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# Breast Ultrasound in Office Gynecology – Ten Years of Experience

## Ambulante Mammasonografie: 10 Jahre Erfahrung

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### Key words

- breast
- screening
- ultrasound
- malignancy

### Zusammenfassung

**Ziel:** Die Mammografie gilt als Goldstandard sowohl als Screeningmethode als auch bei Malignitätsverdacht zur Detektion von Brustkrebs. Ziel dieser Untersuchung war die Bewertung der Mammasonografie (BU) in Ergänzung zur Mamma Palpation in einer gynäkologischen Ambulanz.

**Material und Methoden:** BU wurde ergänzend zu allen Mamma Palpationsuntersuchungen in einer gynäkologischen Ambulanz durchgeführt. Die Ergebnisse aller BUs einer 10 Jahres-Periode wurden mittels der Personalnummer der Patientinnen mit dem dänischen Krebsregister und der dänischen Pathologie Datenbank korreliert. Alle neu diagnostizierten Mammakarzinome vom Zeitpunkt der BU bis zu 12 Monate danach wurden eingeschlossen.

**Ergebnisse:** Insgesamt wurden 3030 BU beider Mammae an insgesamt 1428 Frauen durchgeführt. Achtundzwanzig Mammakarzinome wurden bei 27 Patientinnen diagnostiziert. Mittels Palpation wurde kein Karzinom erfasst, welches nicht auch mit der BU detektiert wurde. Sechzehn der 28 Karzinome waren nicht palpabel (57%), BU detektierte 25/28 Karzinomen, was einer Sensitivität von 89% entspricht. Die Mammografie, die binnen 12 Monaten der Diagnosestellung durchgeführt wurde, war negativ bei 11 Patientinnen, was einer Rate von 44% nicht mittels Mammografie detektierten Karzinomen entspricht. Die Tumoren hatten im Mittel einen maximalen Durchmesser von 11 mm (4-30mm).

**Schlussfolgerung:** BU erwies sich als substanziale Hilfe zur Detektion von Mammakarzinomen. Die Sensitivität ist hoch und im Rahmen gynäkologischer Untersuchungen, bei denen nahezu immer Ultraschall eingesetzt wird, ist es nur natürlich, die Sonografie genauso zur Brustuntersuchung nutzen. Größere Untersuchungen zur Evaluation der Intraobservervariabilität Variabilität in der Detektion von Mammatumoren mittels Ultraschall müssen durchgeführt werden.

### Abstract

**Purpose:** Mammography in screening or on indication is regarded as the gold standard for breast examination to detect breast cancer. The present study was performed to evaluate breast ultrasound examination (BU) as a supplement to physical breast examination in a gynecological office setting.

**Materials and Methods:** BU was performed concomitantly with all physical breast examinations in a gynecological clinic. The results of all BUs during a 10-year period using the patients' personal numbers were crossed with the Danish Cancer Registry and the Danish Pathology Data Bank. All new breast malignancies registered from the date of BU and 12 months later were included.

**Results:** A total of 3030 BUs of both breasts was performed in 1428 women. Twenty-eight new breast malignancies were registered in 27 patients. Physical examination did not reveal any tumors not detected by ultrasound. Sixteen of the 28 malignancies were non-palpable (57%). BU detected 25 of these malignancies, thus yielding a sensitivity of 89%. Mammography performed within 12 months of the diagnosis was negative in 11 patients resulting in a rate of 44% of malignancies with a negative mammography result. The tumors measured an average of 11 mm (range 4 – 30 mm) using the largest diameter.

**Conclusion:** BU offers substantial help for the detection of breast cancer. The sensitivity is high, and in a gynecological setting where ultrasound is used for almost every consultation, it is natural to use the scanner for the breast examination. Larger studies with evaluation of interobserver variability for tumor detection by ultrasound are needed.

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## Introduction

Breast cancer is the most common cancer in women in Denmark with an incidence rate of 4132 new cases in 2006, the rate being 137/100000 women [1]. In the same year 383 cervical cancers were reported. Therefore, for every occurrence of cervical cancer, 10.8 breast cancers were found which gives a certain perspective for the gynecologist. The lifetime risk for breast cancer is 10% and women's concern for contracting this cancer is high. Physical breast examination is often performed in the gynecological office and often upon patient request. The sensitivity of physical breast examination for the detection of breast cancer has never been evaluated in a controlled study [2], and studies in which palpation is included with mammography disclose a sensitivity of only 60% compared with mammography [3, 4]. Bobo et al. [5] found that for every breast cancer detected by physical examination there were 23 false-positive results, thus yielding a positive predictive value of 4%. Therefore, physical examination is a very inaccurate method for screening for breast cancer and should not be recommended. Mammography is regarded as the gold standard for the detection of breast cancer. However, many patients prefer clinical examination or want to avoid radiation and the sometimes painful mammography procedure. Ultrasound examination is painless and free of radiation risk, and many studies have demonstrated a benefit of ultrasound when used as a supplement to mammography [6–8]. Ultrasound has, however, not been evaluated as a standalone screening method. A preliminary series has indicated that breast examination by ultrasound (BU) might be a reliable screening method for breast cancer [9]. This study was undertaken to evaluate the sensitivity of BU. The specificity of BU is not presented here since there was no consecutive registration of patients with normal findings at the regional breast surgery departments after referral under suspicion of cancer. The preliminary series is included in the present material.

## Materials and methods

### Patients

The gynecological clinic opened in 1997. Women seeking the gynecological clinic were after the gynecologic examination offered BU from the start. The offer was given to all women 40 years or older, to women making a special request for this examination, and to women at increased risk for breast cancer, i.e. with breast cancer in the immediate family or who had already been operated on for breast cancer. All patients signed written information explaining the known accuracy of breast ultrasound.

### Ultrasound equipment and examination technique

All ultrasound scans were performed with a near field probe. Until September 2001 an Aloka SSD-121 ultrasound machine was used. The near field probe was 7.5MHz. After September 2001, an Adara Sonoline with a 10MHz near field probe was used. From August 2007 a Sonoline G40 with a 10MHz near field probe was used. All scans were accompanied by a physical breast examination. The patient was placed in the supine position with the arms over the head. Both breasts were examined systematically in longitudinal and transverse planes and in the case of unclear pictures in radial planes from the

nipple. The probe was held in the right hand and the left was used for simultaneously palpation and also to flatten the tissue in front of the probe. A pedal was used to freeze pictures and take prints. Tumors and cysts were measured by electronic calipers. Positive findings were documented by prints. It took 4 to 6 minutes to perform a BU of both breasts. All scans were performed by the author who is a practicing gynecologist.

### Referrals

Tumors and not simple cysts were referred to breast surgery departments as suspicious or with positive findings. Not simple cysts were defined as cysts with broad septae or polyps. Tumors were echo-poor structures. They were all referred for triple test (mammography plus physical examination plus biopsy). An attempt was not made to discern between benign or malignant-looking structures or whether structures had blurred borders or cast shadows. They were all referred. Unclear findings were referred for supplementary mammography. Patients who wanted supplementary mammography were also referred for mammography. Simple cysts were not referred but the fluid was drained upon patient request and was sent for microscopy. Patients with clinical symptoms and no findings by ultrasound or physical examination were also referred to breast surgery departments. Despite the ability to choose a hospital in Denmark, breast patients are required to go to their regional breast surgery department due to the high patient load in these departments.

### Data collection

The study was approved by Datatilsynet (J.nr. 2002–41–2510) and received permission to cross the personal numbers in the clinic with the numbers in the Danish Cancer Registry (DCR) [1] and in the Danish Pathology Data Bank (DPDB) [10]. Ten-digit personal numbers are unique in Denmark. They are assigned at birth and used for life for all contact with authorities and for all medical registration. A personal number thus clearly identifies a citizen. It is composed of the person's birth date plus 4 digits. All cancers and precancerosis, like CIS, have to be reported by law to the DCR using the individual personal numbers and because breast cancer treatment is centralized the registration is regarded complete. The DCR has finished registration of all reported cancers up to the end of 2006. The DPDB is all Danish pathologists mutual, centralized registry, and it is updated currently. All pathologists in Denmark finalize every microscopic examination by registering the sample in the DPDB. Both benign and malignant diagnoses are included. Registration includes the patient's personal number, the date, and the site in the body from which the sample was taken. The DPDB data is also reported to the DCR in the case of malignancy. Since there is no breast cancer diagnosis without pathology, the registration of breast cancer is thus regarded complete.

The personal numbers of all BUs performed in the clinic from 1997 to the end of 2007 were crossed with the DCR and the DPDB to the end of 2008 for breast cancer. The date of 2007 was chosen to allow interval cancers within one year of BU to be registered. All records, diagnoses and procedures performed in the clinic have been stored electronically since the opening. A file with the personal numbers of the patients who underwent BU in the clinic from 1997 to the end of 2007 was provided to the DCR and DPDB in January 2009

and compared to the personal numbers of patients with a reported breast-related malignancy. Both cancers and carcinoma in-situ (CIS) were included. The dates and personal numbers of registered findings in the two registries were compared to the dates and personal numbers of the BUs in the clinic's records. Breast cancer or CIS diagnosed before BU in the clinic and more than 1 year after BU was excluded.

Interval cancers within a year are the gold standard when mammography screening is evaluated [2–4, 11–13]. A normal mammography performed within 12 months of diagnosis was defined as a false-negative mammography.

## Results



### Overall results

During this period a total of 1428 women underwent at least one BU. A total of 3030 BUs of both breasts was performed. Thirty new breast malignancy patients were registered from the day of BU and 12 months later. Two patients had disseminated disease after previous diagnosis of breast cancer and these 2 patients were excluded.

After exclusion, 28 new breast malignancies were registered in 27 patients (▶ **Table 1**). The age of the patients with a malignancy at BU was 62 years (mean) ranging from 37 to 82 years. Physical examination did not reveal any tumors not detected by ultrasound. 16 of the 28 malignancies were non-palpable (57%). Mammography information was not available for 9 patients and one patient rejected mammography. Ten tumors had a negative mammography result yielding a rate of at least 39% of tumors with a negative mammography result.

### Breast cancers found at BU

25 malignancies were seen, measured, and described by BU, resulting in a sensitivity of 89% for the detection of breast malignancies. The size of these 25 malignancies had a mean of 11 mm, ranging from 4 to 30 mm using the largest diameter as measured by ultrasound. 18 were found in the left breast and 7 in the right breast. The diagnosis was ductal carcinoma in 15 patients, lobular carcinoma in 7 patients, ductal CIS (a tumor of 7 mm in diameter) in 1 patient, tubular carcinoma in 1 patient, and a local malignant lymphoma in 1 patient. 13 of the malignancies detected by BU were non-palpable, corresponding to a rate of 52% non-palpable. The mammography result was only partly available in the study. The information is lacking for 9 patients. One patient rejected mammography. For the rest of the patients, mammography performed within 12 months of the diagnosis was considered. Mammography was negative in 11 patients, resulting in a rate of 44% of malignancies with a negative mammography result, and the rate might thus be higher.

### History of patients with delay in treatment

The history of some of the patients reveals a delay in treatment. The exact location of the tumor in question is of course considered.

Patient no. 2 was admitted with an 11-mm non-palpable tumor diagnosed by BU. The regional breast surgery department performed mammography, physical examination, and ultrasound where they failed to see the tumor. The department did not advise follow-up. The patient could palpate the tumor

herself 16 months later and was then referred again and operated on. The tumor had grown to more than 20 mm.

Patient no. 8 had felt her tumor for 4 years. She had been examined 3 times at the regional breast surgery department without being diagnosed. She had also followed the 2-year mammography screening program in her county. A negative biopsy was performed 4 months before she visited the clinic. At the time of BU the tumor measured 2 cm. A biopsy was taken at the clinic and a lobular carcinoma was diagnosed.

Patient no. 22 was admitted with a 4-mm non-palpable tumor detected by BU. The regional breast surgery department performed mammography, physical examination, and ultrasound with negative results. Follow-up was performed 6 months later with physical examination only. One year after the initial finding, the tumor was felt by the patient. The regional breast surgery department then diagnosed the tumor and mastectomy was performed.

Patient no. 24 had a 4-mm tumor detected by BU. The regional breast surgery department performed mammography, physical examination, and ultrasound with negative results. No follow-up was offered. The malignancy was diagnosed when the patient noted a growing cancerous lymph node.

Patient no. 26 had a 9-mm non-palpable tumor and was admitted to the regional breast surgery department. The referral was returned because the patient lived out of the region for the department in question. She was then admitted to another department where she underwent a physical examination. Two weeks after a normal physical examination, she underwent mammography, and biopsy was performed 2 weeks after physical examination. Surgery was carried out 8 weeks after the first BU which showed the tumor.

### History of patients for whom BU failed to detect malignancy

Three malignancies were not detected by BU in the clinic.

Patient no. 6 was admitted to the regional breast surgery department for suspicion of a tumor in the right breast. Mammography showed micro-calcifications in the left breast. Surgery was performed and the final diagnosis was CIS.

Patient no. 10 was admitted to the regional breast surgery department for suspicion of a tumor in the right breast. Mammography showed a tumor in the left breast.

Patient no. 21 had a normal BU. Screening mammography 4 months later showed micro-calcifications and she was operated on for CIS.

## Discussion



This study is not a randomized evaluation of BU as a screening method compared to other methods. It is a controlled study in which the DCR and DPDB are used as the final registration of malignancy.

It is also a quality evaluation of BU and physical examination in a gynecological office setting performed as a consecutive, prospective study of all breast examinations in the clinic.

The purpose of the examination is to detect breast malignancy, preferably at an early stage. It is the first study in which ultrasound is used as a preferred method and mammography as a supplementary investigation on indication.

In the present study BU had a sensitivity of 89%. Although the material is only of moderate size, this rate is rather high. In

**Table 1** Details of breast cancers included in the study.

patient no./ tumor no.	pathology date	age at pathology date	date of ultrasound	registered size of tumor at ultrasound	pathology diagnosis	side of malignancy	detected by ultrasound	palpation	mammography
1	11.2.1999	74	15.12.1998	11 × 8 mm	ductal carcinoma	left	yes	neg	? <sup>1</sup>
2	14.1.2008	73	24.8.2006	10 × 8 × 4 mm	ductal carcinoma	left	yes	neg	neg within a month
3	27.6.2008	40	12.9.2006	ductectasia 4 mm	ductal carcinoma	left	yes	neg	neg 8.1.7
4	9.10.2000	74	22.9.2000	9 × 7 × 6 mm	ductal carcinoma	left	yes	pos	? <sup>1</sup>
5	29.4.2008	82	7.4.2008	7,6 mm	ductal carcinoma	left	yes	neg	neg within a month
6	19.12.2007	48	8.11.2007		DCIS	left	no	neg	pos, referred for right side
7	20.2.1999	51	18.5.2004	13 mm	lobular carcinoma	right	yes	pos	? <sup>1</sup>
8	27.6.2007	63	15.6.2007	15 × 20 mm	lobular carcinoma	right	yes	pos	neg, screening program
9	1.9.2003	37	5.8.2003	13 × 12 × 11 mm	lobular carcinoma	right	yes	pos	neg, 7 months earlier
10	22.7.2004	63	5.3.2004		ductal carcinoma	left	no	neg	pos, referred for right side
11	28.8.2008	70	22.8.2008	7 × 5 mm	ductal carcinoma	right	yes	pos	neg within a month
12	6.5.2003	59	15.4.2003	10 mm	ductal carcinoma	left	yes	pos	neg within a month
13	3.12.2007	75	6.11.2007	9 mm	ductal carcinoma	left	yes	pos	? <sup>1</sup>
14	6.5.2005	68	19.4.2005	10 mm	ductal carcinoma	left	yes	neg	? <sup>1</sup>
15	6.9.2002	61	28.8.2002	7 mm	DCIS	left	yes	pos	? <sup>1</sup>
16	25.9.2000	62	8.9.2000	25 × 30 mm	ductal carcinoma	right	yes	pos	? <sup>1</sup>
17	25.2.2000	43	8.2.2000	10 mm	lobular carcinoma	left	yes	neg	pos
18	14.10.1999	73	21.9.1999	10 mm	ductal carcinoma	left	yes	pos	pos
19	22.7.2005	70	18.5.2005	10 × 7 × 6 mm	ductal carcinoma	left	yes	pos	pos
20	9.3.2005	77	25.2.2005	14 × 10 mm	lobular carcinoma	left	yes	pos	? <sup>1</sup>
21	22.9.2003	50	9.5.2003		ductal carcinoma	right	no	neg	pos, screening program
22 1	17.4.2002	53	11.3.2002	11 mm	lobular carcinoma	left	yes	neg	neg
22 2	18.3.2004	55	2.5.2003	4 mm	lobular carcinoma	left	yes	neg	neg
23	24.11.2006	72	19.5.2006	10 mm	malignant lymphoma	right	yes	neg	neg
24	26.6.2007	60	22.3.2005	4 mm	ductal carcinoma	left	yes	neg	neg
25	16.9.2003	60	4.1.2001	15 mm	ductal carcinoma	right	yes	neg	rejected by patient
26	21.1.2003	56	6.12.2002	9 × 5 mm	ductal carcinoma	left	yes	neg	? <sup>1</sup>
27	2.3.2001	60	30.1.2001	13 mm	lobular carcinoma	left	yes	neg	pos

<sup>1</sup> No information on mammography.

comparison, Rosenberg et al. [11] calculated the sensitivity of mammography screening to be 54–81%, increasing with age in a study of 183134 mammographies. Kerlikowske et al. [12] performed a similar study of 28271 women and calculated the sensitivity to be between 68–87%, also increasing with age. Carney et al. [13] found a sensitivity of 69%–83%, again positively correlated with age, in a mammography screening study of 463,372 women. Age was not an issue in the present study, but malignancy was detected in patients from 37 to 82 years old with a mean age of 62 years.

The most remarkable finding in the present study was that mammography was negative in 44% of the malignancies found by ultrasound. In addition, already detected and referred non-palpable tumors were not detected by the regional breast surgery department because mammography was regarded the gold standard (patients 2, 8, 22 and 24). The ultrasound equipment in the clinic was standard and not sophisticated. If tumors were not detected again at the regional breast surgery department, the reason is probably that mammography was the first choice and ultrasound was only the supplement which was not taken seriously. BU is not time-consuming. It was performed in 4–6 minutes in the clinic and it took only a little longer than the concomitantly performed physical examination.

BU failed to detect 3 malignancies. In 2 cases the patient was admitted with suspicion of a malignancy at another position in the breasts. In the 3<sup>rd</sup> case, BU was found to be normal. A screening mammography later revealed micro-calcifications. Micro-calcifications representing CIS with no tumor seems to be a problem for BU. CIS can in some cases be present as a tumor and be visualized by BU (patient 15). Data regarding the frequency with which CIS is displayed as a tumor on BU and on mammography is not available.

Physical examination was performed concomitantly with BU and 57% of the malignancies were non-palpable. In the group diagnosed by BU, 52% were non-palpable. These figures are similar to the findings in other studies [3–5, 14, 15]. Irwig et al. [16] found that only 1% of cancers evaluated by triple test were notified by physical examination only, being biopsy and mammography negative. Hou et al. [17] examined 935 high-risk women who were close relatives of women with breast cancer with mammography, physical examination and ultrasound. They found 21 breast cancers. Only 33% were detected by physical examination, compared to 52% by mammography and 90% by ultrasound. Regional breast surgery departments in Denmark still perform only physical examination during many visits for breast patients and also advocate physical examination in national guidelines.

The mean size of the malignancies seen by BU was 11 mm (range 4–30). Three tumors measured only 4 mm, and they could not be detected by mammography or by physical examination. Early detection might spare the patient lymphadenectomy and the subsequent complications, and also improve the prognosis. Therefore, the potential of ultrasound does not seem to be appreciated if BU is not included in every physical examination of the breasts.

In conclusion, BU offers substantial help for the detection of breast cancer. The sensitivity is high, and in a gynecological setting where ultrasound is used for almost every consultation, it is natural to use the scanner for the breast examination. Larger studies with evaluation of the interobserver variability for tumor detection by ultrasound are needed.

## Abbreviations

▼  
 BU: breast ultrasound  
 DCR: Danish Cancer Registry  
 DPDB: Danish Pathology Data Bank  
 CIS: carcinoma in-situ  
 MHz: megahertz

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