| ▪ Breast-CT | 4 | D | - |
| ▪ Axillary PET (PET-CT, PET-MR) | 2b | B | - |

* MRI- or CEM guided vacuum biopsy is mandatory in case of MRI- or CEM detected additional lesions (in house or with cooperations).

Individual decision for patients at high familiar risk, with dense breast (density C / D), lobular invasive tumors, suspicion of multilocular disease.

** Histopathology of additional lesions if relevant for treatment

*** Replacement of additional FFDM with SM

Combined DM + DBT + US + MRI

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US+FNA/CNB

1. Evans A, Trimboli RM, Athanasiou A et al. Breast ultrasound: recommendations for information to women and referring physicians by the European Society of Breast Imaging. European of Breast Imaging (EUSOBI) , with language review by Europa Donna-The European Breast Cancer Coalition. *Insights Imaging.* 2018 Aug;9(4):449-461. doi: 10.1007/s13244-018-0636-z. Epub 2018 Aug 9.

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MRT

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Pre-therapeutic Assessment Axilla

| | Oxford | | |
|---|-----------------|----|-----|
| | LoE | GR | AGO |
| ▪ Clinical examination | 5 | D | ++ |
| ▪ Mammography | 2b | B | - |
| ▪ + Tomosynthesis*** | 2b | B | - |
| ▪ CEM (alone) after unclear resection (Rx) if available | 2a | B | - |
| ▪ Ultrasound (Axilla#) | 2a [#] | B | ++ |
| ▪ MRI | 1b | A | + |
| ▪ CNB Axilla, if suspicious LN and marking of the node if TAD planned ≤3 susp. LK | 2b | B | ++ |
| ▪ Breast-CT | 4 | D | - |
| ▪ PET CT / MRI for axillary LN | 2b | B | - |

*** Replacement additional DM through SM

US-Axilla +FNA/CNB

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Pre-therapeutic Staging

| Oxford | | |
|--------|----|-----|
| LoE | GR | AGO |
| 5 | D | ++ |
| 2a | B | + |
| 2b | B | + |
| 5 | C | +/- |
| 5 | D | +/- |
| 2a | B | + |
| 2b | B | +/- |
| 4 | C | +/- |

- History and clinical examination

Only in case of high metastatic potential and/or symptoms and/or indication for (neo-) adjuvant chemotherapy and/or antibody-therapy:

- CT scan of thorax / abdomen / pelvis
- Bone scan
- Chest X-ray
- Liver ultrasound
- Further investigation in case of additional suspicious lesions (e.g. liver-MRI, CEUS*, biopsy etc.)
- FDG-PET or FDG-PET-CT** FDG-PET-MRI**
- Whole body MRI

* Contrast enhanced ultrasound

** especially in patients with high tumor stage (III) if available

Statement: history and physical examination

1. GCP

Statement: high metastatic potential / symptoms

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