GI-RADS reporting system for ultrasound evaluation of adnexal masses in clinical practice: a prospective multicenter study

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KEYWORDS: adnexal masses; ovarian cancer; reporting; ultrasound

ABSTRACT

Objective To assess the clinical usefulness of a structured reporting system based on ultrasound findings for management of adnexal masses.

Methods This was a prospective multicenter study comprising 432 adnexal masses in 372 women (mean age, 44.0 (range, 13–78) years) over a 36-month period. Ninety-three (25%) women were postmenopausal and 279 (75%) women were premenopausal. Patients were evaluated with transvaginal ultrasound by one of three examiners expert in gynecological ultrasound. Reporting was provided to referring clinicians according to Gynecologic Imaging Report and Data System (GI-RADS) classification. A predetermined management protocol was offered to referral clinicians. It was suggested that patients classified as GI-RADS 2 be managed with follow-up scan, patients classified as GI-RADS 3 undergo laparoscopic surgery and patients classified as GI-RADS 4 or 5 be referred to a gynecologic oncologist. Definitive histologic diagnosis was available in 370 cases and 62 additional cases were considered as benign because of spontaneous resolution during follow-up. These outcomes were used as the gold standard for calculating the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (LR+) and negative likelihood ratio (LR−) of GI-RADS classification for identifying adnexal masses for high risk of malignancy, considering GI-RADS 4 and 5 as being malignant.

Results Of the 432 tumors, 112 were malignant and 320 benign. The GI-RADS classification rate was as follows: GI-RADS 2, 92 (21%) cases; GI-RADS 3, 184 (43%) cases; GI-RADS 4, 40 (9%) cases; GI-RADS 5, (27%) 116 cases. Sensitivity for this system was 99.1% (95% CI, 95.1–99.8%), specificity was 85.9% (95% CI, 81.7–89.3%), LR+ was 7.05 (95% CI, 5.37–9.55) and LR− was 0.01 (95% CI, 0.001–0.07). PPV and NPV were 99.6% and 71.1%, respectively.

Conclusions The GI-RADS reporting system performed well in identifying adnexal masses for high risk of malignancy and seems to be useful for clinical decision-making. Copyright © 2011 ISUOG. Published by John Wiley & Sons, Ltd.

INTRODUCTION

Ultrasoundography is currently considered as the primary imaging modality for identifying and characterizing adnexal masses. Several approaches have been proposed for their characterization using this technique, including examiner’s subjective impression, simple descriptive scoring systems, mathematically developed scoring systems, logistic regression models and neural networks.

Subjective impression of an experienced examiner is currently believed to be the best approach and no other method has been proven its superior. However, the examiner’s impression is absolutely subjective and recent evidence has shown that this fact affects not only the performance of the method itself, but also the examiner’s confidence in providing a diagnosis. Furthermore, a recent randomized study demonstrated that examiner experience affects performance and decision-making in clinical practice.

Due to the subjective nature of the examiner’s impression there is a need for a standardized nomenclature and...
definition for all tumor features evaluated by ultrasound. This was provided by the International Ovarian Tumor Analysis (IOTA) consensus. Undoubtedly, this consensus has allowed a better, homogeneous description of adnexal masses. However, there is still significant variation in the reporting of ultrasound examination results for adnexal masses. In fact, a recent consensus conference of the Society of Radiologists in Ultrasound concluded that ‘investigation into structured reporting of adnexal cysts to allow for improved communication of results and recommendations for follow-up’ is needed. In 2009 we proposed a reporting system similar to that used for breast ultrasound (BI-RADS): the Gynecology Imaging Reporting and Data System (GI-RADS), developed to facilitate communication between sonologists/sonographers and referring clinicians. This GI-RADS classification is based on ultrasound findings, representing a summarized standardized report of those findings and also providing an estimated risk of malignancy for a given adnexal mass.

The aim of this study was to assess prospectively the use of this reporting system for decision-making in clinical practice.

SUBJECTS AND METHODS

This was a prospective study comprising all women diagnosed as having an adnexal mass and evaluated at three different centers, one in Spain (Clínica Universidad de Navarra, Pamplona) and two in Chile (Centro Ecográfico Ultrasonic Panoramico and Clínica Oncológica FALP, Santiago), from January 2008 to December 2010. Institutional review board approval was obtained and all women gave informed consent to participate.

All patients were evaluated by transvaginal or transrectal (in cases of virgo-intacta women) ultrasound using a Voluson 730 Expert or Pro machine (GE Healthcare, Zipf, Austria) according to a predetermined scanning protocol. Three expert examiners (F.A., H.V. and J.L.A.), each with more than 15 years’ experience in gynecological ultrasound, performed all examinations and between one and five representative images were stored on the machine’s database, to be used in the report (Figure S1 online).

Reporting was performed according to GI-RADS classification. This system is based on pattern recognition analysis and provides an a priori risk estimation of probability of malignancy, based on data from previous studies. The reporting system includes five categories (Table 1) and the report includes a description of the mass as well as a final GI-RADS classification (Figure S1).

During the examination, tumor volume was also estimated according to the prolate ellipsoid formula \( V = \frac{4}{3} \pi \times \text{length} \times \text{width} \times \text{height} \times 0.5233 \), expressed in mL, but this feature was not taken into consideration for assigning a GI-RADS classification.

The meaning and goal of GI-RADS classification was explained to referring clinicians in several clinical sessions before the study started. A management protocol was offered to referral clinicians with the aim of determining whether this reporting system could be useful for deciding patient management and in avoiding confusion for clinicians. However, while we followed up patients to determine how they were managed ultimately, we were not involved in clinical decision-making.

The suggested management protocol was based on risk of malignancy as estimated by GI-RADS classification. Those patients classified as GI-RADS 1 (e.g., normal ovaries at ultrasound) were excluded from the study and from further analysis. GI-RADS 2 patients were considered for expectant management by follow-up sonography on the basis that these lesions were assumed to be functional. GI-RADS 3 patients underwent surgery by general gynecologists on the basis that these lesions were considered to be probably benign and expected to persist over time. Laparoscopy was preferable, although the surgeon managing the patient made the final decision regarding surgical approach (laparoscopy or laparotomy). Patients classified as GI-RADS 4 and 5 were referred to gynecological oncologists for appropriate additional imaging techniques (computed tomography or magnetic resonance imaging) and surgical management, on the basis

### Table 1 Gynecologic Imaging Report and Data System (GI-RADS) classification system for adnexal masses

<table>
<thead>
<tr>
<th>GI-RADS grade</th>
<th>Diagnosis</th>
<th>Est. prob. malignancy</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Definitive benign</td>
<td>0%</td>
<td>Normal ovaries identified and no adnexal mass seen</td>
</tr>
<tr>
<td>2</td>
<td>Very probably benign</td>
<td>&lt; 1%</td>
<td>Adnexal lesions thought to be of functional origin, e.g. follicles, corpora lutea, hemorrhagic cysts</td>
</tr>
<tr>
<td>3</td>
<td>Probably benign</td>
<td>1–4%</td>
<td>Neoplastic adnexal lesions thought to be benign, such as endometrioma, teratoma, simple cyst, hydrosalpinx, paraovarian cyst, peritoneal pseudocyst, pedunculated myoma, or findings suggestive of pelvic inflammatory disease</td>
</tr>
<tr>
<td>4</td>
<td>Probably malignant</td>
<td>5–20%</td>
<td>Any adnexal lesion not included in GI-RADS 1–3 and with one or two findings suggestive of malignancy*</td>
</tr>
<tr>
<td>5</td>
<td>Very probably malignant</td>
<td>&gt; 20%</td>
<td>Adnexal masses with three or more findings suggestive of malignancy*</td>
</tr>
</tbody>
</table>

*Thick papillary projections, thick septations, solid areas and/or ascites, defined according to IOTA criteria, and vascularity within solid areas, papillary projections or central area of a solid tumor on color or power Doppler assessment. Est. prob., estimated probability.
that these lesions were considered to be probably or very probably malignant.

When surgical removal of the tumor was performed, a definitive histologic diagnosis was obtained. Tumors were classified according to World Health Organization criteria and malignant tumors were staged according to FIGO criteria. Borderline tumors were considered as malignant for analytic purposes. STARD guidelines were followed for designing and conducting the study.

**Statistical analysis**

Categorical variables were compared using the chi-square test. Tumor volumes were compared using the Mann–Whitney U-test. We calculated the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (LR+) and negative likelihood ratio (LR−) of the GI-RADS system for identifying adnexal masses for high risk of malignancy, considering GI-RADS 2 and 3 as low risk and GI-RADS 4 and 5 as high risk. The gold standard was histologic diagnosis (benign or malignant) or spontaneous resolution of the cyst during follow-up (benign).

To determine how useful they found the GI-RADS reporting system for understanding ultrasound findings and for making decisions regarding patient management, referral clinicians involved in patient clinical decisions were asked to complete a simple survey. This survey consisted of a single question: ‘How useful do you think GI-RADS reporting system is for understanding ultrasound findings and giving confidence in clinical decisions regarding your patient?’ and there were five possible answers: (A) quite useful; (B) useful; (C) neither useful nor useless; (D) useless; (E) completely useless.

To assess interobserver reproducibility of GI-RADS classification, two examiners (J.L.A. and A.I.) performed a separate analysis in 60 consecutive women who were already included in the study. Both examiners performed a transvaginal scan, blinded to each other’s results, and each one provided a GI-RADS report. To determine the concordance between examiners we used a weighted Kappa index.

**RESULTS**

A total of 372 women with adnexal masses were included in this study (279 from the Clinica Universidad de Navarra and 93 from Centro Ecográfico Ultrasónico Panamá). Their mean age was 44 (range, 13–78) years. Ninety-three (25%) women were postmenopausal and 279 (75%) were premenopausal. Sixty (16%) patients had bilateral tumors, giving a total number of 432 adnexal masses assessed. The prevalence of malignant tumors was 26% (112 malignant tumors in 87 patients). Malignant tumors were more frequent in postmenopausal women (43.2%) than in premenopausal women (13.2%) \( (P < 0.001) \).

Of the 432 masses assessed, 92 (21%) were classified as GI-RADS 2, 184 (43%) as GI-RADS 3, 40 (9%) as GI-RADS 4 and 116 (27%) as GI-RADS 5. Tumor volume was significantly smaller in GI-RADS 2 and 3 cases compared with GI-RADS 4 and 5 cases, while there was no difference in tumor volume between GI-RADS 2 and 3 cases or between GI-RADS 4 and 5 cases (Table 2). Most referring clinicians managed their patients according to GI-RADS classification. Figure 1 summarizes the classifications, management and final outcomes of the study population, and final histological diagnoses are given in Table 3.

![Figure 1](https://example.com/figure1.png)

**Figure 1** Flow chart showing classification by Gynecologic Imaging Report and Data System (GI-RADS), management and final outcome of the study group of 372 women with 432 adnexal masses.
Table 2. Tumor volume according to Gynecologic Imaging Report and Data System (GI-RADS) in 372 women with 432 adnexal masses.

<table>
<thead>
<tr>
<th>Tumor volume (mL)</th>
<th>Median</th>
<th>Interquartile range</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI-RADS 2&lt;sup&gt;a&lt;/sup&gt;</td>
<td>32.0</td>
<td>55.6</td>
<td>3.9–170.0</td>
</tr>
<tr>
<td>GI-RADS 3&lt;sup&gt;b&lt;/sup&gt;</td>
<td>52.6</td>
<td>92.0</td>
<td>1.6–277.7</td>
</tr>
<tr>
<td>GI-RADS 4&lt;sup&gt;c&lt;/sup&gt;</td>
<td>96.3</td>
<td>263.9</td>
<td>6.9–2237.1</td>
</tr>
<tr>
<td>GI-RADS 5&lt;sup&gt;d&lt;/sup&gt;</td>
<td>106.0</td>
<td>284.6</td>
<td>2.1–3728.9</td>
</tr>
</tbody>
</table>

<sup>a</sup> vs b: P = 0.130; a vs c: P = 0.01; a vs d: P = 0.001; b vs c: P = 0.028; b vs d: P = 0.0001; c vs d: P = 0.684.

There was no malignant tumor classified as GI-RADS 2. There was one such case classified as GI-RADS 3; this false-negative case was a 73-year-old woman with a 580 cm³ cyst diagnosed as benign serous cyst, but histology showed it to be a serous ovarian carcinoma, Stage Ia.

The sensitivity for the GI-RADS reporting system was 99.1% (95% CI, 95.1–99.8%), specificity was 85.9% (95% CI, 81.7–89.3%), LR<sup>+</sup> was 7.05 (95% CI, 5.37–9.45) and LR<sup>−</sup> was 0.01 (95% CI, 0.001–0.07) (Table 4). The PPV and NPV were 71.1% and 99.6%, respectively.

All fifteen (six in Spain and nine in Chile) referring clinicians considered this reporting system to be ‘quite useful’ or ‘useful’ for clinical decision-making in adnexal masses.

The interobserver agreement for GI-RADS classification of adnexal masses was very good (weighted kappa index = 0.846) (Table 5).

Table 3. Gynecologic Imaging Report and Data System (GI-RADS) classification according to specific histologic diagnosis in 372 women with 432 adnexal masses.

<table>
<thead>
<tr>
<th>Histologic diagnosis</th>
<th>GI-RADS 2&lt;sup&gt;+&lt;/sup&gt;</th>
<th>GI-RADS 3</th>
<th>GI-RADS 4</th>
<th>GI-RADS 5</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional cyst&lt;sup&gt;*&lt;/sup&gt;</td>
<td>71</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>73</td>
</tr>
<tr>
<td>Serous cystadenoma</td>
<td>5</td>
<td>36</td>
<td>4</td>
<td>3</td>
<td>48</td>
</tr>
<tr>
<td>Mucinous cystadenoma</td>
<td>0</td>
<td>10</td>
<td>4</td>
<td>3</td>
<td>17</td>
</tr>
<tr>
<td>Endometrioma&lt;sup&gt;1&lt;/sup&gt;</td>
<td>6</td>
<td>78</td>
<td>2</td>
<td>0</td>
<td>86</td>
</tr>
<tr>
<td>Teratoma</td>
<td>0</td>
<td>28</td>
<td>4</td>
<td>0</td>
<td>32</td>
</tr>
<tr>
<td>Paraovarian cyst</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Hemorrhagic cyst</td>
<td>9</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>Cystadenofibroma&lt;sup&gt;2&lt;/sup&gt;</td>
<td>1</td>
<td>5</td>
<td>3&lt;sup&gt;e&lt;/sup&gt;</td>
<td>2</td>
<td>2&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Peritoneal cyst</td>
<td>0</td>
<td>3&lt;sup&gt;1&lt;/sup&gt;</td>
<td>2</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Fibroma</td>
<td>0</td>
<td>3&lt;sup&gt;1&lt;/sup&gt;</td>
<td>6</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Hydrosalpinx</td>
<td>0</td>
<td>9&lt;sup&gt;1&lt;/sup&gt;</td>
<td>2&lt;sup&gt;1&lt;/sup&gt;</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>Tubo-ovarian abscess</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Leiomyoma</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Brenner tumor</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Low malignant potential tumor</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>Primary ovarian cancer</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>75</td>
<td>81</td>
</tr>
<tr>
<td>Metastatic cancer</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>92</td>
<td>184</td>
<td>40</td>
<td>116</td>
<td>432</td>
</tr>
</tbody>
</table>

<sup>a</sup>Spontaneous resolution at follow-up.

DISCUSSION

Reporting in ultrasound evaluation of adnexal masses is an important issue. A recent study from Canada has shown that current reporting practices for ultrasound assessments in women with ovarian masses vary considerably and concluded that the use of a synoptic reporting system would be useful<sup>13</sup>. Inappropriate reporting may lead to unwarranted concern by the patient and referring clinician and could lead to unnecessary additional tests and surgery<sup>21</sup>. In fact, investigation into structured reporting of adnexal masses to allow for improved communication of results and recommendations for management has been advised recently<sup>14</sup>.

For this reason we recently developed a simple reporting system based on the concept developed for breast imaging (the BI-RADS classification), which was originally developed for mammographic findings but has been applied successfully to breast ultrasound. As for BI-RADS, the lexicon of our new system is intended to provide a unified language for ultrasound reporting and to avoid confusion in the communication between the sonographer/sonologist and the clinician. We called this...
GI-RADS reporting of adnexal masses

Table 5 Agreement analysis between two observers for assigning Gynecologic Imaging Report and Data System (GI-RADS) classification in 60 women with xxx adnexal masses

<table>
<thead>
<tr>
<th>Examiner B</th>
<th>GI-RADS 2</th>
<th>GI-RADS 3</th>
<th>GI-RADS 4</th>
<th>GI-RADS 5</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI-RADS 2</td>
<td>10</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>GI-RADS 3</td>
<td>1</td>
<td>21</td>
<td>3</td>
<td>0</td>
<td>25</td>
</tr>
<tr>
<td>GI-RADS 4</td>
<td>0</td>
<td>2</td>
<td>9</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>GI-RADS 5</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>TOTAL</td>
<td>11</td>
<td>24</td>
<td>14</td>
<td>11</td>
<td>60</td>
</tr>
</tbody>
</table>

Data are given as on.

In terms of diagnostic performance, this reporting system performed well, with a very high sensitivity and acceptable specificity. This is not surprising bearing in mind that it is based on IOTA criteria, which have been tested extensively in several multicenter studies and shown to be good criteria for discriminating between benign and malignant adnexal masses. Although one could argue that pattern recognition is a subjective assessment, there is evidence that this is the best method for characterizing adnexal masses and that pattern recognition is reproducible among expert examiners.

In conclusion, this prospective study has shown that GI-RADS classification performs well as a reporting system in adnexal masses and it seems to be useful for clinical decision-making.

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SUPPORTING INFORMATION ON THE INTERNET

The following supporting information may be found in the online version of this article:

Figure S1 Sample report for the Gynecologic Imaging Report and Data System (GI-RADS) classification.
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AQ1 Is the new short title ok (top of page 3): “GI-RADS reporting of adnexal masses”

AQ2 Please check that all affiliations are correct and complete

AQ3 Table 3 - Note in the removal of repeat data in the text, we’ve lost the detail regarding GI-RADS 2 cases as to which persisted and then underwent surgery, and which underwent surgery immediately for pain symptoms – do you wish this to be specified here in the footnote? (E.g. “†Five hemorrhagic cysts and the cystadenofibroma comprised the six GI-RADS 2 cases which underwent surgery following diagnosis, due to pain symptoms.” With a † symbol by the numbers 9 and 1 in the second column. Similarly for GI-RADS 4 cases do you want to add ‡ symbols by the numbers 3 and 2, with footnote “‡ Two hydrosalpinges and one serous cystadenofibroma comprised the GI-RADS 4 cases which underwent laparoscopic surgery by a general gynecologist.”)

AQ4 Table 3 – should ‘Cystadenofibroma’ be changed to ‘Serous cystadenofibroma’ or were there also other kinds? And which is correct, Hydrosalpinx (here) or Hydrosalpinges (text)?

AQ5 I removed the incorrect footnote in Table 5. However, we still need to specify what is in the table. Am I right in thinking it’s ’n’? This is number of women here, right? How many masses were there in these women? In fact, sorry I should’ve clarified this earlier - is the GI-RADS classification for the woman or the individual tumor? Tables 3 and 4 suggests it’s the tumor, but elsewhere you refer to classification of women. Or will a woman with more than one mass always have the same grade for each mass?

AQ6 Should ‘Clinica Oncologica FALP, Santiago’ be removed from here or is clarification needed, if US exams were not performed here?

AQ7 ‘hard copies of each adnexal mass were recorded’ changed to ‘images was stored on the machine’s database to be used in the report.’ – is this correct?

AQ8 Note the rewording around here following removal of text that repeated figure and table. Do you wish to add anything about the false-positive diagnoses in GI-RADS 4 and 5, like you have here about the false negatives?

AQ9 Please feel free to edit the legend to the supplementary report
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