

Full Length Research Paper

Validity of Clinical Evaluation versus Sonographic Findings compared to Surgical Outcomes as a Gold Standard of Gynecological Masses in Patients referred for Pelvic Ultrasonography at Moi Teaching and Referral Hospital in Eldoret, Kenya

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Gynecologic pelvic masses are a significant cause of morbidity and mortality in women, with a prevalence ranging from 8% to 56%. The diagnosis of these masses heavily relies on sonography. Since clinical management decisions are based on sonography, the validity of pre-operative ultrasound results of gynecologic pelvic masses is important. To establish the common clinical presentations, sonographic and surgical findings in women sent for sonography in the evaluation of gynecologic pelvic masses. A cross sectional study was conducted from October 2013 to October 2014 at Moi Teaching and Referral Hospital, in Eldoret, Kenya. Sixty-nine patients with gynecologic masses, who had been examined clinically, had pelvic ultrasound done and subsequently underwent surgery were enrolled. Clinical and sonographic findings were evaluated and compared with the surgical outcome. Data was collected using a structured questionnaire. Analysis was done using Stata version 11. Frequencies, measures of central tendency, sensitivity, specificity and predictive values were calculated. Mean age of participants was 44.4 years (standard deviation = 14.9). Ultrasound sensitivity was; uterine fibroids (95.2%), ovarian cysts (68.8%), dermoid cysts (60%) and endometrial cancer (33.3%). Ultrasound specificity was; uterine fibroids (81.3%), ovarian cysts (94.2%), dermoid and ovarian cysts (96.9%). Sonographic positive predictive value was: uterine fibroids (68.9%), ovarian cysts (78.6%), ovarian cancer and dermoid cysts (60%). The area under the curve for sonography was higher than that of clinical examination for ovarian cyst (0.82 compared to 0.58), dermoid cyst (0.86 compared to 0.49) and ovarian cancer (0.78 compared to 0.67). Most common clinical presentation was abdominal pain and swelling. The accuracy of sonography was significantly higher than clinical examination in the evaluation of uterine masses and ovarian cancer. Sonography had high sensitivity in predicting the organ of origin of a gynecologic mass. Sonographic specificity was high across all the gynecologic masses.

Keywords: Validity, Clinical evaluation, Sonographic findings, Surgical outcomes, Gynecological masses, Moi Teaching and Referral Hospital, Kenya.

INTRODUCTION

Pelvic masses are growths or swellings which arise from the pelvic organs. The female pelvis is an anatomical region where masses can be found originating from the

pelvic organs or abdominal organs, by continuity, by contact or from metastatic spread (La Fianza et al., 1994). Pelvic masses occur in women of all ages. Many

of them remain undiagnosed, therefore, their exact prevalence is unknown (McBee et al., 2007). Pelvic masses may involve either the reproductive organs or the other non-gynecologic structures. These masses may be identified incidentally in asymptomatic women during routine examination or they may cause symptoms, such as pain, abdominal swelling, constipation, and abnormal uterine bleeding (Gawai, 2006 and Schorge *et al.*, 2008).

Gynecologic pelvic masses are a major cause of morbidity and mortality among women. They are a source of both diagnostic and management challenges. Gynecologic masses may be benign or malignant, and distinguishing between the two is a key role of diagnostic modalities (Schorge *et al.*, 2008). Prior to the 1950s in Europe and America, and up to the early 1980s in Kenya, clinical examination was the mainstay of evaluation of pelvic masses. This was done through history taking and physical pelvic examination. The pelvic examination was through abdominal palpation, digital vaginal examination, bimanual pelvic examination and digital rectal examination. With the advent of ultrasound, it became possible to assess pelvic masses in greater detail (Gawai, 2006).

The prevalence of pelvic masses of gynecologic origin varies widely according to age, race and geographical origin of the patient. Pelvic masses were found in 7.8% of premenopausal women (25-40) years who underwent transvaginal ultrasound (Borgfeldt and Andolf, 1999). In a study done by Valentin et al. 2003, found the prevalence of pelvic masses to be 56% in post-menopausal women aged 64-96 years.

In general, most gynecologic pelvic masses are benign. Uterine fibroids are the most common benign tumor of the female genital tract (Okolo, 2008). This study was not designed to determine the incidence of any pelvic mass

A majority of ovarian masses are cysts, which occur in both premenopausal and postmenopausal women. Approximately two thirds of ovarian masses, which occur in the reproductive age group (McBee et al., 2007). The incidence of ovarian cancer globally is 6.3% compared to 4.0% in Eastern Africa (Jemal et al., 2011). Over a third of cases of ovarian cancer occur in women above 65 years of age. The probability of an ovarian mass being a primary cancer is markedly reduced in women below 45 years (McBee et al., 2007).

Pelvic ultrasound (US) scan through trans-abdominal (TA) route for large masses and trans-vaginal (TV) route for smaller masses has a well-established role in the initial evaluation of pelvic masses. The technique has many advantages as it is widely available, inexpensive, involves no exposure to radiation and can be used effectively to differentiate a benign from a likely malignant mass and therefore facilitate triage of a patient with a suspicious mass.

Although sonographic features of a pelvic mass frequently do not allow for a specific histopathological diagnosis, sonography usually provides important clinical parameters for the evaluation of a pelvic mass and can point toward suspicious masses for further evaluation as to whether they are benign or malignant (Aleksander et al., 2009). Pelvic sonography can confirm the presence or absence of a suspected pelvic mass. Also, sonographic features such as size, consistency, probable organ of origin and relationship to other structures can be valuable parameters in the decision making process (Aleksander et al., 2009).

Gynecologic pelvic masses are a leading cause of morbidity among women in Kenya. Appropriate and timely management relies heavily on the results of sonography. As an integral part of the management of gynecologic masses, ultrasound needs to be sufficiently accurate to be clinically useful. Data on the validity of sonography in the evaluation of gynecologic masses in our set up is not widely available. Clinicians managing patients with gynecologic masses were often confronted with situations requiring accuracy of ultrasound for clinical decision making. For instance, if sonography returns a result of uterine fibroids, what is the probability that that diagnosis is right? Validity of ultrasound is especially critical when the ultrasound results are contrary to clinical judgment. It is therefore important to adduce research data on the performance of sonography compared to clinical examination and surgery in the evaluation of gynecological pelvic masses.

Currently, there is a paucity of published studies on the sensitivity and predictive values of sonography in the localization of pelvic masses, their size, consistency and whether benign or malignant both regionally and in Kenya. This data, when available, has the potential to guide the process of developing diagnostic protocols and standards of practice for Moi Teaching and Referral Hospital (MTRH) and other adjacent hospitals. It will also inform clinicians on the interpretation of clinical and ultrasound results thereby improving patient management.

Clinical Presentation and Examination of Pelvic Masses

Patients with pelvic masses present with various symptoms such as abdominal or pelvic discomfort, lower abdominal swelling, pain, abnormal uterine bleeding and dyspepsia. Some however are asymptomatic and are picked on routine examination (McBee et al., 2007).

Physical examination characterizes a mass by its location, tenderness, consistency, and contour, and the presence or absence of ascites and other associated abdominal masses, providing clues as to whether the mass may be benign or malignant (Barber and Graber,

1971). False positive results may be due to pelvic inflammatory disease, bladder distention, obesity or a full rectum (Padilla et al., 2000).

Ultrasound Investigation of Gynecologic Pelvic Masses

Sonography is used for discrimination between benign and malignant adnexal masses and for making a specific diagnosis in adnexal tumors (like dermoid cyst, endometrioma, hemorrhagic corpus luteum among others). It is also useful for diagnosing uterine endometrial pathology in women with bleeding problems, and for confirming or ruling out pelvic pathology in women with pelvic pain (Valentin, 2006).

In recent years, diagnostic ultrasound has undergone rapid advances, with the development of three-dimensional transvaginal grayscale volume and power Doppler imaging. However, the evaluation of adnexal masses still poses a challenge. Scoring systems, morphological pattern recognition and mathematical models are still necessary to help make a diagnosis.

The sonographic features of a pelvic mass is one of the parameters assessed in the Risk of Malignancy Index (RMI) criteria 1,2 and 3 (Davies et al., 1993; Tingulstad et al., 1999 and Tingulstad et al., 1996) (U), in addition to the menopausal status (M) and serum CA125 level of a patient. RMI is calculated as $U \times M \times \text{serum CA125}$. (U being the sonographic appearance of a mass and M being the menopausal status of the patient). Serum CA 125 is a tumor marker which is elevated in cases of advanced ovarian cancer. More recently the tumor size assessed by ultrasound has been introduced in the calculation of risk of malignancy (RMI4) (Yamamoto et al., 2009).

Validation of Clinical Examination

In a study done by Padilla et al. 2000, clinical examination under general anesthesia compared to surgical findings showed physical examination to be 15%-36% sensitive in the detection of adnexal masses. Though sensitivity of clinical examination was low, its importance lay in the assessment of mass tenderness, mobility, nodularity and ascites (Ueland et al., 2005). Another key finding is that examiners often underestimate size. Though the study did not use the case control approach and it did not evaluate sonography, its finding that accuracy depended on the parameter being assessed is useful and sets a precedence that can be used when evaluating sonography.

Validation of Clinical Examination and Sonography

A study done in Bangladesh evaluated pelvic masses, most of which were uterine, and found trans-abdominal sonography to be 87.6% accurate with 9.3% false negatives (Noor, 2003). The above study is most similar in design to this study. A key difference, however, is that this current study evaluated all pelvic masses. The Bangladeshi study did not include surgical results and did not assess the sensitivity and specificity of sonography in estimating the size, site, edges and consistency of these pelvic masses.

A study done in Denmark reported the sensitivity and specificity of sonography to be 99% and 91%, respectively (Dueholm et al., 2002). Eze et al. (2013) in Northeast Nigeria found sensitivity of ultrasound in diagnosing uterine fibroids to be 94.5%, specificity 62.5% and accuracy 92%. This study was conducted among a convenient sample of 100 patients while surgical findings were used as gold standard.

MATERIALS AND METHODS

This cross-sectional study was conducted in Moi Teaching and Referral Hospital in Eldoret, Kenya within a period of one year, from October 2013 to October 2014. Patients with gynecologic pelvic masses who had undergone clinical assessment had sonography done and thereafter had surgery. The study was conducted to evaluate the reliability of clinical and sonographic findings in gynecologic pelvic masses using surgical findings as the gold standard in the assessment of a lesion's organ of origin and size.

The study population was symptomatic female patients with either palpable or non-palpable pelvic masses assessed sonographically. Sample size was calculated using the Buderer formula (Buderer, 1996). A calculated sample size of 69 was obtained.

Systematic random sampling technique was employed. Patients who had surgery following pelvic ultrasound were enrolled. Their biodata were retrieved from the case files.

Technique of Sonographic Examination

The machines used were Aloka's Prosound Alpha 7 (Tokyo, Japan) and Phillips HD 11xe (Eindhoven, Netherlands). For transabdominal examination, each patient was examined with bladder adequately distended. A 3.5 MHz transducer frequency was used with the patient in supine position. Morphological characteristics of the pelvic organs were assessed and measurements were taken. In some cases where

masses were small and of ovarian, endometrial or from cervix, additional transvaginal scan was done.

Data collection and Analysis

Data was collected using a structured data collection tool divided into four sections. These were: patient demographics including symptoms and duration; physical examination; sonographic findings like location, size and consistency of mass; and surgical findings. The patients' clinical history and physical examination findings were carried out by the gynecologist. The ultrasound was done by the sonologist/radiologist with the characteristics of the mass(es) and the sonographic impression were recorded. Lastly, the surgical findings were recorded.

Data was analyzed using Stata version 11. Univariate analysis was used to calculate frequencies of socio-demographic characteristics, clinical features, sonography findings and surgical characteristics.

RESULTS

Clinical presentation

Study participants presented with the following complaints: 63.8% (n=44) abdominal pain, 60.9% (n=42) abdominal swelling, 29% (n=20) vaginal bleeding, 1.5% (n=1) constipation and 1.5% (n=1) urinary retention. The median duration of symptoms was 180 days (Interquartile Range=305). The shortest duration of symptoms was one day while the longest was 3,650 days. Thirty five percent (n=24) had been ill for 1 to 90 days, 33% (n=23) for more than 360, 16% (n=11) for 91 to 180, 13% (n=9) for 181 to 270 and 1.5% (n=1) for 271 to 360. Twenty eight percent (n=19) were referrals from other facilities.

Physical Examination

Pelvic masses were palpable in 82.6% (n=57) of the cases. Out of these, 79% (n=49) were firm, 73.4% (n=47) were mobile, while 95.4% (n=66) were palpable above the pubic symphysis. (Table 1).

The clinical impressions recorded by the attending clinicians were extracted. Uterine fibroids, 42% (n=29), was the most common impression followed by ovarian cysts, 13% (n=9). A number of conditions had only one case each. These included: cystic abdominal mass, dermoid cyst, endometrial mass, pelvic inflammatory disease and uterine sarcoma (Figure 1).

Sonographic Characteristics of Gynecologic Masses

A total of 52.9% (n=36) masses were characterized as solid and 47.1% (n=33) as cystic. Of the cystic masses, 84.4% (n=27) were complex cysts. Features of malignancy such as irregularity of contour, multiple vascularized septations, solid components or ascites were reported in 20.6% (n=14) of the masses. By organ of origin, 49.3% (n=33) were uterine, 41.8% (n=28) ovarian and 9% (n=6) tubo-ovarian. The widest diameter of the largest masses measured more than 10 centimeters (38.2%, n=26), followed by five to ten centimeters (47.1%, n=32) and less than five centimeters (14.7%, n=10). Uterine fibroids (42%, n=29) was the most common ultrasound diagnosis followed by ovarian cyst (20%, n=14) and dermoid cyst (7%, n=5) (Figure 2).

Surgical Characteristics of Gynecologic Masses

When surgery was conducted, 49.3% (n=34) were found to be uterine masses, 44.9% (n=31) were ovarian, 4.4% (n=3) were tubo-ovarian, while 1.5% (n=1) was an abdomino-pelvic abscess. Most masses, 55.1% (n=38) measured 5 to 10 centimeters in their widest diameter, followed by those greater than 10 centimeters (27.5%, n=19), while 5.8% (n=4) were less than five centimeters. Twelve percent (n=8) did not have their sizes recorded. Regarding the consistency of the masses, 56.9% (n=37) were firm, while 43.1% (n=28) were cystic. Fifty nine percent (n=41) had regular contours compared to 34.8% (n=3) that had irregular edges, whereas 4.3% (n=3) did not have the nature of their edges recorded. Surgical assessment classified 33.3% (n=23) masses as being malignant Figure 3-6.

Sensitivity of Diagnostic Modalities in Characterization of Gynecologic Masses

For characterization of size, consistency and organ of origin of the masses, surgical findings were used as a standard in comparison to clinical and ultrasound findings. On the consistency of gynecologic masses, whether cystic or solid, physical examination correctly characterized 74.1% (CI=61.0 – 84.7) while ultrasound correctly characterized 92.3% (CI=83.0 – 97.5). Clinical examination did not indicate the probable organ of origin; on the other hand, ultrasound correctly predicted the affected organ in 82.6% of the patients, sensitivity was highest for uterine masses (94%, CI=79.8 – 99.3). The widest diameter of the masses was accurately predicted by ultrasound in 68.3% (CI=55 – 79.7) (Table 2).

Table 1. Physical Examination Characteristics of Gynecologic Masses

Examination Finding	Number (N=69)	Percent
Palpable mass	57	82.6
Mass well defined	10	14.5
Mass bimanually palpable	5	7.3
Mass is mobile	47	73.4
Tenderness	27	39.1
Ascites	8	11.6
Contour:		
Regular	40	64.5
Irregular	22	35.5
Consistency:		
Firm	49	79.0
Cystic	13	21.0
Size (Equivalent to pregnancy Weeks above Symphysis):		
<12	3	4.6
12-14	22	33.9
15-19	14	21.5
20-24	14	21.5
25-29	3	4.6
>=30	9	13.9

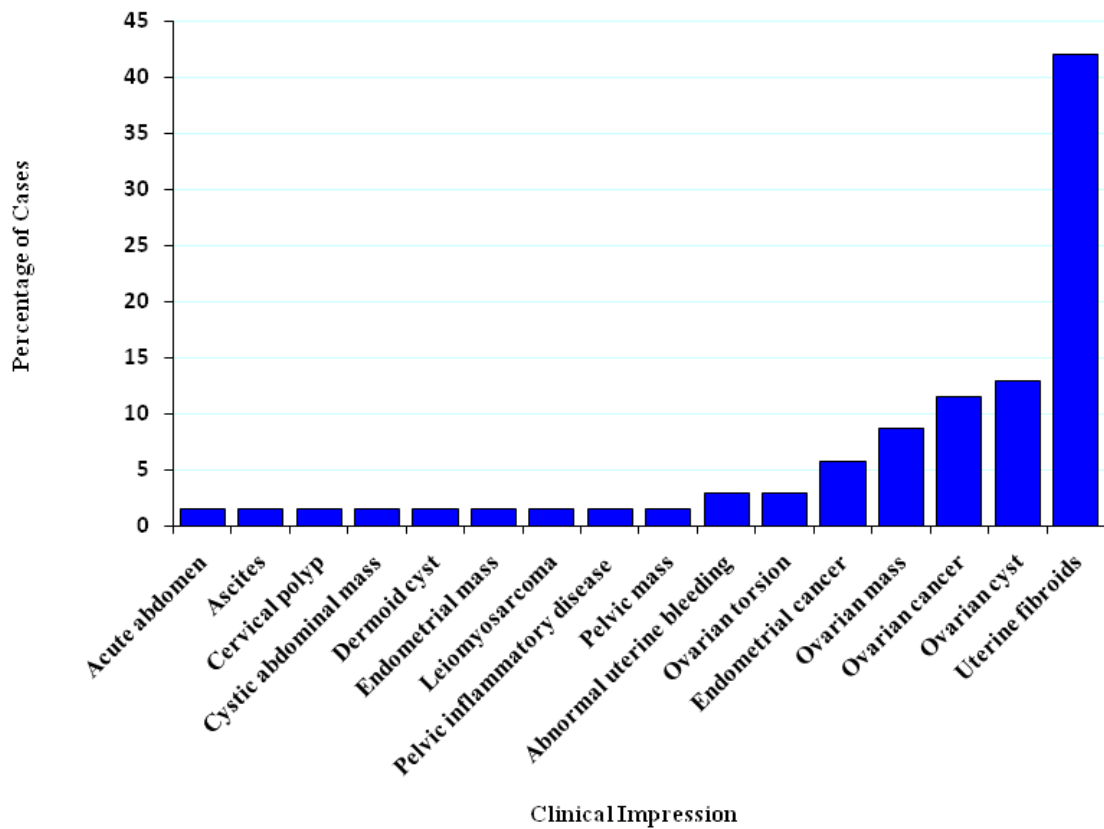


Figure 1. Distribution of Clinical Impression of Gynecologic Masses

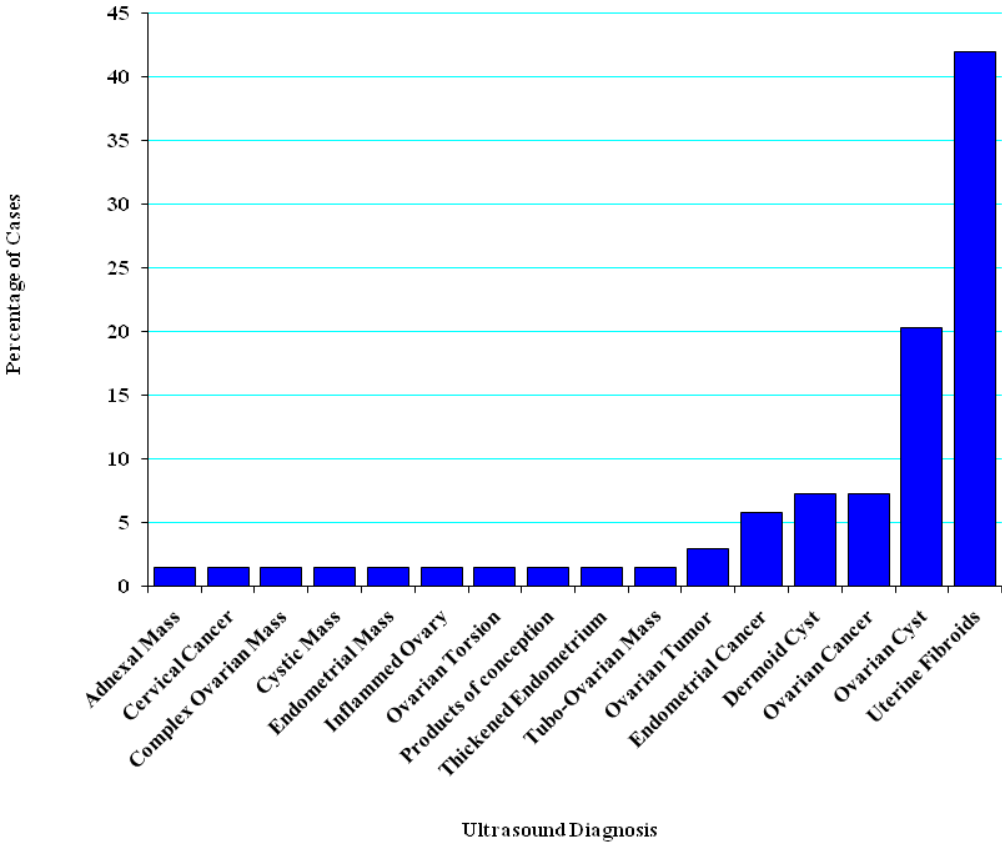


Figure 2. Distribution of Ultrasound Diagnoses of Gynecologic Masses

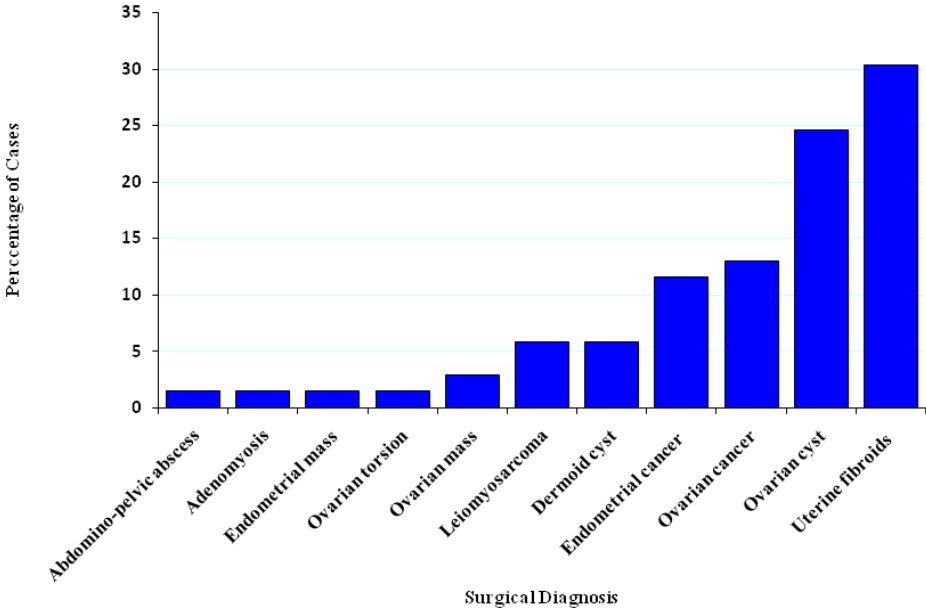


Figure 3. Distribution of Gynecologic Pelvic Masses by Surgical Diagnosis

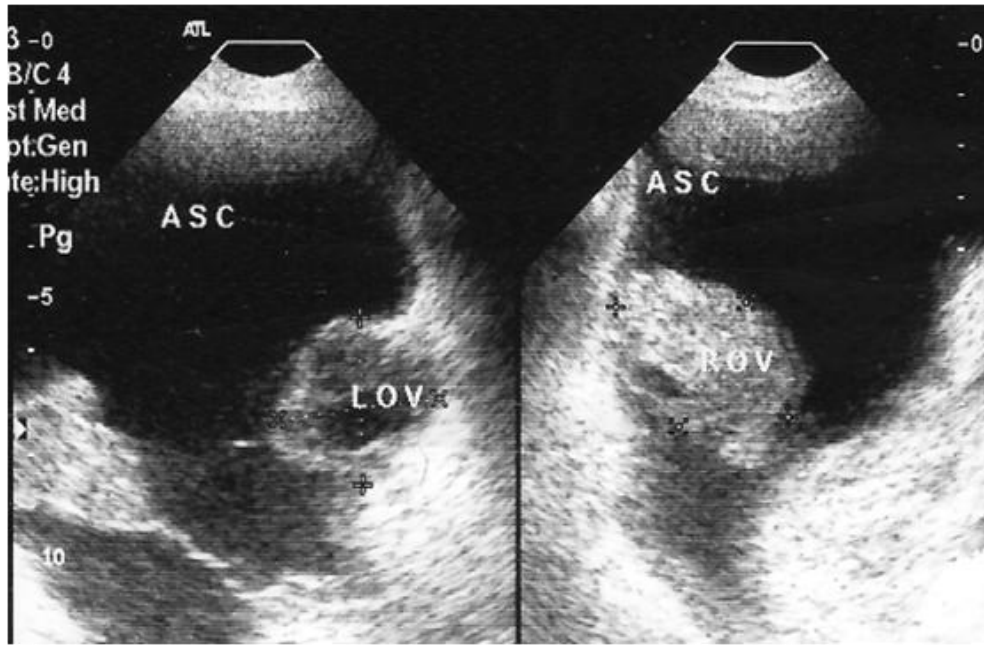


Figure 4. Pelvic scan of a 42 year old reported as a complex left ovarian mass with massive ascites. Intra-op 5 liters of pus was drained, cytology reported it as a sterile abscess

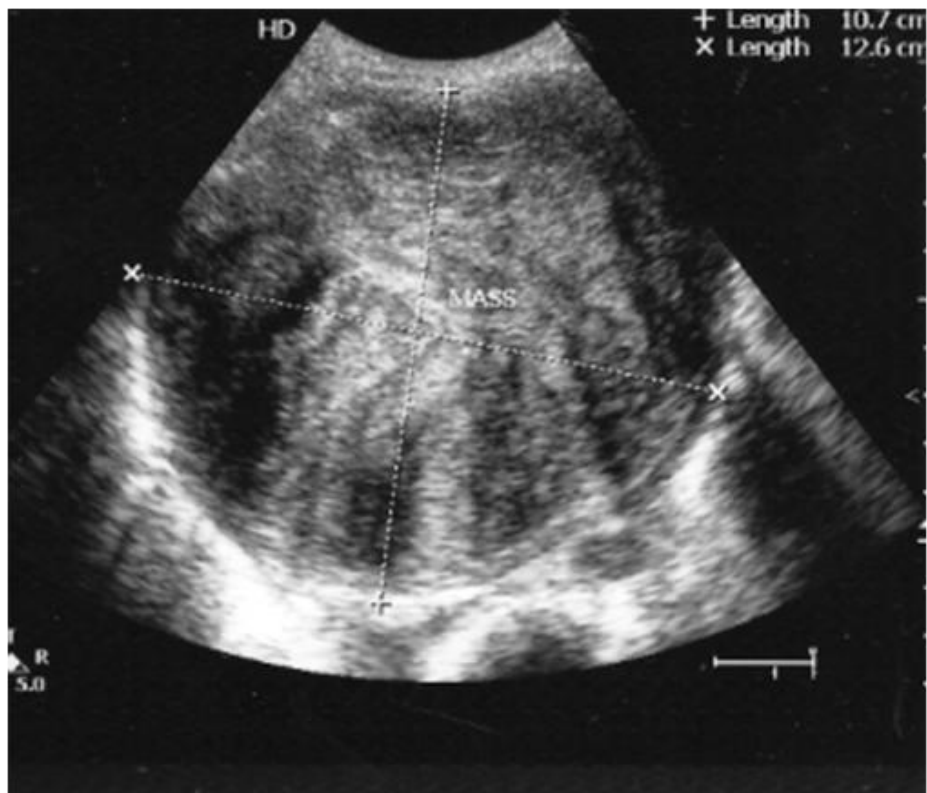


Figure 5. 26 year old with a single large, well defined intramural solid mass confirmed by histopathology to be a leiomyoma

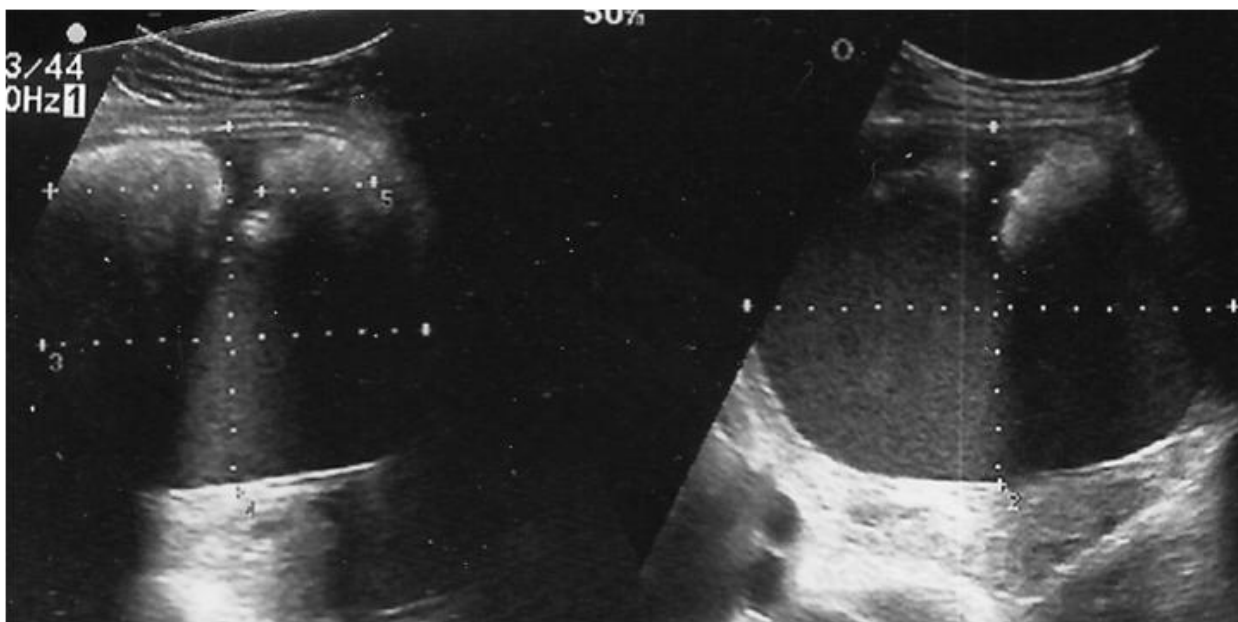


Figure 6. 40 year old with a dermoid cyst on ultrasound which was confirmed by histopathology

Table 2. Sensitivity of Diagnostic Modalities in Characterization of Gynecologic Masses

Clinical Findings		Surgical Findings		Sensitivity (95% CI)
<i>Consistency of the mass</i>		<i>Cystic</i>	<i>Solid</i>	
Cystic		10	3	45.5 (24.4 - 67.8)
Solid		12	33	91.7 (77.5 – 98.2)
<i>Contour</i>		<i>Irregular</i>	<i>Regular</i>	
Irregular		10	10	43.4 (23.2 – 65.5)
Regular		13	25	71.4 (53.7 – 85.4)
<i>Total</i>		23	35	60.3 (46.6 – 73.0)
Ultrasound		Surgical		Sensitivity
<i>Location</i>	<i>Ovarian</i>	<i>Tubo-ovarian</i>	<i>Uterine</i>	
Ovarian	25	2	0	83.3 (65.3 – 94.4)
Tubo-ovarian	3	1	2	33.3 (0.8 – 90.6)
Uterine	2	0	31	94.0 (79.8 – 99.3)
<i>Consistency</i>	<i>Cystic</i>		<i>Solid</i>	
Cystic	27		4	96.4 (81.7 – 99.9)
Solid	1		33	89.2 (74.6 – 97.0)
<i>Size (cm)</i>	<i>< 5</i>	<i>5 – 10</i>	<i>>10</i>	
Less than 5 cm	1	4	2	33.3 (0.8 – 90.6)
5 – 10 cm	1	25	2	65.8 (48.6 – 80.4)
Greater than 10 cm	1	9	15	78.9 (54.4 – 93.9)

Sensitivity and Specificity of Diagnostic Modalities

Table 3 presents the sensitivity and specificity of clinical examination findings. Sensitivity of clinical examination was highest for uterine fibroids (90.5%, CI=69.6-98.8)

and lowest for dermoid cyst (0%). On the other hand, clinical examination scored highly on specificity for leiomyosarcoma (100%), dermoid cysts (98.5% CI=91.7-99.9) and endometrial cancer (95.5% CI= (87.3–99.1).

Table3. Validity of Clinical Examination by Gynecological Mass

Disease	TP	FN	FP	TN	Sensitivity	Specificity	PPV	NPV
Uterine fibroids	19	2	10	38	90.5 (69.6-98.8)	79.2 (65-89.5)	65.5(45.7-82.1)	95(83-99.4)
Ovarian cyst	4	12	5	48	25 (7.2-52.4)	90.6 (79.3-96.9)	44.4 (13.7-78.8)	80 (67.7-89.2)
Leiomyosarcoma	1	6	0	62	14.3 (0.4-57.8)	100	100	91.2 (81.8-96.7)
Ovarian cancer	3	2	5	59	60 (14.7-94.7)	91.2 (82.7-97.4)	37.5 (8.5-75.5)	96.7 (88.7-99.6)
Dermoid cyst	0	5	1	63	0	98.5 (91.7-99.9)	0	94.1 (85.6-98.4)
Endometrial cancer	1	2	3	63	33.3 (08 – 90.6)	95.5 (87.3 – 99.1)	25 (0.6-80.5)	96.9 (89.3-99.6)
Adenomyosis	0	2	0	67	0	100	0	97.1(89.9-99.6)
Endometrial hyperplasia	0	1	0	68	0	100	0	98.6(92.2-99.9)
Ovarian fibroma	0	2	0	67	0	100	0	97.1(89.9-99.6)
Cervical cancer	0	1	0	67	0	100	0	97.1(89.9-99.6)

Abbreviations: TP- True Positive, FP-False Positive, FN-False Negative, TN-True Negative

Positive Predictive Value (PPV) and Negative Predictive Value (NPV) of Diagnostic Modalities

Clinical examination had high PPV for leiomyosarcoma (100%) followed by uterine fibroids (65.5%, CI=45.7-82.1). PPV for all other conditions was less than 50%. On the contrary, PPV for ultrasound was highest for ovarian cysts (78.6%, CI= (49.2-95.3), followed by uterine fibroids (68.9%, CI=49.2-84.7); only endometrial cancer and leiomyosarcoma scored less than 50%. NPV scored above 80% in all conditions on clinical examination. The same was observed in ultrasound diagnosis.

Receiver Operating Characteristics (ROC) Analysis

Sonography was significantly more accurate compared to clinical examination of benign gynecologic masses. The ROC of area under the curve (AUC) was 0.578 (0.461-0.694) for clinical diagnosis of ovarian cysts and 0.815 (0.694-0.937) for sonography (p value=0.0001) as seen in Figure 7.

A similar pattern of sonographic examination being significantly higher than clinical examination was observed for dermoid cysts (Figure 8). The ROC area for sonography was 0.86 while that of clinical examination was 0.49.

Ovarian cancer was the only malignant condition where sonography was significantly more accurate than clinical examination (Figure 9). The AUC for sonography was 0.78 compared to 0.67 for clinical examination (p value = 0.007). (Table 5)

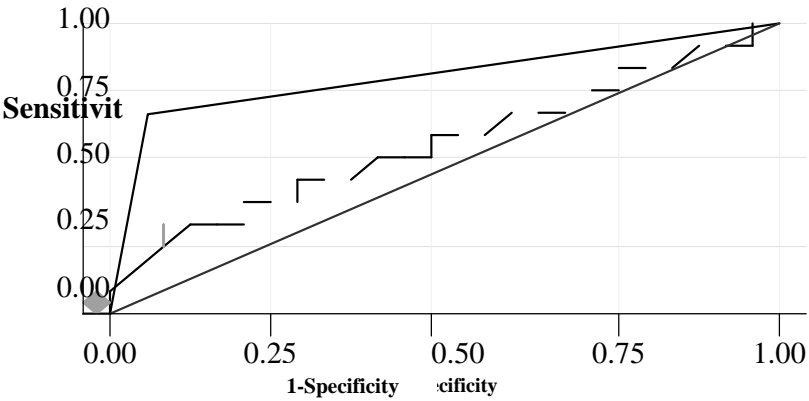
DISCUSSION

Sonography has become the modality of choice in the initial evaluation of gynecologic masses (Arthur and Stephen, 2001). In this regard, sonography helps in confirming the presence of a mass, its location, size and the likely diagnosis. In many instances, it also differentiates between masses that are likely to be malignant from benign ones. Sonographic findings are influential in determining the clinical management of patients with gynecologic masses and often determine whether surgical intervention is required (Jabeen, 2006).

Socio-demographic Characteristics

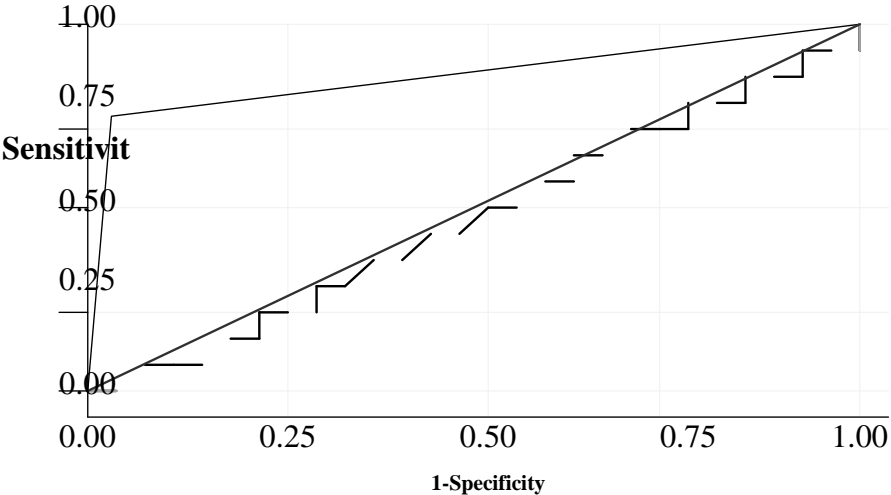
The mean age of participants in this study was 44 years with 67% of them being above 35 years. Age is a strong determinant of the type of pelvic mass in women; whereas malignancies are common in those aged above 50 years benign conditions dominate the under 50 years category (Hernandez and Miyazawa, 1988; Schem et al., 2007). Age is known to be a risk factor for most malignancies. This has practical implication on sonography of pelvic masses in those above 50 years. Hence, radiologists should consider carefully the possibility of malignancy in this age group.

The mean age at menarche was 13.7 years, while the mean parity was 3.5. Younger age at menarche and low parity has been associated with ovarian and endometrial cancers (Fujita *et al.*, 2008). However, in this study no significant relationship was observed for menarche, while those with ovarian and endometrial



— CysUs* ROC area: —◆— CysClin** ROC area:
Reference
* (CysUs) = Ultrasound Diagnosis of Ovarian Cyst; ** (CysClin) = Clinical diagnosis of Ovarian cyst

Figure7. ROC Curve Comparing Clinical and Sonographic Diagnosis of Ovarian Cyst



— DermUs* ROC area: 0.8596 DermClin** ROC area:
Reference
* (DermUs) = Ultrasound diagnosis of dermoid cyst; ** (DermClin) = Clinical diagnosis of dermoid cyst

Figure 8. ROC Curve Comparing Clinical and Sonographic Diagnosis of Dermoid Cyst

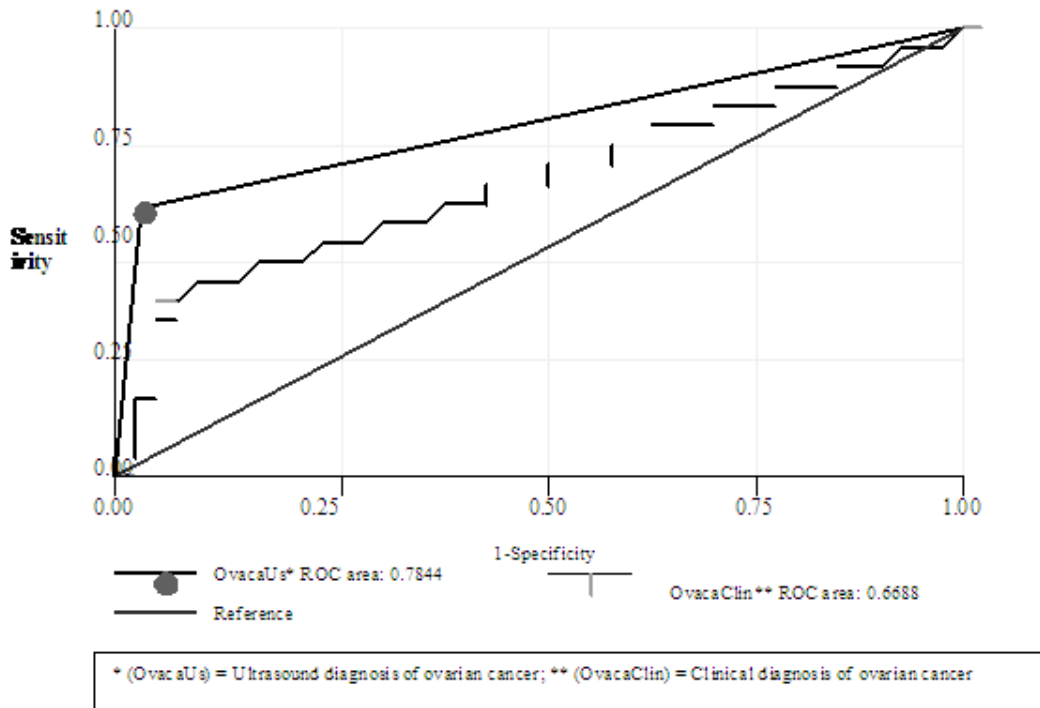


Figure 9. ROC Curve Comparing Clinical and Sonographic Diagnosis of Ovarian Cancer

Table 5. Accuracy of Various Diagnostic Modalities by Type of Gynecologic Pelvic Mass

Diagnostic Modality	AUC	95% CI	p Value
Uterine fibroids			
Clinical	0.84	0.76-0.93	0.33
Ultrasound	0.93	0.81-0.96	
	0.86-1.0		
Ovarian cyst			
Clinical	0.58	0.46-0.69	0.0001
Ultrasound	0.82	0.69-0.94	
Leiomyosarcoma			
Clinical	0.5	0.5-0.5	
Ultrasound	0.5	0.5-0.5	
Ovarian cancer			
Clinical	0.67	0.43-0.91	0.007
Ultrasound	0.78	0.54-1.0	
Endometrial cancer			
Clinical	0.48	0.46-0.50	0.195
Ultrasound	0.64	0.32-0.97	
Dermoid cyst			
Clinical	0.49	0.48-0.51	0.000
Ultrasound	0.86	0.61-1.0	

cancers had higher parity than those without. Our finding on parity may actually be a representation of fertility choices of older women. Secondly, the difference in study design could account for the variation in results.

Clinical, Sonographic and Surgical Characterization of Gynecologic Masses

The most common complaint was abdominal pain 64% followed by abdominal swelling 61%. Symptoms are important in the evaluation of a pelvic mass, they could point to the etiology (Russel, 1995). Another study, however, found vaginal bleeding (38%) to be the most common symptom followed by abdominal swelling (21%) and abdominal pain (15%) (Noor, 2003). Like in this study, abdominal pain was the most common symptom (64%) in a study by Munir et al., (2010). This finding may be a reflection of the health care seeking behavior in the community. Patients are more likely to seek treatment for pain compared to other symptoms. Pain in these masses may have resulted from degenerating fibroids and hemorrhage or torsion of ovarian cysts. Pain may also be caused by malignancies and pressure exerted by the mass on the pelvic wall. Torsion of ovarian cysts causes acute pain which is often on the right side and maybe confused with appendicitis (Givens et al., 2009; Hoey et al., 2005). Pain of gradual onset associated with fever or purulent vaginal discharge may indicate pelvic inflammatory disease (Givens et al., 2009). It is necessary to take a careful history and physical examination and corroborate with imaging findings. Signs and symptoms alone have low sensitivity in the diagnosis of pelvic masses (Goff et al., 2007).

The median duration of symptoms was 6 months (range 1 to 365 days) and 33% had symptoms for more than 360 days. A study on ovarian tumors found the median duration of symptoms before detection to be 4 months for invasive tumors and 6 months borderline tumors (Vine et al., 2001). Another study noted that most patients diagnosed with ovarian cancer reported having had symptoms for three months or more (Smith, 2006). Goff et al. 2000 found that having multiple symptoms to be a determinant of delay in making a diagnosis of ovarian cancer. Delay sometimes occurs because of vague, non-specific symptoms, in the case of ovarian cancer these occur for months in up to 93% of patients (Olson et al., 2001). There is marked delay in seeking treatment for gynecologic masses among study participants. Conditions such as ovarian cyst torsion, which present with acute pain, accounted for the shortest durations. Timeliness in seeking treatment of gynecologic masses is critical, as early detection of malignancies would lead to better outcomes of treatment. Delay in seeking care for pelvic masses

poses a huge public health challenge, thus the need for health education.

Ultrasound is a cardinal adjuvant to clinical examination in the evaluation of pelvic masses. Sonography is instrumental in confirming the presence of a mass, the organ of origin, the consistency, contour, size, and vascularity of the mass (Munir et al., 2010; Wani and Hammad, 2002). These anatomic characteristics are crucial in determining the ultrasound diagnosis and may be relied upon to make distinctions between benign and malignant masses. In this study, most (52.9%) masses were characterized by ultrasound as solid in consistency and the rest as cystic. Eighty four percent (27) of the cystic masses were characterized as complex. Thirty eight percent of the masses measured more than 10 centimeters in their widest diameter. By organ of origin, 53.6% were of uterine origin. These findings reflect the distribution of pelvic masses in our environment. Most of the masses turned out to be fibroids, which are solid. A mass whose size is greater than 10 centimeters among other factors like ascites, complex cysts or solid components may be suggestive of malignancy (McDonald *et al.*, 2010). In this case, the sizes above 10 centimeters were not associated with malignancy and may have resulted from either inaccurate measurement or delay in seeking treatment.

When the anatomic characteristics were compared to surgery, sonography performed highly in predicting uterine masses and consistency but poorly on size especially for those masses whose widest diameters measured less than five centimeters. A number of studies have validated sonography in the evaluation of gynecologic masses; as in Ong's (1996) study, which reported on the predictive value of anatomic characteristics. This study, therefore, provides information that would be useful to the clinical decision-making process. Ultrasound, in this set up, provides accurate information on the organ of origin for uterine and ovarian masses but is inaccurate for tubo-ovarian masses. Ong et al., (1996) found ultrasound to be much more accurate than clinical examination in predicting the organ of origin of a pelvic mass; uterine masses were better predicted than ovarian. The concurrence of these two studies demonstrates the value of ultrasound in accurately differentiating masses of uterine origin from ovarian ones. When masses are reported as tubo-ovarian, however, corroboration with clinical findings would be necessary. Similarly, masses which measure less than five centimeters in their widest diameter are not accurately reported by transabdominal ultrasound. In these cases, transvaginal ultrasonography should be done as this provides improved resolution, though with limited field of view (Weissman and Barloon, 1996).

In some instances, surgical diagnosis were not indicative of gynecologic pelvic masses diagnosed

clinically and on sonography. One was a sterile abscess; which occurred in a 42 year old woman who was being managed as a case of ovarian cancer. Sonography reported it as a complex left ovarian mass with ascites, with a diagnosis of ovarian cancer. This was corroborated by CT scan which confirmed the ultrasound diagnosis. When surgery was done, no ovarian mass was found; rather it was an abdomino-pelvic abscess. There is a study which reported that a solid component is the most significant predictor of malignancy (Brown et al., 1998). A similar case whereby TB peritonitis was misdiagnosed as ovarian carcinomatosis has been reported, and in this case, ultrasound also reported ascites and bilateral adnexal masses (Boss et al., 2012). This case exposes the need to consider infectious etiology alongside malignancy when ultrasound detects ascites. Age is one of the factors that can assist in distinguishing between the two; women with abdomino-pelvic TB for instance are noted to be 20 to 40 years old (Xiet *al.*, 2010). In this study, the patient was 42 years.

Sensitivity and Specificity of Clinical and Sonographic Diagnosis

A number of studies have sought to validate sonography in the evaluation of pelvic masses using different methods. Whereas some studies used surgical findings as gold standard (Jabeen, 2006; Ong et al., 1996; Wani and Hammad, 2002), others used histopathology as gold standard (Munir et al., 2010; Noor, 2003). This difference in methods makes comparability and reproducibility of results difficult. Although surgery is useful in revealing the gross anatomical features of the mass, it would not be accurately predictive of histopathological findings. In general, studies that used surgical findings as gold standard may have overestimated the reliability of both clinical examination and ultrasound.

The sensitivity of ultrasound was highest (95%) for uterine fibroids. This was higher than clinical sensitivity. This was however lower than the 99% sensitivity for uterine fibroids established in Denmark (Dueholm et al., 2002). Eze et al. (2013) in Nigeria found a similar sensitivity of 94.5%. These findings confirm previous assertions that ultrasound is adequately sensitive in detecting benign gynecologic masses (Munir et al., 2010). Furthermore, it confirms the conclusion by Ong *et al.* 1996, that ultrasound sensitivity in detecting uterine masses is higher than ovarian ones. Although there has been wide variability in the study designs employed by different studies, sensitivity of ultrasound has ranged from 77.8% to 94% (Jabeen et al., 2010; Noor, 2003; Wani and Hammad, 2002). It is useful to note that the 87.6% reported by Noor *et al.* (2003) was reported as accuracy rather than sensitivity, while Munir et al. (2010) used surgical findings as gold standard. Also, there are

differences in the manner the parameters were calculated, especially the one reported as accuracy. The sensitivity reported in this study for uterine fibroids is therefore higher. When a test is very sensitive in detecting a particular disease, the test is most useful in ruling out the disease if the result is negative (Sackett et al., 2000). In this set up, therefore, ultrasound is believable if it rules out uterine fibroids.

Ultrasound classified four of the leiomyosarcomas as uterine fibroids and two as endometrial masses. Failure to differentiate uterine fibroids from uterine leiomyosarcomas is the major factor in the low sensitivity reported. Gray scale sonography alone is not useful in distinguishing leiomyomas from leiomyosarcomas. Sensitivity in distinguishing the two can be improved by conducting gray scale combined with color Doppler sonography, paying attention to vascular distribution within the mass (Exacoustos et al., 2007). Patients with leiomyosarcomas have been noted to be older than those with leiomyomas (Aviram et al., 2005). Older patients with uterine masses, therefore, could be subjected to gray scale combined with color Doppler sonography to improve sensitivity of detecting leiomyosarcomas. Three criteria were developed by DePriest and DeSimone (2003) to assess ovarian masses which included tumor volume, cyst wall structure and septa structure.

Specificity of sonography ranged from 78% to 100% for (uterine fibroids) while specificity of clinical examination ranged from 79% to 100%. A number of similar studies did not report specificity (Jabeen, 2006; Munir et al., 2010; Noor, 2003). The specificity of ultrasound in detecting uterine masses was reported as 99% by one study while clinical examination was 94%; specificity of ultrasound on ovarian masses was 71% (Ong et al., 1996). In general, values for specificity far exceeded those of sensitivity for all modalities.

As such, ultrasound scored similar to clinical examination. All the three modalities (clinical examination, sonography and surgery) would be good in confirming the presence of a gynecologic mass, but differ on the specific diagnoses.

In interpreting sensitivity and specificity, a few points have to be noted. First, sensitivity is a computation of the probability of testing positive among those who have disease, it does not account for the people without disease who test positive (false positive) (Mayer, 2004). Likewise, specificity only computes the probability of testing negative among those who do not have disease but does not account for those with disease who will test negative (false negative). The biggest limitation of sensitivity and specificity, therefore, is that they are not useful to clinicians in estimating the probability of disease in individual patients (Akobeng, 2007). For instance, if a patient with a pelvic mass returns with an ultrasound diagnosis of uterine fibroids; what is the

probability that the diagnosis is true? Neither sensitivity nor specificity can answer this question, predictive values would.

Predictive Values of Clinical and Sonographic Diagnoses

In this study, sonography PPV ranged from 25% for endometrial cancer to 78.6 for ovarian cancer; PPV for uterine fibroids was 68.9%. PPV of clinical examination of endometrial cancer was equal to that of sonography, 25%. PPV of sonography was highest for ovarian cancer, 78.6%. This is actually higher than PPV of 69% reported for ovarian cancer in a previous study which concluded that majority of ovarian tumors are correctly identified by ultrasound (Hartman et al., 2012). However, these values were lower than 97% reported by (Voss et al., 1983). The PPV reported by Voss *et al* (1983) was higher because they calculated prediction of a mass but not the histopathology diagnosis. On the other hand, clinical examination had its highest PPV as (100%) for leiomyosarcoma. In general, PPV of ultrasound was higher across all conditions than clinical examination. PPVs are quite informative as they display the probability of a diagnosis being true. In MTRH, for instance, this study shows that 78.6% of all ultrasound diagnoses of ovarian cancer turn out to be true while only 68.9% of diagnoses of uterine fibroids are true. PPV values provided in this study, therefore, provide important statistics to consider in making decisions about the plan of treatment. They are also useful in counseling patients on the probability of having a disease based on clinical and sonography findings. NPV values may be less useful because clinical examination and sonographic examination do not usually return "negative" verdicts.

The reason of subjecting patients to diagnostic tests like ultrasound is to help in making a diagnosis. It is therefore useful to know the probability that test will return a correct diagnosis (Altman and Bland, 1994a). Positive predictive value (PPV) is the proportion of those who test positive who actually have disease while Negative Predictive Value (NPV) is the proportion of those who test negative who actually do not have disease. PPV is a measure of how good a test is in ruling in disease while NPV is a measure of how good the test is in ruling out disease (Bossuyt et al., 2013). PPV is viewed as 'post-test probability of disease given a positive test' (Akobeng, 2007). PPV and NPV vary with different levels of prevalence (pre-test probability) of disease. The higher the prevalence the higher the PPV and the lower the prevalence the higher the NPV (Bossuyt et al., 2013). Due to their dependence on prevalence, comparison of predictive values from studies conducted in different localities must factor in differences

in prevalence. Results from one locality would not be generalizable to other localities with different prevalence (Akobeng, 2007).

Accuracy of Clinical and Sonographic Diagnoses

The AUC of ultrasound for uterine fibroids was 0.88, dermoid cyst was 0.86, ovarian cyst was 0.82, ovarian cancer was 0.78 and endometrial cancer was 0.64. Ultrasound was more accurate than clinical examination in all cases but was exceeded by surgical examination. Most studies have not provided ROC analysis results (Jabeen, 2006; Noor, 2003; Wani and Hammad, 2002). The closest estimation of AUC of ultrasound examination was done by Bouzari *et al.* 2011 which obtained 0.94. This AUC is higher because it was calculated for the risk of malignancy index which incorporated serum CA125 levels thus making it more accurate.

ROC curves are widely used to decide cut-off points for disease when the diagnosis is based on a continuous variable like random blood sugar. They are also used in estimating and comparing the overall accuracy of diagnostic tests (Altman and Bland, 1994b; Obuchowski et al., 2004). In this study, ROC analysis was used to estimate overall accuracy of clinical examination and sonography; and to compare the values. The Area Under the Curve (AUC) represents the average sensitivity given all values of specificity (Bossuyt et al., 2013). AUC values range from 0.5 to 1 where the former represents an uninformative test whereas the latter represents a test with 100% sensitivity and 100% specificity (Crichton, 2002). Tests with AUC of above 0.9 have high accuracy, 0.7 to 0.9 have moderate accuracy while 0.5 to 0.7 have low accuracy; 0.5 is a chance result (Fischer et al., 2003). The accuracy (represented by AUC values) obtained in this study for ultrasound examinations were all moderate with the exception of endometrial cancer where the accuracy is low. The accuracy of ultrasound was higher for benign masses than for malignant ones. Although ultrasound is expected to give as accurate a diagnosis as possible, it cannot give histopathology diagnoses (Athey and Hadlock, 1985). The accuracy reported in this study, therefore, is within the acceptable range.

Study limitation

There was a long lag time between ultrasound and surgery.

CONCLUSIONS

Most common clinical presentation was abdominal pain

and swelling. Most of the gynecological masses in this study were solid and majority were uterine fibroids.

Ultrasound had higher Positive Predictive Values than clinical examination for most of the masses. Negative Predictive Values of sonography were high across the diagnoses.

The sensitivity of sonography was high in the diagnosis of benign masses; but lower for malignancies. Sonography had high sensitivity in predicting the organ of origin of a mass. Sonographic specificity was high across all the gynecologic masses. The accuracy of sonography was significantly higher than clinical examination in the evaluation of uterine masses and ovarian cancer.

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