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Efficacy of automated breast ultrasound as a screening tool for detecting breast lesions in comparison with mammography and breast biopsy

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Thesis Approval

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Dedication

This thesis is dedicated to my loving family, whose unwavering support and encouragement have been my greatest source of strength throughout this journey. To my parents, who have always believed in me and provided me with the opportunities to pursue my dreams.

To my partner, for your endless patience, understanding, and for being my constant source of inspiration and motivation. Your belief in me has been a guiding light, especially during the most challenging times.

To my friends, for your encouragement, insightful conversations, and for always being there to lend a helping hand or a listening ear. Your support has made this journey not only bearable but enjoyable.

Finally, I dedicate this work to my teachers and mentors, whose guidance and wisdom have shaped my academic path and fueled my passion for learning and discovery. Your influence will forever be a part of who I am.

Ahlam Mohammad Mubarak

Declaration

I certify that this thesis submitted to the degree of master is the result of my own research, except where otherwise acknowledged, and that this thesis or any of its parts has not been submitted for higher degree to any other university or institution.

Signature: Ahlam

Ahlam Mohammad Asad Mubarak

Date: 14/12/2024

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Abstract

Automated breast ultrasound (ABUS) has been developed as an advanced imaging technology designed to overcome the limitations of conventional breast screening modalities, particularly the reduced sensitivity of mammography in dense breast tissue and the operator dependency of handheld ultrasound (HHUS). This study aimed to evaluate the efficacy of ABUS as a screening tool for detecting breast lesions in comparison with mammography and breast biopsy. A descriptive, retrospective cross-sectional study was conducted involving 133 women who underwent both mammography and ABUS at Yazan Radiology Center in Bethlehem between January and December 2023. The mean age of participants was 51.71 years. Breast density distribution showed that 38.3% were classified as category C, 37.6% as category B, 13.5% as category D, and 10.5% as category A. Findings demonstrated that ABUS exhibited higher sensitivity than mammography, particularly in women with dense breasts, and detected a greater number of lesions. The overall accuracy of ABUS was 61.65%, representing a statistically significant difference compared to mammography. No significant associations were observed between ABUS-detected lesions and demographic characteristics except for breast density. In conclusion, ABUS shows substantial potential as an effective screening modality, offering improved lesion detection in dense breast tissue and demonstrating advantages over mammography in sensitivity and diagnostic performance.

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List of abbreviations

MS	Mammographic Screening
oPt	Occupied Palestinian territory
ACR	American college of radiology
ABUS	Automated breast ultrasound system
US	Ultrasound
HHUS	Handheld ultrasound
BIRADS	Breast imaging reporting and data system
MRI	Magnetic resonance imaging
FFDM	Full-field digital mammography
CEM	Contrast-enhancement mammography
FOV	Field of view
CC	Craniocaudal
MLO	Mediolateral oblique
AP	Anteroposterior
LAT	Lateral
MED	Medial

Chapter one

Introduction

1.1 Background

Breast diseases detection are on the rise globally as a result of increased public awareness of breast cancer. The two most important terms to understand when it comes to breast injuries are benign and malignant lesions (Medanta, 2020). The term "lesion" is derived from the Latin word "Laesio," which means "attack or injur". Lesions can develop as a result of any disease or injury which characterized by an abnormal change in a tissue or organ, Benign breast lesions develop in non-cancerous areas where breast cells proliferate abnormally and rapidly, these cells form lumps, but they do not cause cancer (Sissons, 2023). Benign lesions are common in the breast but are frequently overlooked because they are not as dangerous as malignant lesions (Medanta, 2020).

In 2022, breast cancer (BC) accounted for an estimated 2.3 million newly diagnosed cases and 660,000 related deaths worldwide, underscoring its global public health burden. In Palestine, BC is the most common and widely distributed malignancy. According to the Palestinian Ministry of Health's Annual Report (2023), the incidence of BC is 18.5 cases per 100,000 individuals in the general population and 37.4 cases per 100,000 among females, with a mortality rate of 11.7 per 100,000 for all cancers. In the West Bank, 540 new BC cases were recorded in 2022, representing 15.8% of all newly diagnosed cancers. Mortality was notably higher in the southern governorates, where 32% of registered cases were reported in Hebron and 13% in the Bethlehem governorate. (Titi & Sharif, 2024)

In regard with the mammography and ultrasound mammography, primary health care clinics in the Palestinian Ministry of Health provide mammography services in the West Bank's various health directorates, The total number of cases examined in the various governorates was 5,131, with 1809 abnormal cases accounting for 35.3% of the total number of cases investigated (PMOH, 2020). In the various West Bank governorates, there were 1,948 ultrasound cases, of which 1,205 were abnormal and accounted for 61.9% of the investigated cases (PMOH, 2020).

The focus on mammographic screening (MS) and the provision of mammography machines in the occupied Palestinian territory. A politically volatile low-income country, has involved the Palestinian government, as well as international humanitarian and local nongovernmental organizations. The Palestinian government states in its 2017-2022 national health strategy document that providing more MS services is one of its top priorities (PMOH, 2020). In the West Bank, there are 19 mammographic machines, and in Gaza, there are 20 as (19 in the government sector, with the remainder in the private and nongovernmental sector) (AlWaheidi et al., 2020).

Moreover, 90% of these machines are either nonfunctional or underutilized, partly due to a lack of well-trained personnel to operate them and interpret mammographic films, and partly due to frequent strikes in the health system as a result of wage withholding, despite this, many health care facilities are allocating a larger portion of their budgets to the purchase of mammographic machines (AlWaheidi et al., 2020).

However, the purpose of early breast lesions detection is to reduce morbidity and mortality rates (Medanta, 2020). MS has been established as an imaging modality for breast cancer screening and early detection, the main disadvantage of mammography is its low sensitivity and specificity, particularly in women with dense breasts. Due to the low contrast between the density of tumor tissue and the density of surrounding breast tissue (Mostafa et al., 2019).

Breast ultrasound in combination with mammography has been shown to improve tumor detection rates in women with dense breasts (ACR C and D types) (Pawlak et al., 2023c). Breast ultrasound is traditionally operator-dependent, which means that the results are influenced by the operator's skill and experience, resulting in a loss of standardization (Mostafa et al., 2019).

Breast ultrasonography and breast MRI are two other screening methods, although sonography is a less expensive and more widely available screening tool than MRI, it is operator-dependent, time-consuming, and non-reproducible, especially in large breasts (Abd Elkhalek et al., 2019).

ABUS is a new tool for overcoming such drawbacks (Abd Elkhalek et al., 2019).

Automated breast ultrasound (ABUS) is a technological advancement in the field of ultrasound imaging that was created to overcome the issue of operator dependence in traditional US scanning by standardizing the images acquired, this is accomplished through the volumetric acquisition of multiple US images of the breast, which can then be saved and post-processed, i.e., 3D and multiplanar reformatting, for later reading and evaluation (Mostafa et al., 2019)

Despite the fact that automated breast ultrasound (ABUS) has been available for more than a decade, previous systems provided insufficient image quality for proper interpretation, recent advancements in ABUS systems, such as the use of high-frequency transducers, have allowed for the reproduction of images of high quality in a short period of time (Mostafa et al., 2019)

1.2 Problem statement

Mammographic screening has a lower sensitivity for dense breasts, which are an independent risk factor for breast cancer (Mostafa et al., 2019). Breast cancers that are

mammographically occult are expected to be detected using supplemental breast ultrasound (US) screening, Due to limited human resources and a heavy workload, radiologists are unable to widely use handheld US (HHUS) with the increasing demands of supplemental US screening and operator dependency (Vourtsis & Berg, 2018). In the United States and Europe, ABUS has been approved as a screening adjunct to mammography, particularly for asymptomatic women with dense breasts (Vourtsis & Berg, 2018). Therefore, this study will be conducted to assess the role of ABUS as screening tool in comparison to mammogram and breast biopsy in breast lesions detection.

1.3 Study Justification

Screening ABUS, like screening HHUS, yielded high diagnostic performance in several studies, breast cancer detection increased by 1.9–7.7 cases per 1000 women with additional ABUS screening (Kim et al., 2020). However, ABUS can be used to detect additional breast lesions in women where mammography alone may be ineffective due to their dense breasts, there is no ionizing radiation used in it, and ABUS is a quick, painless, and effective way to image dense breasts (George Washington University Hospital, 2022). Radiologists can examine hundreds of breast tissue image "slices" to look at layers of dense tissue to find breast lesions that may have been missed on a mammogram using 3D ultrasound volume and U-Systems software, A full ABUS exam lasts about 15 minutes (Vourtsis & Berg, 2018). Most patients report that the ABUS procedure is painless when they are comfortably positioned on the exam table; however, some women with extremely sensitive breast tissue have complained about minor discomfort during the scanning process (George Washington University Hospital, 2022). Also, Automated breast US (ABUS) was developed to overcome the limitations of operator dependency and lack of reproducibility in HHUS, and it saves radiologists' time (Vourtsis & Berg, 2018). To the best of our knowledge, this will be the first study deals with the issue of ABUS among the Palestinian population.

1.4 Study Aim

The aim of this study is to assess the Efficacy of ABUS as a screening tool for detecting breast lesions in comparison with mammography and breast biopsy**.**

1.5 Study Objectives

A. To determine the unique features of ABUS in comparison with mammography and breast biopsy (Detected lesions and correlated BIRADS).
B. To assess the effectiveness of ABUS in lesion detection in participants with dense breast.
C. To assess the accuracy measurements for the ABUS in comparison with Mammogram and Biopsy.
D. To assess the relationship between the detected lesions by ABUS and the demographic characteristics of participants.
E. To assess the relationship between the detected BIRADS by ABUS and the demographic characteristics of participants.

1.6 Research Questions

A. What are the distinctive features of lesions detected by ABUS when compared to those identified by mammography and confirmed through breast biopsy, particularly in terms of lesion characteristics and correlated BIRADS classifications?
B. What is the comparative efficiency of ABUS in lesion detection in participants with dense breast?
C. How do the accuracy measurements of ABUS compare with those of mammography and biopsy in detecting and characterizing breast lesions?
D. Is there a significant relationship between the characteristics of lesions detected by ABUS and the demographic characteristics of participants?
E. What is the association between the BIRADS classifications generated by ABUS and the demographic characteristics of participants?

Chapter Two

Literature Review

2.1 Introduction

Breast cancer is the most common malignant cancer in women and accounts for 685,000 of all female deaths worldwide, early detection is crucial for treatment effectiveness in breast cancer, which presents a significant medical and societal burden (Wilkinson & Gathani, 2022). The 5-year survival rate for patients with breast cancer stage I is 98–100%, while the rate for patients with stage III cancer is only 66–98%, as per the data obtained from the Validation Study of the American Joint Committee on Cancer Eighth Edition Prognostic Stage Compared with the Anatomic Stage in Breast Cancer. This highlights the importance of early diagnosis in the course of cancer treatment (Pawlak et al., 2023).

2.2 Automated Breast Ultrasound (ABUS)

Automated Breast Ultrasound (ABUS) is a recent technique that can identify up to 30% more cancers in women with dense breast tissue, characterized by more fibrous or glandular tissue rather than fatty tissue, even if dense tissue is their sole additional risk factor. (Automated Breast Ultrasound System (ABUS), 2023). In women whose dense breast tissue makes mammography insufficient, ABUS can detect extra breast lesions. ABUS doesn't use ionizing radiation, in contrast to mammography. It provides a rapid, painless, and efficient way to image dense breast tissue. Thanks to 3D ultrasound volume and U-Systems software, radiologists may analyze hundreds of breast tissue imaging "slices," allowing them to closely investigate layers of thick tissue and discover breast tumors that a mammogram might miss. (George Washington University Hospital, 2022).

On the other hand, a full ABUS exam lasts about 15 minutes, most patients report that the ABUS procedure is painless when they are comfortably positioned on the exam table; however, some women with extremely sensitive breast tissue have complained about minor discomfort during the scanning process (Zanotel et al., 2017).

Also, the ABUS transducer connects to a membrane before beginning the exam, then, a layer of ultrasound gel or lotion is put to the breast in order to assure that the skin and the ultrasound transducer make good contact, to ensure the best image quality (George Washington University Hospital, 2022).

By identifying intraluminal echoes in dilated lactiferous ducts, the coronal plane enables the reconstruction of the complete breast's ductal system, which in turn makes it easier to detect ductal dilatation associated with intraductal papillary lesions or even ductal cancer in situ. Furthermore, ABUS outperformed HHUS in the preoperative assessment of tumor extension, demonstrating encouraging outcomes (Ioana Boca, 2021). After two cycles of neoadjuvant chemotherapy, the coronal plane can assist in predicting the entire pathological response with a sensitivity of 85.7–88.1% and specificity of 81.5–85.1%, respectively (Ioana Boca, 2021).

2.3 Mammogram

A mammogram is a type of X-ray that examines the breast, it is used to detect and diagnose breast disease in women who have breast complaints, such as a lump, pain, or nipple discharge, as well as in women who do not have breast complaints. The procedure enables the detection of breast cancers, benign tumors, and cysts before palpation (touch) (John Hopkins Medicine, 2022). It cannot prove that an abnormal area is cancer, but if it raises a strong suspicion, tissue will be removed for a biopsy, tissue can be removed via needle biopsy or open surgical biopsy and examined under a microscope to determine whether it is cancerous (John Hopkins Medicine, 2022).

Mammography has been used for about 30 years, and technological advances in the last 15 years have greatly improved both the technique and the results. (John Hopkins Medicine, 2022). Today, dedicated equipment used only for breast X-rays produces high-quality but low-radiation-dose studies, radiation risks are regarded as insignificant (John Hopkins Medicine, 2022).

The types of mammography could be a screening mammogram which is an X-ray of the breast that is used to detect breast changes in women who do not have any symptoms of breast cancer, it usually consists of two X-rays of each breast, it is possible to detect a tumor that cannot be felt using a mammogram (Giger et al, 2016).

Also, could be a diagnostic mammogram which is an X-ray of the breast that is used to detect unusual breast changes such as a lump, pain, nipple thickening or discharge, or a change in breast size or shape, a diagnostic mammogram is also used to assess abnormalities discovered on a screening mammogram, it is a basic medical tool that can be used in the evaluation of breast changes regardless of a woman's age (John Hopkins Medicine, 2022).

Mammography has an overall sensitivity of about 85% and enables the early diagnosis of nonpalpable breast tumors. However, 40% of American women have dense breast tissue, which reduces mammography's sensitivity and leaves almost one-third of breast tumors undetectable on mammograms, Furthermore, compared to breast cancers identified in women with non-dense breast tissue, those diagnosed in women with dense breast tissue typically have larger tumors that are node-positive (Giger et al, 2016). However, dense breast tissue is not only associated with decreased mammography sensitivity, but it also stands

alone as a risk factor for breast cancer, compared to women with fatty breast tissue, those with dense breast tissue had a four- to six-fold higher chance of getting breast cancer (Pawlak et al., 2023). The limits of mammography in conjunction with the higher risk of breast cancer in women with dense breast tissue point to the necessity for alternative imaging modalities to enhance breast cancer detection (Giger et al, 2016).

2.4 Breast Biopsy

The use of percutaneous imaging-guided needle biopsy as a substitute for surgical biopsy in the histologic evaluation of breast lesions is growing, compared to surgical biopsy, percutaneous biopsy is less expensive, less intrusive, and faster, automated core needles or directional vacuum-assisted biopsy probes are used for tissue acquisition. MRI has been used more recently, along with stereotaxis and ultrasound, to guide percutaneous biopsy procedures, the type of lesion and the outcomes of diagnostic imaging tests determine imaging advice (Silva et al., 2023).

With a sensitivity value of approximately 97.5%, this method has many advantages over other imaging techniques for biopsy guidance, including non-ionizing radiation, low cost, real-time needle control, accessibility in challenging locations, multidirectional punctures, and superior patient and radiologists' comfort. Because of all these benefits, this method is the most commonly utilized one for doing a biopsy on a worrisome breast lesion, the biggest drawback is that lesions that are not visible on ultrasonography are not biopsied. Sufficient radiological–pathological correlation is required to reduce the number of false-negative findings (Luis Apesteguía, 2011). A dependable method for taking a biopsy of breast lesions that are clearly visible on ultrasound is ultrasonography-guided CNB, in order to obtain a histological diagnosis, percutaneous imaging-guided breast biopsy has become a dependable substitute for surgical biopsy (Silva et al., 2023). Less invasive than surgery, percutaneous biopsies can be completed quickly, leave minimal scars, don't deform the breast, and have a lower rate of complications (less than one case in 1,000), because fewer surgeries are required for patients who undergo percutaneous biopsies, diagnosis costs are also reduced (Park & Hong, 2014).

Percutaneous biopsy procedures aim to provide as much information as possible about the tumor5 (type, grade, invasion, hormonal receptors, HER-2 NEU, etc.) and to achieve the highest level of accuracy feasible, Core-needle biopsy (CNB), vacuum-assisted biopsy (VAB), and fine-needle aspiration cytology are the next in line of percutaneous biopsy devices that have developed to meet these goals (Team, 2024). For the majority of lesions observed on ultrasound, the most common method for performing a percutaneous biopsy is now ultrasonography-guided core needle breast biopsy, under ultrasound supervision, samples can be taken from nearly any breast lesion that is clearly visible on an ultrasound. Thanks to the widespread use of ultrasonography CNB, many surgical biopsies that were previously required due to questionable radiological findings are no longer essential (Elibol et al., 2020).

Furthermore, surgical specimens retrieved following a confirmed malignant outcome are typically more appropriate for the size of the tumor. As a result, there are now fewer surgical treatments performed for malignant lesions. Thus, due to the widespread use of ultrasound CNB and other percutaneous biopsy techniques, the number of surgical procedures for both benign and malignant lesions have significantly decreased. The inability to perform a biopsy for lesions not seen on ultrasound is the primary drawback of ultrasound CNB. Ultrasonography is usually not able to identify most clustered microcalcifications, particularly if they are not inside a mass. Even in the absence of a bulk, some grouped microcalcifications can be seen by high-resolution transducers. While the majority of ultrasound CNB treatments are simple to perform, a high level of skill is required in certain particular conditions to obtain trustworthy findings, such as deeply situated lesions, patients with implants, axillary lesions, etc (Gao et al., 2018).

Any lesion that is classified as BI-RADS 4 or 5 and is readily visible on ultrasonography is eligible for ultrasound CNB. This technique can also be used for some BI-RADS 3 lesions under specific circumstances, such as genetic or family risk, medical or social follow-up issues, pregnancy, extreme anxiety, and others, including the patient's decision. Collaboration may be difficult for individuals with severe mental problems and ultrasound CNB is contraindicated in certain cases of severe blood dyscrasia (Luis Apesteguía, 2011)

2.5 Dense breast

The assessment of breast tissue composition holds significance in the radiological evaluation of the breast for two primary reasons. Firstly, dense fibroglandular tissue is identified as a risk factor for breast cancer. Secondly, the presence of this dense tissue reduces the sensitivity of mammography in detecting breast cancer. Consequently, mammography reports commonly include a description of the overall tissue composition of the breast, considering its implications for cancer risk and diagnostic accuracy (Conant et al., 2018).

The American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) categories breast composition into four distinct categories: A (predominantly fatty), B (scattered fibroglandular densities), C (heterogeneously dense), and D (extremely dense) (Conant et al., 2018).

A retrospective study conducted by (Pawlak et al., 2023) aimed to assess the performance of full-field digital mammography (FFDM), contrast-enhanced mammography (CEM) and automatic breast ultrasound (ABUS) in the group of patients with (ACR) categories C and D as well as A and B with FFDM. The study conducted among 297 patients in a period from 2020 to 2022, The results showed that the pairing of FFDM and ABUS demonstrated a 100% sensitivity across various breast categories. The accuracy rates were 75% for breast types C and D, and 81.36% for types A and B. The research underscores the prevalence of breast anatomy types C and D, revealing the limited diagnostic efficacy of FFDM within this subset, and for breast types C and D, ABUS identified 72% of all lesions, CEM identified 56%, and FFDM detected 29% ($p = 0.008$, $p = 0.000$), showcasing significant differences. In terms of invasive cancers, ABUS diagnosed all cases, while CEM and FFDM identified 83% and 59%, respectively ($p = 0.000$, $p = 0.023$). For 100% of DCIS cases, ABUS was

effective, compared to 93% with CEM and 59% with FFDM. It suggests that ABUS and CEM could serve as supplementary approaches for enhancing breast cancer diagnostics. (Pawlak et al., 2023).

2.6 Indications of ABUS

There are several indications to use ABUS in breast lesion detection and diagnosed like: family history of breast cancer, personal history of breast cancer, gene mutation and assessment of lesions detected on other Imaging Modalities. But the main indications are screening women with dense breast and screening of women younger than the mammogram age group recommended (Wolterink et al., 2024).

2.7 Diagnostic Accuracy of ABUS, Mammogram and Breast Biopsy

In a previous study conducted by Mostafa et al. in 2019, the investigation focused on assessing the incremental value of Automated Breast Ultrasound (ABUS) in the screening of women presenting suspected breast masses as compared to conventional mammography and hand-held ultrasound (HHUS). The study cohort comprised 200 patients who underwent screening with mammograms, ultrasound, and ABUS. Various parameters, including sensitivity, specificity, positive predictive value, and negative predictive value, were evaluated for both ABUS and HHUS. The findings of the study indicated a statistically significant improvement in the detection of lesions by ABUS compared to HHUS, with an increase in overall accuracy from 93% to 98%, sensitivity from 82% to 95%, and a substantial enhancement in negative predictive value from 89.6% to 96.8% (Mostafa et al., 2019).

Furthermore, the study revealed a significant increase in the detection of lesions when ABUS was added to mammography, as opposed to the use of mammography alone. Specifically, 38 out of 40 lesions were detected when ABUS was combined with mammography, compared to 24 out of 40 lesions detected by mammography alone, with a p-value < 0.001, signifying a statistically significant difference (Mostafa et al., 2019).

The sensitivity of lesion detection by mammography alone was reported to be 60%, but when combined with ABUS, it increased to 95%. The study also highlighted a statistically significant improvement in the detection of lesions smaller than 5 mm by ABUS when compared to HHUS. Overall, the results of this previous study emphasize the added diagnostic benefit of incorporating ABUS into breast cancer screening protocols, particularly in cases of suspected breast masses (Mostafa et al., 2019)

Another study conducted by Giuliano and Giuliano (2013) aimed to investigate the effectiveness of automated breast ultrasound (ABUS) as an adjunct diagnostic modality for detecting non-palpable breast cancers in asymptomatic women with mammographically dense breasts. A total of 3418 asymptomatic women with mammographically dense breasts underwent ABUS. The study evaluated the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), relative risk, odds risk, and other relevant metrics.

The stand-alone digital mammography demonstrated a sensitivity of 76.00% (95% CI: 54.87% - 90.58%) and specificity of 98.2% (95% CI: 97.76% - 98.59%). The positive predictive value was 20.43% (95% CI: 12.78% - 30.05%), with a breast cancer prevalence rate of 0.60% (95% CI: 12.78% - 30.05%). The cancer detection rate was 4.6 per 1,000, and the mean tumor size detected by mammography was 21.3 mm (N=19) (Giuliano & Giuliano, 2013).

In comparison, ABUS showed a higher sensitivity of 97.67% (95% CI: 87.67% - 99.61%) and an even higher specificity of 99.70% (95% CI=99.46% – 99.86%) in mammographically dense breasts. The positive predictive value of ABUS was 80.77% (95% CI=67.46% - 90.36%). These results suggest that ABUS significantly improves the detection of breast cancers in asymptomatic women with mammographically dense breasts compared to stand-alone digital mammography (Giuliano & Giuliano, 2013).

2.8 Diagnostic Utility of ABUS, Mammogram and Breast Biopsy

A prospective study conducted by (Mohammed et al., 2018) aimed to evaluate the utility of automated breast ultrasound system (ABUS) in detection of different breast lesions especially in dense breast in comparison to mammogram among 25 women outreached for digital mammography or handheld ultrasound examination at the general Egyptian hospitals. The results showed that the use of ABUS with the mammogram shows significant increased frequency of detection of positive benign lesions in ACR class C and D in comparison to class A and B and insignificance malignant lesions detection. The researchers concluded that ABUS reflects a promising modality in breast imaging however appears to be on a par with mammogram in terms of diagnostic quality.

Another retrospective study conducted by Wolterink et al. (2024) aimed to evaluate the diagnostic efficacy of 3D automated breast ultrasound (3D-ABUS) for breast cancer screening within a clinical context. The retrospective analysis included all individuals who underwent 3D-ABUS screening from January 2014 to January 2022. The images were interpreted by one of six breast radiologists utilizing the Breast Imaging Reporting and Data Systems (BI-RADS). The assessment involved the correlation of 3D-ABUS findings with digital breast tomosynthesis (DBT), and various parameters such as recall rate, biopsy rate, positive predictive value (PPV), and cancer detection yield were calculated. The study encompassed 3616 screenings conducted on 1555 women, with predominant breast density categorized as C/D in 95.5% (n = 3455/3616) of cases, A/B in 4.0% (n = 144/3616), and unknown density in 0.5% (n = 17/3616). Notably, 259 lesions were identified on 3D-ABUS, comprising 87.6% (n = 227/259) masses and 12.4% (n = 32/259) architectural distortions. The recall rate was determined as 5.2% (n = 188/3616), with only 36.7% (n = 69/188) of cases requiring further evaluation on a subsequent date. Over time, a decline in the recall rate was observed, biopsies were performed in 3.4% (n = 123/3616) of cases, and 52.8% (n = 65/123) of these biopsies were prompted by abnormalities detected exclusively in 3D-ABUS. Among these, 10 lesions were identified as malignant, resulting in a PPV of 15.4% (n = 10/65). The cancer detection yield of 3D-ABUS was determined to be 2.77 per 1000 screening tests (CI 1.30–5.1) (Wolterink et al., 2024).

In conclusion, the cancer detection yield of 3D-ABUS in this clinical screening setting aligned with the outcomes reported in prior prospective studies, demonstrating lower recall and biopsy rates. The findings suggest that 3D-ABUS may serve as a viable alternative for screening when mammography is not feasible or declined (Wolterink et al., 2024).

2.9 Advantages in Technology

With its many benefits over HHUS, automated breast ultrasound (ABUS) seemed like an alternative choice. The assignment of the acquisition responsibility to the technicians, the ability to record and reproduce images, process images at the workstations and create image reconstruction, a wider field of view (FOV), and the potential for computer-aided detection (CAD) applications are the most significant ones. (Pawlak et al., 2023).

On the other hands ABUS offers numerous benefits in both screening and diagnostic contexts. It enhances the breast cancer detection rate, streamlines workflow, and decreases the time required for examinations (Ioana Boca, 2021).

The acquisition time of Automated Breast Ultrasound (ABUS) is consistently more reliable. On average, the total acquisition time is around 15 minutes for a patient with an average-sized breast, and it might be slightly longer for women with larger breasts, especially if more than the standard three views of each breast are necessary. This consistent acquisition time allows for appropriate scheduling, ensuring that each patient is allocated a designated time slot without unexpected delays, thereby facilitating a more efficient workflow (Shin et al., 2015). In terms of physician time, ABUS requires only the time for interpretation, in contrast to Handheld Ultrasound (HHUS), which includes both the time for conducting the examination and interpreting the results. Once a radiologist becomes proficient in reviewing and interpreting ABUS images, it typically takes about 3 minutes to evaluate a negative examination. This time might extend to approximately 5 minutes when there are one or two significant findings. In some cases, a more thorough interpretation and reporting of results may take 10 minutes or longer (Shin et al., 2015).

According to recent research on Automated Breast Ultrasound (ABUS), using ABUS in conjunction with mammography improves the accuracy of breast cancer diagnosis and boosts callback confidence, especially for women with thick breast tissue. The most recent ABUS machines include benefits such operator dependency reduction, efficiency while surveying large breast areas, and reproducibility. Assuming that accidental benign lesions can be adequately observed, it is imperative to guarantee consistent lesions identification in subsequent tests. Moreover, the modern ABUS machines are helpful for patients receiving neoadjuvant chemotherapy, since breast ultrasonography has been shown to be accurate in monitoring tumor size following this treatment. A high degree of repeatability for ABUS lesion characterization is anticipated (Chang et al., 2015). For mass localization, size measurement, and characterization, the ABUS produced reproducible images that could be helpful for follow up patients (Chang et al., 2015).

2.10 Screening Guidelines

Several major organizations have released updated screening guidelines for breast cancer throughout the previous Later. There are differing opinions on the appropriate age range, the frequency of screenings, and even if breast screenings should be provided at all. Significant discrepancies in estimates of the key benefit (reduction in breast cancer mortality) and the major problem (overdiagnosis) account for the variation between recommendations (Jørgensen. 2017).

Screening guidelines recommended by the American Cancer Society for women with an average risk of breast cancer These recommendations are for women whose risk of breast cancer is average. For screening purposes, a woman is deemed to be at average risk if she has not had chest radiation therapy prior to the age of 30, has no personal history of breast cancer, a strong family history of breast cancer, or a genetic mutation known to increase risk of breast cancer (such as in a BRCA gene). Every year, women between the ages of 40 and 44 can choose to begin mammography screening. Annual mammograms are recommended for women aged 45 to 54. Women who are 55 years of age and above have the option of continuing with annual mammograms or switching to one every other year. As long as a woman is in excellent health and is anticipated to live for at least ten more years, screening should continue. Every woman should be aware of what to anticipate from a mammography, including what the test can and cannot perform, in order to screen for breast cancer. For women at average risk, clinical breast exams are not advised for breast cancer screening at any age (ACS Breast Cancer Screening Guidelines, n.d.)

2.11 Previous Studies

2.11.1 Detected lesions

A cross sectional study conducted by (Philadelpho et al., 2021) aimed to compare hand-held breast ultrasound (HHBUS) and automated breast ultrasound (ABUS) as screening tool for cancer among 440 patients with mammographically dense breasts was conducted, and both HHBUS and ABUS were performed. Hand-held breast ultrasound was acquired by radiologists and ABUS by mammography technicians and analyzed by breast radiologists. The results showed that Automated breast ultrasound identified 12 (12.9%) BI-RADS 2, 75 (80.7%) BI-RADS 3, and 6 (6.4%) BI-RADS 4, including 3 lesions detected by HHBUS and confirmed as IDCs, in addition to 1 invasive lobular carcinoma and 2 high-risk lesions not detected by HHBUS. The amount of time required for the radiologist to read the ABUS was statistically inferior compared with the time required to read the HHBUS ($p<0.001$). The overall concordance was 80.9%. A total of 219 lesions were detected, from those 70 lesions by both methods, 126 only by HHBUS (84.9% not suspicious by ABUS) and 23 only by ABUS. The researchers concluded that ABUS allowed adequate sonographic study in supplemental screening for breast cancer in heterogeneously dense and extremely dense breasts (Philadelpho et al., 2021).

Another study conducted by Chang et al. (2015), the aim of this retrospective study was to assess the consistency of Automated Breast Ultrasound (ABUS) in terms of mass

localization, size measurement, and characterization. Bilateral whole breast ultrasound images were captured twice using a commercially available ABUS system with an average interval of 1.3 days. The study involved 24 patients who underwent imaging before biopsy or surgery, consisting of 24 breast cancers and nine benign cases. Two breast radiologists examined each paired three-dimensional dataset to evaluate lesion visibility, the reproducibility of documented location (clockface location, distance from nipple, and lesion depth), lesion size, and similarity in lesion characteristics. Lesion similarity was categorized as identical, similar, or different through consensus reading using the SomoVu workstation. Intraclass correlation coefficients (ICCs) and the Bland-Altman method were employed to determine the level of agreement in assessments of lesion location and size (Chang et al, 2015). Results indicated that out of 33 breast lesions, 31 were consistently depicted in both serial examinations. The ICCs for displayed lesion location (clock face location, distance from nipple), and individual size of detected lesions were 0.994, 0.926, and 0.980, respectively, suggesting excellent reliability. However, the ICC for lesion depth from the skin was 0.342, indicating lower reliability. In terms of lesion similarity, 16 cancers and five benign lesions were classified as identical, while six cancers and two benign lesions were classified as similar. Two benign lesions were assessed to have different characteristics and final assessment categories. In conclusion, ABUS demonstrated reproducible images for mass localization, size measurement, and characterization, suggesting its potential utility in follow-up studies (Chang et al, 2015).

2.11.2 Sensitivity, specificity, positive predictive value, negative predictive value and accuracy

The study conducted by Maryellen L. Giger et al. examines the impact of adding 3D automated breast ultrasound (ABUS) to full-field digital mammography (FFDM) in breast cancer screening for women with dense breasts. In a reader study involving 17 radiologists and 185 cases, the combination of FFDM with ABUS demonstrated a significant improvement in cancer detection compared to FFDM alone. Specifically, the study found a 14% relative improvement in the diagnostic accuracy (AUC increased from 0.72 to 0.82), a significant increase in sensitivity (from 57.5% to 74.1%), and maintained specificity (78.1% for FFDM alone versus 76.1% for FFDM with ABUS). These results highlight the potential benefits of incorporating ABUS into breast cancer screening protocols for women with dense breasts, showing that it can significantly improve the detection of cancers that may be missed by mammography alone without substantially affecting the rate of false positives (Giger et al, 2016).

Another retrospective study, the objective was to reassess non-mass-like lesions (NMLs) in mammography (MG) categorized as high-risk for breast cancer. This reevaluation was conducted through targeted ultrasound (US) and Automated Breast Ultrasonography (ABUS), aiming to analyze the correlation between different imaging findings and factors influencing lesion classification. A total of 161 patients with 166 breast lesions, initially diagnosed as BI-RADS 4 or 5 by MG and identified as NML on ultrasound, were included in the study. All NMLs underwent mammography, targeted US, and ABUS before breast surgery or biopsy in a consistent breast position. Both imaging and pathological features of

the cases were collected, and lesions were classified according to the ACR BI-RADS lexicon.

The results revealed significant differences between benign and malignant breast NMLs in all the features observed in targeted US and ABUS. US, particularly ABUS, demonstrated superiority over MG in distinguishing malignant breast NMLs. Notably, there were significant differences in the detection rates of calcification between MG and targeted US ($p < 0.001$), as well as in the detection rates of structural distortion between ABUS and MG ($p < 0.001$). In conclusion, targeted US, especially ABUS, emerged as a valuable tool for significantly improving the sensitivity, specificity, and accuracy in diagnosing high-risk NMLs identified in MG. Features such as blood supply, hyper echogenicity, ductal changes, peripheral changes, and coronal features from targeted US and ABUS were identified as useful predictors for distinguishing between benign and malignant lesions. Additionally, the coronal features of ABUS exhibited higher sensitivity in revealing structural abnormalities compared to targeted handheld ultrasound (HHUS) in this retrospective study (Zhang et al., 2021).

The sensitivity of mammography plus ABUS was found to be higher than that of mammography alone in all published studies. The incremental breast cancer detection ranged from 1.9 to 7.7. The majority of aggressive, small-sized, and node-negative cancers that were only evident with ABUS were diagnosed at an early stage, which had significant prognostic implications. Conversely, adding ABUS to screening mammography doubled the recalls that resulted in a biopsy and raised recall rates, all while decreasing the positive predictive value (Rella et al., 2018).

2.11.3 Association between detected lesions and demographic characteristics

A prospective study conducted by (Abd Elkhalek et al., 2019) aimed to evaluate the ABUS machine as non-X-ray hazardous tool in early detection of different breast lesion among 25 women underwent breast screening. Mammography was performed using a GE Healthcare device with dual-energy acquisitions CEDM "Senographe 2000 D full field digital mammography Essential GE Healthcare." A full-field system using a detector with flat panel and Csl absorber was used with field size of 19 × 23 and pitch of 100 mm with image matrix = 1914 × 2294. The results of the study showed that the sensitivity of the ABUS is about 100%, which as in all the results of the mammogram study, ABUS can detect it without significant change, while the specificity of the ABUS was about 62% and was more evident in benign lesions. Also, it showed that the detected lesions by ABUS in the age group below 40 years was more than the mammogram while in the age group above 40 years the ABUS found 1 case only more than the mammogram study. Finally, the researchers concluded that ABUS has advantages of better diagnostic accuracy of breast lesions in terms of early detection, better categorization, and accurate assessment and the ABUS with the mammography could add more value in the breast lesions diagnostic field (Abd Elkhalek et al., 2019).

In a prior investigation, the focus was on assessing the influence of adding 3D automated breast ultrasound (3D ABUS) to full-field digital screening mammography (FFDSM) concerning breast cancer detection and recall rates in asymptomatic women with dense

breasts. The study involved 1668 asymptomatic women, aged 40–74 years, with either heterogeneously dense parenchyma (ACR3) or extremely dense breasts (ACR4) (Wilczek et al., 2016).
FFDSM, including standard craniocaudal (CC) and mediolateral oblique (MLO) views, followed by anteroposterior (AP), lateral (LAT), and medial (MED) acquisitions of 3D ABUS in both breasts, was conducted. All mammograms underwent double reading by two dedicated breast radiologists. The first radiologist immediately reviewed the 3D ABUS after reading the mammograms, while the second reader examined the 3D ABUS only when consensus discussion was necessary due to unclear or abnormal findings in mammograms or 3D ABUS. The results showed that the combined of FFDSM and 3D ABUS showed a total of 6.6 cancers per 1000 women screened (95% CI: 3.0, 10.2; $p < 0.001$), in contrast to 4.2 cancers per 1000 women screened (95% CI) for FFDSM alone. The increase in yield was a significant additional 2.4 detected cancers per 1000 women screened (95% CI: 0.6, 4.8; $p < 0.001$). The corresponding recall rate per 1000 women screened was 13.8 (95% CI: 9.0, 19.8) for FFDSM alone and 22.8 for combined FFDSM and ABUS (95% CI: 16.2, 30.0), resulting in a notable additional 9.0 recalls per 1000 women screened (95% CI: 3.0, 15.0; $p = 0.004$), Finally the researcher concluded that the integration of 3D ABUS with FFDSM in women with ACR3 or ACR4 breast density significantly enhanced the detection rate of invasive breast cancer, with an acceptable increase in recall rates (Wilczek et al., 2016).

2.11.4 Association between detected BIRADS and demographic characteristics

The primary objective of study conducted by Vourtsis and Kachulis (2017) was to assess the effectiveness of automated breast ultrasound (ABUS) in comparison to hand-held traditional ultrasound (HHUS) concerning the visualization and BIRADS (Breast Imaging Reporting and Data System) characterization of breast lesions. The research was conducted between January 2016 and January 2017, involving 1,886 women categorized with breast density as either C or D, with an average age of 48.6±10.8 years. All participants underwent examinations with both ABUS and HHUS, while a subset of 1,665 women also received mammography. (Vourtsis & Kachulis, 2017)

The study findings revealed an impressive overall agreement of 99.8% between HHUS and ABUS, with a kappa value of 0.994 ($p<0.0001$). Notably, two cases initially classified as BI-RADS 1 in HHUS were reclassified as BIRADS 4 in ABUS, leading to the discovery of a radial scar through biopsy. Additionally, discrepancies between mammography and ABUS were observed, with three carcinomas initially categorized as BI-RADS 2 in mammography but as BI-RADS 4 in ABUS. Two more carcinomas were initially rated as BI-RADS 2 in mammography but elevated to BI-RADS 5 in ABUS. Moreover, two carcinomas, initially perceived as a well-circumscribed mass or developing asymmetry in mammography, were classified as BI-RADS 4 in mammography but escalated to BI-RADS 5 in ABUS. (Vourtsis & Kachulis, 2017).

In conclusion, ABUS demonstrated efficacy in both visualizing and characterizing breast lesions. It appeared to surpass HHUS, particularly in detecting architectural distortion on the

coronal plane, and it was deemed as a valuable adjunct to mammography for identifying non-calcified carcinomas in women with dense breast tissue. (Vourtsis & Kachulis, 2017)

The aim of another retrospective study conducted by Chen et al. (2021c) was to assess the reliability of automated breast ultrasound (ABUS) in comparison to handheld ultrasound (HHUS) and mammography (MG) in determining the Breast Imaging Reporting and Data System (BI-RADS) category and accurately sizing malignant breast lesions. A total of 344 confirmed malignant lesions were included in the study, and each participant underwent examinations with MG, HHUS, and ABUS. The study evaluated agreements on the BI-RADS category and compared lesion sizes determined by the three imaging methods with the pathological results serving as the control. Additionally, correlation coefficients between imaging and pathological sizes were examined for the four major molecular subtypes of breast cancer (Chen et al., 2021). The findings indicated a substantial agreement of 86.63% (kappa = 0.77) between ABUS and HHUS in the BI-RADS category, while the agreement was lower at 32.22% (kappa = 0.10) between ABUS and MG. In terms of accurately assessing lesion size, ABUS demonstrated correct assessments in 36.92%/52.91%, HHUS in 33.14%/48.84%, and MG in 33.44%/43.87%, with the applied thresholds of 3 mm/5 mm, respectively. The correlation coefficient of size between ABUS and pathology (0.75, Spearman) was statistically higher than that of MG and pathology (0.58, Spearman) with a significance level of $P < 0.01$. However, there was no significant difference between the correlation coefficient of ABUS-Pathology and HHUS-Pathology (0.74, Spearman) with $P > 0.05$. Specifically, in the triple-negative subtype, luminal B subtype, and luminal A subtype, the correlation coefficient of ABUS-Pathology was significantly higher than that of MG-Pathology ($P < 0.01$) (Chen et al., 2021).

2.12 Conceptual Framework

2.12.1: Theoretical Definitions

ABUS: automated breast ultrasound system (ABUS) is a development in breast ultrasound technology designed to overcome the limitations of handheld ultrasound (HHUS) and decouple detection from picture capture. With the use of high frequency transducers, 3D ABUS creates a wide field of view, providing high-resolution images and scanning a large portion of the breast in a single sweep (Vourtsis, 2019).

Mammogram: is a medical procedure involving X-ray imaging of the breast. It serves the purpose of screening and diagnosing breast-related conditions in women, whether they are experiencing issues like lumps, pain, or nipple discharge, or if they have no apparent breast concerns. This diagnostic method enables the early detection of breast cancers, benign tumors, and cysts that may not be detectable through manual palpation (John Hopkins Medicine, 2022).

Breast Biopsy: is a procedure that involves extracting tissue or, in some cases, fluid from the suspicious area, the collected cells are scrutinized under a microscope and subjected to additional tests to ascertain the presence of breast cancer. A biopsy stands as the sole diagnostic method capable of definitively confirming whether the identified area of concern is cancerous or not (Team, 2024).

Breast Lesions: An abnormal development or lump in the breast tissue can arise from hormonal fluctuations or be a consequence of surgery or injury to the breast area. Individuals may detect a palpable mass beneath the skin or observe alterations in the breast, such as sensitivity or discharge from the nipple (Sissons, 2023).

Breast BIRADS: Breast Imaging Reporting And Data System is a standardized approach for reporting breast disease seen on mammography, ultrasound, and magnetic resonance imaging (MRI), this well-organized framework promotes uniformity between reporting and provides a vocabulary of descriptions, a reporting structure that links evaluation categories to management recommendations, and a system for data collection and auditing, all of which help to promote clear communication between the radiologist and other medical professionals (Plaxco et al., 2017).

Sensitivity: is typically represented as a percentage and defines the ratio of true positives (TP) to the sum of true positives and false negatives (FN) in a given group of individuals with the disease: Sensitivity = TP / (TP + FN). In simpler terms, sensitivity gauges the likelihood of obtaining a positive test result in individuals who have the disease (Eusebi, 2013).

Specificity: is characterized by the ratio of individuals without the disease who receive a negative test result to the total number of individuals without the disease, expressed as TN / (TN + FP). In simpler terms, specificity quantifies the likelihood of obtaining a negative test result in individuals who are free from the disease. Essentially, it assesses the diagnostic procedure's capacity to correctly identify individuals as healthy (Eusebi, 2013).

Positive Predictive value: is a measure that defines the probability of an individual being ill when they receive a positive test result. In mathematical terms, PPV represents the proportion of true positives (TP) divided by the sum of true positives and false positives (FP): PPV = TP / (TP + FP). It indicates the likelihood that a positive test result accurately identifies the presence of the condition in the tested population (Eusebi, 2013).

Negative Predictive value: (NPV) characterizes the probability of an individual not having a disease when they receive a negative test result. Mathematically, NPV is calculated as the proportion of true negatives (TN) divided by the sum of true negatives and false negatives (FN): NPV = TN / (TN + FN). It represents the likelihood that a negative test result accurately indicates the absence of the condition in the tested population (Eusebi, 2013).

Accuracy: is a metric that gauges a test's capability to differentiate and/or forecast the presence of disease or health. It reflects how closely a particular set of measurements aligns with their actual or true values (Eusebi, 2013).

2.12.2: Operational Definitions

Breast Lesions: Categorized into two groups, positive and negative lesions.

Breast BIRADS: In the binary logistic regression categorized into two groups, the first one was <3 and the second one was ≥3

Sensitivity: Calculated using Chi-square test = TP / (TP + FN).

Specificity: Calculated using Chi-square test TN / (TN + FP).

Positive Predictive value: Calculated using Chi-Square test TP / (TP + FP).

Negative Predictive value: Calculated using Chi-Square test = TN / (TN + FN).

Accuracy: Calculated using Kappa agreement = The number of Predictions/ Number of Correct Predictions ×100%

2.13 Conclusion

There has been encouraging progress in improving the detection and characterization of breast lesions with the combination of Automated Breast Ultrasound (ABUS) with conventional imaging techniques including mammography and portable ultrasound. High sensitivity and specificity are demonstrated by ABUS, which helps to improve diagnostic accuracy by identifying lesions that mammography alone is unable to detect. Furthermore, repeatability in mass localization, size measurement, and lesion characterization is demonstrated by ABUS, providing important information for patient follow-up. The results highlight the potential of ABUS as an additional screening tool for breast cancer, particularly for women with thick breast tissue, to help with early lesion detection and therapy.

Chapter Three

Methodology

3.1 Introduction

This chapter described the methodology used in this study includes study setting, study design, sampling process that used in this study, selection criteria, statistical analysis and study instrument.

3.2 Study setting and population characteristics

The study conducted at Yazan Radiology Center, it is a private radiology center located in Bethlehem city it offers a many of radiological service including ultrasound, Dual-energy X-ray absorptiometry DEXA scan, routine X-ray, dental X-ray and there is a breast imaging unit contains mammogram and ABUS that the first and only ABUS machine in Palestine.

3.3 Study design

This study is descriptive, retrospective cross-sectional in nature, which concerned with assessing the efficacy of automated breast ultrasound as a screening tool for detecting breast lesions in comparison with mammography and breast biopsy.

3.4 Sampling size process

The study used a non-probability sampling, using a picture archiving and communication system (PACS). PACS used to archive the demographic and clinical data, including patient's serial number, age, and marital status; past history; family history; provisional diagnosis and the results of mammogram and ABUS reports.

Study cases: the cases that underwent mammography and ABUS during the period between January 2023 and December 2023 which was equal to 133 cases, the mean age of the cases was 51.71years with the youngest patient 35 years old and the oldest 74 years old.

3.5 Sample size determination

All of the cases who attended to breast imaging unit at Yazan radiology center during the period between January 2023 and December 2023.

3.6 Data Collection Procedure

Data collection took place in the period between 1/12/2023 to 10/1/2024. After obtaining permission from the director of the medical imaging center, the data about each patient will be obtained through the PACS. And take the results of the reports provided for each case. And then collect the data of each patient in an excel sheet.

3.7 Study Instrument

After reviewing the literatures of the similar studies, a tables for data collection were modified and developed based on the aims and objectives of the study and its conceptual framework (Appendix 2).

Acquisition technique

The ABUS images were performed by a trained females radiology technicians using ABUS (Invenia™ Automated Breast Ultrasound System, General Electric Healthcare, Sunnyvale, CA, USA) using a C 15-6XW reverse curve, 10 MHz transducer with an aperture length of 15.3 cm, a curved transducer covered by dedicated membrane travel distance of 16.9 cm with constant speed across the breast, and a depth up to 6 cm. An abundant layer of US gel is applied to the breast in order to maximize the coupling between the transducer and the skin. Each breast was examined in four standard projections: anteroposterior, lateral, medial and axillary and if necessary, depending of breast size additional projections inferior or superior were performed. The patients lie down in supine position.
Slices had a thickness of 0.5 mm. Volume acquisitions were performed in the axial plane, and the 3D reconstructions in the sagittal and coronal planes were automatically provided using a dedicated workstation.

3.8 Validity

The study tool evaluated by four experts. The experts included researchers, statisticians, radiologist and field experts. They were asked to perform content validity in order to evaluate how well the items can measure what needs to be measured and to improve instrument relevancy. All suggestions for instrument modification were evidenced.

Data evaluation: Mammogram and ABUS data were collected from a radiological report, which were reviewed by two of board-certified radiologist with more than 10 years' experience.

For each image, assessments were recorded according to the ACR BIRADS assessment as follows: 0, incomplete; 1, negative; 2, benign; 3, probably benign; 4A, low suspicion; 4B, intermediate suspicion; 4C, moderate suspicion; or 5, highly suggestive of malignancy. A BI-RADS assessment of 0, 4A, 4B, 4C, or 5 was considered "positive", and a BI-RADS assessment of 1, 2, or 3 was considered "negative" (Choi et al., 2014).

3.9 Statistical analysis

Statistical Package for the Social Sciences (SPSS) version 25 software was used to analyze the data statistically in this study. To enumerate the features of the variables under examination, such as the clinical and demographic data, descriptive analysis techniques were used. In order to gain insight into the distribution of the study population across several categories, this involved computing frequencies and percentages for categorical variables. To further comprehend the central tendency and variability of the data, statistics like mean and standard deviation were generated for continuous variables. The association between predictor variables and the desired outcome was investigated using univariate analysis, most especially binary logistic regression, One Way ANOVA, paired t-test, chi-square test. The statistically significant difference considered at a level of $p < 0.05$.

3.10 Ethical consideration

Ethical approval was obtained from Al Quds University Ethical Research committee (REC).

And this study was approved by the director of Yazan radiology center (Appendix 2). All the collected data remains private and used only for the research purpose, ensuring that no harm comes to the participants.

Chapter Four

The Results

4.1 Introduction

This chapter will show the descriptive analysis for the participants characteristics (N=133) and the binary logistic regression which showed the association between the number of lesions detected and the number of BIRADS in regard with the participants characteristics.

4.2 Descriptive analysis

Table (4.1) provides a comprehensive overview of demographic characteristics for the study participants. The mean age of the participants is 51.71 years, with a standard deviation of 8.43, as the minimum was 35 years and the maximum was 74. In terms of marital status, the majority of participants (89.5%) are married, while 10.5% are single. Regarding past medical history, a significant proportion (95.5%) of participants have free past history of Breast cancer, whereas 4.5% have a positive history of breast cancer. Family history of breast cancer shows that 82.7% have free family history, while 17.3% have a positive result. The provisional diagnosis reveals that 93.2% of participants have a benign diagnosis, while 6.8% have a malignant diagnosis. Additionally, breast density according to the ACR scale varies, with 10.5% falling under category A, 37.6 in category B,38.3% in category C, and 13.5% in category D.

Table 4.1: Demographic characteristics of the participants (N= 133)

Variables		Frequency	Percentage (%)
Age	Mean ±SD Range	51.71 ± 8.43 (35-74)	
Marital Status	Single	14	10.5
	Married	119	89.5
Past History	Free	127	95.5
	Positive	6	4.5
Family History	Free	110	82.7
	Positive	23	17.3
Provisional Diagnosis	Benign	124	93.2
	Malignant	9	6.8
ACR density of the breast	A*	14	10.5
	B*	50	37.6
	C*	51	38.3
	D*	18	13.5

ACR: A: Almost entirely fatty B: Scattered fibro glandular densities C: Heterogeneously dense D: Extremely dense

Table 4.2 outlines the distribution of detected lesions by mammogram and their correlation with the Breast Imaging Reporting and Data System (BIRADS). Among the study participants, 33.8% were identified as positive on mammograms, while 66.2% showed negative results. The BIRADS classification further characterizes these findings, with the majority (66.9%) falling under BIRADS 0.00. BIRADS 3.00 represents 23.3% of cases, indicating, while BIRADS 4.00 accounts for 4.5%. BIRADS 1.00 and 2.00 are relatively infrequent at 2.3% and 1.5%, respectively. Also, the range of the number of detected lesions was between (0-6) with mean 0.69 and standard deviation 1.21.

Table A-4.2**: Detected lesions by mammogram and correlated BIRADS**

Lesions		Frequency	Percentage
Mammogram	Positive	45	33.8
	Negative	88	66.2
Mammogram BIRADS	0.00	89	66.9
	1.00	3	2.3
	2.00	2	1.5
	3.00	31	23.3
	4.00	6	4.5
	5.00	2	1.5
Number of Lesions	0.00	83	62.4
	1.00	34	25.6

Table B-4.2**: Detected lesions by mammogram and correlated BIRADS**

	2.00	4	3.0
	3.00	3	2.3
	4.00	6	4.5
	5.00	2	1.5
	6.00	1	.8
Number of Lesions	Mean ± SD Range	0.69 ± 1.21 (0-6)	

Table 4.3 provides an overview of detected lesions through Automated Breast Ultrasound (ABUS) and their correlation with the Breast Imaging Reporting and Data System (BIRADS). Of the study cases, 63.2% were identified as positive for lesions using ABUS, while 36.8% yielded negative results. The ABUS BIRADS classification further categorizes these findings, with BIRADS 1.00 representing 39.8% of cases, indicating a negative assessment. BIRADS 2.00 and 3.00 account for 28.6% and 24.1%, respectively, suggesting benign and probably benign lesions. BIRADS 4.00, indicative of suspicious findings, constitutes 7.5% of cases. Also, the mean of number of detected lesions was 1.83 ranged between (0-10).

Table 4.3 **: Detected lesions by ABUS and correlated BIRADS**

Lesions		**Frequency**	**Percentage**
ABUS*	Positive	84	63.2
	Negative	49	36.8
ABUS BIRADS**	1.00	53	39.8
	2.00	38	28.6
	3.00	32	24.1
	4.00	10	7.5
Number of lesions	Mean ± SD Range	1.83 ± 2.11 (0.00-10.00)	

***ABUS: Automated Breast Ultrasound ** BIRADS: Breast Imaging Reporting and Data System**

4.3 Univariate Analysis

Table 4.4 presents a comparison between detected lesions and their correlated Breast Imaging Reporting and Data System (BIRADS) classifications using mammogram and Automated Breast Ultrasound (ABUS), along with the results of a paired T-test. Notably, a statistically significant difference is observed in the number of positive lesions identified by mammogram (33.8%) compared to ABUS (63.2%), with a p-value of .000. Moreover, the BIRADS mean values for mammogram (1.007 ± 1.51) and ABUS (1.99 ± 0.97) further underscore the disparity in their assessments, with a paired T-test value of 7.461 and a p-value of .000. The number of detected lesions showed statistically significant difference between the mammogram and the ABUS as the mean of the ABUS was higher than mammogram. Also, according to the ACR density which studied with the detected lesion using a chi-square test, the ABUS showed increasing the detection of ACR density. ABUS detected 94.4% of the D category with lesions in comparison with 16.7% by the

mammogram (P.value <0.05). These findings emphasize the discordance in lesion detection between the two modalities, suggesting that ABUS may offer enhanced sensitivity in identifying breast lesions compared to traditional mammography, as evidenced by the statistical significance in chi-square and paired t test.

Table (4.4)**:** Comparison between detected lesions and correlated BIRADS by mammogram and ABUS

		Mammogram		**ABUS**		**Test value**	**P.value**	**Test used**
		No.	**%**	**No.**	**%**			
Lesion	**Positive**	45	33.8	84	63.2	**16.154**	**.000**	**Chi-square**
	Negative	88	66.2	49	36.8			
BIRADS	**Mean ± SD Range**	1.007 ± 1.51 (0-5)		1.99 ± 0.97 (1-4)		**7.461**	**.000**	**Paired T Test**
Number of lesions	**Mean ± SD Range**	0.69 ± 1.21 (0-6)		1.83 ± 2.11 (0.00-10.00)		**-4.89**	**.000**	**Paired T Test**
ACR Density by the detected lesions	**A**	12	85.7%	9	64.3%	**Mammo: 41.96 ABUS:13.76**	**Mammo:0.000 ABUS:0.003**	**Chi-square**
	B	26	52%	34	68.0%			
	C	4	7.8%	24	47.1%			
	D	3	16.7%	17	94.4%			

Table 4.5 illustrates a comparative analysis between detected lesions and their correlated Breast Imaging Reporting and Data System (BIRADS) classifications by mammogram and Automated Breast Ultrasound (ABUS). The data reveals a statistically significant difference between positive mammogram and ABUS results, with 46.4% of lesions detected as positive on both. However, a significant number of lesions identified as negative on mammograms (87.8%) were found to be positive on ABUS. This difference is statistically significant, as indicated a p-value of .000. These findings underscore the increased sensitivity of ABUS in detecting lesions compared to mammography, suggesting the potential complementary role of ABUS in improving the accuracy of breast lesion detection, particularly in cases where mammograms yield negative results.

Table (4.5): Comparison between detected lesions and correlated BIRADS by mammogram and ABUS

	Positive Mammogram	**Negative Mammogram**	**Test Value**	**P.value**
Positive ABUS	39 (46.4%)	45 53.6%	16.154	.000
Negative ABUS	6 (12.2%)	43 (87.8%)		

Table 4.6 presents a comparison between the number of detected lesions and the (ACR) breast density categories using two diagnostic tools: mammogram and Automated Breast Ultrasound System (ABUS). For mammograms, the mean number of detected lesions ± the standard deviation (SD) in each density category are as follows: A (1.00 ± 1.29), B (0.57 ± 0.95), C (0.77 ± 1.47), and D (0.50 ± 0.85) with a p-value of 0.62, suggesting no significant difference in lesion detection across the density categories for mammograms.

On the other hand, the mean ± SD for ABUS in the density categories A, B, C, and D are: A (2.24 ± 2.53), B (1.44 ± 1.69), C (1.49 ± 1.99), and D (2.47 ± 0.58), respectively, with a statistically significant p-value of 0.002. Tukey HSD was used to correctly interpret the statistical significance of the difference between means that have been selected for comparison because of their extreme values. Which reveals significant differences in the number of lesions detected by ABUS between certain ACR breast density categories. Specifically, a significant difference is observed between breast density categories B and D, and between categories C and D. The number of lesions detected in category D is significantly higher than in both categories B and C. This is indicated by the negative mean differences of -2.00444 (B vs. D, p=0.002) and -1.95425 (C vs. D, p=0.003). These findings suggest that ABUS is particularly effective or sensitive in detecting a higher number of lesions in breasts with the highest density category, D, compared to lower density categories B and C as shown in table (4.6.A).

Table (4.6A): Comparison between the number of detected lesions and ACR density by mammogram and ABUS

Diagnostic tool	**A**	**B**	**C**	**D**	**Test Value**	**P.value**	**Test used**
Mammogram Mean ± SD	1.00 ± 1.29	0.57 ± 0.95	0.77 ± 1.47	0.50± 0.85	0.58	0.62	One way ANOVA
ABUS Mean ± SD	2.24 ± 2.53	1.44± 1.69	1.49 ± 1.99	2.47±0.58	5.33	0.002	One way ANOVA

Table (4.6.B): Multiple Comparison between the number of detected lesions and ACR density by ABUS

Multiple Comparisons						
Dependent Variable: Number of lesions detected by ABUS						
Tukey HSD						
(I) ACR density of the breast	(J) ACR density of the breast	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
A	B	.98857	.61112	.372	-.6021	2.5792
	C	.93838	.60981	.417	-.6489	2.5256
	D	-1.01587	.72021	.495	-2.8905	.8587
B	A	-.98857	.61112	.372	-2.5792	.6021
	C	-.05020	.40223	.999	-1.0971	.9967
	D	-2.00444*	.55554	.002	-3.4504	-.5585
C	A	-.93838	.60981	.417	-2.5256	.6489
	B	.05020	.40223	.999	-.9967	1.0971
	D	-1.95425*	.55410	.003	-3.3965	-.5120
D	A	1.01587	.72021	.495	-.8587	2.8905
	B	2.00444*	.55554	.002	.5585	3.4504
	C	1.95425*	.55410	.003	.5120	3.3965
*. The mean difference is significant at the 0.05 level.						

Table 4.7 presents a comparison between detected lesions and their correlated Breast Imaging Reporting and Data System (BIRADS) classifications based on results from Breast Biopsy and Automated Breast Ultrasound (ABUS). The data shows that 86.9% of lesions identified as positive on ABUS were not subjected to a biopsy, while 3.6% were confirmed as benign and 9.5% as malignant based on biopsy results. Notably, all lesions identified as negative on ABUS (100%) did not undergo biopsy. The p-value of 0.030 indicate a statistically significant difference between ABUS findings and the nature of biopsy results. This suggests that ABUS can potentially aid in identifying lesions that may warrant further investigation through biopsy, particularly those with malignant characteristics. However, the high percentage of positive ABUS results not confirmed by biopsy emphasizes the need for cautious interpretation and additional diagnostic steps for a conclusive assessment of lesion malignancy.

Table (4.7): Comparison between detected lesions and correlated BIRADS by Breast Biopsy and ABUS

	Not done	**Benign Biopsy**	**Malignant Biopsy**	**Test Value**	**P.value**
Positive ABUS	73 (86.9%)	3 (3.6%)	8 (9.5%)	6.99	0.030
Negative ABUS	49 (100.0%)	0 (0.0%)	0 (0.0%)		

Table 4.8 presents a comprehensive assessment of the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and associated statistical significance of Automated Breast Ultrasound (ABUS) in comparison with Mammogram, using Kappa Agreement as the benchmark. The results indicate that ABUS demonstrates a sensitivity of 86.7%, which reflects its effectiveness in correctly identifying true positive cases. However, the specificity is relatively lower at 48.9%, indicating a higher rate of false positives. The positive predictive value (PPV) stands at 46.4%, showcasing the proportion of positive identifications that are truly positive. The negative predictive value (NPV) is high at 87.8%, indicating ABUS's reliability in correctly identifying true negative cases. The overall accuracy of ABUS is 61.65%, signifying its overall diagnostic precision. The associated p-value of 0.000 indicates a statistically significant difference between ABUS and Mammogram in terms of their diagnostic performance. These findings suggest that while ABUS exhibits high sensitivity, there is a trade-off with specificity, emphasizing the need for a comprehensive evaluation of both modalities in clinical settings.

Table (4.8): Ratio of sensitivity and specificity of ABUS in comparison with Mammogram Kappa Agreement

Accuracy

ABUS	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Accuracy**	**P.value**
	86.7%	48.9%	46.4%	87.8%	61.65%	0.000

Table (4.9) presents the ratio of sensitivity and specificity of the provisional diagnosis by ABUS and Mammogram in comparison with Biopsy Kappa Agreement. The results indicate that the provisional diagnosis has a sensitivity of 12.5%, specificity of 98.4%, positive

predictive value (PPV) of 77.8%, negative predictive value (NPV) of 99.2%, and an overall accuracy of 97.74%. The p-value of 0.001, which is less than the commonly used significance threshold of 0.05, suggests that these diagnostic measures are significantly associated with the biopsy results.

The low sensitivity value of 12.5% indicates that the provisional diagnosis has a limited ability to correctly identify true positive cases among all actual positive cases. However, the high specificity of 98.4% suggests that the provisional diagnosis has a strong ability to correctly identify true negative cases among all actual negative cases. The positive predictive value (PPV) of 77.8% indicates the probability that cases identified as positive by the provisional diagnosis are indeed positive, while the negative predictive value (NPV) of 99.2% indicates the probability that cases identified as negative are indeed negative. The overall accuracy of 97.74% reflects the proportion of correctly classified cases among all cases.

Table (4.9): Ratio of sensitivity and specificity of Provisional Diagnosis by (ABUS and Mammogram) in comparison with Biopsy Kappa Agreement

Provisional Diagnosis by (ABUS and Mammogram)	Sensitivity	Specificity	PPV	NPP	Accuracy	P.value
	12.5%	98.4%	77.8%	99.2%	130/133*100 97.74	0.001

The provided Crosstabulation displays the contingency table for the provisional diagnosis and the results of biopsy. It reveals the distribution of cases across different categories, showing the count and percentage for each combination. In this table, the majority of cases (120 out of 124) diagnosed as benign through provisional diagnosis indeed resulted in a benign biopsy, representing a high concordance rate of 96.8%. However, three cases diagnosed as benign in the provisional diagnosis were found to be benign upon biopsy, constituting 2.4% of the cases. On the other hand, among the cases initially diagnosed as malignant through provisional diagnosis (9 cases), seven were confirmed as malignant by biopsy (77.8%), while two cases turned out to be not performing the biopsy (22.2%). The Chi-Square Test exhibit significant p-values ($p < 0.001$), indicating a strong association between the provisional diagnosis and the results of biopsy. This suggests that the provisional diagnosis is significantly related to the actual biopsy results, highlighting the diagnostic accuracy and predictive value of the provisional diagnosis in identifying benign and malignant cases as indicated in the Chi-Square Tests section as shown in table (4.10).

Table (4.10): provisional diagnosis * Results of biopsy Crosstabulation					
		Results of biopsy			
		Not done	Benign	malignant	Total
provisional diagnosis	Benign	120	3	1	124
		96.8%	2.4%	0.8%	100.0%
	Malignant	2	0	7	9
		22.2%	0.0%	77.8%	100.0%

Chi-Square Tests

	Value	Df	Asymptotic Significance (2-sided)
Pearson Chi-Square	87.950[a]	2	.000
Likelihood Ratio	39.414	2	.000
Linear-by-Linear Association	78.765	1	.000
N of Valid Cases	133		

a. 3 cells (50.0%) have expected count less than 5. The minimum expected count is .20.

Table (4.11) shows the binary logistic regression for the lesion's detection according to the patient's demographic characteristics, as there is no statistically significant difference in regard with (age, marital status, family history, past medical history, provisional diagnosis and detected BIRDAS by ABUS).

There is a statistically significant difference in the lesion's detection according to the ACR density category concerning the reference category D. ACR density category A demonstrates an odds ratio of 9.444, indicating that individuals falling into this category have 9.44 times higher odds of detecting lesions compared to those in category D (p-value = 0.015 <0.05). On the other hand, there is no statistically significant difference in the detected lesions between D and B categories nor between D and C categories.

Also, there is a statistically significant difference in the detected lesion by ABUS according to the number of detected BIRDS by Mammogram as the OR=5.98 higher to detect the

lesions by ABUS for patients who have less than 3 detection BIRADS by Mammogram (p-value=0.002). For nominal variables (Marital Status, Past History, Family History, Provisional Diagnosis), the reference category was chosen based on either clinical relevance or interpretive clarity, rather than frequency alone. For ordinal variables (Age, ACR Density), the reference was selected considering natural ordering or clinical importance.

Table (4.11): Binary Logistic regression for the detected lesions by ABUS with patients' demographic characteristics

Variables		OR	P.value
Age	<45 Years	0.99	0.90
	≥ 45 Years	Ref.	Ref.
Marital Status	Single	Ref.	Ref.
	Married	0.28	1.88
Past History	Free	.328	.379
	Positive	Ref.	Ref.
Family History	Free	.289	1.883
	Positive	Ref.	Ref.
Provisional Diagnosis	Benign	.999	6.35
	Malignant	Ref	Ref.
ACR density of the breast	A	9.444	.015
	B	8.000	.055
	C	19.125	.053
	D	Ref.	.006
BIRADS by Mammogram	<3	0.002	5.98
	≥ 3	Ref.	Ref.
BIRADS by ABUS	<3	0.997	0.15
	≥ 3	Ref.	Ref.

Table (4.12) outlines the outcomes of binary logistic regression examining the detected BIRADS by ABUS in regarding with patients' demographic characteristics. The analysis reveals that, among demographic variables, age, marital status, past history, and family history do not appear to be significant predictors of having a BIRADS score greater than or equal to 3. Also, a provisional diagnosis of "benign" demonstrates a substantial impact, with an odds ratio of 0.067 and a significant p-value of 0.016, indicating a strong association with a lower likelihood of having a BIRADS score of 3 or higher. Moreover, ACR density categories A, B, and C exhibit odds ratios of 0.643, 0.382, and 0.266, respectively, suggesting a decreasing likelihood of a higher BIRADS score compared to category D, although the significance varies. ACR density category C showed statistically significant difference with a p-value of 0.033. On the other hand, BIRADS by mammogram does not show statistical significance, with an odds ratio of 1.678 and a p-value of 0.298. For nominal variables (Marital Status, Past History, Family History, Provisional Diagnosis), the reference category was chosen based on either clinical relevance or interpretive clarity, rather than frequency alone. For ordinal variables (Age, ACR Density), the reference was selected considering natural ordering or clinical importance.

Table (4.12): Binary Logistic regression for the detected BIRADS by ABUS with patients' demographic characteristics

Variables		OR	P.value
Age	<45 Years	.774	.617
	≥ 45 Years	Ref.	Ref.
Marital Status	Single	.996	.995
	Married	Ref.	Ref.
Past History	Free	1.097	.931
	Positive	Ref.	Ref.
Family History	Free	.730	.584
	Positive	Ref.	Ref.
Provisional Diagnosis	Benign	.067	.016
	Malignant	Ref.	Ref.
ACR density of the breast	A	.643	.566
	B	.382	.127
	C	.266	.033
	D	Ref.	.165
BIRADS by Mammogram	<3	1.678	.298
	≥ 3	Ref.	Ref.

4.4 Conclusion

The study's findings highlight the usefulness of Automated Breast Ultrasound (ABUS) as a supplement to mammography, especially when it comes to identifying lesions that conventional methods overlook and improving sensitivity, particularly in denser breast tissues. The necessity of include ABUS in breast cancer screening procedures is shown by the notable difference in lesion detection rates between ABUS and mammography. Furthermore, the remarkable correlation between the results of the ABUS and the biopsy highlights the clinical value of the test in directing future diagnostic and therapy choices. All things considered, ABUS has great promise for increasing the accuracy of lesion detection and enhancing current diagnostic techniques, which will ultimately lead to improved breast cancer detection and treatment plans.

Chapter Five

Discussion

5.1 Introduction

This chapter will introduce the discussion of the major findings of the study related with the previous studies that concerned with the role of ABUS, mammogram and biopsy in breast lesions detections.

5.2 Summary of the results

The mean age of participants was 51.71 years, as (89.5%) of them married with free history of breast cancer represented by (95.5%) and (82.7%) free family history. In regard with the provisional diagnosis, 93.2% categorized within the benign lesions whereas 6.8% within the malignant category. For the breast density,38.3% categorized within category c and 37.6% of the participants categorized within category B, 13.5% in category D and 10.5 in category A. In comparison between Mammogram and ABUS, there is a statistically significant difference in the lesion detection as 63.2% of the positive lesions detected by ABUS whereas 33.8% of them detected by mammogram. Also, ABUS showed increased sensitivity and detected more lesions in breasts with higher density. Overall accuracy of ABUS was 61.65%, with a significant difference from mammogram.

ABUS implicated as an effective method in detecting more lesions in breast with highest density (category D) in comparison with the lower density categories. Moreover, there is statistically significant difference between the ABUS and biopsy results, as the biopsy confirmed 3.6% of lesions as benign and 9.5% as malignant. The Overall accuracy of the provisional diagnosis was 97.74%, significantly associated with biopsy results.

The logistic regression emphasize that ACR density categories A, B, and C showed higher odds of lesion detection compared to category D and the patients with fewer BIRADS detections by mammogram had higher odds of lesion detection by ABUS. On the other hand, there is no statistically significant difference between the detected lesions by ABUS and the patients' demographic characteristics such as age, marital status, family history and past

history Except the ACR density. Also, there is no statistically significant difference in the detected BIRADS according to the patients' characteristics except provisional diagnosis and ACR density (C category).

Comparison between detected lesions and correlated BIRADS by mammogram and ABUS

The current study revealed that there is a statistically significant difference in the number of positive lesions identified by mammogram (33.8%) compared to ABUS (63.2%). This finding is in discrepancy with the findings by (Mohammed et al., 2018) as they discovered that there is no statistically significant difference between the number of positive lesions found by mammogram and ABUS 68.0% and 80.0% respectively. This difference could be due to the differences of the sample characteristics as they used only 25 participants.

Also, according to the ACR density which studied with the detected lesion using a chi-square test, the ABUS showed increasing the detection of ACR density. ABUS detected 94.4% of the D category with lesions in comparison with 16.7% by the mammogram (P.value <0.05).

These findings emphasize the discordance in lesion detection between ABUS and mammogram, indicating that ABUS may provide enhanced sensitivity in identifying breast lesions compared to mammogram, as evidenced by the statistical significance in chi-square and paired t test.

Also, this study confirmed that there is a statistically significant difference between positive mammogram and ABUS results, with 46.4% of lesions detected as positive on both. However, a significant number of lesions identified as negative on mammograms (87.8%) were found to be positive on ABUS. This difference is statistically significant, as indicated a p-value of .000. These findings underscore the increased sensitivity of ABUS in detecting lesions compared to mammography, suggesting the potential complementary role of ABUS in improving the accuracy of breast lesion detection, particularly in cases where mammograms yield negative results.

Comparison between the number of detected lesions and ACR density by mammogram and ABUS

This study compares the number of detected lesions across different ACR breast density categories using two breast screening tools: mammogram and ABUS. The findings highlight the differences in lesion detection efficacy between these modalities and emphasize the potential advantages of ABUS in specific breast density categories.

For mammograms, the mean number of detected lesions ± standard deviation (SD) across the ACR breast density categories were as follows: Category A: 1.00 ± 1.29 Category B: 0.57 ± 0.95 Category C: 0.77 ± 1.47 Category D: 0.50 ± 0.85. The p-value of 0.62 indicates that no significant difference in lesion detection among the different breast density categories. This suggests that mammogram efficacy in detecting lesions is relatively consistent across varying breast densities, though generally lower in denser breasts (category D).

For ABUS, the mean number of detected lesions ± SD across the ACR breast density categories were as follows: Category A: 2.24 ± 2.53 Category B: 1.44 ± 1.69 Category C: 1.49 ± 1.99 Category D: 2.47 ± 0.58 A statistically significant p-value of 0.002 indicates

substantial differences in lesion detection across different breast density categories. Tukey HSD post hoc analysis further reveals significant differences between specific categories:

Category B vs. Category D: Mean difference of -2.00444 (p=0.002)

Category C vs. Category D: Mean difference of -1.95425 (p=0.003)

These results show that ABUS is particularly effective in detecting lesions in breasts with the highest density (category D) compared to lower density categories B and C. These findings suggest that ABUS is particularly effective or sensitive in detecting a higher number of lesions in breasts with the highest density category, D, compared to lower density categories B and C

This finding aligns with (Pawlak et al., 2023) that they confirmed that ABUS visualized 99% of lesions in breast density category C and D, while mammograms visualized only 4.3% of them.

Comparison between detected lesions and correlated BIRADS by Breast Biopsy and ABUS

This study evaluates the correlation between lesions detected by ABUS and subsequent biopsy results, The data indicates that 86.9% of lesions identified as positive by ABUS were not subjected to biopsy. Of the lesions that were biopsied, 3.6% were confirmed as benign and 9.5% as malignant. Interestingly, all lesions identified as negative by ABUS (100%) did not undergo biopsy. The p-value of 0.030 suggests a statistically significant difference between ABUS findings and the nature of biopsy results.

These findings underscore the potential role of ABUS in identifying lesions that may warrant further investigation through biopsy, particularly those with malignant characteristics. The ability of ABUS to detect a substantial number of lesions that were subsequently confirmed as malignant emphasizes its sensitivity and potential utility in early breast lesions detection.

The high percentage of positive ABUS results that did not proceed to biopsy (86.9%) highlights a critical area for further consideration. While ABUS can identify potential lesions, the lack of subsequent biopsy for a majority of these cases indicates a need for cautious interpretation of ABUS results. This high rate of non-biopsied lesions suggests clinical evaluation, and possibly short-term follow-up may be required to ensure that significant lesions are not overlooked and to avoid unnecessary biopsies.

Ratio of sensitivity and specificity of ABUS in comparison with Mammogram Kappa Agreement

This study evaluates the diagnostic performance of ABUS in comparison to mammography, highlighting its sensitivity, specificity, and overall accuracy in identifying breast lesions.

ABUS demonstrates a high sensitivity of 86.7%, indicating its effectiveness in correctly identifying true positive cases. This high sensitivity underscores ABUS's potential as a powerful tool for early detection of breast lesions, particularly in dense breast tissue where mammography may be less effective. However, the specificity of ABUS is relatively lower at 48.9%, indicating a higher rate of false positives. This lower specificity suggests that while

ABUS is adept at identifying potential lesions, it also flags a significant number of benign findings as positive, which can lead to unnecessary anxiety and follow-up procedures.

The positive predictive value (PPV) of ABUS stands at 46.4%, indicating that less than half of the lesions identified as positive by ABUS are confirmed as true positives upon further investigation. This highlights the need for careful consideration and additional diagnostic steps following a positive ABUS finding to avoid unnecessary biopsies and interventions.

Conversely, the negative predictive value (NPV) is high at 87.8%, reflecting ABUS's reliability in correctly identifying true negative cases. This high NPV means that when ABUS identifies a lesion as negative, there is a strong likelihood that the lesion is indeed benign, providing reassurance and potentially reducing the need for further invasive procedures.

The overall accuracy of ABUS is 61.65%, indicating moderate diagnostic precision. This accuracy rate signifies that while ABUS is a useful tool, its results should be interpreted within the broader context of a comprehensive diagnostic workup, including mammography and other imaging modalities.

The associated p-value of 0.000 indicates a statistically significant difference between the diagnostic performances of ABUS and mammography. This statistical significance emphasizes that the differences observed in sensitivity, specificity, and overall accuracy are not due to random chance, thereby validating the comparative analysis.

The findings suggest that ABUS, with its high sensitivity, can be particularly valuable in detecting breast lesions that might be missed by mammography, especially in patients with dense breast tissue. However, the trade-off with specificity necessitates a cautious approach.

Integrating ABUS into clinical practice requires a balanced approach. It is essential to utilize ABUS as a complementary tool rather than a standalone diagnostic method. By combining ABUS with mammography, healthcare providers can leverage the strengths of both modalities, enhancing overall diagnostic accuracy and improving patient outcomes.

The Association between the detected lesions by ABUS and the patients' demographic characteristics

The current study revealed that there is no statistically significant difference in regard with (age, marital status, family history, past medical history, provisional diagnosis and detected BIRDAS by ABUS). In regard with the age, this finding is in discrepancy with the findings by (Elkhalek et al., 2019) as they discovered that the number of lesions found by ABUS in the age group under 40 years old was greater than the number found by the mammography (ABUS = 7 cases and mammogram = 5 cases), but in the age group over 40 years old, ABUS only found 1 case that was greater than the mammography study. This difference could be attributed the differences between study sample characteristics in the age groups as the present investigation mean age was 51 years old.

However, there is a statistically significant difference in the lesion's detection according to the ACR density category concerning the reference category D. Category A demonstrates an odds ratio of 9.444, indicating that participants falling into this category have 9.44 times

higher odds of detecting lesions compared to those in category D. This finding supported by (Kumar et al., 2019) as they confirmed that breasts classified as Category A usually have glandular and fibrous tissue that is less dense, making lesions easier to see on imaging scans such as mammography or ultrasound. On the other hand, breasts in category D have denser tissue, which is more compact and can mask lesions, making them more difficult to see.

On the other hand, there is no statistically significant difference in the detected lesions between D and B categories nor between D and C categories. This could be explained by that the most of the study participant fall among those categories.

Also, there is a statistically significant difference in the detected lesion by ABUS according to the number of detected BIRDS by Mammogram as the OR=5.98 which means that patients with fewer than three detected BIRADS lesions by mammography are nearly six times more likely to have lesions discovered by ABUS than patients with higher BIRADS scores. This finding suggests that ABUS may be especially useful in detecting lesions that mammography may have overlooked or failed to detect, particularly in situations when mammography reveals fewer suspicious findings. It highlights the potential supplementary function of ABUS in improving the detection of breast cancer, particularly when mammography may not be enough on its own.

The Association between the detected BIRADS by ABUS and the patients' demographic characteristics

The current study reveals that there is no statistically significant difference in the detected BIRADS by ABUS in terms with the demographic characteristics of the study participants such as the age, family history of breast cancer and past history of breast cancer, except the ACR density (C category) and benign provisional diagnosis. For the age, our result aligns with (Elkhalek et al., 2019; Ren et al., 2023). In regard with the family and past history of breast cancer, these results are contrast with the findings of a multicenter population-based study by (Ren et al., 2023) as they assessed the effectiveness of mammography (MAM) alone against MAM in conjunction with second-look automated breast ultrasounds (ABUS) in women who did not exhibit any symptoms. It also looked at how well handheld ultrasonography (HHUS) and ABUS augmentation performed which was conducted between 2018 and 2022 in six hospitals in China among 19171 women, 72 of them diagnosed with breast cancer. They confirmed that there is a statistically significant difference in the detected lesions by ABUS according to age, breast disease history, family history of breast cancer and breast density. These differences could be attributed to the differences of sample characteristics and the smaller sample size in the current study. On the other hand, marital status and ACR density results are consistent with the findings by (Ren et al., 2023) as they confirmed that there is statistically significant difference in the detected lesions according to the ACR density as they confirmed that the highest number of lesions detected from (4-5) among Category c represented by 677(69.65%) which is in similar with the current study findings which showed that there is statistically significant difference in the detected BIRADS with 0.26 odds ratio which means that the highest number of BIRADS could be detected (≥3) among C category.

However, the provisional diagnosis showed that there is statistically significant difference in the detected BIRADS as the provisional diagnosis of benign lesions has a higher odds ratio (OR) of.067 when compared to malignant lesions, indicating a strong correlation between this diagnosis and the possibility of being classified as benign instead of malignant. This finding emphasizes the importance of accurately diagnosing breast lesions to detect the appropriate treatment decisions.

5.7 Conclusion

The study concludes that automated breast ultrasonography (ABUS) is a potential screening technology that can effectively detect breast abnormalities, especially in dense breasts where mammography may not be as effective. When compared to mammography, ABUS showed a better sensitivity for finding lesions, particularly in breasts with higher density categories. The results highlight the possible additional benefit of ABUS in enhancing lesion detection, especially when mammography yields fewer concerning results. Furthermore, whereas some demographic traits did not significantly correlate with the identification of lesions by ABUS, others, such breast density and provisional diagnosis, did. These findings highlight how crucial it is to take into account ABUS as an additional tool for breast cancer screening and diagnosis, especially in groups with a variety of demographic traits and breast densities.

5.8 Recommendations

Recommendations for Policy makers

A. The purchase of ABUS technology and the education of medical personnel in its application should be adequately funded by policymakers. This covers financial allocations for the acquisition, upkeep, and training of personnel.
B. National breast cancer screening guidelines ought to incorporate ABUS as a suggested screening technique. To reflect the significance of ABUS in early detection efforts, policy makers can work with relevant medical societies and experts to amend the current guidelines.

Recommendations for Healthcare providers

A. Education and Training: A thorough education in the use of ABUS technology, encompassing picture acquisition, interpretation, and reporting, should be provided to healthcare personnel. In order to guarantee staff members' expertise and competence, continuing education programs must to be made available.
B. Standardized Protocols: To guarantee accuracy and consistency across various healthcare settings, healthcare professionals should create standardized protocols for ABUS screening processes. This covers recommendations for situating patients, specifications for acquiring images, and standards for reporting.
C. Quality Assurance Measures: To track and assess the effectiveness of ABUS technology in clinical practice, healthcare professionals should have quality assurance measures in place. In order to guarantee compliance with best practices and care standards, this entails frequent audits, peer review meetings, and feedback systems.

Recommendations for Further research

A. Conduct further research with different study design such as longitudinal studies to assess the long-term efficacy of ABUS screening in lowering breast cancer death rates and enhancing patient outcomes. Also, qualitative study design to investigate patient experiences and preferences with regard to ABUS screening for pay particular attention to variables that affect acceptability, satisfaction, and screening recommendation adherence. This can direct initiatives to maximize ABUS screening programs' patient-centeredness.
B. Conduct further research with larger sample size to determine the differences of the patients' characteristics.

Study limitations

A. The small number of participants who underwent a biopsy.
B. Inability to evaluate the performance of ABUS against traditional HHUS.
C. Limited Financial Support.

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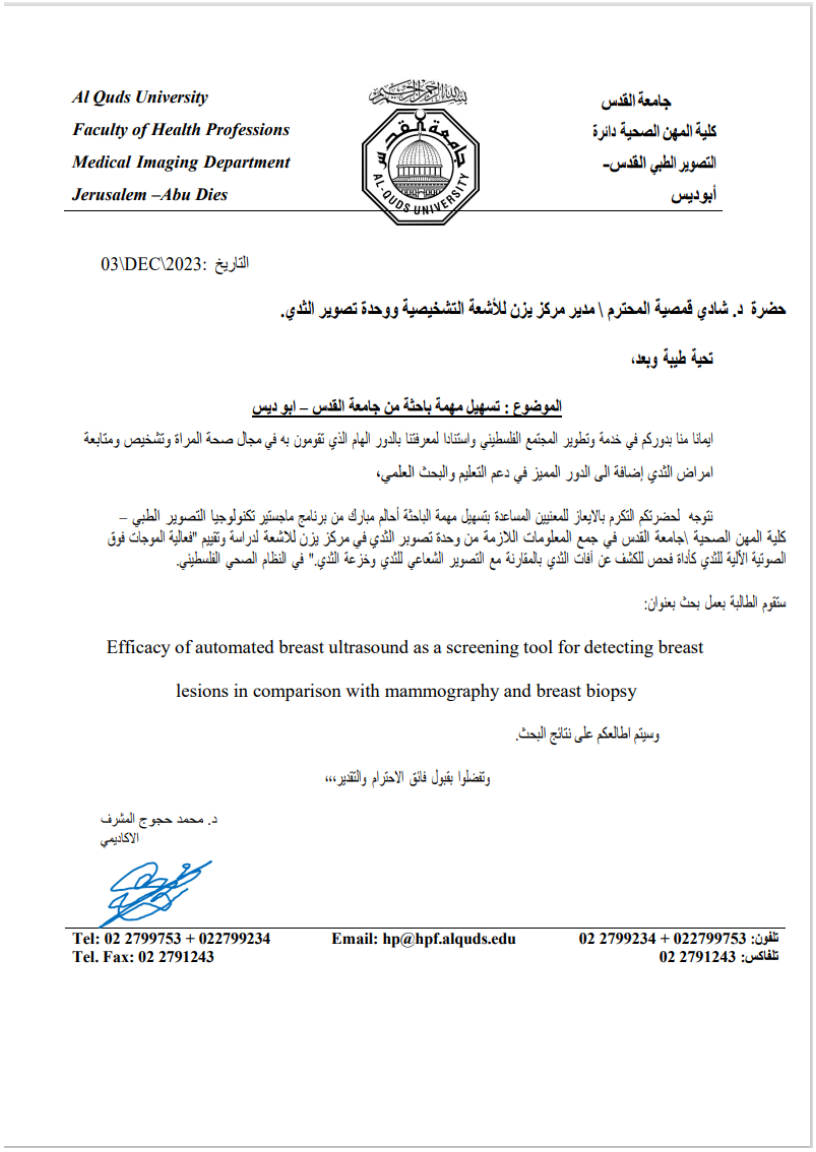
Appendices

Appendix 1: The ethical approval to start the study from Yazan radiology center



Al Quds University
Faculty of Health Professions
Medical Imaging Department
Jerusalem –Abu Dies

جامعة القدس
كلية المهن الصحية دائرة
التصوير الطبي القدس-
أبوديس

التاريخ :03\DEC\2023

حضرة د. شادي قمصية المحترم \ مدير مركز يزن للأشعة التشخيصية ووحدة تصوير الثدي.

تحية طيبة وبعد،

الموضوع : تسهيل مهمة باحثة من جامعة القدس – ابو ديس

ايمانا منا بدوركم في خدمة وتطوير المجتمع الفلسطيني واستنادا لمعرفتنا بالدور الهام الذي تقومون به في مجال صحة المراة وتشخيص ومتابعة امراض الثدي إضافة الى الدور المميز في دعم التعليم والبحث العلمي،

نتوجه لحضرتكم التكرم بالايعاز للمعنيين المساعدة بتسهيل مهمة الباحثة أحلام مبارك من برنامج ماجستير تكنولوجيا التصوير الطبي – كلية المهن الصحية \جامعة القدس في جمع المعلومات اللازمة من وحدة تصوير الثدي في مركز يزن للاشعة لدراسة وتقييم "فعالية الموجات فوق الصوتية الآلية للثدي كأداة فحص للكشف عن آفات الثدي بالمقارنة مع التصوير الشعاعي للثدي وخزعة الثدي." في النظام الصحي الفلسطيني.

ستقوم الطالبة بعمل بحث بعنوان:

Efficacy of automated breast ultrasound as a screening tool for detecting breast lesions in comparison with mammography and breast biopsy

وسيتم اطلاعكم على نتائج البحث.

وتفضلوا بقبول فائق الاحترام والتقدير،،،

د. محمد حجوج المشرف
الاكاديمي

Tel: 02 2799753 + 022799234 Email: hp@hpf.alquds.edu تلفون: 02 2799234 + 022799753
Tel. Fax: 02 2791243 تلفاكس: 02 2791243

Appendix 2: Table of data collection

Variables		
Age		
Marital Status	Single	
	Married	
Past History	Free	
	Positive	
Family History	Free	
	Positive	
Provisional Diagnosis	Benign	
	Malignant	
ACR density of the breast	A*	
	B*	
	C*	
	D*	

Lesions		
Mammogram	Positive	
	Negative	
Mammogram BIRADS	0.00	
	1.00	
	2.00	
	3.00	
	4.00	
	5.00	
Number of Lesions	0.00	
	1.00	
	2.00	
	3.00	
	4.00	
	5.00	
	6.00	
Number of Lesions		

Lesions		
ABUS*	Positive	
	Negative	
ABUS BIRADS**	1.00	
	2.00	
	3.00	
	4.00	
Number of lesions		

Appendix 3: Ethical approval from Research Ethics Subcommittee Chair

Al Quds University
Faculty of Health Professions
Jerusalem –Abu Dis

جامعة القدس
كلية المهن الصحية
القدس – أبو ديس

Research Ethics Subcommittee of Faculty of Health Professions
Letter of approval

Dec. 15, 2025
Ref. No.: **RESC/2026-13**

Dear Applicants, (**Dr. Mohammad Hjouj, Ms. Ahlam Mubarak**)

Program: **MSc Medical Imaging Department**

The Research Ethics subcommittee of the Faculty of Health Professions has recently reviewed your proposal entitled (**Role of Automated Breast Ultrasound as Screening Tool in Comparison to Mammogram and Breast Biopsy in Breast Lesions Detection**) submitted by (**Dr. Mohammad Hjouj**). Your proposal is deemed to meet the requirements of research ethics at Al-Quds University, but further assessment is required by the Central Research Ethics Committee of Al-Quds University. We wish you all best for the conduct of the project.

Hussein ALMasri, PhD
Associate Professor of Medical Imaging
Research Ethics Subcommittee Chair
Faculty of Health Professions

Hussein ALMasri

CC: File
CC: Committee members

Tel. Fax: 02 2791243 Email: dean@hpro.alquds.edu تلفاكس: 02 2791243

الملخص بالعربية:

فعالية الموجات فوق الصوتية الآلية للثدي كأداة فحص للكشف عن آفات الثدي بالمقارنة مع التصوير الشعاعي للثدي وخزعة الثدي.

إعداد: أحلام محمد مبارك

إشراف: د. محمد حجوج

الملخص:

خلفية الدراسة: تقدم تكنولوجي جديد في مجال التصوير بالموجات فوق الصوتية يسمى نظام الموجات فوق الصوتية الآلي للثدي الذي تم إنشاؤه للتغلب على تحديات وسلبيات أدوات فحص الثدي الأخرى مثل: اعتماد التصوير بالموجات الصوتية على المشغل، وعلى التصوير بالرنين المغناطيسي المكلف للوقت وانخفاض حساسية التصوير الشعاعي للثدي في الكشف عن آفة في الثدي الكثيف.

مشكلة الدراسة والمبررات: تعتبر حساسية الفحص الشعاعي للثدي أقل بالنسبة للثدي الكثيف، والذي يُعتبر عامل خطر مستقل لسرطان الثدي. من المتوقع ان يكشف الفحص بالموجات فوق الصوتية اليدوية للثدي عن سرطانات الثدي التي قد يفوتها التصوير الشعاعي للثدي. ومع ذلك فان الطلب المتزايد على الفحص بالموجات فوق الصوتية اليدوية الى جانب الموارد البشرية المحدودة واعباء العمل الثقيلة يجعل من الصعب على أطباء الاشعة استخدام الموجات فوق الصوتية للثدي على نطاق واسع بسبب اعتماده على المشغل. لذلك تهدف الدراسة الحالية الى تقييم فعالية الموجات فوق الصوتية الآلية للثدي كأداة فحص للكشف عن آفات الثدي مقارنة بالتصوير الشعاعي للثدي وخزعة الثدي.

الأهداف الرئيسية: تهدف هذه الدراسة إلى تقييم فعالية الموجات فوق الصوتية الآلية للثدي كأداة فحص للكشف عن آفات الثدي بالمقارنة مع التصوير الشعاعي للثدي وخزعة الثدي. وتشمل أهدافها تحديد الميزات الفريدة للموجات فوق الصوتية الآلية للثدي مقارنة بالتصوير الشعاعي للثدي وخزعة الثدي (الآفات المكتشفة وتصنيف (BIRADS) المرتبط). وتقييم دقة قياسات الموجات فوق الصوتية الآلية للثدي مقارنة بالتصوير الشعاعي للثدي والخزعة، وتقييم فعالية الموجات فوق الصوتية الآلية للثدي في الكشف عن الآفات لدى المشاركين ذوي الثدي الكثيف.

منهجية الدراسة: هذه الدراسة وصفية، ذات تصميم مقطعي رجعي، تتكون من 133 مشاركًا خضعوا للتصوير الشعاعي للثدي والموجات فوق الصوتية الآلية للثدي في مركز يزن للأشعة في بيت لحم خلال الفترة من يناير 2023 إلى ديسمبر 2023، وكان متوسط عمر الحالات 51.71 سنة.

التحليل الاحصائي: تم إدخال البيانات وتحليلها باستخدام حزمة البرمجيات الإحصائية للعلوم الاجتماعية (SPSS)الإصدار 25. لاستخلاص ميزات المتغيرات قيد الدراسة، مثل البيانات السريرية والديموغرافية، تم استخدام تقنيات التحليل الوصفي. شمل ذلك حساب التكرارات والنسب المئوية للمتغيرات الفئوية لفهم توزيع عينة الدراسة عبر الفئات المختلفة. ولزيادة فهم الاتجاه المركزي وتفاوت البيانات، تم توليد إحصائيات مثل المتوسط والانحراف المعياري للمتغيرات المستمرة. تم التحقيق في العلاقة بين المتغيرات المستقلة والنتيجة المرجوة باستخدام التحليل الأحادي المتغير، وخاصة الانحدار اللوجستي الثنائي، وتحليل التباين(One Way ANOVA) ، واختبار t للعينات المترابطة، واختبار كاي–مربع. تم اعتبار الفرق ذو دلالة إحصائية عند مستوى$p < 0.05$.

الاعتبارات الأخلاقية: تم الحصول على الموافقة الأخلاقية من لجنة الأبحاث في جامعة القدس. كما تمت الموافقة على هذه الدراسة من قبل مدير مركز يزن للأشعة.

النتائج: كشف تحليل بيانات الراسة ان متوسط عمر المشاركين كان 51.71 سنة. بالنسبة لكثافة الثدي، تم تصنيف 38.3% من المشاركين ضمن الفئة C، و37.6% ضمن الفئة B، و13.5% ضمن الفئة D، و10.5% ضمن الفئة A. بالقارنة بين التصوير الشعاعي للثدي والموجات فوق الصوتية الآلية للثدي: أظهرت الموجات فوق الصوتية الآلية زيادة في الحساسية واكتشاف المزيد من الآفات في الثدييات ذات الكثافة العالية حيث بلغت دقته نسبة 61.65% مع وجود فرق ذو دلالة إحصائية مقارنة بالتصوير الشعاعي للثدي. من ناحية أخرى، لا يوجد فرق ذو دلالة إحصائية بين الآفات المكتشفة بواسطة الموجات فوق الصوتية الآلية والخصائص الديموغرافية للمرضى مثل العمر، الحالة الاجتماعية، التاريخ العائلي والتاريخ المرضي السابق باستثناء كثافة ACR

الملخص: تُعتبر تقنية الموجات فوق الصوتية الآلية للثدي (ABUS) تقنية فحص محتملة يمكنها الكشف بفعالية عن تشوهات الثدي، خاصة في الثدي الكثيف حيث قد لا يكون التصوير الشعاعي للثدي (Mammography)فعالًا بنفس القدر. عند مقارنتها بالتصوير الشعاعي للثدي، أظهرت ABUS حساسية أفضل في اكتشاف الآفات، خصوصًا في الثدي ذي الفئات الأعلى كثافة .