Guidelines Breast
Version 2017.1

Early Detection and Diagnosis

Early Detection and Diagnosis

- **<u>Versions 2005–2016:</u>**
  Albert / Blohmer / Fersis / Junkermann / Maass / Scharl / Schreer

- **<u>Version 2017</u>:**
  Albert / Müller-Schimpfle

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Version 2017.1

Early Detection Mammography

Age	Interval	Oxford LOE /	Oxford GR	AGO
< 40	na	-	-	- -
40–49	12–24	1b	B	+
50–69*	24	1a	A	++
70–74	24	1a	A	++
>75**	24	4	C	+

*National Mammography-Screening-Program
**health status + life expectacy more than 10 years

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Further Information

References

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Breast Cancer Mortality Reduction

Meta-Analyses	RR 95%CI
Independent UK Panel, 2012	
13-year metaanalysis	0.80 (0.73–0.89)
Cochrane Review, 2011	
Fixed-effect metaanalysis of 9 RCT-trials	0.81 (0.74–0.87)
As above, but excluding women <50 years	0.77 (0.69–0.86)
US Task Force, 2009	
Women 50–59 years	0.86 (0.75–0.99)
Women 60–69 years	0.68 (0.54–0.87)
Estimates weighted average	0.81
Canadian Task Force, 2011	
Women aged 50–69 years	0.79 (0.68–0.90)
Duffy et al., 2012	
Review of all trials and age groups	0.79 (0.73–0.86)

Breast Cancer Mortality Reduction

Meta-Analyses		RR (95%CI)
Case-Control Studies		
Broeders et al	Screening Mx	0.46 (0.4 – 0.54)
	Corr. for self selection	0.52 (0.42-0.65)
	Invited for screening	0.69 (0.57-0.83)
Incidence-based Mortality Studies		
Broeders et al	Screening Mx	0.62 (0.56-0.69)
	Invited to screening	0.75 (0.69-0.81)
Randomized Clinical Trials		
Gotsche and Jorgenson	Screening Mx	0.81 (0.74-0.87)

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Version 2017.1

Breast Cancer Mortality Reduction

Age Group (yrs)	NNS	
	Mortality Reduction 20%	40%
40 - 49	1770	753
50 - 59	1087	462
60 - 69	835	355

4 systematic reviews of 8 RCTs,
1 systematic review of 7cohort studies and metaanalysis of case-control studies

Oeffinger KC et al JAMA 2015;314

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References

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Breast Cancer Screening
ACS Guideline Update 2015

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American Cancer Society Guideline for Breast Cancer Screening, 2015
These recommendations represent guidance from the American Cancer Society (ACS) for women at average risk of breast cancer: women without a personal history of breast cancer, a suspected or confirmed genetic mutation known to increase risk of breast cancer (eg, *BRCA*), or a history of previous radiotherapy to the chest at a young age.
The ACS recommends that all women should become familiar with the potential benefits, limitations, and harms associated with breast cancer screening.

Recommendations

1.Women with an average risk of breast cancer should undergo regular screening mammography starting at age 45 years. (*Strong Recommendation*)
    1a. Women aged 45 to 54 years should be screened annually. *(Qualified Recommendation)*
    1b. Women 55 years and older should transition to biennial screening or have the opportunity to continue screening annually. *(Qualified Recommendation)*
    1c. Women should have the opportunity to begin annual screening between the ages of 40 and 44 years. *(Qualified Recommendation)*
2.Women should continue screening mammography as long as their overall health is good and they have a life expectancy of 10 years or longer. *(Qualified Recommendation)*
3.The ACS does not recommend clinical breast examination for breast cancer screening among average-risk women at any age. *(Qualified Recommendation)*

[a]A strong recommendation conveys the consensus that the benefits of adherence to that intervention outweigh the undesirable effects that may result from screening. Qualified recommendations indicate there is clear evidence of benefit of screening but less certainty about the balance of benefits and harms, or about patients' values and preferences, which could lead to different decisions about screening.[1]

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Version 2017.1

Breast-Cancer Screening- Viewpoint of the IARC Working Group

Method	Strength of Evidence
Reduces breast-cancer mortality in women 50-69 yr of age	Sufficient
Reduces breast-cancer mortality in women 70-74 yr of age	Sufficient
Reduces breast-cancer mortality in women 40-44 yr of age	Limited
Reduces breast-cancer mortality in women 45-49 yr of age	Limited
Detects breast cancer that would never have been diagnosed or never have caused harm if women had not been screened (overdiagnosis)	Sufficient
Reduces breast-cancer mortality in women 50-74 yr of age to an extent that its benefits substantially outweigh the risk of radiation-induced cancer	Sufficient
Produces short-term negative psychological consequences when the result is false positive	Sufficient
Has a net benefit for women 50-69 yr of age who are invited to attend organized mammographic screening programs	Sufficient

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Mammography-Screening
Women 40–49 Years

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Version 2017.1

RR (invited women)	**0.74**	**(95%CI 0.66-0.83)**
40–44 J	**0.83**	**(95%CI 0.67-1.00)**
45–49 J	**0.68**	**(95%CI 0.59-0.78)**
Participants	**0.71**	**(95%CI 0.62-0.80)**
NNS	**1252**	**(95%CI 958-1915)**

(1 live saved / 10 years screening)

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References

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Hellquist BN et al. Cancer 2011; 117(4) : 714-722

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Version 2017.1

Early Detection Sonography

	Oxford / LOE	AGO / GR	
➢ **Screening-Breast Sonography**	5	D	- -
➢ **Automated 3D-Sonography**	3b	C	- -
As an adjunct:			
➢ **Dense mammogram (density 3–4/composition C-D)**	2b	B	++
➢ **Elevated risk**	1b	C	++
➢ **Mammographic lesion**	2b	B	++
➢ **Second-look US (MRI-only detected lesions)**	2b	C	++

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References

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Early Detection
Clinical Examination

	Oxford LOE	AGO GR	
As stand alone procedure			
➢ Self-examination	1a	A	-*
➢ Clinical breast examination (CBE) by health professionals	3b	C	-*
➢ CBE because of mammo/sonographic lesion	5	D	++
CBE in combination with imaging	BCP		++

* 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	++
➢ Additional Tomosynthesis (vs spot compression)	3b	B	+
➢ **Sonography**	2b	B	++
➢ Elastography (shear-wave)	2a	B	+
➢ Automated 3D-sonography	3b	B	+/-
➢ **MRI***	2b	B	+/-
➢ **Minimally invasive biopsy**	1c	A	++

*** If clinical examination, mammography and sonography do not allow a definite diagnosis**

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Pretherapeutic Assessment and Staging

	Oxford / LOE / GR		AGO
➢ Clinical examination	5	D	++
➢ Mammography	2b	B	++
➢ Mammography + Tomosyntheses + Sonography	3b	B	+
added MRI	3b	B	-
➢ Sonography	2b	B	++
Axilla + FNP/CNB	2b	B	++
➢ MRI *	1b	B	+/-
➢ Minimally invasive biopsy**	1b	A	++

*** MRI-guided vacuum biopsy is mandatory in case of MRI-detected additional lesions. Individual decision for patients at high-risk, with dense breast (density 3-4/composition C-D), lobular invasive tumors, suspicion of multilocular disease. No reduction in reexcision rate.**

**** Histopathology of lesions if relevant for treatment**

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Further Information

References

MRI: Preoperative Staging

- **9 eligible studies (2 randomized trials; 7 comparative cohorts)**
- **3112 patients with BC**
- **MRI versus no-MRI:**
  - **Initial mastectomy 16.4% versus 8.1% [OR, 2.22 (P < 0.001); adjusted OR, 3.06 (P < 0.001)]**
  - **Re-excision after initial breast conservation 11.6% versus 11.4% [OR, 1.02 (P = 0.87); adjusted OR, 0.95 (P = 0.71)**
  - **Overall mastectomy 25.5% versus 18.2% [OR, 1.54 (P < 0.001); adjusted OR, 1.51 (P < 0.001)]**

N Houssami et al. Ann Surg 2013; 257

MRI: Preoperative Staging in Lobular Invasive Breast Cancer

- **766 patients with invasive lobular cancer (ILC)**
  - **Initial mastectomy: 31.1% versus 24.9% [OR, 1.36 (P = 0.056); adjusted OR, 2.12 (P = 0.008)]**
  - **Re-excision after initial breast conservation 10.9% versus 18.0% [OR, 0.56 (P = 0.031); adjusted OR, 0.56 (P = 0.09)]**
  - **Overall mastectomy 43.0% versus 40.2% [OR, 1.12 (P = 0.45); adjusted OR, 1.64 (P = 0.034)]**

N Houssami et al. Ann Surg 2013; 257

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Version 2017.1

MRI Sceening (High-risk) Benefit

- **Early detection of cancer cases additionally to conventional imaging**
- **Improved patient prognosis? (Mortality reduction? Reduction of interval cancers?)**

MRI Screening in Women with High Familiar Risk

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				MRT		Mammographie	
Autor	Hochrisiko / Mutation	Anzahl Frauen	Anzahl Karzinome	Sensitivität (%)	Spezifität (%)	Sensitivität (%)	Spezifität (%)
Kriege 2004	M	1909	50	80	90	33	95
Warner 2004	M	236	22	77	95	36	99
Hagen 2004	M	491	25	86	-	50	-
Leach 2005	H / M	649	35	94	77	40	93
Riedl 2007	H / M	327	28	50	98	85,7	92
Kuhl 2010	H / M	687	27	93	98,4	33	99,1
Rijnsburger 2010	M	594	97	77,4	89,7	41	-
Sardanelli 2011	H / M	501	52	91	97	50	-
Passaperuma 2012	M	496	57	90	97	19	97
Gareth 2014	H / M	649	139	93	63	60	-

Prospective study results for MRI screening in women with high familiar risk (H) and muatation carriers (M)

MRI Screening (High-risk) Problems

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Version 2017.1

MRI in addition to mammography	RR
False-positive MRI	**3,43–4,86**
Benign biopsies	**1,22–9,50**
Benign surgical biopsies (MARIBS)	**2**
False-negative MRI (MRISC)	**22%**

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Further Information

References

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MRI and DCIS

Study	No. Cases	Overall accuracy (%)	Sens. (%)	Spec. (%)
Gilles et al 1995	172	70	95	51
Westerhof et al 1998	63	56	45	72
Bazzocchi et al 2006	112	80	79	68
Kuhl et al 2007	75	-	88	-
Baur et al 2013	58	-	79,3	

„Negative breast MRI findings should not be considered a sure marker of benignancy.“

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Further Information

References

Early Detection and Diagnosis (2/19)

Further information and references:

Screened data bases:
- Pubmed 2013 - 2016
- Medline 2013 – 2016
- Cochrane 2013 - 2016

Guidelines:
- S3 Brustkrebsfrüherkennung
- S3 Diagnostik, Therapie, Nachsorge
- 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

Early Detection – Mammography (3/19)

Further information:

The aim of early detection and screening of breast cancer is to reduce the risk of dying from the disease.
Detecting invasive breast cancer at an early stage (Stage I-IIA) offers the chance of survival with less treatment impairement and better quality of life.
Professionals and women need to be infomed about the benefits and harms of cancer screening tests before making medical decisions. This includes clear and understandable information in absolute terms about false positives, false negatives, overdiagnosis and overtreatment. (IARC 2016, European Commission 2016, ACS 2015, USPSTF 2016)

Meta-analysis and reviews from randomised trials:
Conclusion of the meta-analysis of the Independen UK Panel on Breast Cancer Screening: "Considering the internal bias in the trials, which were done a long time ago, the relative risk reduction in breast cancer mortality from inivitation to mammography screening is estimated to be 20%."

Data from observational studies and registries:
The EUROCREEN Working Group has published their report about the impact of population-based screening with mammography on breast cancer in Europe. They conclude: "the best "European" estimate of of breast cancer reduction is 25-31% for women invited for screening, and 38-48% for women actually screened. The estimate of overdiagnosis range from 1-10%. The chance for saving a woman's life by population-based mammographic screening of appropriate quality is greater than that of over-diagnosis".
The population-based data from the United States (SEER-Cancer Statistics 1976 - 2009) showed an marked increase in early-stage breast cancer (DCIS and localised breast cancer) and a reduction of late-stage cancer of 37% compared with the prescreen trends.
Since 2006 mammography screening is offered to women age 50-69 in Germany within a population-based organised quality assured program in accordance with the European Guidelines for Quality Assurance in Mammography Screening.

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Breast Cancer Mortality Reduction (4/19)

No further information

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Breast Cancer Mortality Reduction (5/19)

No further information

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Breast Cancer Mortality Reduction (6/19)

No further information

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Breast Cancer Screening – ACS Guideline Update 2015 (7/19)

No further information

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Breast Cancer Ccreening – Viewpoint of the IARC Working Group (8/19)

No further information

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Mammography Screening Women 40–49 years (9/19)

Further information:

On the basis of randomized controlled trials there is evidence of a 26% mortality reduction. The only one especially designed for this age group ("Age-Trial") achieved a mortality reduction of 17% for those invited and 24% for those participating. These results were not yet statistically significant (95% CI, 0.66-1.04)), because the follow-up time was to short for this young age group. Recently a significant reduction in breast cancer mortality in the first 10 years after diagnosis as noted in the intervention group compared with the control group (RR 0.75, CI 0.58-0.97), but not thereafter. The data have been underlined by study results of several service screening studies (Moss 2015)

To estimate overdiagnosis within the "Age-Trial" Markov-modelling was performed and yielded the following results (Gunsoy N, 2012): "The sensitivity of mammography for invasive and in-situ breast cancers was 90% (95% CI, 72-99) and 82% (43-99), respectively. The screen-detectable mean sojourn time of preclinical non-progressive and progressive in-situ cancers was 1.3 (0.4-3.4) and 0.11 (0.05-0.19) years, respectively, and 0.8 years (0.6-1.2) for preclinical invasive breast cancer. The proportion of screen-detected in-situ cancers that were non-progressive was 55% (25-77) for the first and 40% (22-60) for subsequent screens. In our main analysis, overdiagnosis was estimated as 0.7% of screen-detected cancers. A sensitivity analysis, covering a wide range of alternative scenarios, yielded a range of 0.5% to 2.9%." The authors conclude: "The extent of overdiagnosis due to screening in women aged 40-49 was small. Results also suggest annual screening is most suitable for women aged 40-49 in the United Kingdom due to short cancer sojourn times."

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Early Detection Sonography (10/19)

Further information:

The arguments against hand held ultrasound (HHUS) use as stand alone screening modality are reproducibility, high false-positive rate, low ppv for biopsy, inability to detect most DCIS cases, operator dependency and lack of quality assurance.

There is no evidence that evaluated the comparative effectiveness or diagnostic accuracy of screening breast ultrasound as an adjunct to mammography among average-risk women aged 50 years and over (Gartlehner 2013, Health Quality Ontario 2016).
Immature but interesting data are the first results after 1 year of the RCT (J-Start, Japan) revealing a high sensitivity for adjunct ultrasound (n 36859) vs mammography alone (36139) for women 40-49 years with average risk and annual screening exam (91·1%, 95% CI 87·2-95·0 vs 77·0%, 70·3-83·7; p=0·0004), significantly lower specificity (87·7%, 87·3-88·0 vs 91·4%, 91·1-91·7; p<0·0001) a higher cancer detection rate (184 [0·50%] vs 117 [0·32%], p=0·0003) and cancer at lower stage 0 and I (144 [71·3%] vs 79 [52·0%], p=0·0194) (Ohuchi 2015).

Supplemental breast ultrasound in the population of women with mammographically dense breast tissue (ACR 3,4 breast composition C-D (ACR 2013, Müller-Schimpfle 2016)) permits detection of small, otherwise occult, breast cancers (Schaefer 2010). Potential adverse impacts for women in this intermediate risk group are associated with an increased recall and biopsy rate (Nothacker 2009, Corsetti 2008,. Supplemental ultrasound is associated with increasing costs (Corsetti 2011). Modeling suggests for women between the ages of 50 and 74 years with heterogeneously or extremely dense breast tissue may avert only 0.4 breast cancer deaths but result in 354 additional biopsy recommendations per 1000 women screened compared with biennial screening mammography alone, with a cost-effectiveness ratio of $325 000 per quality-adjusted life-year gained (Sprague BL, et al 2015).

Automated ultrasound (ABUS/AVUS) might overcome the time-consuming and costly nature of hand-held, physician-performed whole-breast ultrasound but data are immature and limited. (Golatta 2013-2015, Choi 2014, Wojcinski 2013, Shin 2015, Brem 2015, Hellgren R 2016, Wilczek 2016, Ginger 2016) ,.

The IARC Working Group statement on ultrasound as an adjunct to mammography in women with dense breasts and negative results on mammography are: Inadequate evidence concerning breast cancer mortality reduction, limited evidence for breast cancer detection rate, inadequate evidence for a reduction of the interval cancer rate and sufficient evidence for an increase of FPs (Lauby-Secretan 2015, IACR 2016). This is in line with the recommendations of the U.S. Preventive Services Task Force (Melnikow 2016). Women need to be informed about their benefit and harms of ultrasound

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Early Detection Clinical Examination (11/19)

Further information:

In a large well performed randomized study no difference in breast cancer mortality emerged after 11 years of follow-up. The only difference was that women in the self-examination arm had nearly twice as many biopsies for benign lesions than women in the control arm (Thomas D 2002, Kosters J 2003). Therefore based on current evidence breast self-examination cannot be recommended anymore.
No randomized studies have been performed, where screening-examination by health professionals is compared to no screening. One Japanese case-control study suggests that examination by health professionals might reduce mortality from breast cancer. A randomized trial in Canada showed no difference in breast cancer mortality between a group of women offered clinical breast examination or mammography combined with clinical breast examination.
Nevertheless in asymptomatic women participating in mammography screening programs there is the risk of interval cancer development. This is the reason why in the US mammography screening is recommended in close connection with clinical examination. Recent data (Haakinson 2010) underscore this strategy.
The ACS updated Guideline 2015 does not recommend clinical breast examination for breast cancer screening among average-risk women at any age. The IARC Working Group states that there is inadequate evidence for a reduction of breast cancer mortality.

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Assessment of Breast Symptoms or Lesions (12/19)

Further information:

If clinical examination, mammography and ultrasound are not conclusive, morphological diagnosis based on biopsy material is warranted. MRI has a high sensitivity but a low specificity to allow definitive diagnosis.
Digital breast tomosynthesis (DBT) in the diagnostic setting (specifically, evaluation of mammographic abnormalities) has been shown to be at least as effective as spot compression views for workup of noncalcified abnormalities, including asymmetries and distortions. For DBT combined with 2-view full-field digital mammography (FFDM) radiation doses are elevated, at a maximum by a factor ~2 ¼ of that for FFDM alone. A replacement of FFDM with synthetic 2D-views reduces the breast dose approximately by half. Problems to be solved concern additional reading time, IT storage, overdiagnosis and cost effectiveness (Gilbert FJ, et al 2015).

Shear wave elastography (SWE) is a promising adjunct to greyscale ultrasound in differentiating benign from malignant breast masses adding improved specificity of breast US mass assessment without loss of sensitivity thus reducing the need for core biopsy by downstaging US-BIRADS III and IVa lesions. A systematic review and metaanalysis using shear-wave elastography combined with conventional ultrasound resulted in a sensitivity of 0.971 (95% Ci 0.941-0.986) and specificity of 0.801 (95% CI 0.733-0.856) (Liu B, 2015).

Accuracy studies demonstrate that automated ultrasound (ABUS/AVUS) is a potentially feasible way to overcome limitations of hand-held breast ultrasound such as operator dependence and non-reproducibility.

Minimally invasive biopsy allows definitive diagnosis in most cases at reduced expenditure.
In case of suspicious microcalcifications extensively distributed in mammography several percutaneous biopsies should be performed before deciding upon mastectomy.

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Pretherapeutic Assessment of Lesion Extension and Staging (13/19)

Further information:

Sonography corresponds better than mammography with the pathological tumour size of the invasive component of breast tumours. Mammography delineates the in situ component better if microcalcifications are present. In these cases magnification mammography is warranted. MRI is the most sensitive method for both invasive and non- invasive tumours, but lacks specificity. Thus MRI findings should be verified by percutaneous biopsy before definite treatment.
A recent prospective study examined the accuracy of of digital breast tomosynthesis (DBT) and magnetic resonance imaging (MRI) added to digital mammography (DM) and ultrasound (US) in the preoperative assessment of breast cancer. DBT had higher sensitivity than DM (90.7% vs. 85.2%). Combined DM and DBT with US yielded a 97.7% sensitivity; despite high sensitivity of MRI (98.8%), the addition of MRI to combined DM with DBT and US did not significantly improve sensitivity. Overall accuracy did not significantly differ between MRI and DM with DBT and US (92.3% vs. 93.7%). Breast density affected sensitivity of DM and DBT (statistically significant difference for DM), not MRI.
The authors concluded that there is little gain in sensitivity and no gain in overall accuracy, by performing MRI for patients who have been evaluated with DM with DBT and US (Mariscotti G et al 2014).

Axillary ultrasound is recommended for pretherapeutic assessment to guide axillary surgery (Feng Y et al 2015). Elastography of lymph nodes might add prognostic information additional to that provided by conventional preoperative tumor assessment and staging. A general recommendation for the use of lymph node elastography cannot be given as data on quality assurance is lacking.

MRI for preoperative staging may be helpful in individual cases (high-risk women, multifocality/ multicentricity demonstrated at conventional imaging and pathologically proven, invasive lobular cancer with inconclusive findings at conventional imaging), but considering the present evidence no general recommendation can be given for preoperative MRI in patients before breast conservation in both invasive and non invasive cancer.

In case of large areas of highly suspicious microcalcifications on mammography several percutaneous biopsies to define tumour size should be performed before deciding upon mastectomy.

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Combined DM + DBT + US + MRI

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MRI: Preoperative Staging (14/19)

No further information

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MRI Preoperative Staging in Lobular Invasive Breast Cancer (15/19)

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MRI Screening (High-risk) – Benefit (16/19)

No further information

No references

MRI Screening in Women with High Familiar Risk (17/19)

Further information:

Six prospective multicentre studies and further systematic reviews showed that additional use of MRI increased the sensitivity significantly and that cancers could be detected at a better stage. Overall sensitivity levels ranged from 77% - 100%. About 33% of malignancies were detected by MRI alone, about 11% by mammography alone and only 3% by ultrasound alone. Therefore MRI should be the first imaging method used for intensified screening in high-risk women. It is still unclear whether early detection by MRI will translate into improved disease-free and overall survival.

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MRI Screening (High Risk) Problems (18/19)

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MRI and DCIS (19/19)

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