Gynecologic Imaging Reporting and Data System

A New Proposal for Classifying Adnexal Masses on the Basis of Sonographic Findings

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Objective. The purpose of this study was to describe a new reporting system called the Gynecologic Imaging Reporting and Data System (GI-RADS) for reporting findings in adnexal masses based on transvaginal sonography. ***Methods.*** A total of 171 women (mean age, 39 years; range, 16–77 years) suspected of having an adnexal mass were evaluated by transvaginal sonography before treatment. Pattern recognition analysis and color Doppler blood flow location were used for determining the presumptive diagnosis. Then the GI-RADS was used, with the following classifications: GI-RADS 1, definitively benign; GI-RADS 2, very probably benign; GI-RADS 3, probably benign; GI-RADS 4, probably malignant; and GI-RADS 5, very probably malignant. Patients with GI-RADS 1 and 2 tumors were treated expectantly. All GI-RADS 3, 4, and 5 tumors were removed surgically, and a definitive histologic diagnosis was obtained. The GI-RADS classification was compared with final histologic diagnosis. ***Results.*** A total of 187 masses were evaluated. The prevalence rate for malignant tumors was 13.4%. Overall GI-RADS classification rates were as follows: GI-RADS 1, 4 cases (2.1%); GI-RADS 2, 52 cases (27.8%); GI-RADS 3, 90 cases (48.1%); GI-RADS 4, 13 cases (7%); and GI-RADS 5, 28 cases (15%). The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were 92%, 97%, 85%, 99%, and 96%, respectively. ***Conclusions.*** Our proposed reporting system showed good diagnostic performance. It is simple and could facilitate communication between sonographers/sonologists and clinicians. ***Key words:*** adnexal mass; reporting system; sonography.

Abbreviations
GI-RADS, Gynecologic Imaging Reporting and Data System; NPV, negative predictive value; PPV, positive predictive value; RI, resistive index; TVS, transvaginal sonography

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Transvaginal sonography (TVS) has become the first-step imaging technique for characterizing adnexal masses. When used by experienced examiners, this technique achieves high sensitivity for identifying ovarian cancer, and it has been shown to be useful for selecting the best surgical approach.[1–3] However, despite the tremendous 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 may be operator experience, as has been shown in a recent randomized trial.[5] Another reason could be a problem in the transmission of information about findings from the sonologist or sonographer to the clinician who makes final decision. As a matter of fact, reports describing sonographic findings are sometimes confusing.[6]

In breast imaging, this problem was solved by the introduction of the Breast Imaging Reporting and Data System developed by the American College of Radiology in 1993.[7] Although this system was originally developed for standardizing reporting of mammographic findings, it has been adopted for breast sonography.[8]

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

Materials and Methods

This was a prospective study comprising 171 women suspected of having an adnexal mass evaluated between January and December 2007. Institutional Review Board approval was obtained, and all women gave verbal informed consent. The patients' mean age was 39 years (range, 16–77 years). Fifty-four women (31.5%) were postmenopausal, and 117 (68.5%) were premenopausal.

All patients were evaluated by TVS using Voluson 730 Expert and Pro machines (GE Healthcare, Milwaukee, WI) according to a predetermined scanning protocol.[9] Briefly, once the endovaginal probe was gently inserted into the vagina, the uterus and adnexal regions were scanned. Special attention was paid to adnexal masses. First, the tumor volume was calculated according to the prolate ellipsoid formula ($A \times B \times C \times 0.5233$, expressed in cubic centimeters). A morphologic evaluation was performed according to International Ovarian Tumor Analysis Group recommendations for the following parameters: bilaterality, wall thickness, septations, papillary projections, solid areas, and echogenicity.[10] The presence of ascites was also recorded. Pattern recognition analysis was used for adnexal masses highly suggestive of given diseases such as endometrioma,[11] mature teratoma,[12] hydrosalpinx,[13] peritoneal cyst,[14] hemorrhagic cyst,[15] follicular cyst,[16] paraovarian cyst,[17] tubo-ovarian abscess,[18] simple cyst,[19] and cystadenofibroma.[20]

After the morphologic evaluation was performed, the color Doppler gate was activated to identify vascular color signals within the tumor. If blood flow was detected, it was stated as "peripheral" (color signals in the tumor wall or periphery of a solid tumor) or "central" (blood flow detected in septa, papillary projections, solid areas, or the central part of a solid tumor). A subjective amount of flow was stated as scanty, moderate, or abundant. In tumors with both peripheral and central blood flow, only central blood flow was used for analysis.

Once a vessel 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 more than 1 vessel, the lowest RI was used for analysis. On the basis of previously reported data, we took only the RI into account because the pulsatility index and peak systolic velocity had lower performance.[9]

Two examiners (F.A. and H.V.) with more than 20 years of experience with gynecologic sonography performed all examinations, and 1 to 5 representative hard copy images of each adnexal mass were recorded. When any premenopausal woman was evaluated in the luteal phase of the menstrual cycle, the Doppler evaluation was not performed to avoid confusion with corpus luteum vascularization.

After the examinations, the GI-RADS was used, with the following classifications:

GI-RADS 1, definitively benign. Normal ovaries were identified, and no adnexal mass was seen.

GI-RADS 2, very probably benign. This category included adnexal lesions thought to be of functional origin, such as follicles, corpora lutea, and hemorrhagic cysts (Figure 1).

GI-RADS 3, probably benign. This category included neoplastic adnexal lesions thought to be benign, such as endometrioma, teratoma, simple cyst, hydrosalpinx, paraovarian cyst, peritoneal pseudocyst, pedunculated myoma, and findings suggestive of pelvic inflammatory disease (Figures 2–4).

GI-RADS 4, probably malignant. This category included adnexal lesions that could not be included in the above groups and with 1 or 2

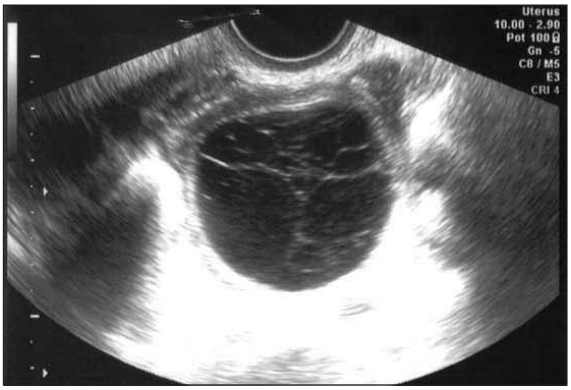


Figure 1. Transvaginal sonogram of an adnexal mass diagnosed as a hemorrhagic cyst and classified as GI-RADS 2. The patient was followed, and the cyst resolved spontaneously after 2 months.

findings suggestive of malignancy (ie, thick papillary projections, thick septations, solid areas, central vascularization, ascites, and a lowest RI <0.5; Figure 5).

GI-RADS 5, very probably malignant. This category included adnexal masses with 3 or more of the findings suggestive of malignancy listed for GI-RADS 4 (Figure 6).

Most patients with GI-RADS 1 and 2 tumors were treated expectantly, except those (n = 5) with GI-RADS 2 tumors and pain symptoms, who underwent surgery. All GI-RADS 3, 4, and 5 tumors were removed surgically, and a definitive histologic diagnoses were obtained. In those cases in which no surgery was performed, patients were followed, and a functional cyst was diagnosed when spontaneous resolution of the cyst was observed.

The GI-RADS classification was compared with the final histologic diagnosis. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, positive likelihood ratio, and negative likelihood ratio were calculated for this system. Interobserver reproducibility was assessed by the κ index. Two different examiners, who were blinded to each other, evaluated 34 consecutive cases.

Results

Twenty-one patients (12.6%) had bilateral tumors, giving a total of 183 adnexal masses evaluated. Definitive final diagnoses are shown in Table 1. The prevalence rate for malignant tumors was 13.4% (25 malignant tumors in 21 patients).

Overall GI-RADS classification rates were as follows: GI-RADS 1, 4 cases (2.1%); GI-RADS 2, 52 cases (27.8%); GI-RADS 3, 90 cases (48.1%); GI-RADS 4, 13 cases (7%); and GI-RADS 5, 28 cases (15%). No further follow-up was done in GI-RADS 1 cases. All but 5 GI-RADS 2 cases were followed until cyst resolution.

Interobserver reproducibility was high (κ = 0.84; 95% confidence interval, 0.7–0.99). Benign and malignant tumors according to GI-RADS classification are shown in Table 2. With GI-RADS 5

Figure 2. Transvaginal sonogram of an adnexal mass diagnosed as an endometriotic cyst and classified as GI-RADS 3. Surgery was performed, and the diagnosis was confirmed on histopathologic analysis.

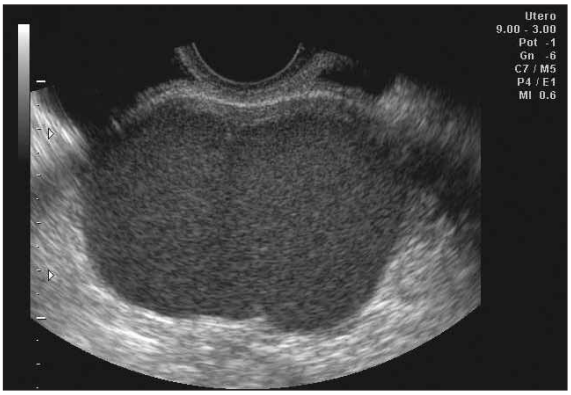
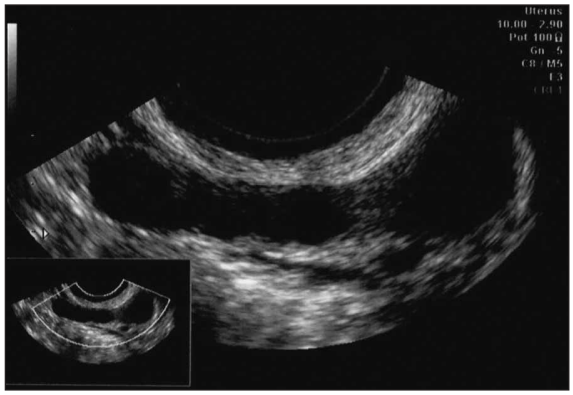


Figure 3. Transvaginal sonogram of an adnexal mass diagnosed as hydrosalpinx and classified as GI-RADS 3. Surgery was performed, and the diagnosis was confirmed on histopathologic analysis.



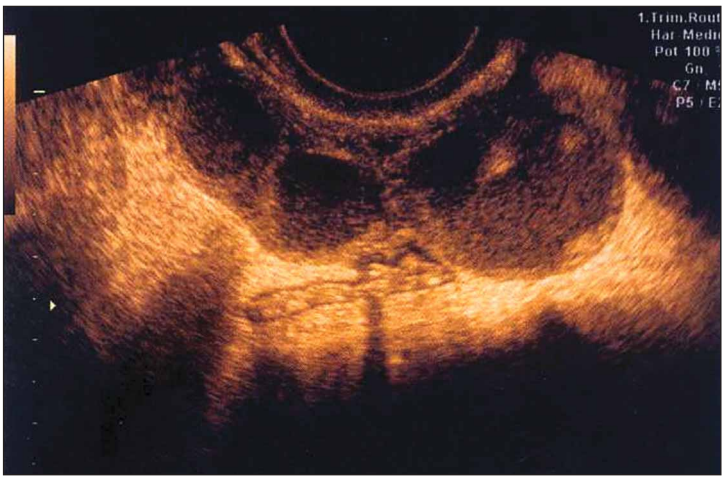


Figure 4. Transvaginal sonogram of an adnexal mass diagnosed as acute salpingitis in the clinical setting of pelvic inflammatory disease and classified as GI-RADS 3. Surgery was performed, and the diagnosis was confirmed on histopathologic analysis.

considered very probably malignant, the sensitivity, specificity, PPV, NPV, positive likelihood ratio, and negative likelihood ratio for this system are shown in Table 3. There were 5 cases with false-positive findings (Table 4) and 2 cases with false-negative findings: an immature teratoma in a 68-year-old woman and a tumor with low malignant potential in a 41-year-old woman; both cases were classified as GI-RADS 4.

Discussion

Adnexal masses are common problems in clinical practice. Sonography is considered the first-line imaging technique for discriminating between malignant and benign lesions, and it has been shown to be useful for determining optimal treatment.[1–3] In most institutions, a different person from the one who treats the patient and makes clinical decisions performs the sonographic examination. Usually the clinical management decision is based on data provided in the sonographic report. Many sonographers and sonologists use scoring systems to characterize adnexal masses,[21–23] whereas others use the so-called pattern recognition approach.[24] However, sometimes sonographic reports are misleading and confusing for the clinician.[6] Although some groups have made considerable efforts in establishing terms and definitions for sonographic findings in adnexal masses,[10] currently available reporting guidelines are scanty.[25,26]

In this study, we proposed a new data reporting system for sonographic findings in adnexal masses. This system is based on the concept developed for breast imaging, namely the Breast Imaging Reporting and Data System classification. Originally developed for mammographic findings, it has been successfully applied to breast sonography.[8] Like its breast sonographic

Figure 5. Transvaginal sonogram of an adnexal mass showing a solid area that arises from the surface of the internal walls. No flow was detected within this solid area, and the mass was classified as GI-RADS 4. Surgery was performed, and histopathologic analysis revealed cystadenofibroma.

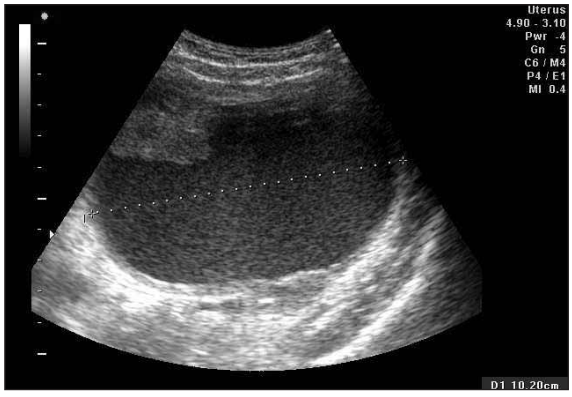
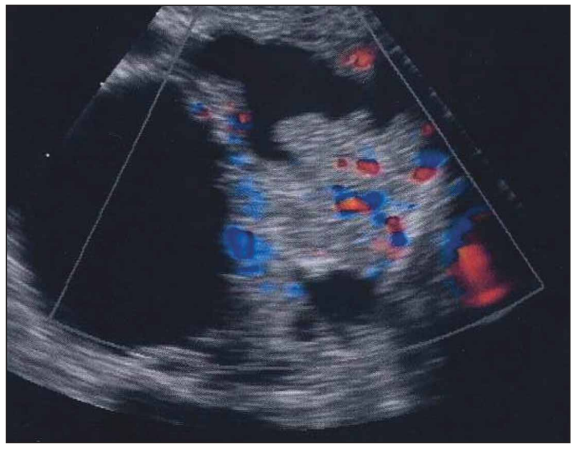


Figure 6. Transvaginal sonogram of an adnexal mass showing a solid area with irregular contours and blood flow within it. The mass was classified as GI-RADS 5. Surgery was performed, and histopathologic analysis revealed primary serous ovarian carcinoma.



counterpart, the GI-RADS lexicon is intended to provide a unified language for sonographic reporting and for avoiding confusion in communication between the sonographer/sonologist and the clinician.

This system is based on a description of the adnexal mass using the pattern recognition approach and the a priori risk for malignancy in each group. On this basis, the proposed classification enables the sonologist or sonographer to give the clinician as much information as possible in a summarized way, as well as an estimated risk of malignancy, based only on the sonographic characteristics of the images. For this classification to be useful, it is essential that the presumptive etiologic diagnosis of the adnexal lesion be highly precise. Currently, there is enough evidence to indicate that when an experienced examiner performs the sonographic examination, such accuracy is achievable for most types of adnexal masses.[12–19]

The preliminary results herein reported are good, achieving sensitivity of 92% and specificity of 97%. The positive likelihood ratio was 29.8. According to this classification, we had 2 cases with false-negative findings and 5 with false-positive findings. The cases with false-negative findings were 1 early-stage immature teratoma, which is a rather uncommon entity in postmenopausal women, and 1 early-stage tumor with low malignant potential. Regarding the false-positive findings, 1 of them was cystadenofibroma; another was fibroma; and another was struma ovarii. Both ovarian fibroma and struma ovarii are known to be difficult to classify, showing features suggestive of malignancy in many instances.[27,28] The case of cystadenofibroma was notable because for some authors, this kind of tumor may show typical findings, such as a thin-walled cyst with hyperechoic mural nodules[20]; however, others have found this tumor very difficult to classify.[27]

If we had also considered GI-RADS 4 as malignant, the sensitivity would have increased to 100%; the specificity would have dropped to 90%; and the positive likelihood ratio would have been lower (10.1; 95% confidence interval, 6.55–16.6). Perhaps GI-RADS 4 would need a subclassification into at least 2 groups with different risks for malignancy.

Table 1. Final Diagnoses in All Masses

Diagnosis	n	%
Functional cyst	18	9.6
Paraovarian cyst	2	1.1
Hemorrhagic cyst	29	15.5
Hydrosalpinx	7	3.7
Pelvic inflammatory disease	10	5.3
Cystadenoma	27	14.7
Endometrioma	37	20.2
Teratoma	18	9.6
Leiomyoma	5	2.7
Ovarian fibroma	2	1.1
Struma ovarii	1	0.5
Periappendicular abscess	2	1.1
Tumor with low malignant potential	5	2.7
Primary ovarian carcinoma	19	10.2
Metastatic carcinoma	1	0.5
Total	183	100

Table 2. Gynecologic Imaging Reporting and Data System Classification According to Specific Final Diagnosis

	GI-RADS					
Final Diagnosis	1	2	3	4	5	Total
Normal ovaries	4					4
Functional cyst		18				18
Paraovarian cyst			2			2
Hemorrhagic cyst		29				29
Hydrosalpinx			7			7
Pelvic inflammatory disease			10			10
Cystadenoma		3	16	7	1	27
Endometrioma		2	30	3	2	37
Teratoma			18			18
Leiomyoma			4	1		5
Ovarian fibroma			1		1	2
Struma ovarii					1	1
Periappendicular abscess			2			2
Tumor with low malignant potential				1	4	5
Primary ovarian carcinoma				1	18	19
Metastatic carcinoma					1	1
Total	2	52	90	13	28	187

Table 3. Diagnostic Performance of the GI-RADS System

GI-RADS	Benign	Malignant
1–4	157	2
5	5	23

Sensitivity, 92% (95% confidence interval, 75%–98%); specificity, 97% (93%–99%); PPV, 85%; NPV, 99%; positive likelihood ratio, 29.8 (12.5–71.2); and negative likelihood ratio, 0.08 (0.02–0.31).

Table 4. Characteristics of Cases With False-Positive Findings

Patient Age, y	GI-RADS	Tumor Volume, cm^3	Final Diagnosis
44	5	115	Endometrioma
44	5	898	Endometrioma
66	5	55	Struma ovarii
44	5	1011	Fibroma
35	5	84	Cystadenofibroma

In conclusion, this system would allow an easier clinical decision making by the clinician. However, it should be tested prospectively in larger series and by different groups of researchers to definitively establish its actual value.

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