SCORING OF OVARIAN MASSES USING GYNECOLOGIC IMAGING REPORTING AND DATA SYSTEM (GI-RADS)

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ABSTRACT

Background: Ovarian cancer is the most common gynecological disease-causing death in women. Transvaginal sonography (TVS) has turned into the first step imaging method for describing adnexal masses.

Aim of the study: The aim of this study was to report the findings in adnexal masses based on TVS and defining the risk of malignancy according to Gynecologic Imaging Reporting and Data System (GI-RADS) classifications.

Patients and methods: A total number of 48 patients, their ages ranged from 23 to 65 years. Our patients were referred from the outpatient clinics of obstetrics and gynecology department of Zagazig university hospitals. Transabdominal and Transvaginal ultrasound was done for all cases. Gynecologic imaging reporting and data system (GI-RADS) was described to reduce false positive results due to miscommunication between examiner and operator, it is based on summarized standardized report of ultrasound findings which may predict the risk of malignancy of the adnexal lesion.

Results: Number of true-positive, true-negative, false-positive, and false-negative cases were 9, 29, 1 and 3 cases, respectively based on histopathologic diagnosis in low- and high-risk Gynecologic Imaging Reporting and Data System groups. Validity of Gynecologic imaging reporting and data system in diagnosis of adnexal lesions showed cut off value >4 with a sensitivity of 75% and specificity of 96.6%.

Conclusion: This study demonstrated that GI-RADS is a standardized and clear reporting method could be used to estimate the incidence of malignancy, so that a clinician can use this system to perform effective clinical management.

Key words: Ovarian Masses, Gynecologic Imaging Reporting and Data System (GI-RADS).

I. INTRODUCTION:

The adnexal masses represent a variety of diseases, ranging from normal luteal cysts to ovarian cancer, from gynecological or non-gynecological origins. Ovarian malignancy is diagnosed in the United States over 22,000 times a year, making it the second most prevalent gynaecological disease; in 2010, nearly 14,000 women died of ovarian cancer (1).

Incidence of ovarian cancer increases with age, women with a family history of breast and gynecologic malignancies, those with known or suggested presence of BRCA or other hereditary cancer syndromes, null parity, obesity, delayed childbearing, use of fertility-enhancing medications. Also, the patient’s reproductive status and contraception technique play a role (1).
Transvaginal sonography (TVS) has turned into the first step imaging method for describing adnexal masses, when utilized by an experienced physician, this procedure accomplishes high affectability for recognizing ovarian disease, and it has been appeared to be valuable for choosing the best careful approach (2) & (3), However, despite the advanced progress in the diagnostic capability of TVS, a large multicenter study reported that the false positive rate could be as high as 24% (4).

One explanation for this high false-positive rate might be administrator experience, as has been appeared in an ongoing randomized trial (5). Another reason could be an issue in the transmission of data about findings from the sonographer to the clinician who choose an appropriate choice. Indeed, reports portraying sonographic findings are sometimes confusing (6).

In this study, we planned to describe and propose a reporting system, which we call the Gynaecologic Imaging Reporting and Data System (GI-RADS), for revealing findings in adnexal masses based on TVS and characterizing the risk of malignancy according to this classification.

We aimed in this study to report the findings in adnexal masses based on TVS and defining the risk of malignancy according to GI-RADS classifications.

II. PATIENTS AND METHODS:

2.1. The current study was conducted at Radiodiagnosis Department, Zagazig University hospitals. This study included 48 female patients with history of symptoms include: pain or discomfort in the lower abdomen and pelvis, abdominal distention, abnormal vaginal bleeding, fullness, painful intercourse. Ovarian cysts smaller than 6 cm usually cause no symptoms unless complications, such as twisting, bleeding, or rupture occur. Their ages ranged from 23 to 65 years (average age 30 years). All patients were referred from the outpatient clinic of Obstetric and Gynecologic department, Zagazig University hospitals after obtaining the approval of the institutional review board (IRB) of Zagazig University.

2.2. A consent form approved by the committee of human rights in research in Zagazig University was obtained from each participant before the study initiation.

2.3. Patients who were included in this study were any female suspected to have adnexal mass with age range 23 - 65 years.

2.4. All patients who were categorized as GI-RADS 1 (GR1), e.g., normal ovaries at US (n = 2), patients who refused to sign consent despite informed discussion with the sonographer, all pregnant patients at the time of examination, virgin patients, and patients who had vaginitis (relative contraindication that can be corrected if the patient take appropriate antibiotic and continue the exam) were excluded from the study.

2.5. The patients who met the inclusion criteria and were suitable candidates for the study have been subjected to:

1. Full clinical History taking:
   - Personal history: Including age, parity.
   - Present history: Including:
     - Analysis of patient complaint.
     - Menstrual cycle (Regular or not).
     - Time of menopause.
   - Past history: previous gynecological troubles or operations and positive family history of gynecological malignancy.

2. Clinical examination:
Local and general examination.
3. Imaging:
Transabdominal and Transvaginal ultrasound was done for all cases. Siemens Acuson X300 Premium Edition Model 10566144 was used to perform the ultrasound examination. Transabdominal scan using a multifrequency curvilinear transducer was done. Before the examination, good filling of the urinary bladder was required (ideal 1–2 cm above the uterine fundus).

Transvaginal sonography (TVS) using a multifrequency curvilinear transducer after emptying the urinary bladder to minimize discomfort and to bring the uterus and ovaries into the focal zone was performed. The probe was disinfected, ultrasound (US) gel was applied to the transducer head.

Color and power Doppler were done for all cases to detect the vascularity of the lesions and to differentiate between suspicious solid component and benign lesions. Once a flow was identified by color Doppler sonography, the pulsed Doppler gate was activated to obtain a flow velocity waveform. The resistive index (RI = [systolic velocity – diastolic velocity]/systolic velocity) was automatically calculated from at least 3 consecutive flow velocity waveforms. In those tumors with multiple flow vascularity, the lowest RI was used for analysis.

2.6. Statistical analysis:
Analysis of data was done using Statistical Program for Social Science version 20 (SPSS Inc. Released 2009, PASW Statistics for Windows, Version 18.0: SPSS Inc., Chicago, IL, USA). Quantitative variables were described in the form of mean and standard deviation. Qualitative variables were described as number and percent. If P value < 0.05, it was considered significant.

III. RESULTS:
Mean of age was 38.47y and range of age (23 -65Y), most of cases were multipara with right side lesion (Table 1).

27 (64.28%) cases out of 42 cases with benign lesions and 3 (7.14%) patients were borderline lesions and only 12 (28.58%) with malignant lesion (Table 2).

The number of true-positive, true-negative, false-positive, and false-negative cases were 9, 29, 1 and 3 cases, respectively based on histopathologic diagnoses in low- and high-risk GI-RADS groups (Table 3, Figure 1).

4 atypical cases out of 48 cases were reported, 4.1% as ectopic pregnancy and 4.1 % as polycystic ovary. 61.9 % of lesions with no vascularity, 16.7% with central vascularity, 21.4 % with peripheral vascularity (Table 4).

Validity of Gynecologic imaging reporting and data system in diagnosis of adnexal lesions showed cut off value >4 with a sensitivity of 75% and specificity of 96.6%. (Table 5, Figure 2).

Table (1): History of disease among patients (N=48):

<table>
<thead>
<tr>
<th></th>
<th>Mean ± SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (N =30)</td>
<td>38.47 ± 12.07</td>
<td>(23 -65)</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nullipara</td>
<td>10</td>
<td>20.8</td>
</tr>
<tr>
<td>Primipara</td>
<td>15</td>
<td>31.3</td>
</tr>
<tr>
<td>Multipara</td>
<td>23</td>
<td>47.9</td>
</tr>
<tr>
<td>Side of affection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>22</td>
<td>45.8</td>
</tr>
<tr>
<td>Left</td>
<td>20</td>
<td>41.7</td>
</tr>
<tr>
<td>Bilateral</td>
<td>6</td>
<td>12.5</td>
</tr>
</tbody>
</table>

Table (2): Histological diagnosis according to the probably low- and high-risk Gynecologic Imaging Reporting and Data System groups (N=42)

<table>
<thead>
<tr>
<th>Pathology</th>
<th>GI-RADS group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GI-RADS II and III</td>
</tr>
</tbody>
</table>

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Benign
Hemorrhagic cyst 4 0 4
Corpus luteum 3 0 3
Dermoid cyst 4 0 4
Endometrioma 3 0 3
Simple cyst 9 0 9
Fibroma 1 0 1
Fibrothecoma 0 1 1
Tubo ovarian Abscess 1 1 2
Serous cystadenoma 2 0 2
Mucinous cystadenoma 0 1 1

Borderline
Borderline ovarian Serous cystadenoma 0 3 3

Malignant
Serous cystadenocarcinoma 0 3 3
Mucinous Cystadenocarcinoma 0 2 2
Endometrioid tumor 0 2 2
Germ cell tumor 0 2 0

Total 27 15 42

Table (3): Distribution of true-positive, true-negative, false-positive, and false-negative cases based on histopathologic diagnosis in low- and high-risk Gynecologic Imaging Reporting and Data System groups.

<table>
<thead>
<tr>
<th>GI-RADS group</th>
<th>Pathology</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Benign</td>
<td>Malignant</td>
</tr>
<tr>
<td>GI-RADS II and III</td>
<td>29</td>
<td>3</td>
</tr>
<tr>
<td>GI-RADS IV and V</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>12</td>
</tr>
</tbody>
</table>

Fig. (1): Column chart showing distribution of malignant and benign lesions diagnosed by histopathologic examination in the four categorized Gynecologic Imaging Reporting and Data System groups. AMs categorized as GR2, 7 cases (23.3%) were benign, and none was malignant. AMs categorized as GR3, 20 cases (66.7%) and none was malignant; of the AMs categorized as GR4, 3 cases (10%) were benign, and 3 cases (25%) were malignant; and of AMs categorized as GR5, 9 cases (75%) were malignant.

Table (4): Distribution of Atypical cases (N=4) and Type of vascularity in the lesions (N=42).

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Ectopic pregnancy</td>
<td>2</td>
<td>4.1</td>
</tr>
<tr>
<td>* Polycystic ovary</td>
<td>2</td>
<td>4.1</td>
</tr>
<tr>
<td>Vascularity</td>
<td>N</td>
<td>%</td>
</tr>
</tbody>
</table>
Table (5): Validity of Gynecologic imaging reporting and data system in diagnosis of adnexal lesions show cut off value >4 with a sensitivity of 75% and specificity of 96.6%.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cut off</th>
<th>AUC (95% CI)</th>
<th>Sens.</th>
<th>Spec.</th>
<th>PPV</th>
<th>NPV</th>
<th>Accuracy</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validity of GI-</td>
<td>&gt; 4</td>
<td>0.87 (0.69 -1.0)</td>
<td>75.0</td>
<td>96.6</td>
<td>90.0</td>
<td>90.6</td>
<td>90.47</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>RADS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig. (2): Receiver operating curve of the Gynecologic Imaging Reporting and Data System for distinguishing malignant adnexal lesions in comparison with histopathology.
Figure 3: Fig (a): There is a left side mixed solid (mainly) & cystic ovarian lesion measuring 137 x 90 mm, of lobulated margins. No calcifications. The fluid content is turbid with high level internal echoes. There is mild free fluid in the pelvic cavity. Fig b: Color doppler shows there is vascularity noted within the solid portion of the lesion. Fig c: Pulsed doppler image show RI = 0.52 (Low Resistive arterial flow pattern). A 51 years-old female patient. The mass was diagnosed as a malignant neoplastic lesion and classified as GIRADS 5, the mass was surgically removed, histopathologic examination revealed ovarian germ cell tumor.

IV. DISCUSSION:

Ovarian cancer is fatal cancer among gynecological malignancies (7). In Egypt, ovarian cancer represented 2.2% of all incident cancers and accounted for 4.4% of all newly diagnosed female cancers (7).

The assessment of an adnexal mass is difficult and needs a meticulous exam preoperatively, to avoid the disproportionate numbers of women with benign ovarian tumors who are being referred to specialized centers and conversely women with ovarian malignancy who are being inappropriately operated in non-specialized centers (8).

Ultrasonography (US) is considered as the primary imaging modality for the detection and characterization of adnexal masses (9).

Despite the progress in its diagnostic capability, there is a high false-positive rate (24%) reported by a large multicenter study that could be explained by dependence on operator experience and a transmission problem of sonographic information from the sonographer to the clinician who makes a final decision (5).

Several studies have proposed for the characterization of the ovarian masses, including examiner’s subjective impression, mathematically developed scoring systems, simple descriptive scoring systems, logistic regression models, and neural networks (7).
In 2009, Amor et al. (10), proposed a unified and structured language for an ultrasonographic report of adnexal masses similar to that used for a breast ultrasound (BI-RADS) called Gynecology Imaging Reporting and Data System (GI-RADS) (10).

This system is based on pattern recognition analysis and prior risk estimation of the probability of malignancy, based on previous studies (10).

GI-RADS was developed to facilitate communication between radiologists and referring clinicians aiming to reduce the confusion and to help predict the probability of malignancy, thereby improving and individualizing treatment options (7).

The lexicon of GI-RADS is aimed to offer a unified language for US reporting and for preventing misinterpretation in communication between the physician and the sonographer (11).

In this study, the mean age of the studied cases was 38.47 ± 12.07, it ranged from 23 - 65 years and this was lower than age documented in Khalaf et al (7).

study that included 116 women who were suspected of having ovarian lesions and had transvaginal ultrasound examination the mean age was 42 ± 16.16 years, ranged from 10 – 82 years (7), also it was in agreement with Basha et al., (12) study that evaluated the diagnostic performance and inter-reviewer agreement (IRA) of GI-RADS for diagnosis of AMs by pelvic ultrasound (US), included 308 women with mean age, 41 ± 12.5 years; and ranged from 15–73 years. The mean presenting age for malignant AMs was 51.5 ± 11.3 years. No significant difference between benign and malignant AMs as regards patient age (p = 0.064). Malignant AMs were more common in postmenopausal women (62.2%) than in premenopausal women (37.8%) (p = 0.002) (12).

In the current study, 47.9 % of cases were multipara, 31.3 % were primipara and 20.8 % were nullipara, 45.8% of cases had right side lesion, 41.7 % had left side lesion and 12.5 % had bilateral lesions and this was in accordance with Amor et al (10) where bilateral tumors detected in 12.6 % of cases.

64.28% of cases at our study had benign lesions and 7.14% of the patients had borderline lesions and only 28.58% had malignant lesions. Final diagnosis of all GI-RADS 2 ovarian masses such as simple cyst, hemorrhagic cysts, corpus luteal cysts, GI-RADS 3 ovarian masses as fibroma, GI-RADS 4 and 5 documented in 15 cases of 48 cases such as abscess in 2 cases as benign lesion, borderline ovarian serous cystadenoma in 3 cases, adenocarcinoma, Transition cell, Ovarian endometrioma and Papillary cyst in 3, 2, 2, 2 cases respectively as malignant lesions and this was in agreement with Khalaf et al(7). Study, where final diagnosis of all GI-RADS 2 ovarian masses such as functional cyst, hemorrhagic cysts, corpus luteal cysts, and 21 cases of GI-RADS 3 masses as simple cysts were made by spontaneous resolution of these masses at follow-up after 6 weeks.

In our study, we found the number of true-positive, true-negative, false-positive, and false-negative cases were 9, 29, 1, and 3 cases, respectively, based on histopathologic diagnoses in low- and high-risk GI-RADS and these findings were nearly similar to Khalaf et al (7). study where there was a strong agreement between the GI-RADS diagnosis and the final diagnosis as its kappa value was 0.91. The GI-RADS classifications in their studied lesions when compared with the gold standard test that was specific for each category demonstrated that among 103 benign ovarian lesions and normal ovaries, 100 lesions (97.1%) were diagnosed as GI-RADS 1, 2, and 3 by US, and this diagnosis was proved pathologically in 15 cases of GI-RADS 3. The missed three masses were classified as GI-RADS 4 (false positive), but the histopathological examination diagnosed them as serous cystadenoma = 1 case and mucinous cystadenoma = 2 cases. This could be explained by the presence of echogenic locules that is misdiagnosed as a solid element, falsely indicated malignancy in this benign neoplasm in addition to the presence of ascites. Furthermore, 52 (98.1%) masses out of 53 malignant masses had GI-RADS 4 and 5. There was one false-negative mass was classified as GI-RADS 3 (7).

The GI-RADS classification in our study performed well as a diagnostic tool for prediction of malignancy in ovarian masses as it reported high sensitivity, specificity, and accuracy. This is not a surprising result as the sonographic evaluation of the ovarian masses in this study is based on the IOTA criteria, which have been tested in several multicenter studies and shown to be good criteria that can be used in the discrimination between benign and malignant adnexal masses. Furthermore, PPV (90 %) and NPV (90.6 %) were high, and these values are not
affected by disease prevalence in our study, as there is one selection bias in our study which is the relatively high prevalence of normal ovary and benign tumors.

In the current study, the AUC was 0.87, the cutoff point of GI-RADS was >4, with sensitivity 75% and specificity 96.6% and accuracy of 90.47% and this was in agreement with Khalaf et al (7), study where the AUC of the diagnostic performance of the GIRADS in predicting the malignant ovarian masses was 0.96, and it was highly significant, with P value < 0.002, the sensitivity was 98.11% and the specificity was 95.15% (7).

In Basha et al., (12) study, on a lesion-based analysis, the GI-RADS had a sensitivity, a specificity, and an accuracy of 92.9%, 97.5%, and 95.7%, respectively. The GI-RADS revealed 100% sensitivity and 48% specificity in very probably benign AMs (GR2), and 92.9% sensitivity and 97.5% specificity in probably malignant AMs (GR4). Moreover, GR4 and GR5 combination was significantly superior to GR5 alone (p = 0.047), the sensitivity and NPV were significantly increased (97.6% and 98.4%, respectively), whereas the specificity and PPV were minimally decreased (93.9% and 91.2%, respectively). Thus, they recommended to combine both GR4 and GR5 for the diagnosis of malignant AMs because GR5 alone as conclusive for malignant AMs diagnosis, the GI-RADS would miss a relevant number of malignant AMs, and this was higher than what we documented in our study as our sensitivity was 75%, specificity was 96.6% and accuracy of 90.47% and this may be attributed to their larger study sample (135 patients). In Basha et al., the best cutoff value for predicting malignant AMs was >GR3, the use of this cutoff value was associated with a sensitivity of 97.6%, and a specificity of 93.3%, while in our study, the cutoff point of GI-RADS was >4 (12).

Amor et al. reported more slightly high sensitivity, specificity, accuracy, LR−, PPV, and NPV, the difference in this result between the two studies may be due to a large number of studied lesions in Amor et al. as it was 432 because it is a multicenter study. Also, Amor et al. used the bilaterality as a parameter in the evaluation of the ovarian masses, but we documented bilateral lesions only in 12.5% of cases (10).

In contrary to our study, Migda et al (13), reported that GI-RADS classification was not an effective method for predicting the malignancy of ovarian tumors when combined with CA-125 level measurement, low sensitivity and high specificity (66.0 and 93.8%, respectively) for GI-RADS when it added to the CA-125 marker, but it showed higher sensitivity and lowest specificity for GI-RADS 4 and 5 (94.3 and 72.2%, respectively). GI-RADS performance were similar to those published by Zhang et al.(14), despite the fact that the authors did not analyze the CA-125 levels as an additional marker for malignancy discrimination (13, 14).

Finally, in keeping with our results, several authors have tested GI-RADS and considered this system as an effective classification for US examination of malignant AMs (15). Moreover, some authors (13) are trying to enhance the diagnostic power of GI-RADS with the addition of CA-125. Therefore, the GI-RADS can stand alone and works like BIRADS as a universal system that helps the clinician to go from one imaging technique such as US towards CT and MRI. However, the GI-RADS needs further modification to become accurate, useful, and comprehensive of all pertinent descriptors and definitions.

V. CONCLUSION:

This study demonstrated that GI-RADS is a standardized and clear reporting method could be used to estimate the incidence of malignancy, so that a clinician can use this system to perform effective clinical management. We found that GI-RADS has been carried out with a high degree of sensitivity and reasonable specificity; Diagnosed correctly most benign GI-RADS lesions 2-3, avoided further imaging and operation for the patient. The high percentage of benign lesions that were recognized as GI-RADS 4 needed additional markers to improve the GI-RADS grouping accuracy.

We recommend using GIRADS system in categorizing adnexal masses in high-risk patients for early diagnosis of malignancies and better prognosis.

Conflict of Interest: No conflict of interest.

REFERENCES


