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Guidelines Breast
Version 2021.1D

FORSCHEN
LEHREN
HEILEN

Diagnostik und Therapie früher und fortgeschrittener Mammakarzinome

Früherkennung und Diagnostik



Früherkennung und Diagnostik

- **Versionen 2005–2020:**
**Albert / Blohmer / Fallenberg / Fersis / Junkermann /
Maass / Müller-Schimpfle / Scharl / Schreer**
- **Version 2021**
Fallenberg / Gerber

Screened data bases

Pubmed	2018 - 2020
Medline	2018 - 2020
Cochrane	2018 - 2020

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 DGOG 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

Früherkennung bei asymptomatischen Frauen durch Mammographie

Alter	Intervall (Monate)	Oxford		AGO
		LOE	GR	
< 40	na	-	-	--
40-44	na	1b	B	-
45-49	24-36	1a	B	+ [#]
50-69*	24	1a	A	++
70-74	24	1a	A	+ [#]
> 75**	24	4	C	+/- [#]

* Nationales Mammographie-Screening-Programm

** Abhängig von Gesundheitszustand + Lebenserwartung mehr als 10 Jahre

[#] Cave: rechtfertigende Indikation ist notwendig

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<http://www.cancer.org/acs/groups/content/documents/document/acspc-046315.pdf>. Zugriff am 11. August 2016
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Früherkennung bei asymptomatischen Frauen Tomosynthese

	Oxford		
	LOE	GR	AGO
Digitale Tomosynthese (DBT+DM oder SM)*	1a	B	+
Ersatz der DM durch synthetische MG+DBT **	2a	B	++

Es muss immer auch der komplette Datensatz der Tomosyntheseschichten zur Beurteilung zur Verfügung stehen, die alleinige synthetische Mammographie ist nicht ausreichend

- Sign. höhere Sensitivität, heterogene Spezifität und höhere Kosten [Gerät, Befunder, Archivierung] der digitalen Brust-Tomosynthese (DBT) im Vgl. zur digitalen Mammographie (DM)
- Dosisreduktion durch Berechnung einer synthetischen Mammographie (SM) statt DM
- ** Evaluation für D in randomisierter prospektiver Studie (TOSYMA)

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Brustkrebs Mortalitätsreduktion	
Metaanalysen	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)
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)
Duffy et al, 2020 Review of 549,091 Women (30% eligible Swedish screening population)	0.59 (0.51-0.68) mortality 0.75 (0.66-0.84) advanced BC

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Brustkrebs Mortalitätsreduktion		
Metaanalyses		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)
ECIBC		
	Screening MX	
	45-49	0.88 (0.76 - 1.02)
	50-69	0.77 (0.66 - 0.90)
	70-75	0.77 (0.54 - 1.09)

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Brustkrebsinzidenz und Mortalität

- Annual incidence of breast cancer and mortality in the EU (GLOBOCAN 2012)

Age	Incidence/1000	Mortality/1000
40 to 44	1,2	0,1
45 to 49	1,7	0,2
50 to 69	2,7	0,5
70 to 74	3,0	0,8

From: <http://gco.iarc.fr/>

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Mammographie-Screening Vor- und Nachteile

Grundgesamtheit: per /= 10.000 gescreente Frauen über 10 Jahre
Breast Cancer Surveillance Consortium Registry Data

Lebensjahr	40-49	50-59	60-69	70-74
Vermiedene Brustkrebstodesfälle (CI95%)	3 (0-9)	8(2-17)	21 (11-32)	13 (0-32)
Falsch-positive Fälle (n)	1212	932	808	696
Brustbiopsien (n)	164	159	165	175
Falsch-negative Fälle (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

Früherkennung (normales Risiko) Sonographie /MRT

	Oxford		
	LoE	GR	AGO
▪ Screening-Mammasonographie alleine	5	D	--
▪ Autom. 3D-Sonographie	3a	C	--
▪ Mammasonographie als Ergänzung bei:			
▪ Dichtem Parenchym (inhomogen dicht, extrem dicht)	2a	B	++
▪ Erhöhtem Risiko	1b	C	++
▪ Mammographischer Läsion	2b	B	++
▪ Zur Abklärung susp. Läsionen im MRT	2b	C	++
▪ MRT bei neg. MG und extrem dichter Brust* 50-75 LJ	1b	B	+

* Definition von extrem dicht entspricht BIRADS-Dichtekategorie D inhomogen dicht Kategorie C nach ACR BI-RADS-Atlas 5. ed. 2013

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Recommendations International

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MRI-Screening:

1. M. F. Bakker, S. V. de Lange, R. M. Pijnappel, et al (2019). "Supplemental MRI Screening for Women with Extremely Dense Breast Tissue." *N Engl J Med* 381(22): 2091-2102.
2. Comstock CE, Gatsonis C, Newstead GM, Snyder BS, Gareen IF, Bergin JT, et al. Comparison of Abbreviated Breast MRI vs Digital Breast Tomosynthesis for Breast Cancer Detection Among Women With Dense Breasts Undergoing Screening. *JAMA : the journal of the American Medical Association*. 2020;323(8):746-56.
3. Mann RM, Kuhl CK, Moy L. Contrast-enhanced MRI for breast cancer screening. *J Magn Reson Imaging*. 2019.

Früherkennung

Klinische Untersuchung (clinical breast examination; CBE)

	Oxford		
	LoE	GR	AGO
Als alleinige Untersuchung			
▪ Selbstuntersuchung (BSE)	1a	A	-*
▪ Klinische Brust-Untersuchung (CBE) (außerhalb der Krebsfrüherkennungsuntersuchung (KFU))	1a	C	-*
▪ Klinische Brust-Untersuchung (CBE) (im Rahmen der KFU)	1a	B	++
▪ Medizinisch-taktile Untersuchung durch Blinde/Sehbehinderte	3b	C	-
CBE wegen klinisch-/mammo-/sonographischer Läsion	5	D	++
CBE in Kombination mit Bildgebung	1a	A	++

* Kann Brust-Bewußtsein erhöhen

1. Bancej C, Decker K, Chiarelli A, et al. Contributions of clinical breast examination to mammography screening in the early detection of breast cancer, J Med Screen 2003; 10: 16-21
2. Haakinson DJ, Stucky CCH, Dueck AC, et al. A significant number of women present with palpable breast cancer even with a normal mammogram within 1 year. Am J Surg 2010; 200: 712-718
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4. Kusters J, Gotzsche P. Regular self-examination or clinical examination for early detection of breast cancer, The Cochrane Database of Systematic Reviews 1 2003.
5. Oestreicher N, White E, Lehman C, et al., Predictors of sensitivity of clinical breast examination (CBE), Breast Cancer Res and Treat 2002; 76: 73-81
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7. Thomas D, Gao D, Ray R, et al. Randomized trial of breast-self-examination in Shanghai: Final results, J Nat Cancer Inst 2002; 94 (19): 14445-1457
8. Ngan TT, Nguyen NTQ, Van Minh H, Donnelly M, O'Neill C. Effectiveness of clinical breast examination

as a 'stand-alone' screening modality: an overview of systematic reviews. *Bmc Cancer*. 2020;20(1):1070.

9. Lux MP, Emons J, Bani MR, et al: Diagnostic Accuracy of Breast Medical Tactile Examiners (MTEs): A Prospective Pilot Study. Wunderle M, Sell C, Preuss C, Rauh C, Jud SM, Heindl F, Langemann H, Geyer T, Brandl AL, Hack CC, Adler W, Schulz-Wendtland R, Beckmann MW, Fasching PA, Gass P. *Breast Care (Basel)*. 2019 Mar;14(1):41-47. doi: 10.1159/000495883. Epub 2019 Jan 30

Abklärung von Symptomen

	Oxford		
	LoE	GR	AGO
▪ Klinische Untersuchung	3b	B	++
▪ Mammographie	1b	A	++
▪ Tomosynthese***	2b	B	+
▪ Alleine oder zus. Kontrastmittelmammographie	2a	B	+
▪ Sonographie	2b	B	++
▪ Elastographie (Shear wave)*	2b	B	+
▪ Automat. 3D-Sonographie	3b	B	+/-
▪ Minimalinvasive Biopsie	1b	A	++
▪ MRT**	3a	B	+

* Zusatzuntersuchung
 ** Wenn klinische, mammographische und sonographische Diagnostik inkl. Nadelbiopsie keine endgültige Diagnose erlauben.
 ***Ersatz der DM durch synthetische Mammographie (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

1. Diepstraten SC, Sever AR, Buckens CFM, et al. Value of preoperative ultrasound guided lymphnode biopsy for preventing completion axillary lymphnode dissection in breast cancer: a systematic review and meta-analysis. Ann Surg Oncol 2014;21:51-59
2. Evans A, Rauchhaus P, Whelehan P, et al. Does shear wave ultrasound independently predict axillary lymph node metastasis in women with invasive breast cancer? Breast Cancer Res Treat. 2013 Dec 4. [Epub ahead of print]
3. Feng Y, Huang R, He Y, et al. Efficacy of physical examination, ultrasound, and ultrasound combined with fine-needle aspiration for axilla staging of primary breast cancer. Breast Cancer Res Treat. 2015 Feb;149(3):761-5. doi: 10.1007/s10549-015-3280-z. Epub 2015 Feb 10.
4. 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

1. Mann RM, Loo CE, Wobbes T et al The impact of preoperative MRI on the re-excision rate in invasive lobular carcinoma of the breast. Breast Cancer Res Treat 2010; 119: 415-422
2. Houssami N, Turner R, Morrow M. Preoperative magnetic resonance imaging in breast cancer: meta-analysis of surgical outcomes. Ann Surg. 2013 Feb;257(2):249-55.
3. Debold M, Abramian A, Nemes L, et al. Who may benefit from preoperative MRI? A single-center analysis of 1102 consecutive patients with primary breast cancer. Breast Cancer Res Treat 2015;153(3):531-537
4. Arnaut A, Catley C, Booth CM, et al. Use of preoperative Magnetic Resonance Imaging for breast cancer: A Canadian population-based study. JAMA Oncol 2015;1(9):1238-1250
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6. Houssami N, Turner R, Macaskill P, et al. An individual person data meta-analysis of preoperative magnetic resonance imaging and breast cancer recurrence. J Clin Oncol 2014;32(5):392-401
7. Vos EL, Voogd AC, Verhoef C, et al. Benefits of preoperative MRI in breast cancer surgery studied in a large population-based cancer registry. Br J Surg 2015;102(13)1649-1657
8. Lehman CD, Lee JM, DeMartini WS, et al. Screening MRI in women with a personal history of breast cancer. J Natl Cancer Inst 2016;108(3)
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- 11.El Sharouni M, Postma EL, Menezes GLG et al. High prevalence of MRI-detected contralateral and ipsilateral malignant findings in patients with invasive ductolobular breast cancer: Impact on surgical management. Clin Breast Cancer. 2016 Aug;16(4):269-75.
- 12.Vriens BE, de Vries B, Lobbes MB, et al. Ultrasound is at least as good as magnetic resonance imaging in predicting tumour size post-neoadjuvant chemotherapy in breast cancer. Eur J Cancer. 2016 Jan;52:67-76.
- 13.Health Quality Ontario. Magnetic Resonance Imaging as an Adjunct to Mammography for Breast Cancer Screening in Women at Less Than High Risk for Breast Cancer: A Health Technology Assessment. Ont Health Technol Assess Ser. 2016; Nov 1;16(20):1-30
14. Lobbes MB, Vriens IJ, van Bommel AC, et al. Breast MRI increases the number of mastectomies for ductal cancers, but decreases them for lobular cancers. Breast Cancer Res Treat. 2017;162:353-364.
- 15.Houssami N, Turner RM, Morrow M. Meta-analysis of pre-operative magnetic resonance imaging (MRI) and surgical treatment for breast cancer. Breast Cancer Res Treat. 2017 Sep;165(2):273-283
- 16.Achim Wöckel, Jasmin Festl, Tanja Stüber, et al: Interdisciplinary Screening, Diagnosis, Therapy and Follow-up of Breast Cancer. Guideline of the DGCG and the DKG (S3-Level, AWMF Registry Number 032/045OL, December 2017) – Part 1 with Recommendations for the Screening, Diagnosis and Therapy of Breast Cancer. Geburtshilfe Frauenheilkd. 2018 Oct; 78(10): 927–948.

Reviews CESM:

1. Dromain, C., N. Vietti-Viola, and J.Y. Meuwly, Angiomammography: A review of current evidences. Diagn Interv Imaging, 2019.
2. Patel, B.K., M.B.I. Lobbes, and J. Lewin, Contrast Enhanced Spectral Mammography: A Review. Semin Ultrasound CT MR, 2018. 39(1): p. 70-79.
3. Tagliafico, A.S., et al., Diagnostic performance of contrast-enhanced spectral mammography: Systematic review and meta-analysis. Breast, 2016. 28: p. 13-9.
4. Zhu, X., et al., Diagnostic Value of Contrast-Enhanced Spectral Mammography for Screening Breast Cancer: Systematic Review and Meta-analysis. Clin Breast Cancer, 2018. 18(5): p. e985-e995.

CESM Originalarbeiten:

1. Luczynska, E., et al., Comparison of the Mammography, Contrast-Enhanced Spectral Mammography and

- Ultrasonography in a Group of 116 patients. *Anticancer Res*, 2016. 36(8): p. 4359-66.
2. Fallenberg, E.M., et al., Contrast-enhanced spectral mammography: Does mammography provide additional clinical benefits or can some radiation exposure be avoided? *Breast Cancer Res Treat*, 2014. 146(2): p. 371-81.
 3. Tennant, S.L., et al., Contrast-enhanced spectral mammography improves diagnostic accuracy in the symptomatic setting. *Clin Radiol*, 2016. 71(11): p. 1148-55.
 4. Fallenberg, E.M., et al., Contrast-enhanced spectral mammography vs. mammography and MRI - clinical performance in a multi-reader evaluation. *Eur Radiol*, 2017. 27(7): p. 2752-2764.
 5. Jochelson, M.S., et al., Comparison of screening CEDM and MRI for women at increased risk for breast cancer: A pilot study. *Eur J Radiol*, 2017. 97: p. 37-43.
 6. Kim, E.Y., et al., Diagnostic Value of Contrast-Enhanced Digital Mammography versus Contrast-Enhanced Magnetic Resonance Imaging for the Preoperative Evaluation of Breast Cancer. *Journal of breast cancer*, 2018. 21(4): p. 453-462.
 7. Patel, B.K., et al., Value Added of Preoperative Contrast-Enhanced Digital Mammography in Patients With Invasive Lobular Carcinoma of the Breast. *Clin Breast Cancer*, 2018. 18(6): p. e1339-e1345.
 8. Xing D, Lv Y, Sun B, Xie H, Dong J, Hao C, et al. Diagnostic Value of Contrast-Enhanced Spectral Mammography in Comparison to Magnetic Resonance Imaging in Breast Lesions. *Journal of computer assisted tomography*. 2019;43(2):245-51.

Prätherapeutische Mamma- und Axilladiagnostik

	Oxford		
	LoE	GR	AGO
▪ Klinische Untersuchung	5	D	++
▪ Mammographie	2b	B	++
▪ + Tomosynthese***	2b	B	+
▪ Kontrastmittelmammographie (alleine oder zusätzlich)	2a	B	+
▪ Sonographie (Mamma und Axilla)	2b	B	++
▪ MRT*	1b	B	+
▪ Minimalinvasive Biopsie Mamma** (CNB, VAB)	1b	A	++
▪ Axilla CNB, wenn auffälliger LK-Befund	2b	B	++
▪ Mamma-CT	5	D	-

* Möglichkeit der MRT-gestützten Biopsie (in domo oder im Rahmen einer Kooperation). MRT erwägen bei hohem familiärem Risiko, eingeschränkter Beurteilbarkeit in MG & US (Beurteilbarkeit C/D), invasiv lobulärem Karzinom. Keine Reduktion der Nachresektionsrate.
 ** Histologische Sicherung von Zusatzbefunden im Fall therapeutischer Relevanz.
 *** Ersatz der DM durch synthetische Mammographie (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.
2. Campanino PP, Ruggieri C, Regini E, 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.

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with fine-needle aspiration for axilla staging of primary breast cancer. *Breast Cancer Res Treat*. 2015 Feb;149(3):761-5. doi: 10.1007/s10549-015-3280-z. Epub 2015 Feb 10.

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Biopsie

1. Chan KY, WiseberdFirtell, J, Jois HSR, et al. Localisation techniques for guided surgical excision of non-palpable breast lesions. *Cochrane Database of Systematic reviews* 2015;vol 12
2. Lourenco AP, Mainiero MB Incorporating imaging into the locoregional management of breast cancer. *Semin Radiat Oncol* 2016;26(1)
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5. Sogani J, Mango VL, Keating D, Sung JS, Jochelson MS. Contrast-enhanced mammography: past, present, and future. *Clin Imaging*. 2021;69:269-79.

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4. Fallenberg, E.M., et al., Contrast-enhanced spectral mammography vs. mammography and MRI - clinical performance in a multi-reader evaluation. *Eur Radiol*, 2017. 27(7): p. 2752-2764.
5. Jochelson, M.S., et al., Comparison of screening CEDM and MRI for women at increased risk for breast cancer: A pilot study. *Eur J Radiol*, 2017. 97: p. 37-43.
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7. Patel, B.K., et al., Value Added of Preoperative Contrast-Enhanced Digital Mammography in Patients With Invasive Lobular Carcinoma of the Breast. *Clin Breast Cancer*, 2018. 18(6): p. e1339-e1345.
8. Gluskin J, Rossi Saccarelli C, Avendano D, Marino MA, Bitencourt AGV, Pilewskie M, et al. Contrast-Enhanced Mammography for Screening Women after Breast Conserving Surgery. *Cancers (Basel)*. 2020;12(12).
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10. González-Huebra I, Malmierca P, Elizalde A, Etxano J, Vejborg I, Uhlenbrock D, et al. The accuracy of titanium contrast-

enhanced mammography: a retrospective multicentric study. *Acta Radiol.* 2020;61(10):1335-42.

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14. Schünemann HJ, Lerda D, Quinn C, Follmann M, Alonso-Coello P, Rossi PG, et al. Breast Cancer Screening and Diagnosis: A Synopsis of the European Breast Guidelines. *Annals of Internal Medicine.* 2020;172(1):46-56.

Sensitivitäten CESM (contrast enhanced spectral Mammography)						
Author	n	MG	CESM	MRI	US	Analyse
Dromain 2011	110	78	92			Per patient
Fallenberg 2014	118	77.9	94.7			Per patient
Mokhtar 2014	60	93.2	97.7			Per patient
Lobbes 2014*	113	96.9	100			Per patient
Perez 2015 ECR	98		78		66	Per lesion
Luczynska 2014	152	91	100			
Jochelson 2012	52	81 59	96 83	96 93		Per patient Per lesion
Fallenberg 2013	80	81	100	97		Per patient
Fallenberg 2016	155	81 55	94 72	95 76		Index Per Lesion
Lalji 2016*	199	93	96.9			Per patient 10 reader
Tennant 2016	100	84	95			
Luczynska 2016	116	90	100		92	
Xing 2019	235		91.5	91.5		Per lesion

CESM is comparable to MRI regarding index, a bit inferior for additional lesions

* Recall from Screening

CESM Originalarbeiten:

1. Luczynska, E., et al., Comparison of the Mammography, Contrast-Enhanced Spectral Mammography and Ultrasonography in a Group of 116 patients. Anticancer Res, 2016. 36(8): p. 4359-66.
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5. Jochelson, M.S., et al., Comparison of screening CEDM and MRI for women at increased risk for breast cancer: A pilot study. Eur J Radiol, 2017. 97: p. 37-43.
6. Xing D, Lv Y, Sun B, Xie H, Dong J, Hao C, et al. Diagnostic Value of Contrast-Enhanced Spectral Mammography in Comparison to Magnetic Resonance Imaging in Breast Lesions. Journal of computer assisted tomography. 2019;43(2):245-51.

Prätherapeutisches Staging

	Oxford		
	LoE	GR	AGO
▪ Anamnese und klinische Untersuchung	5	D	++
Nur bei hohem Risiko für Fernmetastasen und / oder Symptomen und / oder Indikation zur (neo-)adjuvanten Chemo-/Antikörpertherapie:			
▪ CT Thorax/Abdomen	2a	B	+
▪ Skelettszintigraphie	2b	B	+
▪ Röntgen-Thorax	5	C	+/-
▪ Leberzonographie	5	D	+/-
▪ Weiterführende Diagnostik je nach Befund (z.B. Leber-MRT/CEUS*/Biopsie etc.)	2a	B	+
▪ FDG-PET oder FDG-PET-CT**	2b	B	+/-
▪ Ganzkörper MRT	4	C	+/-

* Contrast enhanced ultrasound **vorzugsweise bei hohem Stadium (III), wenn verfügbar

Statement: history and physical examination

1. GCP

Statement: high metastatic potential / symptoms

1. Rutgers, EJ et al: Quality control in the locoregional treatment of breast cancer (2001) EJC 37: 447-453
2. Gerber B, Seitz E, Muller H et al: Perioperative screening for metastatic disease is not indicated in patients with primary breast cancer and no clinical signs of tumor spread. Breast Cancer Res Treat 82:29-37; 2003
3. Schneider C, Fehr MK, Steiner RA et al: Frequency and distribution pattern of distant metastases in breast cancer patients at the time of primary presentation Arch Gynecol Obstet. 2003 Nov;269(1):9-12.
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