



**THE DIAGNOSTIVE ACCURACY OF ULTRASOUND
ON OVARIAN TUMOR IN A PATIENTS AT ST.PAUL'S
MILLENNIUM MEDICAL COLLEGE**

**FINAL RESEARCH THESIS TO BE SUBMITTED TO SAINT
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REASERCH APPROVAL

This research by **Dr Tesfahun Tiruneh(MD)** is accepted in its presented form by examiners in satisfying research requirement for the Specialty certificate in radiology.

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I. Abstract

a, Background

Ovarian tumors are one of the most frequently identified entities in gynecological practice. Early differential diagnosis is a key factor in the medical management of each patient. Abdominal ultrasound with simple Risk of Ovarian Malignancy Algorithm (ROMA) score, usually provide sufficient information for a presumptive diagnosis. Minimally invasive surgery as a therapeutic approach is the standard procedure for uncomplicated and benign adnexal masses. Histopathological examination alone, or in conjunction with immunohistochemical testing establishes a more certain diagnosis in the final step of the patient management plan. a cross-sectional analytical study design to retrospectively from medical records Using simple randomization sampling technique, collect data from patients admitted to the Department of Obstetrics and Gynecology at “STPMMC” between January 2018 and July 2019. we recruited a sample of 86 women aged between 15 and 85 years fulfilling inclusion criteria with histopathologically proven ovarian masses presenting for an ultrasound examination in our radiology departments.

Results:

Our retrospective data depicted sensitivity and specificity of ultrasound to be 90.7%, 95%CI (0.77, 0.97) and 91.4%, 95%CI (0.76, 0.98) respectively. Positive predictive value was 93%, 95%CI (0.79, 0.98) and negative predictive value was 89%, 95%CI (0.73, 0.96). A total of 78 ovarian masses were detected, out of which 42 were malignant and 36 were benign.

Conclusions:

Results of our study further reinforce the conclusion that ultrasound should be used as an initial modality of choice in the workup of every woman suspected of having an ovarian mass. It not only results in decreasing the mortality but also avoids unnecessary surgical intervention.

Objective:

To assess the ultrasound features of ovarian tumor in differentiating benign from malignant lesions by correlation with pathologic finding

Methods:

A cross-sectional analytical study will designed to retrospectively from Jan 2018-2019 with non-stratified simple random sampling technique

All data underwent descriptive statistical analysis in order to establish correlations between preoperative test results and definitive diagnoses

II. Introduction

Ovarian tumors in particular ovarian cancer happens to be the second most common malignancy that accounts for 4% of all cancers in female population. Annually more than 190,000 new cases are diagnosed world over with the life time risk of developing ovarian cancer in India is 0.75% which vary considerably world over (Parkin et al., 2003; Jemal et al.,2008). However, the mortality is the highest in comparison to the other gynecological cancers. Different investigation tools such as serum CA-125 and pelvic examinations over a period of past many years have been tested and shown lower sensitivities in the diagnosis of ovarian masses. Owing to this and high mortality rate associated with ovarian malignancy, ultrasound has attained its role as the most important preliminary investigation of choice to rule out ovarian malignancies with sensitivity ranging from 80-100% (Kinkle et al.,2000; Van Calster et al., 2005; Arab et al., 2012). Although, Doppler ultrasound allows detection of tumor flow. However, its role has not been found consistent in diagnosis of malignancy (Kinkle et al., 2005; Liu et al., 2007). Moreover, there exists a wide variation in patient population, imaging techniques, and results making things more complicated to precisely understand and assess the diagnostic ability of existing various imaging techniques.

Ultrasound features of malignant ovarian masses are (Ameye et al2009): Cysts with thickened and irregular walls, internal septae (>3 mm), vegetation or papillary projections, cystic lesions greater than 10 cm diameter, presence of solid components or completely solid lesions. Other associated signs include ascites or peritoneal deposits. Based on these features (Sassone et al., 1991) derived a scale which focused on the features such as echo pattern of the lesion, presence or absence of papillary projection and septae, and wall thickness. As a result they distinguished benign and malignant masses with sensitivity of 100%, and specificity of 83%. Similarly (Jacobs et al., 1990) showed 85% sensitivity and 97% specificity of ultrasound for the detection of malignancy. In 1999, International Ovarian Tumor Analysis Group performed a study which included multiple centers from five European countries. They collected relevant demographic and radiographic data of more than 1,000 patients presenting with persistent adnexal masses prospectively and developed a mathematic model so that the risk of risk of malignancy in an adnexal mass can be calculated, with an area under the receiver operating curve (ROC) of 0.96 (Timmerman et al., 2005).

In 2007, the same group reported sensitivity and the largest randomized controlled trial conducted by United Kingdom collaborative Trial of ovarian Cancer screening published their results of ovarian cancer screening in April 2009. They included more than 200,000 postmenopausal women in their study and reported ultrasound to be 84.9% sensitive for the detection of ovarian malignancy (Menon et al., 2009)

a, Statement of the problem

In developed countries, more than 90% of malignant ovarian tumors are epithelial in origin, 5%–6% of tumors constitute sex cord-stromal tumors (e.g., granulosa cell tumors, thecomas, etc.), and 2%–3% are germ cell tumors (e.g., teratomas, dysgerminomas). Epithelial OC reflects a heterogeneous disease with histologic subtypes (histotypes) that differ in their cellular origin, pathogenesis, molecular alterations, gene expression, and prognosis. Malignant Ovarian cancers are of five main histotypes: high-grade serous (HGSOC; 70%), endometrioid (ENOC; 10%), clear cell (CCOC; 10%), mucinous (MOC; 3%), and low-grade serous (LGSOC; <5%). Within each of these categories, although

most often among serous and mucinous, are tumors of uncertain malignant behavior known as borderline or low malignant potential (LMP) tumors that contain microscopic features of malignancy without frank invasion into surrounding stroma.

Diagnostic imaging plays a crucial role in detection, characterization and staging of adnexal masses.

Ultrasound (US) is often the first imaging study performed in the evaluation of a suspected ovarian lesion because it's widely available, well accepted by patients, non-invasive and of low cost. A combination of greyscale and colour Doppler features, obtained with transabdominal and/or endovaginal scanning, allow for investigation of both morphological structure and vascular organization of the ovarian mass.

The role of imaging is not to determine the histological nature of a lesion, but to distinguish benign from malignant lesions and guide decisions on further management. demonstration of suspicious imaging features

III. Literature Review

The characterization of ovarian masses and distinguishing between benign and malignant pathology is important both to decrease unnecessary anxiety and enable decisions regarding optimal treatment. Benign pathology may be best treated conservatively or in a general gynecology unit using a minimal access approach. Conversely, suspected malignant masses should be managed aggressively according to the protocols.

The aim of this study is to determine sensitivity, specificity, positive and negative predictive values for ultrasound in characterization of ovarian masses in and to address the potential prediction of abdominopelvic ultrasound suspicious and pathologic proven ovarian tumors

Ovarian cancer incidence rates are greater in high than in middle- to low-income countries. Around the world, age-standardized incidence rates range from more than 11 per 100 000 women in Central and Eastern Europe to less than 5 per 100 000 in parts of Africa. Incidence rates are 11.7 per 100 000 in the UK, 8.0 per 100 000 in the US, 5.2 per 100 000 in Brazil and 4.1 per 100 000 in China. Risk increases with age, although the rate of increase slows after the menopause. Only 10–15 percent of cases occur before the menopause, although germ cell cancers, which are uncommon, peak in women aged between 15 and 35

Data collected from several resources aimed to present global comprehensive ovarian cancer incidence (Sherri L. Stewart, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention, USA) rated Africa to have 4.2 cases /100000, sub-Saharan countries 4/100000 and Ethiopia <3.7/100000 (Fig. 1. Map of ovarian cancer rates worldwide. Rates are per 100,000 women and are age standardized to the 1960 world standard population.

Source: Ferlay et al., 2011.). In less developed countries and regions, ovarian cancer rates are relatively lower, and this is likely due in part to the lack of quality data from large portions of the population in these countries.

Nearly all benign and malignant ovarian tumors originate from one of three cell types: epithelial cells, stromal cells, and germ cells.

Ovarian metastasis account for about 5 % of malignant ovarian tumors, and there is a potential risk of misjudgment if the primary tumor is not known. Stomach, colon, breast, lung and contralateral ovary are the most frequent neoplasms to metastasize to the ovaries. Ovarian metastasis is more often bilateral

a) Study area and period

The study conducted from March 2019 to July 2019 G.C at SPHMMC, Addis Ababa, Ethiopia.

b) Study design

The study designed facility based cross sectional study.

c) Source Population

All patient records that fulfil the inclusion criteria included in the study because of low number

IV. Sample Size and Sampling Procedures

The sample size was calculated using a formula for estimating a single population means assuming a confidence level of 95%. Sample size Calculated sensitivity of ultrasound for the detection of ovarian carcinoma is 80% (Jain, 1994; Jung et al., 2002) taking confidence interval of 95% , bound on error of 5%, the calculated sample size $N=76$. $n = [Z^2 \cdot 1-\alpha/2 - P (1-P)] / B^2$

a) Methods of Data Collection

A structured Questionnaires developed based on study objectives and available literature. Data will be collected by the nurses who are appointed in the US unit. The principal investigator will supervise the data collection for the utmost quality.

b) Data Quality Control

The electronic medical system record & tertiary hard copy record used by the hospital (Info World platform), will be provide the demographic, clinical & imaging dates collect by investigator, the data will be cleared for inconsistency and completeness by using Epi-info version 3.5 software

c) Data Processing and Analysis

Editing and sorting of the questionnaires done to determine completeness manually. Data entered and analyzed performed using SPSS version 21. The responses in the completed questionnaires coded and entered into a data entry template. Summary tables and charts used for describing data. A relationship among the major variables will be describe.

V. Graphics

Table.1 Histopathological diagnoses

Benign:	No. (%)
Ovarian cyst	5 (12.8)
Serous cyst adenoma	3 (3.84)
Mucinous cyst adenoma	2 (2.5)
Tubovarian inflammation	2 (2.5)
Corpus albicans	3 (3.84)
Corpus haemorrhagicum	2 (2.5)
Corpus luteal cyst	3 (3.8)
Para tubal cyst	5 (6.4)
Endometrioma	19 (24.4)
Malignant:	
Adenocarcinoma	11(14.1)
Ovarian carcinoma	3 (3.8)
Clear cell carcinoma	1 (1.3)
Endometrioid carcinoma	4 (5.1)
Mature cystic teratoma	3 (3.8)
Papillary carcinoma	2 (2.5)
Spindle cell tumor	2 (2.5)
Serous cyst adenocarcinoma	2 (2.5)

Table 2 accuracy of Ultrasound in Differentiating between Benign and Malignant Ovarian Masses

Diagnosis	Sensitivity (%)
Malignancy	93 (39/42)
Endometriosis	90 (17/19)
Dermoid cyst	00 (0/1)
Para ovarian or Para tubal cyst	100 (3/3)
Tubo-ovarian abscess	100 (2/2)
Simple ovarian/hemorrhagic cyst	91 (10/11)

VI. Results

Results gathered from my retrospective data depicted sensitivity and specificity of ultrasound to be 90.7%, 95%CI (0.77, 0.97) and 91.4%, 95%CI (0.76, 0.98) respectively in characterization of benign and malignant ovarian masses. The age range of patients was between 16-86 years with mean age of $40.95 \pm \text{SD } 16.54$. The mean tumor size was $7.6 \pm 4.03 \times 6.1 \pm 3.13$ in transverse and longitudinal axis respectively for the left ovary and $7.9 \pm 4.22 \times 6.5 \pm 3.00$ for the right ovary. Positive predictive value was 93%, 95%CI (0.79, 0.98) and negative predictive value was 89%, 95%CI (0.73, 0.96). Reasons for exclusion were histopathologically inadequate sample in two and nonspecific tissue in others. 49% of the tumors (42/78) were malignant, rest (36/78) were benign. The histopathological diagnoses of benign and malignant ovarian masses are shown in Table 2. Out of 42 malignant tumors diagnosed on ultrasound, 3 were histopathologically proven benign. Their final diagnoses were as follows: (n=1) serous cyst adenomas, (n=2) hemorrhagic cysts. Similarly, benign diagnosis was suggested in 36 tumors out of which 32 were found to be in concordance with histopathology. Those were: endometriomas (n=19), dermoid cyst (n=1), Para ovarian cyst (n=3), tubo-ovarian abscess (n=2), hemorrhagic cyst (n=6), simple ovarian cysts (n=5). The true positive rate of endometriosis was (17/19), of dermoid cyst (0/1), of tubo-ovarian abscess/inflammation disease (2/2), of Para ovarian cyst (3/3). The incorrect diagnoses of endometrioma represented one mucinous cystadenoma, one mature cystic teratoma; the one incorrect diagnoses of dermoid cyst comprised one mature cystic teratoma; the 1 incorrect diagnoses of ovarian hemorrhagic cyst represented ovarian endometriosis. Thus, ultrasound was able to make 39 correct specific malignant diagnosis and 32 of benign masses.

VII. Discussion

Ultrasonography (US) has established and developed itself as the most important preliminary imaging tool in identification and characterization of the ovarian masses. This has eliminated unnecessary surgeries in those who will not get any benefit out of it. Both Trans abdominal and transvaginal techniques along with Doppler examination provides optimal visualization of ovarian masses (Fleicher et al., 1993). In the current study, mixture of both benign and malignant ovarian masses was present. Most of the benign lesions such as endometriomas, simple ovarian/ Para ovarian cysts, dermoid cysts, hemorrhagic cysts and tubo-ovarian infections were specifically diagnosed. However, malignancies and certain benign solid masses were not further sub classified into teratomas, sarcomas, ovarian fibromas, serous and mucinous cyst adenomas. As from a clinical perspective it has been found sufficient to suggest a benign solid ovarian tumor diagnosis rather than to be more specific.

In the present series, there were no incorrect diagnoses of Para ovarian cyst. One hemorrhagic cyst was misjudged on imaging as an endometrioma (false-positive). There have been no reports of the specificity of ultrasound in the diagnosis of Para ovarian cysts or of the sensitivity and specificity of gray-scale imaging in the diagnosis of peritoneal cysts. We did not come across a peritoneal cyst in our collected data. Our present series of tumors included only two tubo-ovarian abscesses. One was correctly diagnosed; the other was misdiagnosed as an abscess originating from appendicitis (false-negative). Given the complex appearances and echo patterns of tubo-ovarian abscesses as well as absence of relevant clinical information, such confusions are not unexpected (Fleischer et al., 1992). No reports exist in the literature so far regarding the diagnostic accuracy of pelvic abscess. Only Fleischer et al have reported the diagnostic accuracy of ultrasound for diagnosing tubal disease as 83% sensitive and 73% specific. Several studies define Doppler findings of endometriotic cysts, dermoid cysts, tubo-ovarian abscesses and other benign cysts (Aleem et al., 1995; Zalel et al., 1997; Pascual et al., 2000). However, none have proved to be consistent.

In conclusion, this study yielded the diagnostic accuracy of ultrasound to be 91% in the diagnosis of ovarian masses, thus increasing its reliability. Thus ultrasound seems to be an initial modality of choice in the workup of every woman suspected of having an ovarian mass. And, to rule out unnecessary surgical interventions in benign masses

Conclusions:

Results of our study further reinforce the conclusion that ultrasound should be used as an initial modality of choice in the workup of every woman suspected of having an ovarian mass. It not only results in decreasing the mortality but also avoids unnecessary surgical intervention.

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