Chapter One

Introduction

1.1 Introduction:

Diagnosis of breast cancer has been widely improved since the development of high-resolution ultrasound equipment. In the past, ultrasound was only considered useful for the diagnosis of cysts. Meanwhile, it improves the differential diagnosis of benign and malignant lesions, local preoperative staging and guided interventional diagnosis. In dense breasts, mammography has limited sensitivity. Furthermore, women with dense parenchyma have a highly increased risk of breast cancer development. Ultrasound is useful to examine dense breast tissue. Recent studies have shown that the detection of small cancers with high-resolution ultrasound is increased by 3–4 cancers per 1,000 women without clinical or mammographic abnormalities. Furthermore, stage distribution is similar between mammographically and sonographically detected carcinomas. Ultrasound is routinely used for curative diagnosis, to overcome the limitations of mammography. However, within the mammographic screening in Germany, breast density is not considered as important. Ultrasound is only used if a suspicious lesion is detected by mammography. Interestingly, 2 years ago, a screening project started in Austria in which ultrasound is always added in cases of dense breasts. Preliminary data show that the detection of additional carcinomas is increased in the same order as shown in previous studies. Therefore, an improved cancer detection and differentiation can be expected with high-resolution ultrasound. Roentgenology, 1991; 156:449-455.

1.2 History of Breast ultrasound:

Remarkably, sonography of the breast has been performed both in vitro and clinically for 53 years. Initially little more than a curiosity, it became regarded as a possible means of distinguishing between benign and malignant lesions, a goal that many imaging methods have unsuccessfully tried to achieve over the years. Later in the evolution of breast ultrasound, iterations of “automated” devices, designed in theory to completely scan all the
breast tissue, briefly generated hopes of a screening method that could replace x-ray mammography. Breast ultrasound has now come full circle to a method that is viewed as the most important adjunctive breast imaging method available and that serves as the most common guidance system for percutaneous breast biopsy and preoperative localization. The history of this valuable breast-imaging method is important in framing an understanding of the key role it now holds. (Sandra 2012).

The first clinical application of breast ultrasound was reported in 1954 by Wild and Reid. The early researchs in sonographic breast imaging did not consider that this modality might be used as a screening tool. It was quite the opposite. Wild and Reid stated, “The investigation was not planned to detect tumors and was not necessarily intended to replace existing methods of diagnosis of breast lesions.” The focus was, however, clearly on the goal of distinguishing between benign and malignant breast lesions, and the results were remarkably accurate in this regard. Wild and Reid were accurate in preoperatively characterizing 12 of 12 malignant tumors (11 ductal carcinomas and 1 sarcoma) and 9 of 9 benign tumors.

The early 1980s brought digital technology to the field of ultrasound in general and breast ultrasound in particular. Having a digital rather than an analog signal opened the door for numerous immediate improvements in resolution based on beam shaping as well as signal processing. Later, in the early 1990s, digital beam formers and broad-bandwidth capabilities led to developments such as tissue harmonics and real-time spatial compounding. (Proceedings of the 5th Int. Congress on the Ultrasonic Examination of the Breast). 1993.

1.3 The importance of the study:

The Researcher tries to explain the role of ultrasound in assessment of solid breast masses comparing with biopsy result in Khartoum state.
1.4 Objectives:

1.4.1 General objectives:

To evaluate role of ultrasound in assessment of solid breast masses compared to biopsy results.

1.4.2 Specific objectives:

- To Assess the common site of malignancy.
- To correlate the malignancy with the measurement of the mass.
- To correlate the malignancy with the weight of the patient.
- To correlate the malignancy with the age group.
- To correlate the sonographic appearance with ultrasound report.
- To correlate the sonographic appearance with histopathology result.
Chapter Two

Literature review

2.1 Anatomy of the Breast:

The breast is a well-differentiated apocrine sweat gland of the same type found in the axilla and elsewhere in the body.

These glands have evolved into an organ that produces and secretes milk during lactation. (Richard et al. 2012).

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Fig (2-1): Base and apex of breast. The base of the breast is adjacent to the chest wall and the apex is the nipple.

Fig (2-2): Clock time and quadrants. Four named quadrants and clock time describe location in the breast.
2.1.1 External Appearance:

2.1.1.1 External Landmarks:

Breast size and shape vary individually. The external landmarks of the breast include the nipple, inframammary fold, and axilla. The base of the breast is the portion adjacent to the chest wall; the apex is the nipple.

Four named quadrants describe location in the breast:
- Upper outer quadrant
- Upper inner quadrant
- Lower inner quadrant
- Lower outer quadrant

2.1.1.2 Skin:

The skin covering the breast is thickest at the base of the breast (about 2 mm thick) and becomes thinner as it approaches the nipple (0.5 mm). The skin of the nipple–areola complex measures 4 to 5 mm (Fig 2-3). Sweat glands, sebaceous (oil) glands, and hair follicles that open to form skin pores occupy the skin of the body and the breast. The skin pores are sometimes evident mammographically as tiny multiple lucencies across the mammogram. The sebaceous glands are prone to infection and may imitate carcinoma radiographically (Richard et al. 2012).

![Diagram of breast structure]

Fig (2-3): (A) The skin. The cutaway exhibits the thinning of the skin as it approaches the nipple, the thicker areolar complex, and internal breast structures. (B) This digital mammogram shows the thicker skin reflection (arrow) where the breast attaches to the sternum. This is a radiographic landmark when positioning for the craniocaudal (CC) view.
2.1.1.3 Nipple and Areola:

At the breast’s most distal point (the apex) are the areola and nipple (Fig (2-4)). The placement of the areola and nipple again varies individually, but the nipple is the center point, and provides a reference to describe location of normal anatomy and pathology. The areola is a smooth, circular darkening surrounding the nipple. Occasionally small protrusions on the surface of the areola are visible, especially during pregnancy and lactation. The protrusions are called Montgomery glands (named for the doctor who first described them). These glands are a specialized sebaceous type providing lubrication during lactation. The nipple is a raised, darkened, circular extension with multiple crevices.

Within these crevices are five to seven orifices (collecting ducts) that transfer milk from the lactiferous ducts (Richard et al. 2012)

![Fig (2-4): External appearance and landmarks.](image)

Most often the nipple protrudes from the breast. Unilateral or bilateral inverted nipple(s) occur occasionally. However, sudden inversion or flattening of the nipple can indicate underlying malignancy. Each breast usually exhibits one nipple, but one or more accessory nipples can occur anywhere along the mammary Ridge, which is present during our embryonic development. A common location for accessory nipples is the 6:00 o’clock position near or below the inframammary fold. Accessory nipples may have attached glandular structures and therefore are susceptible to developing cancer. For this reason, it is
important to inspect for and screen accessory nipples during mammography (2011 Wolters Kluwer Health)

2.1.2 Internal Anatomy:

The breast lies anteriorly to the pectoralis major muscle, which runs in an oblique line from the humerus to midsternum ((Fig (2-5)). A layer of adipose tissue and connective fascia (not distinguishable from other breast structures on the mammogram) separate the breast from the pectoral muscle, forming the retromammary fat space. (Do not confuse this structure with the mammographic landmark, the retroglandular fat space, discussed later in this chapter.) The posterior fascia and the anterior superficial fascia of the skin completely envelope the breast ((Fig (2-5)). Breast tissue covers a wider area than its outward appearance. The organ can reach as far superiorly as the clavicle (level of the second or third rib), and inferiorly to meet the abdominal wall at the level of the sixth or seventh rib (called the inframammary fold or crease). The breast tissue may also extend laterally to the edge of the Latissimus Dorsi muscle and medially to midsternum. (2011 Wolters Kluwer Health)

Fig (2-5): The margins of the breast. The breast lies anterior to and courses along the pectoral muscle. Its margins can reach the clavicle superiorly, the latissimus dorsi muscle laterally, and the sternum medially; it extends into the axilla.
The organ reaches into the axilla (the tail, axillary tail, or the tail of Spence). 6,7 The anatomic extent of the breast tissue is critical knowledge for efficient mammographic positioning. Internally, the breast includes a varying mixture of fatty tissue and the parenchyma. The parenchyma consists of the glandular components, lymphatic network and blood vessels (Fig 2-6). Followed by a loss of weight, the pendulous presentation is referred to as “Cooper’s droop.” Other tissues that give the breast structures support consist of the extralobular and intralobular stroma. The extralobular stroma holds the larger ductal structures. The intralobular stroma is specialized tissue that gives the lobule its shape and definition. 9 An extensive capillary network allows the exchange of hormones into and secretions out of the lobule and is in close contact with the lymphatic system.

This intimate contact also provides for transmission of cancer cells to the lymphatic network and blood stream. (2011 Wolters Kluwer Health)
2.1.3 The Glandular Parenchyma:

The pattern and distribution of the glandular tissue is essentially the same bilaterally. The tissue from one breast will “mirror” the opposite breast with minor variations. The majority of this tissue lies centrally and laterally within the breast. This distribution is recognizable mammographically. The total amount of glandular tissue increases and decreases with hormonal fluctuation, administration of synthetic hormones, pregnancy, lactation, menopause, and subsequently atrophies with age. Weight gain or loss also affects the radiographic appearance. Atrophy of glandular tissue begins medially and posteriorly, working its way to the nipple. This is an important point when interpreting the mammogram, because “new” tissue or growth of tissue in these areas in an aging woman may signal the presence of malignancy.

The glandular tissue or “parenchyma” consists of 15 to 20 lobes that extend from the nipple in a radial pattern. Consequently. Each of the 15 to 20 lobes contains a tree-like pattern of ductal structures. Two layers of epithelial cells of many differing types line the lumen of the ducts and smaller ductal structures. Beneath the epithelial layer is a layer of myoepithelium. This myoepithelium is a type of smooth muscle that contracts the acini and ducts to empty these structures of milk produced during lactation. The outer layer is the basement membrane. The changes that take place in the breast mostly occur at the level of the epithelia cell; however, the myoepithelium and the basal membrane respond to hormonal changes. These changes occur in the expected normal physiologic conditions as well as in pathologic situations. The lobule is the minute (1 to 2 mm) portion of the duct that holds the milk-producing elements of the breast. A single lobe contains many lobule groupings. The small duct just outside and leading to the lobule is the extralobular terminal duct. divides into the intralobular terminal ducts. The intralobular terminal ducts end at the terminal ductules, numbering anywhere from 10 to 100 in any lobule. The terminal ductule is a blind ending to the ductal pattern corresponding to the acinus. (2011 Wolters Kluwer Health)
2.1.4 Blood Supply:

2.1.4.1 Arterial supply:

- laterally, vessels from the axillary artery-superior thoracic, thoracoacromial, lateral thoracic, and subscapular arteries;
- medially, branches from the internal thoracic artery;
- The second to fourth intercostal arteries via branches that perforate the thoracic wall and overlying muscle (Richard et al. 2012).

2.1.4.2 Venous drainage:

Veins draining the breast parallel the arteries and ultimately drain into the axillary, internal thoracic and intercostal veins (Richard et al. 2012).

2.1.5 Innervation:

Innervation of the breast is via anterior and lateral cutaneous branches of the second...
to sixth intercostal nerves. The nipple is innervated by the fourth intercostal nerve. (Richard et al. 2012).

2.1.6 Lymphatic drainage:

- approximately 75% is via lymphatic vessels that drain laterally and superiorly into axillary nodes;
- most of the remaining drainage is into parasternal nodes deep to the anterior thoracic wall and associated with the internal thoracic artery;
- some drainage may occur via lymphatic vessels that follow the lateral branches of posterior intercostal arteries and connect with intercostal nodes situated near the heads and necks of ribs (Richard et al. 2012).

2.1.7 Classification of breast tissues:

2.1.7.1 Prepuberty:

The neonatal breast contains lactiferous ducts but no alveoli. Until puberty, little branching of the ducts occurs, and any slight mammary enlargement reflects the growth of fibrous stroma and fat. (Susan 2008)

2.1.7.2 Puberty:

In the postpubertal female, the ducts stimulated by ovarian estrogens, become branched. The ends of the branches form solid spheroidal masses of granular polyhedral cells, the potential alveoli. Breast enlargement at puberty is largely a consequence of lipid accumulation (Susan 2008).

2.1.7.3 Changes during menstrual cycle:

In the follicular phase (days 3-14) the stroma becomes less dense. Various changes including luminal expansion take place in the ducts. In the luteal phase (days 15-28) there is a progressive increase in stromal density and the ducts have an open lumen that contains secretion. There are also changes in blood flow, which are greatest at mid cycle and an increase in water content of the stroma in the second half of the menstrual cycle (Susan 2008).

2.1.7.4 Postmenopausal:

Progressive atrophy of lobules and ducts occur after the menopause, and there is fatty replacement of glandular breast tissue. A few ducts may remain. The stroma becomes
much less cellular and collagenous fibres decrease. The breast may return to a condition similar to the prepubertal state (Susan 2008).

2.1.7.5 Changes associated with pregnancy and lactation:

2.1.7.5.1 Pregnancy:

As the output of estrogen and progesterone produced first by the corpus luteum and later by the placenta rises during pregnancy the intralobular ductal epithelium proliferates and the cells increases in size. Alveoli develop at their termini and expand as their cells and lumina fill with newly synthesized and secreted milk (Fig (2-8)).

Secretory activity in the alveolar cells rises progressively in the latter half of pregnancy (Susan 2008).

2.1.7.5.2 Lactation:

True milk secretion begins a few days after parturition as a result of a reduction in circulating estrogen and progesterone, a change which appears to stimulate production of prolactin by the anterior hypophysis. Milk distends the alveoli so that the cells flatten as secretion increases. On hormonal stimulation by oxytocin myoepithelial cells contracts to expel alveolar secretions into the ductal system in readiness of suckling (Fig (2-8)). (Susan 2008).

2.1.7.5.3 Post-lactation:

When lactation ceases, the secretory tissue undergoes some involution, but the ducts and alveoli never return completely to the pre-pregnant state. Two major processes are responsible for the regression of the alveolar-ductal system; a reduction in epithelial cell size and a reduction is cell numbers (Fig (2-8)). (Susan 2008).
Fig (2-8): Lobes of the breast during non pregnant, pregnant and lactation period.

2.2 *Sonographic anatomy of the Breast:*

Anatomically the breast is a modified sweat gland lying within the deep and superficial layers of superficial pectoral fascia. Viewing aschematic sagittal section of the breast turned 90° to correlate with ultrasonographic positioning, we observe the following anatomic structures (from anterior to posterior), which can also be visualized with ultrasound: skin, subcutaneous fat, Cooper ligaments, the superficial mammary fascia, the breastparenchyma (with ducts and lobules), inter lobar fibrofatty tissue, the deep mammary fascia, retromammary fat, muscle fascia, the pectoralis major and minor muscles, the ribs and intercostals spaces, and finally the pleura and lung ((Sandra 2012)).
Fig (2-9): Gross anatomy of the breast. PMa = pectoralis major muscle, PMi = pectoralis minor muscle.

The breast consists of a varying mixture of tissue components, and its composition depends on age, hormonal influences, structural changes (congenital, degenerative, or pathologic), and individual characteristics. As a general rule, the breast tissue of young women consists mostly of parenchyma and contains little fat. With aging, the glandular tissue of the breast is replaced by connective tissue and fat. But there is great individual variation, so that the breasts of young multiparous women who have nursed their infants are predominantly fatty, and even in young girls a substantial portion may consist of fat, especially if the breasts are large. Conversely, the breasts of older women who receive postmenopausal hormone replacement may respond by increasing fibroglandular density, and many older women may have mammographically dense breasts, the density reflecting the fibrous (rather than glandular) predominance of their breast tissue. This should be considered in breast examinations as it will influence the overall interpretation of clinical, sonographic, and mammographic findings. The structural composition of the breast varies with age, functional status, and individual differences in tissue distribution and quantitative make-up. Gross Anatomy 4 Sonographic Anatomy of the Breast and Axilla).

Sonographic morphology of the breast structures display various echo characteristics (Table (2-1)). The sonographic anatomy of the breast is illustrated With immersion scans (Fig (2-10)), which are excellent for depicting general anatomic features.
Compression of the breast can significantly alter its sonographic appearance. In describing the degree of echogenicity, the reference tissue for breast ultrasound is fat, characterized by low-amplitude echoes. Fat is hypoechoic and on ultrasound images is dark gray. Skin and connective tissue fibers such as Cooper ligaments give rise to high-amplitude echoes. When the scanner is properly adjusted, these echogenic or hyperechoic structures should appear bright on the monitor. Fluid within cysts or ducts is generally anechoic and appears black, although inspissated fluid contains internal echoes. Breast parenchyma is moderately echogenic (compared with fat) and is displayed in varying shades of light gray. Breast anatomy can also be evaluated in real-time images despite a small field of view. An extended sectional view can be obtained by splicing several longitudinal scans that progress from the upper to the lower portion of the breast. Similarly, the scope can be broadened in systems that offer wide or panoramic fields of view. Individual images may be sufficient for evaluating glandular structure, depending on the width of the visual field and the experience of the examiner (2011 Wolters Kluwer Health)

<table>
<thead>
<tr>
<th>Anatomical Structure</th>
<th>Echogenicity</th>
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<tbody>
<tr>
<td>Skin</td>
<td>Hyperechoic</td>
</tr>
<tr>
<td>Nipple</td>
<td>Hypoechoic</td>
</tr>
<tr>
<td>Parenchyma</td>
<td>Hyperechoic</td>
</tr>
<tr>
<td>Connective Tissue</td>
<td>Hyperechoic</td>
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<tr>
<td>Subcutaneous Fat</td>
<td>Hypoechoic</td>
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<tr>
<td>Fatty Infiltration</td>
<td>Hypoechoic</td>
</tr>
<tr>
<td>Retromammary Fat</td>
<td>Hypoechoic</td>
</tr>
<tr>
<td>Cooper Ligaments</td>
<td>Hyperechoic</td>
</tr>
<tr>
<td>Lactiferous Ducts</td>
<td>Anechoic</td>
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</tbody>
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Table(2-1): Echogenicity of the various breast tissues (from anterior to posterior)
Fig (2-10): Immersion scan of a dense adolescent breast. Transverse scan through the center of the breast. The breast is composed of parenchyma of varying echogenicity and small amounts of subcutaneous fat. Mammary ducts are visible in cross section in the subareolar region.

Fig (2-11): Immersion scan of an involuted breast (Midsagittal plane).
2.3 Diagnostic ultrasound of the breast:

Ultrasound is a non-invasive, non-painful technique performed with high frequency sound waves, unable to be heard by the human ear.

The use of ultrasound in addition to clinical examination and mammography may result in an increased rate of breast cancer detection. USG is useful to differentiate cystic from solid abnormalities of the breast.

Breast ultrasound requires the use of high-resolution ultrasound equipment. The sonographer must select the appropriate transducer for the area to be examined. Lower frequency transducers may be required for a large breast masses. The image first must be optimized using electronic focusing, overall gain, and time gain compensation (TGC) adjustment. The goal is to balance the image from the low-level echoes of the subcutaneous fat to the low-level echoes of the retromammary fat. This should result in an image that clearly shows all levels of the breast from the skin level through the echogenic breast core and the deeper echogenic chest wall layers. Moderate compression applied with the transducer during scanning will improve detail and decrease the depth of tissue (Carol et al 2011).

![GE U/S machine](image)

Fig (2-12): GE U/S machine

The breast consists predominantly of hypoechoic fat, connective tissue septa, and small hyperechoic islands of residual parenchyma. Relatively low echo amplitudes are characteristic of normal and adolescent breast tissue (Fig. 4.10). The low echogenicity is
partly due to hormonal influences producing a spongy, hydrated structural pattern. A similar pattern is observed in menopausal women on hormone replacement therapy and in edematous parenchyma in the early stage of inflammatory disease (Chapter 9). As the breast ages and fibrocystic changes become more pronounced, the parenchyma becomes more echogenic due to an increased proportion of connective tissue, and the breast appears brighter (Fig. 4.11). Meanwhile, deeper portions of the breast often appear hypoechoic because of increased sound absorption. Compression of the breast improves sound transmission, increasing echogenicity and delineation of deeper tissues. The ducts should be visible in the subareolar region, at least with a high-resolution transducer operating above 7.5 MHz. Converging behind the nipple, ducts appear as tubular, anechoic structures, linear, branching, round and oval, depending on the angle of insonation. In more peripheral areas of the breast, their segmental distribution pattern is best defined on radial scans. The parenchymal zone of the breast is bounded posteriorly by the fascia of the pectoralis major muscle. This fascia appears as anechogenic line bordering the chest wall (Figs. 4.3, 4.5). Muscle fibers are visible between the anterior and posterior fascial planes. The underlying ribs appear on sagittal scans as rounded, hypoechoic structures that appear partially anechoic at their cartilaginous sternal attachments. Because they are ossified, the more distal rib segments resemble circumscribed, hypoechoic masses that cast acoustic shadows (Fig. 4.12 a, b). It is important to maintain proper orientation so that these normal anatomic structures, when seen alone in an image, are not mistaken for intra mammary tumors. It is helpful to recognize the surrounding anatomy: ribs posterior to muscle, not a site for primary breast carcinomas (or fibroadenomas) to occur. In addition, real-time scanning enables one to document the repetitive pattern of ribs. A Breast diagnosis with ultrasound requires a knowledge of normal sonographic anatomy and its variations, recognition of architectural distortion, and the ability to distinguish circumscribed anatomic features from focal abnormalities.
Fig (2-13): A, B Immersion scan of a partially involuted breast. A Midsagittal plane, without compression (top) and b with compression (bottom). The images show thick layers of subcutaneous and retromammary fat with echogenic glandular tissue between them.
Fig (2-14): A, B Real-time scans in a dense adolescent breast. A Right breast. B Left breast. Multiple midsagittal scans along the craniocaudal axis are spliced to give an extended view of breast anatomy. The nipple–areola complex is at the center.

Fig (2-15): Real-time scan at the center of a dense breast.
Fig (2-16): Midsagittal scans of a dense adolescent breast. The cranial and caudal scans show areas of subcutaneous fat, and between them is parenchymal tissue (P).

The abundant connective tissue increases sound absorption, causing deeper portions of the breast to appear hypoechoic and shadow. Compression increases sound transmission and tissue echogenicity, helping to separate artifact from abnormality.

Fig (2-17): A, B Sagittal scans in the medial portion of the breast show a rib in cross section.

A Parasternal scan shows the nearly anechoic cartilaginous portion of the rib. B More lateral scan shows the ossified portion of the rib. Only the anterior surface appears bright. Just below it is the acoustic shadow cast by the dense bone.
2.4 Histopathology:

The basic characteristic feature of all fibroadenomas is proliferation of glandular as well as stromal elements with a sharply defined border and the pericanalicular or intracanalicular or mixed growth pattern (Brijesh 2014).

Fig (2-18): FNA histopathology shows ducts with both tubular and compressed architecture. Note the hypocellular stroma around ducts.

2.5 Common breast pathology:

2.5.1 Hamartoma:

Hamartomas are discrete lesions, usually firm and sharply circumscribed. The lesion appears as a well-defined density surrounded by a narrow zone of radiolucency. It often gives the appearance of being encapsulated (Carol 2005).

Fig (2-19): Breast Hamartoma mammogram (A) and ultrasound (B) (Betty 2007)
2.5.2 Lipoma:

It presents as a solitary mass that is soft and freely movable, and usually well delineated. Microscopically, lipomas are composed of the typical round mature lipocytes (Carol 2005).

![Fig (2-20): Breast lipoma mammogram (A) and ultrasound (B) (Elisabetta 2013)]

2.5.3 Galactocele:

Galactocele is a milk-filled cyst, probably formed by over distension of a lactiferous duct. It usually presents as a firm, occasionally tender mass, commonly in the upper quadrants beyond the areola border. Usually, these lesions occur in younger woman and develop during or after lactation. In U/S appears as an anechoic mass with sharply demarcated smooth margin (Carol 2005).

![Fig (2-21): Breast galactocele mammogram (A) and ultrasound (B) (Carol 2005).]
2.5.4 Mastitis:

Acute nonepидemic mastitis, formerly called (puerperal mastitis) refers to breast soreness, fever, and flulike symptoms that may develop any time during lactation (Carol 2005).

![Figure 2-22: Breast U/S with interstitial edema suggestive of mastitis (Betty 2007)]

2.5.5 Abscess:

Abscesses may be single or multiple. Acute abscesses have a poorly defined border, whereas mature abscesses are well encapsulated with sharp borders. A definite diagnosis cannot be made from a mammogram alone. Aspiration is necessary. Clinical findings include pain, swelling, and reddening of the overlying skin (Sandra L. 2012).

![Figure 2-23: Breast abscess (Elisabetta 2013)]
2.5.6 **Cyst:**

A breast cyst is a fluid-filled sac within the breast. They are echo-free, roundish or oval, with well-defined anterior and posterior margins and posterior enhancement. They are usually aspirated (Carol 2005).

![Breast cyst](image)

**Fig (2-24): Breast cyst**

2.5.7 **Phyllodes tumor:**

Phyllodes tumor applies to mixed epithelial-mesenchymal lesions with often a foliated structure, a double layered epithelial component and an overgrowth of the stromal component. The latter shows increased cellularity and proliferative activity, or even a sarcomatous appearance (Werner 2006).

![Phyllodes tumor](image)

**Fig (2-25): Phyllodes tumor (Werner 2006).**
2.5.8 Intraductal Papilloma:

An intraductal papilloma is a small, benign tumor that grows within the acini of the breast. It occurs most frequently in women 35 to 55 years of age (Sandra 2012).

Fig (2-26): Intraductal papilloma (Werner 2006).

2.5.9 Ductal Carcinoma in Situ (DCIS):

DCIS is also known as intraductal carcinoma. DCIS is characterized by cancer cells that are present inside the ducts but have not yet spread through the walls of the ducts into the fatty tissue of the breast (Sandra 2012).

Fig (2-27): DCIS (Werner 2006).
2.5.10 Invasive Ductal Carcinoma (IDC):

IDC accounts for nearly 80% of breast cancers. Similar to DCIS, these cancers begin in the ducts, but in contrast to DCIS, they invade the fatty tissue of the breast and have the potential to metastasize via the bloodstream or the lymphatic system (Sandra 2012).

![Image](image_url)

Fig (2-28): shows the infiltrative nature of the IDC

2.5.11 Lobular Carcinoma:

Arise from the lobules classified into lobular carcinoma in situ and invasive lobular carcinoma (Carol 2005).

![Image](image_url)

Fig (2-29): Lobular carcinoma with cystic contents (Sandra 2012).
2.5.12 Papillary Carcinoma:

Papillary carcinoma is a tumor that initially arises as an intra ductal mass. It may also take the form of an intra cystic tumor, which is rare (Sandra 2012).

Fig (2-30): Papillary breast carcinoma U/S (Prasad et al 2013).

2.5.13 Paget’s disease:

Paget’s disease arises in the retroareolar ducts and grows in the direction of the nipple, spreading into the intraepidermal region of the nipple and areola. Any ulceration, enlargement, or deformity of the nipple and areola should suggest Paget’s disease (Sandra 2012).

Fig (2-31): shows Paget's disease (Prasad et al 2013).
2.3 diagnostic ultrasound of the breast:

Ultrasound is a non-invasive, non-painful technique performed with high frequency sound waves, unable to be heard by the human ear. The use of ultrasound in addition to clinical examination and mammography may result in an increased rate of breast cancer detection. USG is useful to differentiate cystic from solid abnormalities of the breast. 2.3.1 Equipment: Breast ultrasound requires the use of high-resolution ultrasound equipment. The sonographer must select the appropriate transducer for the area to be examined. Lower frequency transducers may be required for a large breast masses. The image first must be optimized using electronic focusing, overall gain, and time gain compensation (TGC) adjustment. The goal is to balance the image from the low-level echoes of the subcutaneous fat to the low-level echoes of the retro mammary fat. This should result in an image that clearly shows all levels of the breast from the skin level through the echogenic breast core and the deeper echogenic chest wall layers. Moderate compression applied with the transducer during scanning will improve detail and decrease the depth of tissue (Carol et al 2011).
2.3.2 Positioning:

Patients are usually scanned in the supine position with the use of a hand-held, high-resolution transducer. The patient is positioned with her arm behind her head on the side of the breast to be examined. This spreads the breast tissue more evenly over the surface of the chest and provides a more stable scanning surface and easier access to the axilla. When the medial portion of the breast is scanned, a supine position works well. For the lateral margin of the breast, the patient can be rolled slightly toward the opposite side (approximately 30 to 45 degrees) and stabilized with a cushion under her shoulder and hips (Sandra 2012).
2.3.3 Technique:

The most common scanning technique is to initially scan using the grid scanning pattern, followed by a radial (clock face) technique for the hard copy imaging.

2.3.3.1 Grid scanning pattern:

- Scan up and down the breast in rows, making sure you overlap each row slightly to ensure no breast tissue is overlooked.
- Begin in the upper outer quadrant, scanning in transverse. Slide inferiorly from top to bottom.
- Move across and repeat the sweep inferior to superior.
- Repeat this across the breast.
- Rotate into a sagittal plane and repeat the pattern.
2.3.3.2 Radial scanning pattern (Clock-face):

- The breast is scanned and described as a clock-face.
- Begin at 12 o'clock in a sagittal plane with the toe of the probe at the nipple.
- Scan by rotating the probe around the nipple.
- Depending on breast size, a second pass further from the nipple may be required.
• If pathology is identified, rotate the probe 90 degrees in the 'anti-radial' plane (Ultrasound paedia 2016).

Figure 2.19: Radial scanning pattern for breast U/S (Ultrasound d paedi 2016).

2.3.4 :Documentation:

Labeling son graphic images of the breast is extremely important in the identification and correlation of breast images with images from other modalities.
2.3.4.1 **Quasi-grid pattern:**

Most imaging centers have traditionally used the quasi-grid pattern. This views the breast as a clock face. Directly above the nipple on either breast is 12 o’clock. Right medial breast and left lateral breast are 3 o’clock. Directly below the nipple bilaterally is 6 o’clock, and right lateral breast and left medial breast are 9 o’clock.

![Quasi-grid pattern](image)

**Figure 2.20:** Quasi-grid pattern (Sandra 2012).

2.3.4.2 **Clock method:**

Many imaging centers will further subdivide the breast with three concentric circles, with the center being the nipple. The first ring circles one third of the breast tissue, encompassing the area just outside the nipple, or zone 1. The second ring is about two thirds of the breast surface from the nipple, or zone 2. The final ring is to the breast periphery, or zone 3. Lesions located close to the nipple are labeled “A,” lesions in the middle of the breast are labeled “B,” and lesions located at the outer margin of the breast are labeled “C” (Sandra 2012).
Breast anatomy is described by two methods: the quadrant method (right/left, upper/lower, and inner/outer quadrants) and the clock face method (Sandra 2012).

### 2.3.4.3 Depth labeling:

Finally, the depth of any pathologic condition is documented. The breast again is divided into thirds from the skin to the pectorals major. Depth A is the most superficial third of the breast, depth B is the middle layer, and depth C is the deepest third of the breast. Superficial lesions located close to the skin...
surface are labeled “1,” lesions in the middle of the breast are labeled “2,” and deeper lesions located toward the chest wall are labeled “3” (Sandra 2012).
2.6 Previous studies:

A study done by Shalini Iaraswat (2014), in Moradabad study aimed to evaluate the characterization of breast lumps. With complementary X-ray mammography and US for further evaluation and diagnosis of breast masses, Histopathological confirmation was done in all the cases by FNAC/ excision biopsy. And thus avoids unnecessary breast surgeries in benign conditions study, samples were 64 patients with ultrasound findings in various breast lumps and pathologies. Study revealed distribution of lesions was found to be Fibro adenoma (31.1%), Breast cyst (20.7%), Intra ductal papilloma (5.2%), Lipoma (3.4%), Breast abscess (3.4%), Galactocele (3.4%), Cyst sarcoma phyllodes (3.4%), Hamartoma Fibro Aden Lipoma (3.4%) & Fat necrosis (3.4%), Invasive ductal carcinoma (17.4%), Invasive lobular carcinoma (5.2%).

Another Study done by Deise Santiago in Brazil from November 2008 to August 2012, to detect the breast cancer features in women under the age of 40 years Study Objective is to describe the clinical features, imaging findings and pathological aspects of breast cancer diagnosed in women under the age of 40 years, (120) patients were included, of whom 112 underwent mammography, 113 underwent ultrasonography, and 105 underwent magnetic resonance imaging (MRI). The histopathological data was obtained in most cases from post-surgical analysis, which was available for 113 patients; the mean age at diagnosis of primary breast cancer was 34 years. Only 11 patients (9.0%) had a family history of breast or ovarian cancer in first-degree relative. (92) Patients sought medical attention after showing breast symptoms, and the presence of a palpable nodule was the main complaint. (122) primary tumors were diagnosed, of which 112 were invasive (95%). The most common histological type was invasive ductal carcinoma (73.8%). Luminal B was the predominant molecular subtype (42.6%). Ultrasonography was positive in 94.5% of the cases and the most common finding were nodules (94.8%): Most cases of breast cancer diagnosed in patients under the age of 40 years, in that population, had symptoms at diagnosis and tumor with more aggressive biological behavior.

The study which had been done by Katrina N. Glazebrook, enrolled 2, 809 women from 21 sites (in the United States, Canada, and Argentina) between Aprils 2004 and February 2006 the average age of participants at enrollment was 55 years. Of the 2,637 eligible participant for whom the investigators have been able to compile complete set of
date, 1,400 (53%) had personal history of breast cancer and 1,812 (69%) had a family history of breast cancer. Cancer was diagnosed in 1.5% of eligible study participants (40 women) with complete data, did the combination of mammography and ultrasound discover more cancer than mammography alone, mammography alone showed 20 cancer (50 percent of all cancer detected) for a cancer detection rate of 7.6 per 1,000 women screened, the combination of both exams revealed 31 cancer (78 percent of all cancer detected) for a cancer detection rate of 11.8 cancer per 1,000 women screened.

Sandra L. Hagen-Ansert and M. Elizabeth Glenn 2012 Shown in a study if a mass measures longer in the antero posterior dimension (height) than in the transverse or sagittal plane (width), it has a vertical orientation, is usually described as “taller-than-wide,” and is suspicious for malignancy. Malignant lesions tend to be highly hypo echoic relative to fat and usually have weak internal echoes. Malignant tumors are often stone hard and irregular with a gritty feel. Posterior acoustic shadowing, non-compressible and hyper vascular.
Chapter Three

Material and Methods

3.1 Materials:

The study intended to evaluate the sonographic findings in patients with breast masses. The data used in this study was collected in Khartoum state from Apr 2017 to Jun 2017. The data has been collected from Alzara hospital, KBCC & Dar Alelag Hospital.

3.2 Subjects:

Study cases were 50 patients, their age (33-79 years). All were complain from breast lump, any patient lactating are excluded from the study, all patients underwent ultrasound examination and histopathology.

3.3 Machine used:

All patients where scanned on GE Logiq P5 ultrasound machine using linear high frequency transducer (7.5-12 MHz) and curve linear transducer (5MHZ) for large masses assessment.

3.4 Method:

USG examination of 50 cases of pathological confirmed (FNA, Core biopsy & excisional biopsy), breast masses was done by an expert Sonologist in the department of radiology. The sonographic findings of the lesions were analyzed.

3.4.1 Technique used:

The area for evaluation was fixed and skin adequately lubricated to facilitate ultrasound transmission. The transducer was gently applied and both longitudinal and transverse scans were taken.

3.4.2 Patient Care:

Patients having breast examinations require special care and attention. Patients are often well informed on breast lesion detection, management and outcomes, and can be anxious and demanding. Take care to explain to the patient the examination procedure and the process by which the patient will receive the results before starting the examination.
This will hopefully avoid difficult questions from the patient at the end of the examination.

3.4.3 Image interpretation:

The scans included sonographic information regarding the shape, margins, calcification, site, echogenicity, internal echo texture, and vascularity of the breast masses.

3.4.4 Data analysis:

It has been carried out by statically package for social sciences (SPSS) and Microsoft Office Excel.
Chapter Four

Results

4.1 Results:

This study included 51 patients aged between (33-79) years all were complaining of solid breast masses compared with biopsy result and the results of ultrasonic examination and were as follows:

<table>
<thead>
<tr>
<th>Age group</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-45 years</td>
<td>21</td>
<td>42.0</td>
<td>42.0</td>
<td>42.0</td>
</tr>
<tr>
<td>46-60 years</td>
<td>27</td>
<td>54.0</td>
<td>54.0</td>
<td>96.0</td>
</tr>
<tr>
<td>61-75 years</td>
<td>1</td>
<td>2.0</td>
<td>2.0</td>
<td>98.0</td>
</tr>
<tr>
<td>more than 75 years</td>
<td>1</td>
<td>2.0</td>
<td>2.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Minimum=30, maximum=79, mean=48.44, Std.Deviation=9.530
Fig (4.1): Shows Frequency distribution of age group

Table (4.2): Frequency distribution of mass site

<table>
<thead>
<tr>
<th>Site</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td>25</td>
<td>50.0</td>
<td>50.0</td>
<td>50.0</td>
</tr>
<tr>
<td>Left</td>
<td>25</td>
<td>50.0</td>
<td>50.0</td>
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<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
Fig (4.2): Shows Frequency distribution of mass site

Table (4.3): Shows Frequency distribution of mass echogenicity

<table>
<thead>
<tr>
<th>Echogenicity</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoechoic</td>
<td>46</td>
<td>92.0</td>
<td>92.0</td>
<td>92.0</td>
</tr>
<tr>
<td>Hyperechoc</td>
<td>2</td>
<td>4.0</td>
<td>4.0</td>
<td>96.0</td>
</tr>
<tr>
<td>Isoechoic</td>
<td>2</td>
<td>4.0</td>
<td>4.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
Fig (4.3): Shows Frequency distribution of mass echogenicity

Table (4.4): Presence of calcification

<table>
<thead>
<tr>
<th>Calcification</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>38</td>
<td>76.0</td>
<td>76.0</td>
<td>76.0</td>
</tr>
<tr>
<td>No</td>
<td>12</td>
<td>24.0</td>
<td>24.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
Table (4.5): Shows frequency distribution of vascularity

<table>
<thead>
<tr>
<th>Vascularity</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>46</td>
<td>92.0</td>
<td>92.0</td>
<td>92.0</td>
</tr>
<tr>
<td>No</td>
<td>4</td>
<td>8.0</td>
<td>8.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Fig (4.4): Shows frequency distribution of presence of calcification
Fig (4.5): Shows frequency distribution of vascularity

Table (4.6): Frequency distribution of echotexture of the mass

<table>
<thead>
<tr>
<th>Echotexture</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homogeneous</td>
<td>12</td>
<td>24.0</td>
<td>24.0</td>
<td>24.0</td>
</tr>
<tr>
<td>Heterogeneous</td>
<td>38</td>
<td>76.0</td>
<td>76.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
Fig (4.6): Shows frequency distribution of echotexture of the mass

Table (4.7): Frequency distribution of outline of the mass

<table>
<thead>
<tr>
<th>Outline</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Well defined</td>
<td>17</td>
<td>34.0</td>
<td>34.0</td>
<td>34.0</td>
</tr>
<tr>
<td>Ill defined</td>
<td>33</td>
<td>66.0</td>
<td>66.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
Fig (4.7): Shows frequency distribution of outline of the mass

Table (4.8): Frequency distribution of shape of the mass

<table>
<thead>
<tr>
<th>Shape</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Round</td>
<td>8</td>
<td>16.0</td>
<td>16.0</td>
<td>16.0</td>
</tr>
<tr>
<td>Oval</td>
<td>9</td>
<td>18.0</td>
<td>18.0</td>
<td>34.0</td>
</tr>
<tr>
<td>Speculated</td>
<td>33</td>
<td>66.0</td>
<td>66.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
Fig (4.8): Shows frequency distribution of shape of the mass

Table (4.9): Frequency distribution of ultrasound final diagnosed

<table>
<thead>
<tr>
<th>Ultrasound final diagnosed</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benign</td>
<td>1</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Malignant</td>
<td>49</td>
<td>98.0</td>
<td>98.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
Fig (4.9): Shows frequency distribution of ultrasound final diagnosed

Table (4.10): Frequency distribution of results of histopathology

<table>
<thead>
<tr>
<th>Histopathology Results</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ductal Carcinoma In situ</td>
<td>1</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Invasive Ductal Carcinoma</td>
<td>47</td>
<td>94.0</td>
<td>94.0</td>
<td>96.0</td>
</tr>
<tr>
<td>Invasive Lobular Carcinoma</td>
<td>1</td>
<td>2.0</td>
<td>2.0</td>
<td>98.0</td>
</tr>
<tr>
<td>Multi-centeric Ductal Carcinoma</td>
<td>1</td>
<td>2.0</td>
<td>2.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
Fig (4.10): Shows frequency distribution of results of histopathology

Table (4.11): Cross tabulation age group and results of histopathology

<table>
<thead>
<tr>
<th>Age group</th>
<th>Histopathology results</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ductal carcinoma Insitu</td>
<td>Invasive ductal carcinoma</td>
<td>invasive lobular carcinoma</td>
<td>multicenteric ductal carcinoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-45 years</td>
<td>0</td>
<td>20</td>
<td>0</td>
<td>1</td>
<td></td>
<td>21</td>
</tr>
<tr>
<td>46-60 years</td>
<td>1</td>
<td>25</td>
<td>1</td>
<td>0</td>
<td></td>
<td>27</td>
</tr>
<tr>
<td>61-75 years</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>more than 75 years</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1</strong></td>
<td><strong>47</strong></td>
<td><strong>1</strong></td>
<td><strong>1</strong></td>
<td></td>
<td><strong>50</strong></td>
</tr>
</tbody>
</table>

P value = 0.960
Chapter five

Discussion, Conclusion & Recommendations

5.1 Discussion

This study aimed to assess breast solid masses using ultrasonography comparing with biopsy results in Khartoum state. It included 50 patients aged between (30-79) years, with mean age (48.4 +9.5) years as described in table (4-1).

The study divided the subjects into 4 age groups; (30-45), (46-60), (61-75), and more than 75 years, with frequency distribution of (42%), (54%), (2%), and (2%) respectively as shown in figure (4-1).

The study described the mass site; it was found that 50% of patients have the mass on the right site, similarly 50% of patients have the mass on the left side figure (4-2).

The echogenicity of the mass is also described in this study; it was found that most of the patients (92%) has hypoechoic mass, and also (4%) has isoechoic masses, as shown in figure (4-3).

Figure (4-4) describes the frequency distribution of presence of calcification it showed that (76%) were with calcification, while (24%) were with no calcification, the study also described the vascularity of the mass; it was found that (92%) were with vascularity while (8%) has no vascularity as shown in figure (4-5).

The echo texture of the mass is also studied; it was found that (24%) of the patients were with homogenous masses, while (76%) were with heterogeneous masses as described in figure (4-6).

The frequency distribution of outline of the mass is also studied; it was found that
(34%) were with well defined outlines, while (66%) with ill defined outline figure (4-7). The frequency distribution of the shape of the mass is described in figure (4-8); it was found that (16%), (18%), and (66%) were round, oval, and speculated respectively.

The final diagnosis of these masses is studied; it was found that just (2%) were benign masses, while the rest (98%) were malignant masses as shown in figure (4-9).

Finally the study include the frequency distribution of results of histopathology; it was found that almost all the patients has invasive ductal carcinoma (94%), while the rest pathologies were with the same percent (2%), and these pathologies are ductal carcinoma in situ, invasive lobular carcinoma and multi centric ductal carcinoma as shown in figure (4-10).

This study reveals that there is no significant difference in histopathological results in respect to age groups which is range from (30-45) up to more than 75 using T test at P = 0.9.
5.2 Conclusion:

Ultrasonography is one of the well accepted and high sensitive imaging modality for the diagnosis and follow-up of breast cancer. The main objective of this study was to determine the role of ultrasound in assessment of solid breast masses compared with biopsy results. The study was carried out on 50 patients aged between (33-79) years all were complaining of solid breast masses compared with biopsy in Khartoum state in the ultrasound departments of Alzara hospital, KBCC & Dar Alelag Hospital and during period from Apr 2017 to Jun 2017. A total of 50 women with solid breast masses were evaluated, it is more common in the age between (46-60) years (54%). The dominant sonographic presentation of breast cancer is ill defined, speculated, hypo echoic, heterogeneous with calcification and vascularity .it presented in left side equally to right side. Most results of histopathology are Invasive ductal carcinoma.
5.3 Recommendation:

- Ultrasound is a simple, time saving tool for evaluation of breast masses. It should be the first investigation to be done in young females or pregnant women when mammography is not advisable.

- The sonographic evaluation of a simple breast cancer with the typical sonographic features should eliminate the need for further invasive procedures including biopsy.

- The role of ultrasound in the diagnosis of large breast masses needs further assessment.

- Educating and training sonographers technologist and radiologists to perform optimum examination and correct interpreting are of prime importance.

- The most profound limitation of the study was the small sample size. So we recommend that study with larger sample be considered.
5.4 References:


