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The diagnostic efficacy of Gynecology Imaging Reporting and Data System (GI-RADS): single-center prospective cross-sectional study

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Abstract

Background: To assess the validity and accuracy of GI-RADS classification in the prediction of malignancy and in triaging the management protocol in ovarian lesions.

Results: One hundred fifty-six ovarian lesions were detected in the examined 116 women. The prevalence of malignant tumors was 44%. Overall GI-RADS classification rates were as follows: 41 cases (26.3%) were classified as GI-RADS 1, 26 cases (16 .7%) as GI-RADS 2, 34 cases (21.8%) as GI-RADS 3, 14 cases (8.9%) as GI-RADS 4, and 41 cases (26.3%) as GI-RADS 5. No follow-up was done in GI-RADS 1 patients. A final diagnosis of all GI-RADS 2 ovarian masses such as functional cyst (n = 10), hemorrhagic cysts (n = 8), corpus luteal cysts (n = 6), and some GI-RADS 3 as simple cysts (n = 10) was made by spontaneous resolution of these masses at follow-up after 6 weeks. Fifteen cases of GI-RADS 3 as mature teratoma, serous and mucinous cystadenoma, endometrioma, and ovarian torsion and all GI-RADS 4 and 5 underwent laparoscopic or surgical removal of the ovarian mass with histopathological examination. The diagnostic performance of the GI-RADS in predicting the risk of malignancy in ovarian masses was as follows: 98.11% sensitivity, 95.15% specificity, 91.2% positive predictive value (PPV), 99.2% negative predictive value (NPV), and 20.2 positive likelihood ratio, and the overall accuracy was 96.2% (area under receiver operating curve (AUC) = 0.96, $P < 0.001$).

Conclusion: GI-RADS classification performs well as a reporting system of the ovarian masses with high diagnostic performance in the prediction of malignancy, and it seems to be a helpful tool in triaging management in patients with ovarian masses.

Trial registration: The trial was registered in the US National Library of Medicine, under clinical trial number NCT03175991. Also, the ethical committee approval number of the Faculty of Medicine, Assiut University, was 17100016 on February 28, 2017.

Background

Ovarian cancer is fatal cancer among gynecological malignancies [1]. In Egypt, ovarian cancer represented 2.2% of all incident cancers and accounted for 4.4% of all newly diagnosed female cancers [2]. The assessment of an adnexal mass is difficult and meticulous preoperatively, which leads to a disproportionate number of women with benign ovarian tumors being referred to specialized centers, and conversely women with ovarian malignancy being inappropriately operated in non-specialized centers [3].

Ultrasonography (US) is currently considered as the primary imaging modality for the detection and characterization of adnexal masses [4]. Despite the progress in its diagnostic capability, there is a high false-positive rate (24%) reported by a large multicenter study that

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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, 6].

Several studies have proposed for the characterization of the ovarian masses, including examiner's subjective impression [7], mathematically developed scoring systems [8], simple descriptive scoring systems [9], logistic regression models [10], and neural networks [11]. The subjective impression of an experienced radiologist is currently considered to be superior to other methods [4, 12], but its subjective nature affects the performance of the method and the examiner's confidence in providing a diagnosis [13].

The International Ovarian Tumor Analysis (IOTA) consensus applies a standardized nomenclature and definition for all tumor features evaluated by ultrasound that improve the characterization of adnexal masses [14]. However, there is still significant variation in the ultrasound reporting for adnexal masses that can be confusing for clinicians [15]. In 2009, Amor et al. 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) [16]. This system is based on pattern recognition analysis [8] and prior risk estimation of the probability of malignancy, based on previous studies [17]. 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. A prospective multicenter study of GI-RADS was published in 2011; that study reported that GI-RADS is effective in the prediction of malignancy in adnexal masses and in clinical decision making among patients from Spain and Chile; however, these results still required verification in other countries [18].

In this study, we apply the GI-RADS classification in ovarian lesions aiming to assess its validity and accuracy in the prediction of malignancy and triaging the management protocol in our locality.

Methods

Patient selection

This was a prospective cross-sectional study comprising 116 out of 300 women who are suspected of having ovarian lesions on the basis of previous examination, previous clinical or US examination by the obstetric and gynecological surgeon, accidentally discovered ovarian lesion on US examination by non-radiologists, ovarian lesion on computed tomography, high CA125, and clinical symptoms of ovarian lesions such as pelvic pain and back pain, between March 2017 to August 2018. The sample size was calculated using Open Epi software program, version 23.1. A total of 184 patients were excluded from our study when they underwent neoadjuvant chemotherapy before US examination (n = 50), had previous surgery on the ovary (n = 47), and had no pathological reports after surgery (n = 83). This study was approved by our institutional review board. Written informed consent for participation and publication was obtained from each patient after receiving information about the details of the study. Confidentiality of patient's records was assured and maintained throughout the study. The trial was registered in the US National Library of Medicine, under clinical trial number NCT03175991.

Method

All patients' pelvises were examined by using the Pro-Sound Alpha 7 ultrasound (Hitachi Aloka Medical America, Inc. Germany) by transvaginal ultrasound in lithotomy position using endovaginal transducer and/or transabdominal ultrasound in the supine position using a 3.75-MHz sector transducer, in transverse and longitudinal plane and evaluated by B-mode ultrasonography, color, and spectral Doppler. Two expert examiners (G.S.S and L.M.R.K), with more than 10 years' experience in gynecological ultrasound, performed all examinations and stored between one and four representative images on the database.

Sonographic data analysis

A morphologic evaluation was performed according to the International Ovarian Tumor Analysis Group (IOTA) recommendations for the following parameters: wall thickness, septation, papillary projections, presence and echogenicity of solid areas, presence of mixed component, cystic component, and presence of ascites [15], and intra-abdominal metastases (peritoneal deposits, liver metastasis, and malignant abdominal lymphadenopathy) was also recorded. Pattern recognition analysis was also used for ovarian masses [4].

Then, the lesion volume was calculated according to the prolate ellipsoid formula (length × width × height × 0.523, expressed in cubic centimeters). Ten cubic centimeters for postmenopausal women and 20 cm^3 for premenopausal women were considered as a cutoff point between the normal and suspicious ovarian lesion [19]. This feature was not taken into consideration for assigning a GI-RADS classification.

After the morphologic evaluation was performed, the color Doppler was activated to identify vascular color signals within the tumor with no aliasing. A tumor was considered to have no flow when no signal could be detected. 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). The central blood flow was used for analysis when there was both peripheral and central blood flow. The evaluation of the amount of flow was subjective and stated as scanty, moderate, or abundant [15]. Then, the pulsed Doppler was activated at the lowest pulse repetition frequency to calculate the resistive index (RI) and pulsatility index (PI). The lowest RI was used for analysis when there is more than one vessel. Morphological features considered suspicious of malignancy included thick wall ≥ 3 mm, thick septum ≥ 3 mm, solid papillary projection, solid and mixed component, presence of ascites, intra-abdominal metastasis, and central blood flow.

After the examinations, a combination of morphological features, color and spectral Doppler features, and then the lesion was evaluated according to GI-RADS classification, and the suggested management protocol was based on the risk of malignancy [16] as follows:

- GI-RADS 1 patients did not undergo follow-up on the basis that these lesions are considered to be normal.
- GI-RADS 2 patients were treated expectantly and underwent follow-up after 6 weeks on the basis that these lesions were functional.
- GI-RADS 3 patients that did not resolve on follow-up by the radiologists on the basis that these lesions are most probably benign and underwent laparoscopic removal of the lesion.
- GI-RADS 4 and 5 patients were referred to gynecological oncologists and surgeon for surgical removal on the basis that these lesions were very probably malignant, taking into consideration that the diagnosis of GI-RADS 4 depends on the presence of one or two sonographic findings suggestive of malignancy and three or more sonographic findings suggestive of malignancy in GI-RADS 5.
- Finally, the referral to surgery and decision-making was consulted in accordance with a multidisciplinary team meeting (MDT). A definitive histopathological diagnosis was obtained as a gold standard test for all patients with GI-RADS 4 and 5 and 15 cases of GI-RADS 3 patients after laparoscopic or surgical removal of the masses. Resolution of the lesions on follow-up was considered as a gold standard test for all patients with GI-RADS 2 and 21 patients with GI-RADS 3.

Histopathological diagnosis

A histopathological examination of all the surgical specimens was done. Tissue sections with formalin fixed and paraffin processed were stained with hematoxylin and eosin. Tumors were classified according to the WHO criteria [20]. Borderline tumors were considered as malignant for analytic purposes.

Statistical analysis

Data was collected and analyzed using SPSS (Statistical Package for the Social Science, version 20, IBM, and Armonk, New York). Continuous data were expressed in the form of mean ± SD or median (range) while nominal data were expressed in the form of frequency (percentage). Categorical variables were compared using the chi-square test, and tumor volumes were compared using the Mann–Whitney U test. 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 ovarian masses at high risk of malignancy were calculated using the receiver operating characteristic (ROC) curve. For interrater reliability testing between sonographic findings and histopathological data, Cohen's kappa (κ) test was used and the result was interpreted as perfect agreement when its value lies between 0.81 and 1.00.

Results

One hundred and fifty-six ovarian lesions were detected in the examined 116 women, 68 women (68.6%) were pre-menopausal, and 48 women (41.4%) were post-menopausal. Their mean age were 42 ± 16.16 years, range 10–82 years. Malignant tumors were more frequent among postmenopausal women than premenopausal women $P < 0.001$. Additionally, patients with malignant tumors had larger tumor volume, non-hyperechoic solid and mixed component, thick internal septation, ascites, and intra-abdominal metastases more than patients with benign tumors ($P < 0.001$).

The final diagnosis of the examined ovarian lesions with their corresponding GI-RADS scoring

All GI-RADS classification rates were demonstrated in Fig. 1. Most referring clinicians managed their patients according to their GI-RADS classification. No further follow-up was done in GI-RADS 1 patients, and a 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 (Fig. 2) were made by spontaneous resolution of these masses at follow-up after 6 weeks as summarized in Table 1. Fifteen cases of GI-RADS 3 as mature teratoma, serous and mucinous cystadenoma, endometrioma, and ovarian torsion and all GI-RADS 4 and 5 (Fig. 3) underwent laparoscopic or surgical removal and a histopathological examination.

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 our studied lesions when compared with the gold standard test that is specific for each category demonstrated that among 103 benign ovarian lesions and normal ovaries, 100 lesions (97.1%)

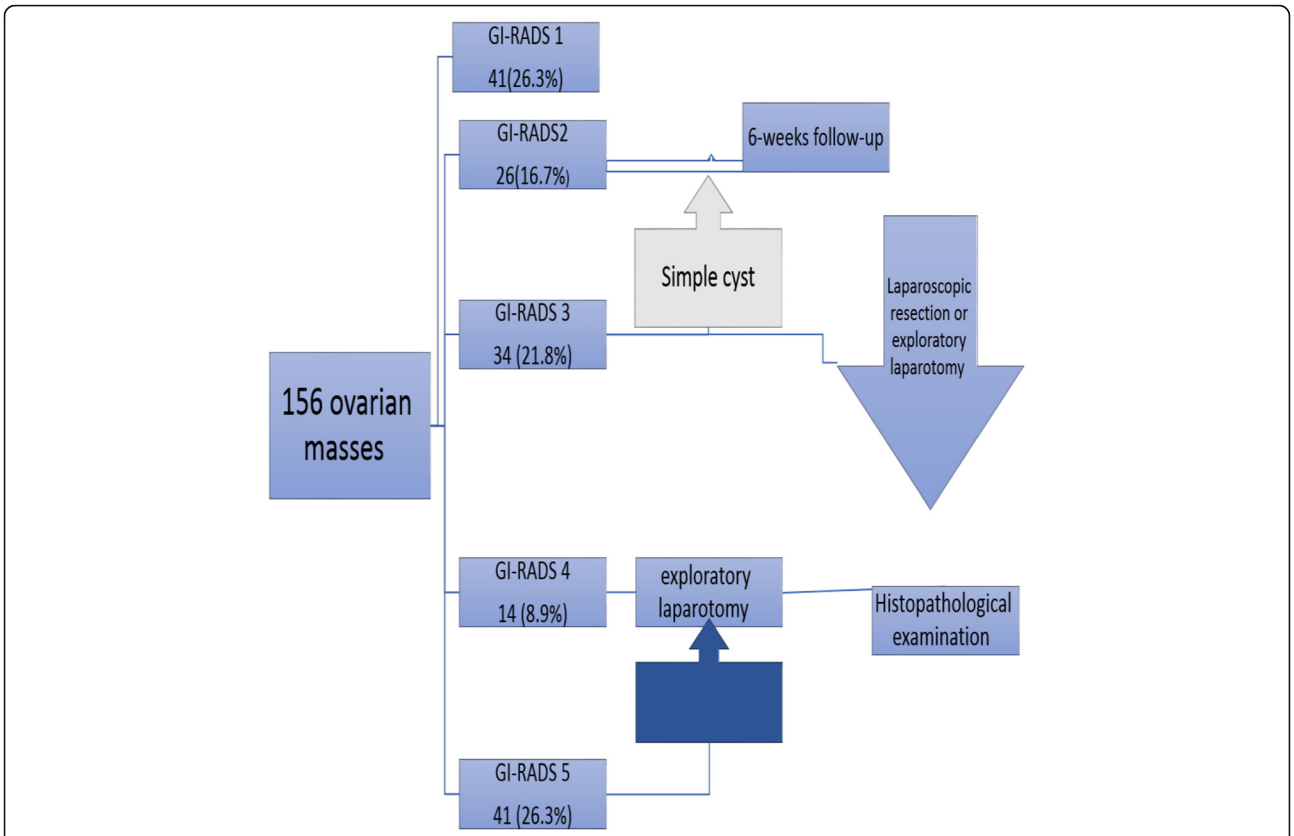

Fig. 1 Flow chart demonstrated the Gynecologic Imaging Report and Data System (GI-RADS) rate and the management of the studied 116 women with 156 ovarian lesions

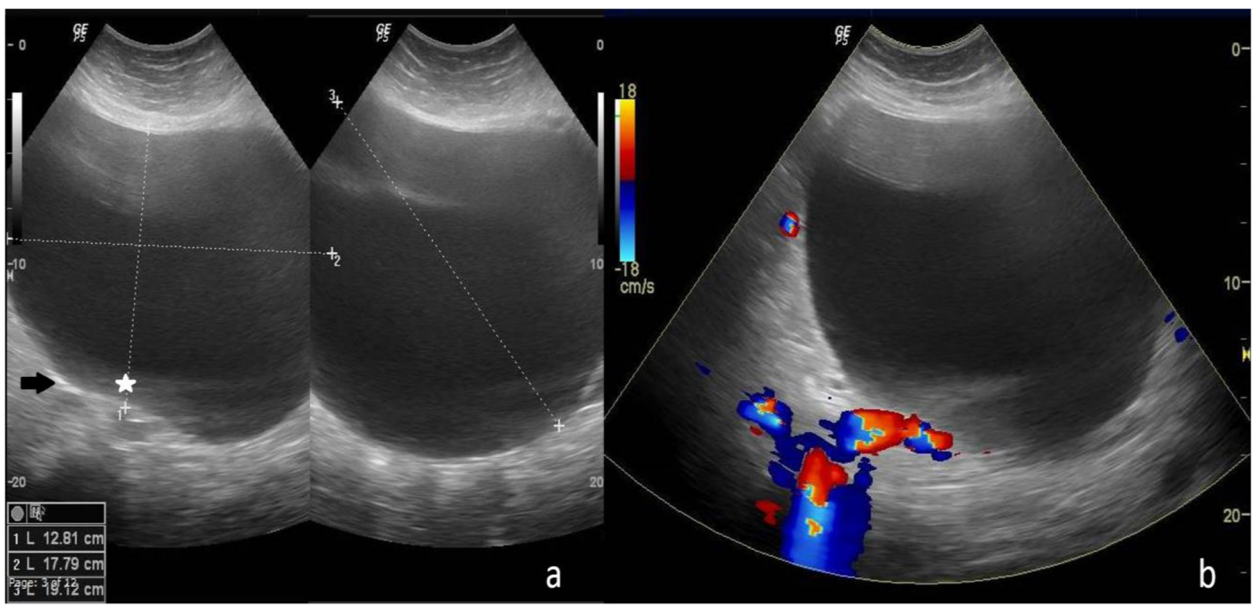

Fig. 2 Transabdominal ultrasound of right ovarian mass. **a** A large right ovarian cystic mass. It has thin wall (black arrow) with slight echogenic fluid component at the bottom of the mass (white star). **b** Color Doppler shows no color flow signal. This mass was diagnosed as simple cyst and classified as GI-RADS 3. It was followed and resolved spontaneously after 6 weeks

Table 1 The final diagnosis of the examined ovarian lesions with their corresponding GI-RADS scoring

Final diagnosis	No. of masses	GI-RADS 1	GI-RADS 2	GI-RADS 3	GI-RADS 4	GI-RADS 5
Normal ovaries	41	41	0	0	0	0
Hemorrhagic cyst*	10	0	10	0	0	0
Functional cyst*	9	0	9	0	0	0
Corpus luteal cyst*	6	0	6	0	0	0
Hyperstimulation syndrome*	1	0	1	0	0	0
Simple cyst *	21	0	0	21	0	0
Mature teratoma	4	0	0	4	0	0
Serous cystadenoma	4	0	0	3	1	0
Mucinous cystadenoma	3	0	0	1	2	0
Endometrioma	3	0	0	3	0	0
Ovarian torsion	1	0	0	1	0	0
Metastatic carcinoma	24	0	0	0	4	20
Serous cyst adenocarcinoma	14	0	0	0	4	10
Papillary cyst-adenodencarcinoma	3	0	0	0	0	3
Mucinous adenocarcinoma	6	0	0	0	2	4
Malignant teratoma	1	0	0	1	0	0
Pseudomyxoma pertionii	1	0	0	0	1	0
Dysgerminoma	1	0	0	0	0	1
Adult granuolsa cell tumor	1	0	0	0	0	1
Endometriod carcinoma	1	0	0	0	0	1
Yolk sac tumor	1	0	0	0	0	1

*Spontaneous resolution at follow-up

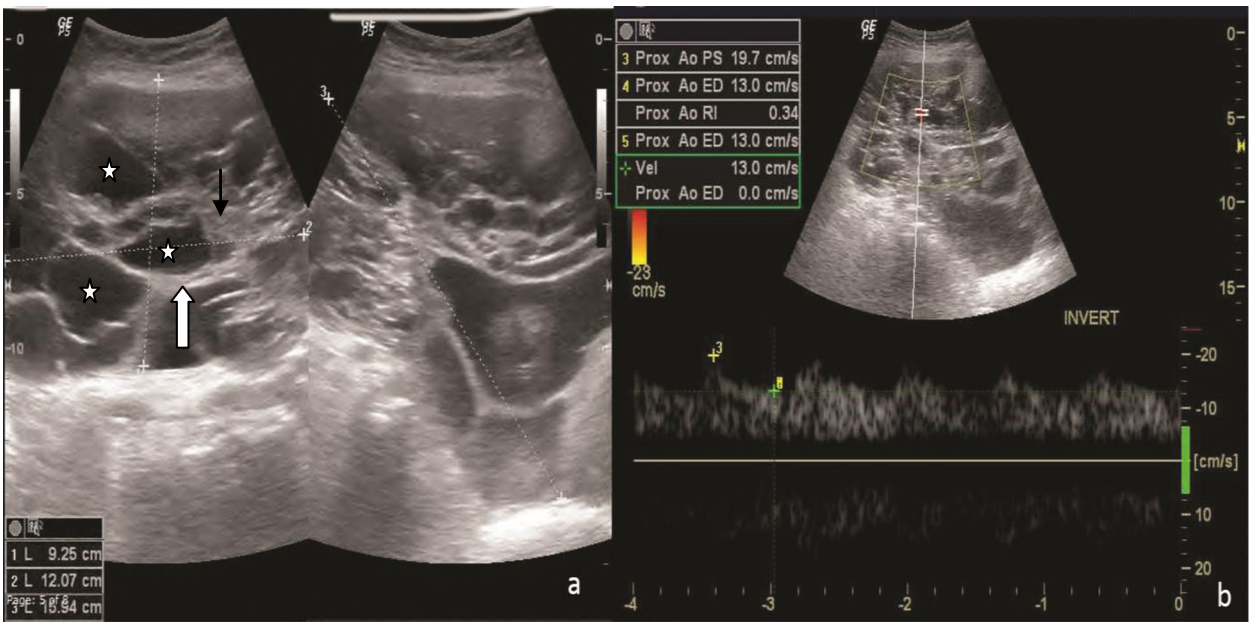

Fig. 3 Transabdominal ultrasound of right ovarian mass. **a** Right ovarian mixed solid and cystic mass. It has a solid component (black arrow) with thick septa (thick white arrow) and multiple locules (white stars). **b** Color and spectral Doppler revealed a moderate amount of central blood flow within the solid component, RI = 0.3 and PI = 0.5. It was diagnosed as malignant mass and classified as GI-RADS 5. Total abdominal hysterectomy with bilateral salpingo-oophorectomy was done and histopathology proved it to be adult granulosa cell tumor

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 (Table 1 and Fig. 4). This could be explained by the presence of echogenic loculues 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 (Table 1); this case was a 63-years-old woman with the feature of mature teratoma, but histopathological examination proved it to be early-stage immature teratoma which was a rare entity in postmenopausal women (Fig. 5).

The diagnostic performance of the GI-RADS in predicting the risk of malignancy in ovarian masses

The AUC of the diagnostic performance of the GI-RADS in predicting the malignant ovarian masses was 0.96, and it was highly significant, with P value < 0.002 as summarized in Table 2.

Discussion

Differentiation between benign and malignant ovarian masses is a common problem in clinical practice. Sonography is considered the first-line imaging modality used for this purpose, and it has been shown to be useful for determining optimal treatment [21]. Many radiologists use pattern recognition approach [8], others use the scoring system [9], and considerable efforts have been made by some authors in the characterization of the

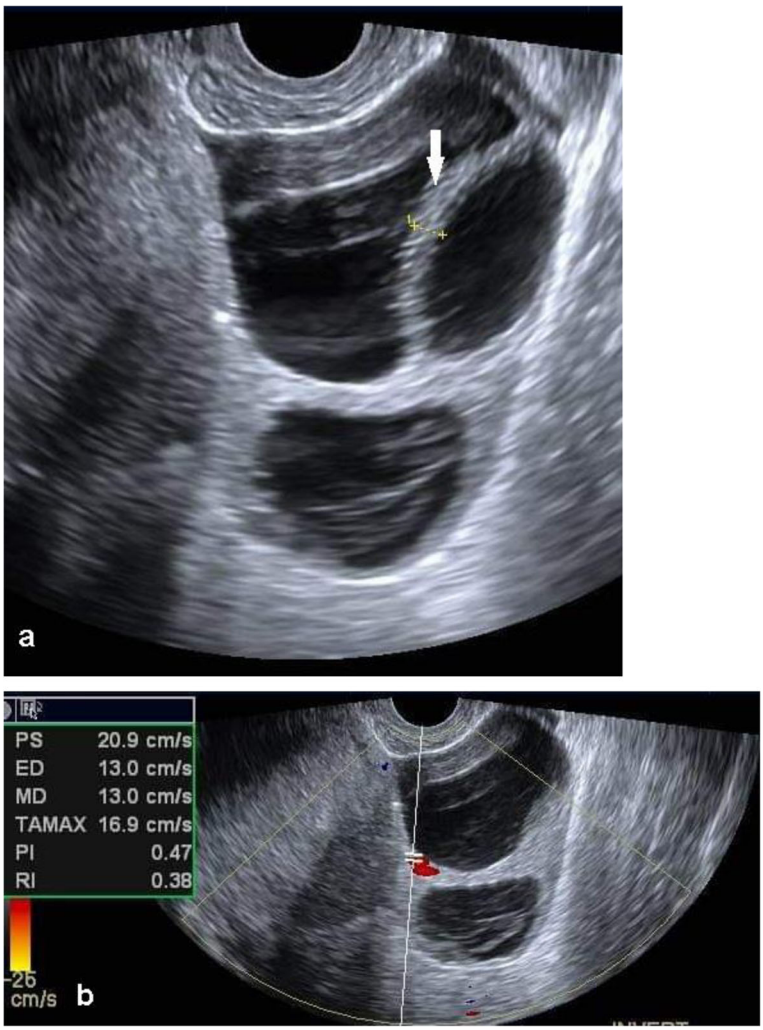

Fig. 4 Transvaginal ultrasound (**a**) shows a large multilocular cystic mass with thick septa 6 mm (white arrow). **b** Duplex transvaginal ultrasound shows color flow signal within the septa with 0.3 RI. This mass diagnosed as suspicious ovarian mass and classified as GI-RADS 4. She underwent surgical removal of the mass and the histopathological report was mucinous cystadenoma

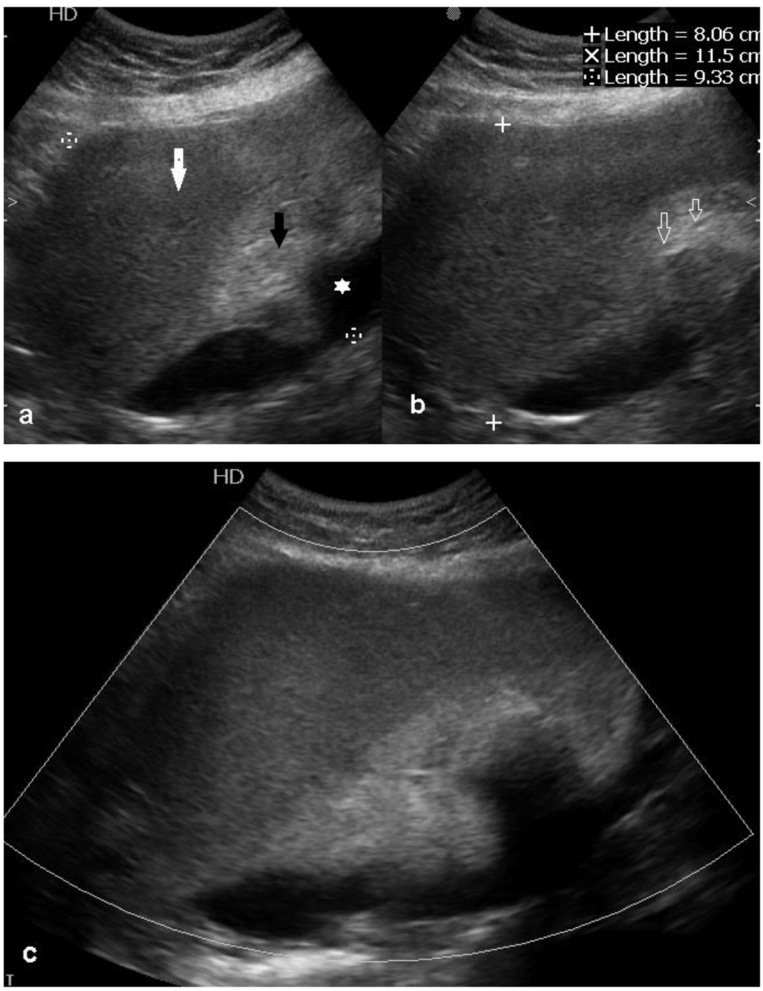

Fig. 5 Transabdominal ultrasound in a 40-year-old woman. **a** A large cystic left ovarian mass, with echogenic turbid content in its upper part (solid white arrow) and clear cystic portion in its lower part (white star) with hyperechoic fatty portion (black arrow) in its middle part. Dots of calcification within the hyperechoic portion (white open arrow) (**b**). **c** Color Doppler ultrasound shows no flow within the mass. This mass was diagnosed as a mature teratoma and classified as GI-RADS 3. She underwent surgical removal, and the histopathological report was immature teratoma

Table 2 Diagnostic performance of GI-RADS

Indices	Values
Sensitivity	98.11%
Specificity	95.15%
Positive predictive value	91.2%
Negative predictive value	99.2%
Positive likelihood ratio	20.2
Negative likelihood ratio	0.02
Accuracy	96.2%
Are under the curve (AUC)	0.96
P value	< 0.001

P value was significant if < 0.05

ovarian masses [15]. However, sometimes, the sonographic reports are misleading and confusing for the clinician [7]. As a matter of fact, the decision of clinical management is based on the data provided in the sonographic report. Consequently, a strategy that provides a structured reporting system of the ovarian masses called GI-RADS, which is based on the concept developed for breast imaging (the BI-RADS classification), has been advised recently. As for BI-RADS, the lexicon of our new system is intended to provide a unified language for ultrasound reporting that improves the communication between the radiologists and clinicians, and recommendations for patient's management [16]. In this study, we assessed the validity and accuracy of our GI-RADS reporting system for ultrasound evaluation of ovarian masses in the prediction of malignancy and clinical decision-making preoperatively.

Description of the ovarian masses on this system depends on the basis of using the pattern recognition approach and a priori risk for malignancy in each group. On this basis, the GI-RADS classification helps the radiologists 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 features of the lesions [22]. To the best of our knowledge, this is the first standardized reporting system applicable to ovarian masses in our locality.

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 [4].

Furthermore, PPV and NPV 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. Amor et al. [18] reported similar high sensitivity, specificity, accuracy, LR−, PPV, and NPV, but their LR+ values were lower than in our study; the difference in this result between the two studies may be due to a large number of studied lesions in Amor et al. [18] as it was 432 because it is a multicenter study. Also, Amor et al. [18] used the bilaterality as a parameter in the evaluation of the ovarian masses, but we did not use it, and we use the presence of mixed component, intra-abdominal metastasis and a measurement of PI in our analysis algorithm in addition to the previously mentioned parameters in which both studies were similar in it. It is noteworthy that the results of the study done by Amor et al. [16] show nearly the same results as ours, as regards the high sensitivity, specificity, PPV, and NPV, but differ in the LR+ and LR− as they were higher in Amor et al. [16]. This could be explained by the difference in the number of studied lesions. In contrary to our study, Migda et al. [23] reported 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).

There is a strong agreement found between GI-RADS classification and the final diagnosis in our study, its kappa value was 0.91. Therefore, the GI-RADS classification system was a useful tool used for identifying malignant ovarian masses, triaging the management, and making clinical decisions as it can detect the ovarian masses at high risk of malignancy. Consequently, ovarian malignancy is appropriately operated in a specialized center. This was similar to the results of previous studies [23, 24].

There were some limitations to our study. First, the performance of all ultrasound by expert radiologists affect diagnostic performance; therefore, further research into how this reporting system performs when used by non-expert radiologists is needed. Second, there is a relatively small sample size relative to the previous researches. Third, there is a high prevalence of normal ovary and benign ovarian masses because our selection criteria depend on all the referral patients to the radiodiagnosis department who are suspected of having an ovarian mass. Fourth, MRI was not applied in our study to compare their diagnostic accuracy with transvaginal US in the evaluation of GI-RADS; we recommended another study to compare between these two modalities. A further weakness is that our study was done in ovarian masses only not in adnexal masses.

The strength of this study is the meticulous prospective recording of the ultrasound data based on IOTA and recognition pattern on GI-RADS reports that leads to high sensitivity and specificity.

Conclusions

In conclusion, this prospective study demonstrated that GI-RADS classification performs well and valid as a reporting system of the ovarian masses with high diagnostic performance in prediction of malignancy, and it seems to be a helpful tool in triaging patient's management and clinical decision making. The goal of the GI-RADS classification should be explained to the referring clinicians before the application of the treatment as it can improve patient care.

Abbreviations

AUC: Area under receiver operating curve; GI-RADS: Gynecology imaging reporting and data system; IOTA: International Ovarian Tumor Analysis; LR−: Negative likelihood ratio; LR+: Positive likelihood ratio; NPV: Negative predictive value; PI: Pulsatility index; PPV: Positive predictive value; RI: Resistance index; ROC: Receiver operating characteristic; US: Ultrasonography

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Not applicable

Authors' contributions

With the submission of this manuscript, I would like to declare that all authors have contributed sufficiently to the scientific work regarding the study concepts and design, clinical studies, collecting data, statistical analysis, and manuscript preparation and editing. All authors of this paper have read and approved the final version of the manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

This study was approved by the Reasearch Ethics Committee of the Faculty of Medicine at Assiut University in Egypt on February 28, 2017, and its

number is 17100016. Written informed consent was obtained from all patients to participate in this study.

Consent for publication

All patients included in this research gave written informed consent to publish the data contained within this study.

Competing interests

The authors declare that they have no competing interests.

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