GE HealthCare

Best practices for implementing Invenia™ ABUS

Breast care pathways: multi-modality approach to screening and beyond

This paper reviews best practices for integrating ABUS into patient care at a variety of practice types across the United States and Canada. This includes comprehensive breast centers, multi-disciplinary, community-based imaging practices, hospital-based imaging practices, an obstetrics and gynecology practice, and a private imaging/surgical practice, all that offer breast health care to patients.

Each case study outlines the breast care pathway in relation to the practices' breast cancer screening approach, risk assessment guidelines, acceptance of supplemental screening, and resources. In each case, ABUS has been adopted as a key tool of a multi-modality approach to improve early cancer detection, particularly among women with dense breasts.

Breast density reduces mammography sensitivity

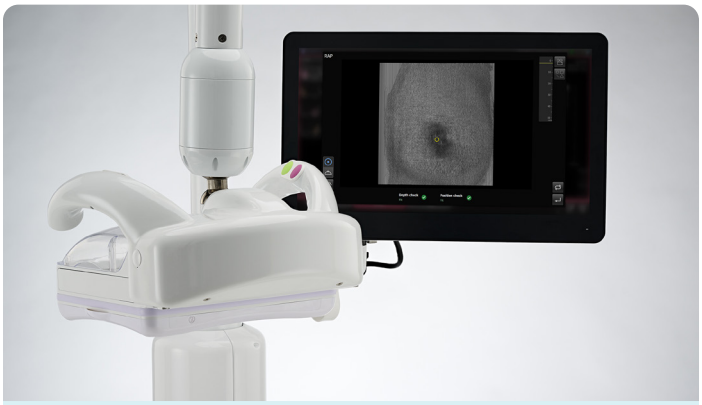
Breast cancer remains the most common cancer in women in the United States, except for skin cancers, and represents about 30 percent of all new female cancers each year.[1] That is why the American Cancer Society, as well as other clinical bodies, recommend that all women between the ages of 45 and 54 get a mammogram each year.[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 one-third of cancers in patients with dense breasts.[3]

Why perform different exams?

Strong support for the implementation of the FDA's National Breast Density Reporting Standard has reinforced that a one-size-fits-all approach to screening is not effective. Advances in imaging technology, including the growing adoption of 3D tomosynthesis and 3D automated breast ultrasound (ABUS), also play a significant role in improved screening.

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.



New era in dense breast imaging

The recent implementation of the FDA's National Breast Density Reporting Standard,[4] requiring all mammography facilities to provide standardized notification to all women and their referring physicians about their breast density, marks a monumental milestone in breast imaging.

Capping more than 15 years of work by radiologists, researchers, advocates, imaging industry leaders, and legislators, the reporting standard is a tremendous step from 2009 when the majority of patients – and many providers – did not know what breast density was or understand the implications on breast cancer risk and screening sensitivity.

Now that breast density reporting is the standard of care, breast imaging practices can focus on implementing a multi-modality approach to screening using mammography, tomosynthesis, ultrasound, ABUS, and breast MRI based on the advantages and disadvantages of each test.

Efficient, effective cancer detection with ABUS

There is a significant breast cancer detection benefit when using screening ultrasound to supplement annual mammography in women with dense breasts.[5] Supplemental screening with Invenia™ ABUS transforms breast care from reactive to proactive. Women whose breast cancer is detected at an early stage have a 90% or higher survival rate.[6]

Multiple studies have demonstrated the clinical power of ABUS in dense breasts to find mammography occult, invasive cancers at an early stage – small and node-negative,[7,8] while maintaining a low recall rate.[9] Results of a recent study demonstrate that ABUS in conjunction with mammography performs comparably with mammography with HHUS when screening women with dense breasts in a real-world clinical setting.[9] The ABUS and mammography approach demonstrated a slightly higher specificity, higher accuracy and lower biopsy recommendation than the approach using HHUS and mammography.[10]

The study, "Supplemental Automated Breast US Screening in Patients With Dense Breasts: 5-Year Experience From an Academic Medical Center," was recently published in the *Journal of Breast Imaging*. Results have shown, in addition to an increased cancer detection, implementation of supplemental ABUS through a Breast Cancer Screening Pathway with a breast imaging super order set, improves quality of care and provider efficiency, patient experience and decreases the time to diagnosis.[11]

ABUS has been shown to deliver clinical benefits for both screening[7-9,11] and diagnostic applications[12-14] while delivering significant improvements in workflow and efficiency that reduce radiologist workload and increase patient throughput.[15] The following cases demonstrate how GE HealthCare's Invenia ABUS, the first FDA-approved ultrasound supplemental screening tool specifically designed for detecting cancer in dense breasts, is transforming breast cancer care.

Georgia G. Spear, MD

Division Chief of Breast Imaging
Endeavor Health/North Shore Health System, Evanston, Illinois

At a glance

Practice setting – 4 comprehensive breast centers and 11 imaging centers

Department staffing – 15 dedicated breast radiologists, and 55 technologists

Modalities – DBT, ABUS, MRI, HHUS

Patient volume – 90,000 screening mammograms, 10,000 diagnostic mammograms per year; 40,000 ABUS exams for screening and diagnostic

Guideline – ACR

Risk stratification – Tyrer-Cuzick 8, genetic testing

The site

Endeavor Health/North Shore Health System, which includes 4 comprehensive breast centers and 11 imaging centers, performs 90,000 screening mammograms and 10,000 diagnostic mammograms per year. Led by Georgia Spear, MD, Division Chief of Breast Imaging, the practice has 15 dedicated breast imagers. Endeavor utilizes digital breast tomosynthesis, ultrasound and breast MRI and operates a large supplemental screening program for women with dense breast tissue, performing 40,000 automated breast ultrasound (ABUS) exams a year utilizing 10 Invenia ABUS units. Endeavor also uses ABUS for diagnostics, particularly for women who cannot have an MRI, such as pregnant women with newly diagnosed breast cancer.

High volume ABUS screening program

Nearly half of women served by Endeavor fall into the BI-RADS® density C and D categories, which is one of the reasons why Dr. Spear adopted ABUS in 2015. When Endeavor started supplemental screening with ABUS, the practice experienced a high cancer detection rate while maintaining a low recall rate. According to Dr. Spear, "we use digital breast tomosynthesis, but the question becomes how can we use a multimodality approach to do better?"

"I have a very inclusive approach to how I look at breast imaging. I think it's critical for us to look at the strengths and weaknesses of each test and how to get the greatest benefit from supplemental screening with different modalities. However, at the end of the day, ultrasound is such a workhorse – it's noninvasive, it's easily accessible and we're seeing great results with it," noted Dr. Spear. "Since implementation, we have performed over 150,000 ABUS exams and over 500 mammography occult cancers have been detected by maintaining a low recall rate."[16]

"We have the tools to use; we can use ABUS, we can use MRI. There are so many ways we can target this so we can make sure to find that cancer early so a woman doesn't lose her life to breast cancer."

"ABUS allows radiologists to look at multiple lesions using the coronal view, which can help with triangulating and understanding the location and distance between multiple findings."

"Adding AI for lesion detection with QVCAD™ enables to view the entire case at-a-glance, increasing productivity and clinical confidence. Reading ABUS with QVCAD takes around 1-2 minutes only."

Chicago, Illinois, USA

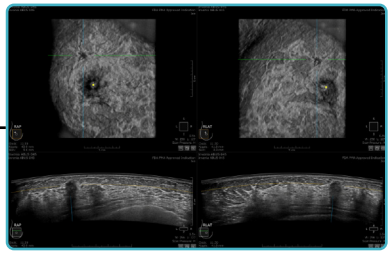
The information described here is based on Dr. Spear's own opinions and on results that were achieved in her unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

Breast screening decision tree

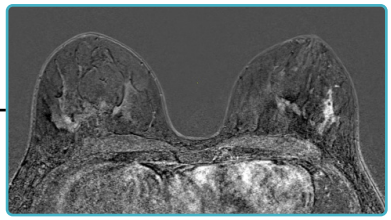
Risk assessment with Tyrer-Cuzick

DBT
For screening women at average risk, not dense

DBT + ABUS
For screening women at average/intermediate risk with dense breasts (BI-RADS C & D)



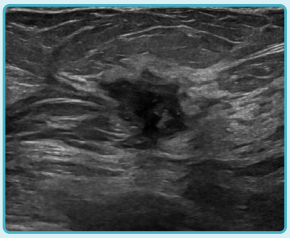
DBT + MRI*
For screening women at high risk with or without dense breasts



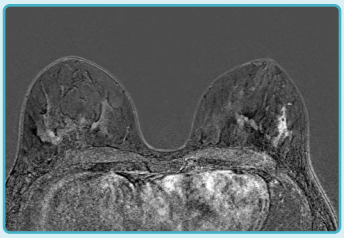
* Annual DBT and MRI for very high risk patients (BRCA positive), with ABUS every 6 months.

Diagnostic tools:

HHUS



MRI – high risk



David Doucette-Preville, MD

Radiologist Partner,
Insight Medical Imaging,
Edmonton, Alberta, Canada

At a glance

Practice setting – Multi-disciplinary, community-based clinic practice

Department staffing – 27 radiologists and 42 ABUS technologists

Modalities – DBT, ABUS, MRI, HHUS

Patient volume – 38,500 screening mammograms; 12,500 diagnostic mammograms per year; more than 14,000 ABUS exams per year

Guideline – CAR (Canadian Association of Radiology), ASR (Alberta Society of Radiology)

Risk stratification – ACR density categories

The site

Insight Medical Imaging is a multi-disciplinary, community-based practice, providing a range of diagnostic imaging at 15 clinics in and around Edmonton and one in Fort McCurray. Insight performs over 50,000 tomosynthesis exams a year, one quarter of those are diagnostic. Insight operates seven ABUS systems at four clinics and two breast centers, offering evening and Saturday ABUS appointments. Insight has seven mammographers and 35 sonographers trained to acquire ABUS exams and 27 radiologists trained to read ABUS exams. To date, Insight has performed over 28,000 ABUS and found 83 biopsy-confirmed breast cancers.

ABUS relieves unmet demand for screening patients with dense breasts

Insight Medical Imaging adopted ABUS in 2022 for both clinical and productivity reasons. "As patients became increasingly aware of breast density, there was a significant unmet need for supplemental screening in Edmonton. From a clinical perspective, the evidence around increased detection of clinically significant breast cancers with supplemental ultrasound was confirmed after we identified several mammographically-occult cancers on ABUS shortly after adoption," said Dr. Doucette-Preville.

Insight follows a pre-read model, where seven breast technologists who have completed mastery certification, are trained to review ABUS exams prior to the radiologist to mark, measure and compare nodules to previous breast ultrasounds, if available. For diagnostic purposes, Insight uses ABUS to screen women who had previous breast cancer with no new concerns.

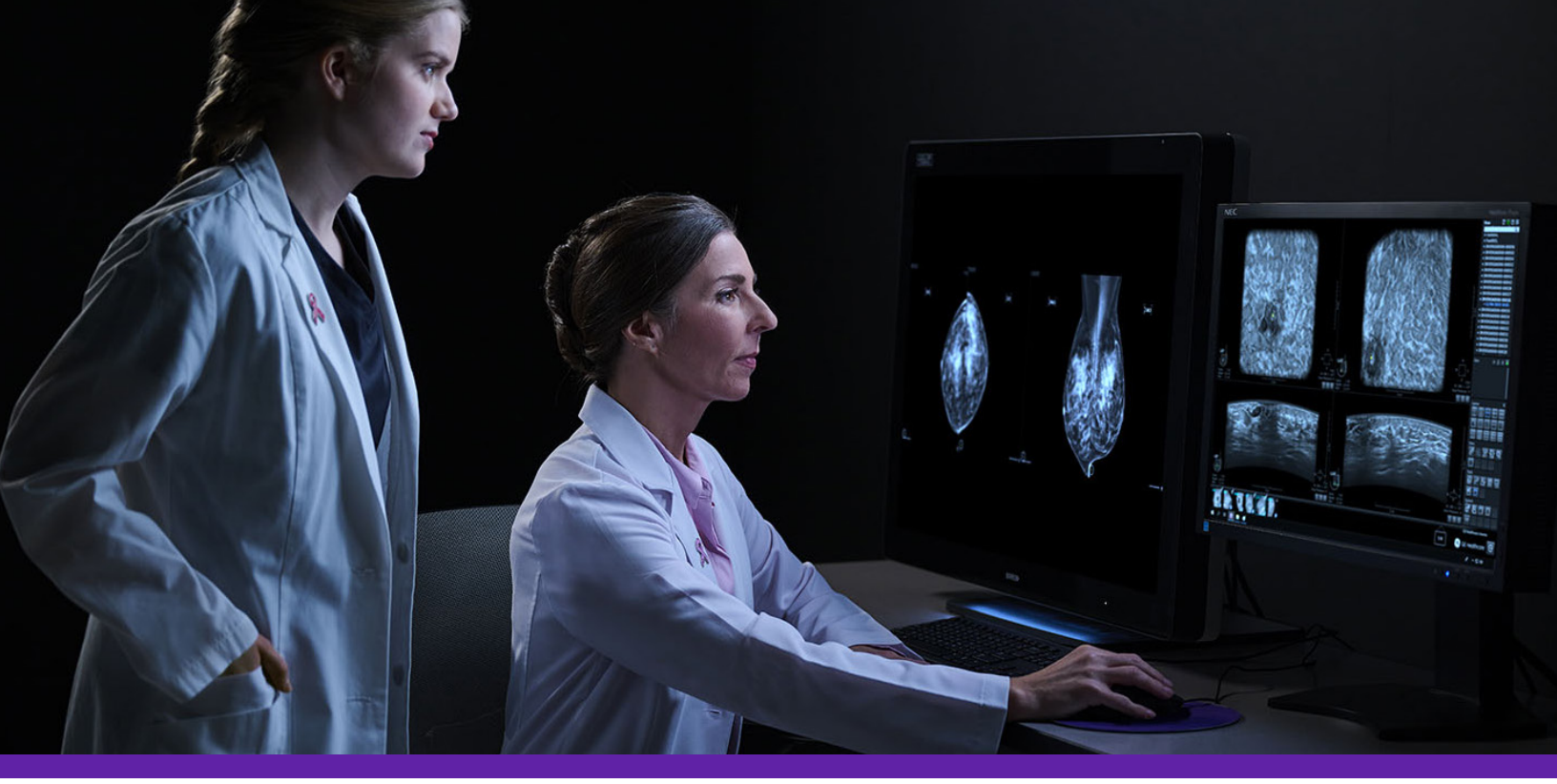
"ABUS provides repeatable, efficient ultrasound screening of breast tissue. It isn't dependent on the individual technologist performing the exam like handheld is. This also takes the repetitive stress off technologists and improves our workflow in terms of providing timely access to breast ultrasound for those individuals with concerns," said Dr. Doucette-Preville.

Edmonton, Alberta, Canada

"All the 83 biopsy-confirmed breast cancers found with ABUS have been mammography and DBT occult and were all in dense breasts."

"ABUS delivers smoother workflow relative to handheld ultrasound, which requires a radiologist on site to supervise and allows decoupling of the acquisition and reading of the exam."

The information described here is based on Dr. Doucette-Preville's own opinions and on results that were achieved in his unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

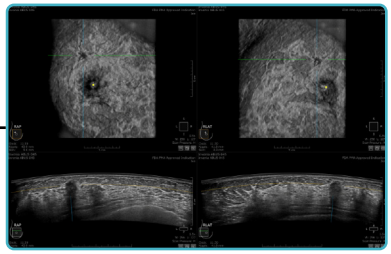


Breast screening decision tree

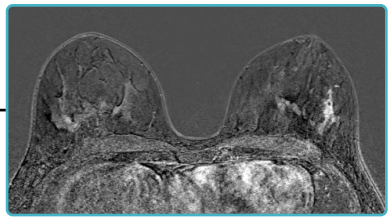
Risk assessment with Tyrer-Cuzick

DBT
For screening women at average risk, not dense

DBT + ABUS
For screening women at average/intermediate risk with dense breasts (BI-RADS C & D)

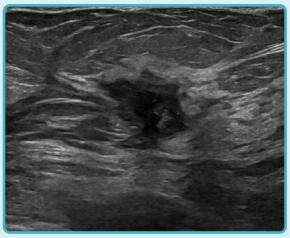


DBT + MRI
For screening women at high risk with or without dense breasts

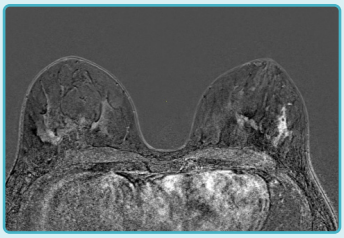


Diagnostic tools:

HHUS



MRI – high risk



Allison H. Zupon, MD

Medical Director,
Imaging for Women,
Kansas City, Missouri

At a glance

Practice setting – High-volume women's imaging center

Department staffing – 2 radiologists; 8-10 technologists

Modalities – DBT, ABUS, CESM, (high-risk patient sent to KU Medical Center for MR), HHUS for diagnostic

Patient volume – More than 17,000 screening patients per year; 50-60% with dense breasts; 30+ daily ABUS for screening and diagnostic

Guideline – ACR and SBI guidelines

Risk stratification – Tyrer-Cuzick 8

The site

Imaging for Women is a high volume, privately owned imaging facility that offers same day screening and diagnostic services. Opened in 1997 as Kansas City's first stand-alone women's imaging center, Imaging for Women offers high-quality imaging services with state-of-the-art technology. The practice performs more than 17,000 screening mammograms per year, using a multi-modality approach to achieve the best clinical outcomes and patient compliance to ongoing screening.

Personalized screening for clinical outcomes and compliance

"We are making strides when it comes to making women aware of breast density and properly screening women based on their personalized risk" said Dr. Zupon. "But cost and access remain a barrier to capturing all the women that need to be screened. Unfortunately, many of the women that we are missing are the ones typically who are at higher risk."

Imaging for Women has a unique model for patient communications, utilizing medical assistants trained by radiologists to communicate normal results to patients same day. Radiologists handle abnormal results with real time conversations and counseling about screening and diagnostic options.

According to Dr. Zupon, Imaging for Women uses ACR and SBI guidelines to inform imaging protocols, particularly for women at high risk. "At the end of the day, however, my philosophy is access and making sure the patient gets some kind of screening that actually finds cancer. Whether it's MRI, CEM, or ABUS, if they cannot tolerate the advanced imaging options, our workflow is based on risk, density and what the patient will do."

"When I lecture about how to use ABUS, I stress that it is not just a screening tool. I use ABUS all the time for diagnostics. For a patient with dense breasts and focal pain or follow-up on a fibroadenoma in a sea of cysts, I'm putting that on the ABUS."

"We emphasize educating patients and referring providers about supplemental screening options, with a focus on managing costs and patient access."

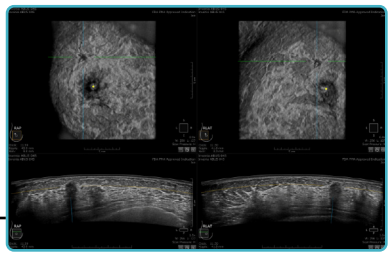
Kansas City, Missouri, USA

The information described here is based on Dr. Zupon's own opinions and on results that were achieved in her unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

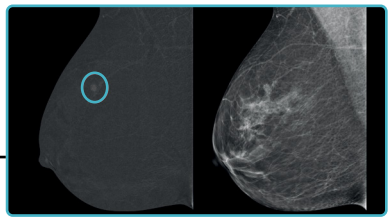
Breast screening decision tree

Risk assessment with Tyrer-Cuzick
Offered onsite genetic testing if indicated

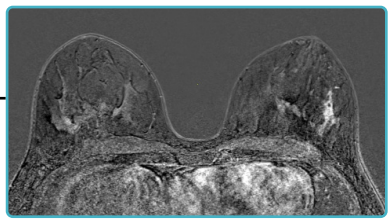
DBT
For screening women at average risk, not dense



DBT + ABUS
For screening women at average risk with dense breasts (BI-RADS C & D)



DBT + CESM*
For screening women at intermediate risk with dense breasts (BI-RADS C & D)



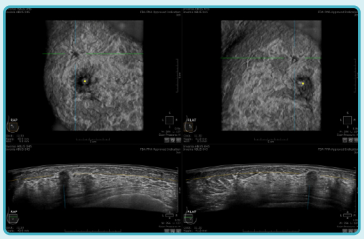
DBT + MRI**
For screening women at high risk with or without dense breasts

* CESM is not currently approved for breast cancer screening in the United States.

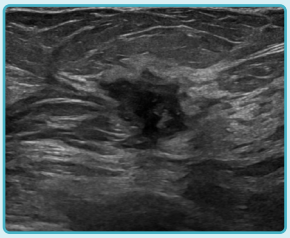
** Patient can't tolerate MRI, patients get CESM.

Diagnostic tools:

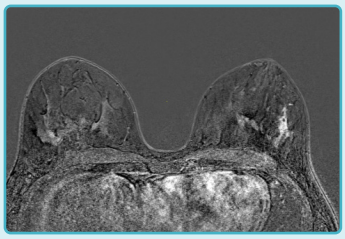
ABUS



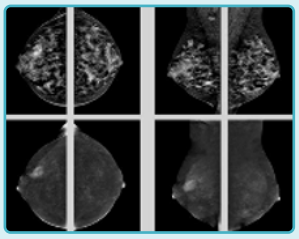
HHUS



MRI outside site – high risk



CEM



Serena Tidwell, MD

Medical Director,
Pink Monarch Breast Center/
Midtown OB/GYN,
Columbus, Georgia

At a glance

Practice setting – Private OB/GYN practice and stand-alone breast center

Department staffing – Radiologist Dr. David Bodne; 5 technologists

Modalities – DBT, ABUS, HHUS

Patient volume – 6,000 screening mammograms; 1,300 ABUS per year; 35-40% with dense breasts

Guideline – ACR

Risk stratification – Tyrer-Cuzick risk assessment and Myriad genetics testing

The site

Serena Tidwell, MD, opened Midtown OBGYN in 2002 with a focus on comprehensive women's health. To better serve that need she opened Pink Monarch Breast Center in 2012. The center initially focused on Mammography but notified women of density status from the time of opening. In 2019, Pink Monarch added ABUS to better serve dense patients. Pink Monarch currently performs about 6,000 screening mammograms annually and 40% of their patients are dense.

Holistic approach to screening and women's health

Pink Monarch recommends automated breast ultrasound (ABUS) for patients with dense breasts (BI-RADS C or D) and MRI for patients with a greater than 20% lifetime risk of breast cancer. "I am not a radiologist, so I generally focus on clinical utilization and efficiency, but we have found ABUS to be an efficient and effective supplemental screening tool," said Dr. Tidwell.

The facility utilizes patient education and notification processes, including text messages, to inform patients of their breast density and screening recommendations.

Pink Monarch radiologists have incorporated ABUS into their diagnostic workflow, using ABUS for patients with bilateral diffuse breast pain. For patients presenting with a mass, especially younger patients, ABUS is often used with handheld ultrasound to evaluate the area of concern.

"Patients need consistent, clear and standard screening, particularly supplemental screening."

"Since we opened in 2012, we've always been very proactive about breast density and we've always put it in reports and we notified patients of their density."

Columbus, Georgia, USA

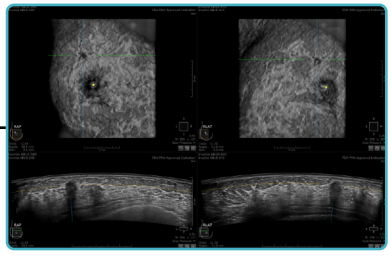
The information described here is based on Dr. Tidwell's own opinions and on results that were achieved in her unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

Breast screening decision tree

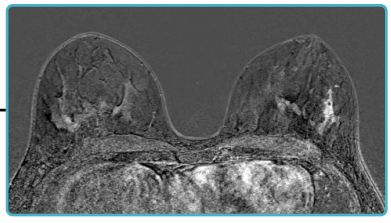
Risk assessment with Tyrer-Cuzick
Offered onsite genetic testing if indicated

DBT
For screening women at average risk, not dense

DBT + ABUS
For screening women at average/intermediate risk with dense breasts (BI-RADS C & D)

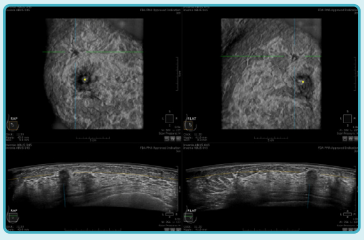


DBT + MRI
For screening women at high risk with or without dense breasts

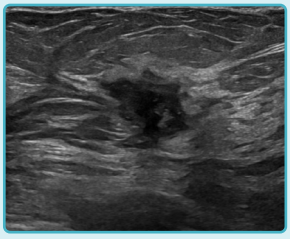


Diagnostic tools:

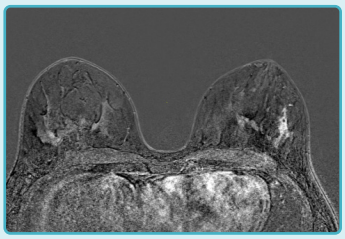
ABUS



HHUS



MRI outside site – high risk



Ian Grady, MD

General Surgeon
North Valley Breast Clinic,
Redding, California

At a glance

Practice setting – Private imaging/surgical practice

Department staffing – 1 radiologist; 1 technologist

Modalities – DBT, ABUS, HHUS

Patient volume – 10,000 screening patients; 80% with dense breasts; 25 ABUS exams per day for screening and diagnostic

Guideline – SBI guidelines

Risk stratification – SBI risk-stratified screening program using Tyrer-Cuzick 7

The site

North Valley Breast Clinic is a private imaging/surgical practice in Redding, California. Operated by Ian Grady, MD, the practice screens approximately 10,000 patients per year, with 80% having dense breasts. The practice follows a risk-stratified screening approach, using ABUS for women at moderate and high risk. Dr. Grady finds 2-3 cancers per month with ABUS that are mammographically occult. ABUS is also used for diagnostic workup and surgical planning, allowing same-day diagnosis and treatment planning.

ABUS used extensively for screening and diagnostics

Delivering improved efficiency, productivity, enhanced cancer detection, North Valley Breast Clinic uses automated breast ultrasound (ABUS) extensively for both screening and diagnostics. As ABUS volume at North Valley surpasses 25 exams per day, Dr. Grady recently integrated another ABUS system to enable the practice to address patient needs.

"We've built the practice around ABUS, using it since 2008. ABUS allows us to implement a "same day workup practice" which is more efficient than doing manual handheld ultrasound, which can take up to 45 minutes. ABUS is faster to read and interpret compared to manual ultrasound and I can compare ABUS results to prior studies and correlate with mammographic findings," noted Dr. Grady. "We have found that ABUS helps detect 2-3 patients per month with small cancers that were not visible on mammograms."

Dr. Grady uses ABUS for diagnostic work-ups and surgical planning, and has developed specialized techniques, such as axillary imaging and palpable mass markers, to extend ABUS capabilities. "Working from anterior to posterior, the coronal plane helps visualize a large amount of data and provides anatomic positioning that helps with surgical planning. I am very optimistic about the future of ABUS, expanding its capabilities across screening, diagnostics and treatment," added Dr. Grady.

Redding, California, USA

"ABUS is enabling technology – it is the 'Swiss army knife of ultrasound'. Without ABUS, we would not be able to operate our same-day workup practice model."

"ABUS is our primary ultrasound imaging modality: we use ABUS for screening workups, for diagnostic workups and for surgical planning. It is the central technology of the entire practice."

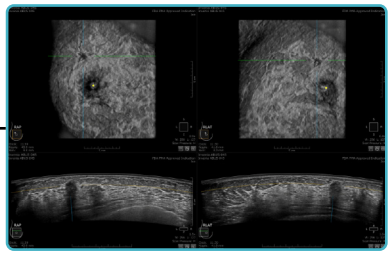
The information described here is based on Dr. Grady's own opinions and on results that were achieved in his unique setting. Since there is no "typical" hospital and many variables exist, i.e., hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

Breast screening decision tree

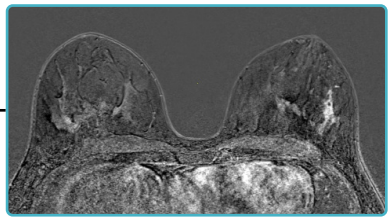
Risk assessment with Tyrer-Cuzick

DBT
For screening women at average risk, not dense

DBT + ABUS
For screening women at average/intermediate risk with dense breasts (BI-RADS C & D)

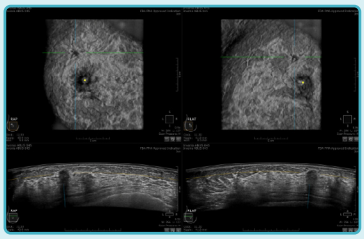


DBT + MRI
For screening women at high risk with or without dense breasts

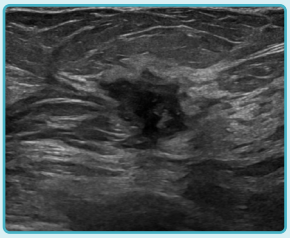


Diagnostic tools:

ABUS
- Surgical planning
- Implant integrity
- Extent of disease
- Axilla



HHUS



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