

Best practices for implementing ABUS

Breast care pathways – ABUS decision tree



Sites at a glance

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Hospital Universitario 12 de Octubre Madrid, Spain This paper reviews best practices for integrating ABUS into patient care across a variety of practice types in five European countries, including Greece, Germany, Turkey, Italy and Spain. This includes private breast centers, public hospitals, academic hospitals, and an obstetrics and gynecology practice that offers breast health and oncology care to patients.

Each case study outlines the breast care pathway – or ABUS decision tree – in relation to the country's breast cancer screening approach, guidelines, overall acceptance of screening, and resources. In each case, ABUS has been adopted as a key tool to improve early cancer detection, particularly among women with dense breasts. Many sites are already informing patients about their breast composition and the benefits of supplemental screening and using risk assessment models to personalize screening. This includes offering a supplemental 3D ABUS exam directly after a digital mammogram or 3D tomosynthesis exam.

Breast density reduces mammography sensitivity

Breast cancer remains the most common cancer amongst women across Europe, with an estimated 576,300 new cases in 2020.¹ In the "Position Paper on Screening for Breast Cancer" published in European Radiology, EUSOBI (European Society of Breast Imaging) attributes a 40% reduction in breast cancer mortality based on population-based screening.²

Mammography is the gold standard for screening; however, it does not work equally well for all women, particularly those who have dense breast tissue. In fact, studies show that mammography misses onethird of cancers in patients with dense breasts.³

The information described here is based on each of the practitioner's own opinions and on results that were achieved in his/her unique setting. Since there is no "typical" hospital and many variables exist, i.e. hospital size, case mix, etc., results may vary.



Improve cancer detection with ABUS

Results from multiple large scale screening ultrasound studies involving thousands of women demonstrate that ultrasound improves cancer detection as a supplement to mammography. The EASY Study (European Asymptomatic Screening Study) shows that it is feasible to implement 3D ABUS into a high-volume mammography center and increase the cancer detection rate while maintaining a low recall rate well within the recommendations of the European guidelines for quality assurance in breast cancer screening and diagnosis.⁴

Designed especially for screening, the sensitivity of the GE HealthCare Invenia[™] ABUS 2.0 is not affected by dense tissue, allowing the detection of non-calcified carcinomas that are obscured in mammography. Major advantages include providing a volumetric global visualization of the whole breast, and the exams are standardized and reproducible, enabling batch reading and double reading of 3D ABUS and allowing a comparison with previous volumes.⁵

EUSOBI guidelines: supplemental screening for breast density

EUSOBI recent guidelines recommend tailored screening programs that take the 'characteristics and personal wishes of individual women into account.' EUSOBI now additionally recommends that women should be informed about their breast density and the implications of having dense breasts. EUSOBI recommends that supplemental screening is recommended in women with extremely dense breasts – in particular, EUSOBI recommends where MRI screening is unavailable, ultrasound in combination with mammography may be used as an alternative.⁶

The recent introduction of the U.S. Food & Drug Administration (FDA) mandate to inform all women of their breast density in their mammography letters reinforces the global movement to enhance screening women with dense breasts and move away from a one-size-fits-all approach.

Why perform different exams?

Imaging techniques differ in the characteristics of cancers detected. This can be seen in everyday practice with mammography, ultrasound and MRI of the breast. Each imaging tool should be specifically used for its proven benefits and a combined approach can further characterize findings and improve sensitivity.

There is a significant breast cancer detection benefit when using screening ultrasound to supplement annual mammography in women with dense breasts. ABUS coupled with tomosynthesis provides optimization of sensitivity while reducing false positives.⁷ This combined approach is the most advantageous screening choice for most women with dense breasts.

Supplemental screening with Invenia ABUS 2.0 transforms breast care from reactive to proactive. Women whose breast cancer is detected at an early stage have a 90% or higher survival rate.⁸



Studies show that mammography misses **one-third** of cancers in patients with dense breasts.³

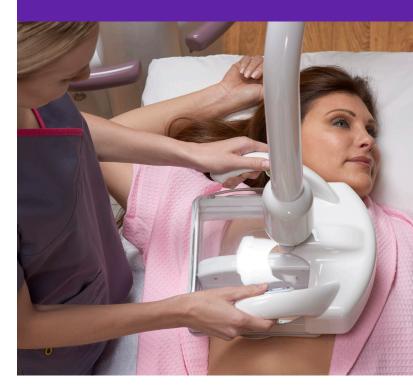


2.4 additional

cancers detected per 1000 women screened.⁴



Women whose breast cancer is detected at an early stage have a **90% or higher** survival rate.⁸



Dr. Athina Vourtsis, MD, PhD



Chief Scientific Advisor and Founder Athena Medical Athens, Greece

At a glance

Practice setting – Private breast imaging and women's health center
Department staffing – 7 radiologists, 8 technicians, 5 staff
Modalities – FFDM, DBT, ABUS, HHUS, MRI, AI density assessment, ABUS CAD, CAD for mammography
Patient volume – 10,000/year; 70% screening; 30% diagnostic
Coverage / reimbursement – Out of pocket / private insurance
Country guideline – ACR/ACS, Hellenic Breast Imaging Society
Risk stratification – Tyrer-Cuzick model

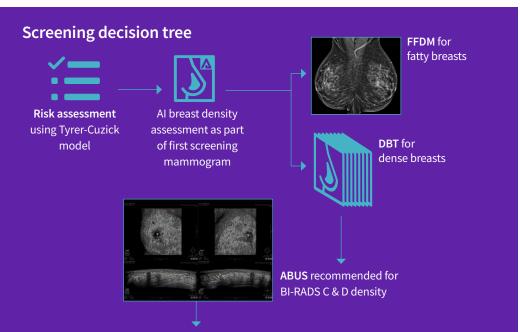
The site

Athena Medical in Athens, Greece is a private breast imaging center dedicated to the prevention and early detection of breast diseases. Offering the most advanced imaging technology for risk-stratified screening, combined with personalized attention from experienced radiologists, Dr. A. Vourtsis and staff at Athena Medical aim to complete all diagnostic assessments and tests in a single visit. The multidisciplinary practice provides comprehensive women's health services, including one stop breast clinic, gynecological, dermatology, cardiology, cardio-oncology and genetic counseling.

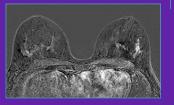
Care pathway for patients with dense breasts

In Greece, the limitations of mammography in women with dense breasts has been well acknowledged. Supplemental screening is suggested in women with heterogenously or extremely dense breasts that is performed either by breast radiologists or general radiologists.

Athena Medical performs 2D mammography, tomosynthesis (DBT), automated breast ultrasound (ABUS) hand-held ultrasound (HHUS) and breast MRI. All ABUS, 2D mammography and DBT examinations are double read. Biopsy of all BI-RADS[®] 4 and 5 lesions is followed. Quantitative density measurement and AI for 2D mammography and ABUS has been adopted.



Breast MRI screening is provided to high risk women in addition to mammography, regardless of breast density. MRI is also recommended for extremely dense breast (BI-RADS D).*



"Seeing 10,000 patients a year, we are detecting cancers seen only with ABUS that are not visualized on mammography and sometimes neither on DBT. Most commonly these cancers are presented as masses, without presence of microcalcifications or architectural distortion on DBT images."

"Due to the global visualization of the breast, ABUS is also an emerging modality for diagnostics and surgical planning. The coronal plane offers special value for surgical planning, due to better imaging of the segmental approach and the similar orientation as the patient is positioned for surgery."

Diagnostic decision tree

Athena Medical applies diagnostic ABUS in all women with dense breasts and women with clinical symptoms and in women under the age of 35 that come in for a breast ultrasound. Breast MRI is followed in women with BI-RADS 4 and 5 findings and in all newly diagnosed breast cancer for the evaluation of extent of disease.



Improving the patient and operator exam experience with Invenia ABUS

* Interval follow up recommended depending on risk and breast size: DBT + ABUS every year, MRI every 2 years

Dr. Alexander Henze, MD



Medical Director Frauenärzte Gesundheitszentrum Aschaffenburg Aschaffenburg, Germany

At a glance

Practice setting – OB/GYN practice (2 locations) offering breast care and oncology to public insured and private patients Department staffing – 5 Gynecologists, 20 MFAs Modalities – FFDM, ABUS, HHUS

Patient volume – 20,000 patients with public insurance, 2,000 private insured patients plus 6000 screening mammography exams

Coverage / reimbursement – Out of pocket for supplemental imaging with public insurance / private insurance reimbursed

Country guideline – Mammography Screening Program rules: Kooperationsgemeinschaft Mammographie. S3 Leitlinie Mammakarzinom Risk stratification – Familial risk documented and risk-adaptive solutions offered

The site

The Gynecological Health Center in Aschaffenburg, Germany is an obstetrics and gynecology practice with two locations that provide care for public and private patients. Practice physicians, all gynecologists, have dedicated qualifications for breast care, radiology, breast ultrasound and oncology care. The medical technologists staff carry extra qualifications in radiology. In addition to patient care, Dr. Henze and staff perform some 6000 screening mammograms and read 4,000 mammograms from surrounding mammography centers. Offering a wide range of breast diagnostics and therapies, the practice focuses on holistic care for women of all ages.

Care pathway for patients with dense breasts

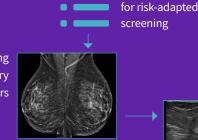
In Germany, the national screening program does not officially include supplemental imaging beyond mammography screening for women with dense breasts. However, the mammography report does include breast density and women with breast density BI-RADS C and D are recommended for a supplemental ultrasound exam.

Gynecological Health Center performs 2D mammography, automated breast ultrasound (ABUS), and hand-held ultrasound (HHUS). Familial risk including the relation grade is documented and risk-adaptive and personalized solutions are offered all patients. MRI is not widely available in Germany to everyone, so the Gynecological Health Center uses ABUS as first line supplemental exam for all asymptomatic women with dense breasts and familial history. "We have found mammography occult cancers with ABUS, which would have been missed with regular 2D Mammography. Additionally, some of the small cancers might be difficult to visualize with handheld ultrasound."

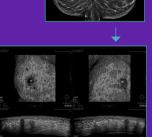
"One of the most relevant benefits of ABUS is to see the entire breast tissue, especially the coronal plane, which provides early patterns of architectural distortions, which is a clear sign for malignancy."

Screening decision tree

FFDM for screening women 50-69 every 2 years



ABUS for first line supplemental exam for all asymptomatic women with dense breasts (BI-RADS C and D) and familial history*



Familial risk used

HHUS used for symptomatic women and those referred for diagnostic ultrasound exam

* There is a dedicated program in Germany, which offers special care in 24 certified University hospitals for women with familial breast and ovarian cancer (Deutsches Konsortium familiärer Brust und Eierstockkrebs)

ABUS exams

On average, Gynecological Health Center performs 2 – 8 ABUS exams every day as it is well accepted by patients and it provides additional clinical information, especially in complex and very dense breasts.



Learn more about Gesundheitszentrum Aschaffenburg

Prof. Erkin Aribal, MD



Head of Multidisciplinary Breast Department Acibadem Altunizade Hospital Istanbul, Turkey

At a glance

Practice setting – Multidisciplinary breast department in private chain hospital
Department staffing – 4 radiologists, 5 technicians, 1 receptionist, 1 patient navigator, 1 patient coordinator
Modalities – HHUS, ABUS, DBT, CSM, MRI (in radiology)

Patient volume - 5,000 patients per year 90% screening 10% diagnostic

Coverage / reimbursement – Government funded in public centers / out of pocket in private centers

Country guideline – Government screening program – biannual screening mammogram for women 40-69

Risk stratification - Gail for low risk women; Tyrer-Cuzick for dense breasts / family history

The site

Prof. Erkin Aribal, MD is Head of the Multidisciplinary Breast Department at the Acibadem Altunizade Hospital in Istanbul, Turkey. The department architecture is designed in a way to ensure patient comfort and privacy. Examination, diagnosis, and treatment are planned and practiced in featured units, which involved a multidisciplinary team including surgeon, radiologist and oncologist to ensure precise and fast diagnosis and treatment for breast cancer patient.

Care pathway for patients with dense breasts

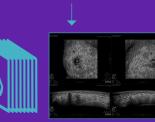
Risk assessment is performed for all patients coming into the multidisciplinary breast department at the Acibadem Altunizade Hospital clinic, using the Gail model for low risk women and Tyrer-Cuzick for women with a family history and/or dense breasts. The clinic performs digital breast tomosynthesis (DBT), contrast enhanced mammography (CEM), automated breast ultrasound (ABUS), hand-held ultrasound (HHUS) and breast MRI.

In Turkey, the limitations of mammography in women with dense breasts are well known. As a result, supplemental ultrasound is routinely offered in conjunction with mammography screening, regardless of breast density. The clinic uses ABUS as the first supplemental screening method after DBT or 2D Mammography. The use of Breast MR is also growing with effectiveness studies and widespread access to Breast MR in Turkey. Contrast Enhanced Mammography is less frequently used, particularly in patients where an alternative method to Breast MR is needed.

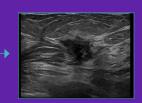
Screening decision tree

Risk stratification
 and personal history
 in breast clinic

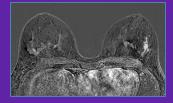




Screening 2D **FFDM/DBT** and **ABUS** for all patients



Focused **HHUS** if findings



MRI recommended every 2-3 years for dense breast (BI-RADS D) and alternating protocols^{*} for high risk patients.

* Annual DBT and MRI for very high risk patients (BRCA positive), with ABUS every 6 months "We have a very full schedule, so we need a smooth patient process. ABUS helps achieve a more efficient workflow, it saves radiologist time and gives us the chance to focus more on the patients and her symptoms or findings."

"ABUS is a fundamental examination for diagnostic patients. It is a very useful complementary tool to mammography, and since it is 3D volume imaging, it is very comparable to Breast MR for surgical planning and ongoing diagnostic monitoring."

Diagnostic ABUS

In diagnostics, ABUS is used if the patient is younger than 40, followed by focused HHUS and DBT depending on the ABUS findings. DBT is used first if the patient is over 40, followed by ABUS and HHUS for findings. For further evaluation of suspicious lesions and disease extent, Breast MR is used.

ABUS is also used as a second look MRI for patients with positive finding on MRI.



Walk in the shoes of a breast care patient in a multimodality breast imaging centre

Prof. Marco Moschetta, MD, PhD



Head of Breast Department University Hospital Bari Bari, Italy

At a glance

Practice setting – Public University Hospital; Second level breast care center

Department staffing – 9 radiologists, 8 technicians, 8 nurses

Modalities - DBT, HHUS, ABUS, MRI, CEM

Patient volume – 23,400-26,000 patients/year; 50% diagnostic; 20% second level screening and recall; 30% oncological

Coverage / reimbursement – Public universal healthcare, screening and supplemental imaging is free

Country guideline – Mammography screening program, bi-annual mammogram for all women aged 49-69

Risk stratification – Technicians perform risk assessment (familial, personal history, high risk conditions)

The site

Prof. Marco Moschetta is Head of the Breast Department at the public University Hospital Bari in Bari, Italy. The breast care unit is a second level center for breast imaging and interventional procedures. The multidisciplinary unit provides comprehensive breast imaging services for diagnostic patients, second level screening and recalls, and personalized screening and surveillance for high-risk patients (BRCA, etc).

Care pathway for patients with dense breasts

Part of the national screening program, the breast department at the University Hospital Bari does not perform first level asymptomatic screening, but performs additional imaging and/or biopsies to diagnose or rule-out suspicious findings and also supplementary screening for women with dense breasts.

The unit performs digital breast tomosynthesis (DBT), automated breast ultrasound (ABUS), hand-held ultrasound (HHUS), breast MRI, and contrast enhanced mammography (CEM). The unit stratifies risk profiles based on personal history and breast density. First-level mammography screening only performed for high-risk women or women outside the screening population age.

Screening decision tree

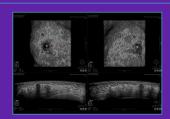


ABUS and DBT for dense breasts (BI-RADS C and D)

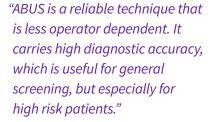
Suspicious finding from first level screening



DBT if ultrasound is suspicious or if they are under 40 but have very high suspicion of cancer on ultrasound



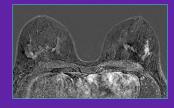
ABUS for symptomatic patients under 40



"ABUS can be an important additional imaging tool in the field of ultrasound that can be used for both screening and diagnostics. It can be applied in a variety of clinical conditions such as monitoring and ABUS might be a good alternative to MRI for T-staging."

Additional ABUS Indications

The unit uses diagnostic ABUS for all mass lesions for better localization and characterization before biopsy, as well as for monitoring and for the T staging. ABUS is also used as a monitoring tool for patients undergoing neoadjuvant chemotherapy and second look ultrasound after MRI.



Breast MRI for high risk patients

Dr. Jose Carmelo Albillos Merino, MD

Head of Radiology Department Hospital Universitario 12 de Octubre Madrid, Spain



Dr. Maria Teresa Fernandez Taranilla, MD, PhD

Consultant Radiologist of the Breast Care Unit Hospital Universitario 12 de Octubre Madrid, Spain

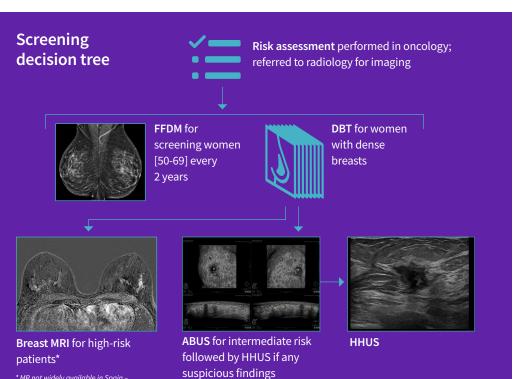


The site

The Breast Care Unit of the Hospital Universitario 12 de Octubre is designed to ensure accurate and fast diagnoses, individualized treatments and risk based follow-up of patients. The multidisciplinary team includes gynecological and plastic surgeons, radiologist, anesthesiologist, oncologist with genetic counseling, nuclear medicine and rehabilitation physicians. All of them focus on breast care patients. The Hospital Universitario 12 de Octubre performs per year 20,000 diagnostic exams, 6,000 screening exams and 3,500 opportunistics exams.

Care pathway for patients with dense breasts

In Spain, the limitations of mammography in women with dense breasts are well known. Hospital 12 de Octubre takes care of patient populations of 500,000 including the screening program. Breast MRI is performed only in high risk patients (>20%) combined with annual mammography as a screening tool and in selected cases with extremely dense breasts. ABUS is implemented during the annual follow-up of patients with intermediate risk (15-20%) and dense breasts (BI-RADS C and D) and also in opportunistic screening as a supplemental technique to increase sensitivity of mammography.



At a glance

Practice setting – Multidisciplinary breast department in a University Public Academic Hospital

Department staffing – 9 radiologists,

11 technicians, 2 nurses and 1 patient coordinator

Modalities – FFDM, DBT, HHUS, ABUS, US-MRI Fusion and MRI

Patient volume – 20.000 patients/year: 60% diagnostic; 40% screening

Coverage / reimbursement – Governmentfunded national healthcare program that includes supplemental screening if needed; Supplemental imaging is free, following radiologist criteria

Country guideline – Government screening program (FFDM for women 50-69 years old every 2 years), EUSOBI guidelines

Risk stratification – Patients referred to oncology department if any familial history/ suspicious; oncology performs risk assessment and sends patient to radiology for imaging. CanRisk, BOADICEA and Tyrer-Cuzick model

"A major benefit of ABUS is being reproducible and standardized, which is the main drawback of HHUS, also the coronal plane helps physicians in cases with multiple nodules and is easy to compare with coronal planes on MRI."

"We have a very full schedule on our daily routine, so ABUS provides a tool to help achieve a more efficient workflow, in order to save radiologists time to focus on really complex cases."

Diagnostic ABUS

Hospital 12 de Octubre applies diagnostic ABUS in women who are over 35 years old with dense breasts and palpable lump (followed by HHUS if needed) and also in the follow-up of patients with known benign nodules BI-RADS 3. In cases with BI-RADS 4 on ABUS, a HHUS is performed afterwards (core needle biopsy) and a Breast MRI to stage the disease.

* MR not widely available in Spain – replace with <u>ABUS if MRI not available</u>

About GE HealthCare

GE HealthCare is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, dedicated to providing integrated solutions, services, and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 100 years, GE HealthCare is advancing personalized, connected, and compassionate care, while simplifying the patient's journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions, and Pharmaceutical Diagnostics businesses help improve patient care from prevention and screening, to diagnosis, treatment, therapy, and monitoring. We are an \$18 billion business with 51,000 employees working to create a world where healthcare has no limits.

Follow us on Facebook, LinkedIn, Twitter, Instagram and Insights for the latest news, or visit our website gehealthcare.com for more information.

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