

# Preoperative diagnosis of 221 consecutive ovarian masses: scoring system and expert evaluation

C. Romagnolo<sup>1</sup>, M.D.; G. Trivella<sup>1</sup>, M.D.; M. Bonacina<sup>1</sup>, M.D.; M. Fornalè<sup>1</sup>, T. Maggino<sup>2</sup>, M.D.; E. Ferrazzi<sup>3</sup>

<sup>1</sup>Department of Obstetrics and Gynecology, Sacro Cuore Hospital, Negrar; <sup>2</sup>Department of Obstetrics and Gynecology, Mirano Hospital, Mirano; <sup>3</sup>Department of Obstetrics and Gynecology, Clinical Sciences Institute Sacco, University of Milan, Milan (Italy)

## Summary

**Objective:** The aim of our work was to assess the diagnostic accuracy of a scoring system versus subjective assessment of the risk of malignancy of pelvic masses achieved by gynecologist/sonologists in the preoperative triage of a busy gynecology department.

**Methods:** One hundred and eighty-two consecutive patients who underwent surgical removal of ovarian neoplasms were examined. In 39 patients pelvic masses were bilateral. The total number of neoplasms analyzed in this series was 221. Lesions were examined and scored according to the sonographic characteristics. Gynecologist/sonologists also recorded a subjective evaluation of the adnexal masses defining them as "probably benign", and "suspicious/probably malignant". Preoperative ultrasound risk assessment was compared to the final pathologic report and diagnostic accuracy was calculated. CA125 was obtained in all patients and its independent and combined accuracy was calculated.

**Results:** The sensitivity of the scoring system and subjective evaluation was 86% and 95% respectively, specificity was 79% and 91% with a positive predictive value of 41% and 53%. The frequency of positive diagnoses for CA125 was 44% due to the high prevalence of endometriosis in this series (48%). In premenopausal patients (75%) the specificity was 93% and 89% for scoring and subjective evaluation, respectively. The combined use of morphological scoring and CA125 achieved higher specificity and positive predictive values both for the whole series and in premenopausal patients.

**Conclusions:** These results confirmed that the experience of gynecological surgeons with ultrasound skills, outperforms the morphological indexing assessment of ovarian masses. Nonetheless an easy sonographic descriptive scoring system is not significantly lower in accuracy than the expertise achieved by gynecologists with sonographic skills.

**Key words:** Transvaginal sonography; Ovarian neoplasm; Morphological scoring system; Serum markers.

## Introduction

The introduction of transvaginal sonography has greatly contributed to the correct preoperative diagnosis of gynecologic pelvic masses [1, 2]. However after years of extensive clinical usage there is still no consensus on consistent reproducible criteria to differentiate between benign and malignant neoplasms and to compare case series among centers. Reported studies encompass the whole range of possible criteria from subjective evaluation based on simple morphological clues [3, 4] to morphological scoring systems [5-8] to even more complex logistic regression models [9, 10] and artificial neural networks [11]. Serum markers can be added to ultrasound examination to improve the specificity of the diagnostic triage [11-13] yet the major role lies on sonographic imaging. The role of color-flow imaging [14, 15] is even less established after ten years of reported series.

This multifaceted scenario is reflected in a national survey among board members of the Italian Society of Gynecological Oncology and the Italian Society of Gynecological Endoscopy [16] according to whom transvaginal sonography is considered the "principal diagnostic instrument" in more than 95% of questionnaires, but with

no agreement on the definition of an ovarian cyst at risk of malignancy. Moreover less than 10% of the centers reported following any reproducible criteria, but they all follow the experience and the opinion of the sonologist. It is very likely that this national survey can be extended to the majority of centers where diagnostic ultrasound is extensively used.

The aim of our work was to assess the diagnostic accuracy of a detailed scoring system versus a subjective assessment of the risk of malignancy of pelvic masses achieved by gynecological sonologists in the preoperative triage of a busy gynecology department.

## Materials and Methods

One hundred and eighty-two consecutive patients who underwent surgical removal of ovarian neoplasms entered the study. In 39 patients the pelvic masses were bilateral and among these, different benign contralateral lesions were found in 11 women. Malignant masses involving both ovaries in a single lesion were considered as a single case. The total number of neoplasms analyzed in this series was 221.

All patients were admitted to the Department of Gynecology because of diagnoses of a pelvic mass. Before surgical intervention all the masses were put in the preoperative diagnostic triage which included history, bimanual pelvic examination, CA125 serum determination (CA125 II™ Roche Diagnostics GmbH, D-682987, Mannheim), and transvaginal ultrasound

Revised manuscript accepted for publication April 10, 2006

examination. Indications for surgery were as follows: symptomatic ovarian cyst, probably benign persistent ovarian cyst in pre- or postmenopause, suspicious ovarian mass, and probably malignant ovarian mass. All patients underwent surgical removal of the pelvic masses by both laparoscopy or laparotomy, with pathological examination of surgical specimens.

A digital sonographic unit (Toshiba SSA 340A) with 6 MHz transvaginal transducer was used. All examinations were supervised by a senior gynecologist/sonologist. The morphological score reported by Ferrazzi *et al.* 1997 was adopted [8, 12] and the suggested cutoff of  $\geq 8$  was used to discriminate masses at high and low risk of malignancy (Table 1). According to this system in order to avoid false-positive cases determined by typical cystic teratome any inhomogeneous mass with irregular hypoechoic and hyperechoic areas with posterior shadowing, not separated by septa, or a homogeneous hyperechoic mass with regular capsule and posterior shadowing was categorized as a typical cystic teratoma. The gynecological sonologists also recorded a subjective evaluation of the adnexal mass defining it as "probably benign", "suspicious/probably malignant". Preoperative ultrasound risk assessment was compared to the final pathologic report and diagnostic accuracy was calculated.

Comparisons between the different accuracy achieved by the two criteria were assessed by means of the K test. Performance of the combination of the morphological scoring system with CA125 was also assessed and compared as an additional test.

Table 1. — *Sonographic morphological score for adnexal masses.*

Score	Capsule	Septa	Papillaries	Echogenicity
1	< 3 mm	absent	absent	sonolucent *
2	> 3 mm	thin (<= 3 mm)		low
3		thick (> 3 mm)		
4	irregular-solid		< 3 mm	with echogenic areas
5	irregular-dishomogeneous-solid	not applicable	> 3 mm	

\* or with fine trabecular and jelly-like content, typical of corpus luteum.

## Results

The mean age of the patients included in this study was  $40 \pm 14$  years, and the percentage of patients in postmenopause was 28%. This age distribution is also reflected in the prevalence of the different pathologic diagnoses (Table 2) among which endometriosis accounted for 47% of cases. Overall we found 21 malignant lesions (9.6%), seven of which were borderline tumors and one tubal carcinoma. Eighteen occurred in 51 postmenopausal patients and the remaining three in 170 premenopausal patients (1.8%). The seven borderline ovarian lesions were all FIGO Stage 1A; the stage of the tubal carcinoma was IC. Ovarian cancers were staged as: one case - IA, two cases - IC, two cases - IIC, and eight cases - IIIC. The mean diameter of benign neoplasms ( $49 \text{ mm} \pm 24$ ) was significantly smaller than the mean diameter of malignant masses ( $76 \text{ mm} \pm 46$ ) ( $p < 0.0001$ ).

The diagnostic accuracy of the morphologic scoring system, subjective risk assessment and serum marker values is reported in Table 3. The frequency of positive diagnoses was 19.5% for the scoring system, 17.2% for the subjective evaluation, and 44.3% for CA125. This last high positive percentage was probably determined by the

high prevalence of endometriosis in this series. The subjective evaluation showed a higher K value among the three diagnostic indices, even though the sensitivity and specificity of the scoring system were not significantly lower than those achieved by subjective evaluation ( $p = 0.3$ ). CA125 with a cutoff of 35 UI/ml demonstrated both low sensitivity and specificity. In premenopausal patients, specificity remained high for both subjective assessment and scoring indexing, 93% and 89%, respectively. In this group the prevalence of endometriosis was 58.2%. The diagnostic performance of the scoring system combined with the results of CA125 was assessed in the 121 cases with positive values: morphologic score  $> 8$ , and CA125  $> 35 \text{ UI/ml}$  (Table 4).

Table 2. — *Histologic diagnosis and mean diameter ( $\pm$  standard deviation) of 221 pelvic masses.*

Pathologic findings	No. of cases (%)	Mean diameter (mm)
<i>Benign neoplasms</i>	200	$49 \pm 24$
Endometriotic cysts	105 (47.5)	$47 \pm 16$
Serous cystoadenoma	51 (23.1)	$53 \pm 25$
Dermoid cysts	17 (7.7)	$60 \pm 29$
Mucinous benign cysts	11 (4.9)	$80 \pm 44$
Ovarian fibroids	6 (2.7)	$45 \pm 11$
Others	10 (4.5)	$42 \pm 24$
<i>Malignant neoplasms</i>	21	$76 \pm 46$
Ovarian carcinoma	13 (5.9)	$83 \pm 57$
Borderline ovarian tumors	7 (3.2)	$70 \pm 11$
Tubal carcinoma	1 (0.5)	40

Table 3. — *Diagnostic accuracy (200 benign lesions, 21 malignant lesions) of the morphologic scoring system (cut-off value for the risk of malignancy  $> 8$ ), subjective evaluation of risk (suspicious and probably malignant classes), and serum marker values (CA 125  $> 35 \text{ UI/ml}$ ) (relative percentages in parentheses).*

	Morphological score	Subjective risk assessment	Serum marker CA125
Sensitivity	18/21 (85.7%)	20/21 (95.2%)	15/21 (71.4%)
Specificity	175/200 (79.2%)	182/200 (91.0%)	117/200 (58.5%)
Positive predictive value	18/43 (41.9%)	20/38 (52.6%)	15/98 (15.3%)
Negative predictive value	175/178 (98.3%)	182/183 (99.4%)	177/123 (55.7%)
K value	193/221 (87.3%)	202/221 (91.4%)	132/221 (59.7%)

Table 4. — *Diagnostic accuracy of the morphologic scoring system (cut-off value for the risk of malignancy  $> 8$ ), combined with serum marker values (CA 125  $> 35 \text{ UI/ml}$ ): 121 cases.*

	Morphological score + CA125
Sensitivity	13/15 (87%)
Specificity	101/106 (95%)
Positive predictive value	13/18 (72%)
Negative predictive value	101/103 (98%)
K value	114/121 (94%)

## Discussion

Laparoscopy is by far the preferred technique for the treatment of benign adnexal masses. The preoperative identification of patients at risk of malignant neoplasms is the sound basis for counselling the patient, and for timing

and choosing the right surgical approach. In most of the busy gynecological surgical departments the gynecologist/sonologist is a member of the clinical staff, which is probably the best setting for exploiting sonographic information at its best, although it must be balanced by consistency of reproducible information.

Our results confirm that the experience of such a professional profile, a gynecologist with ultrasound skills, outperforms the morphological indexing assessment of ovarian masses, but yet is in close contact and not significantly different from the more reproducible indexing system. In fact, the sensitivity of the two methods was 95% and 86%, respectively, with a positive predictive value of 51% and 41%. The two systems also performed well in premenopausal patients among whom the prevalence of complex endometriotic lesions was high. This finding confirms both the quality of the scoring system when confronted with endometriotic lesions and the experience of the sonologists who are used to inspecting and treating endometriotic lesions by laparoscopy. In fact, in premenopausal patients the specificity provided by the two methods combined was 93% and 89% respectively, in spite of the high prevalence (58.2%) of endometriosis, which was the main cause of false-positive results.

As expected, the combined use of sonographic indexing and serum markers did not improve the sensitivity, but was able to improve the predictive value up to 72%, with a specificity ranging up to 95%. This very high percentage was confirmed also in premenopausal patients in spite of the high prevalence of endometriotic lesions (58.2%) which could have increased the false-positive assessment of both methodologies.

These findings are in good agreement with diagnostic accuracy values reported by recent series [12, 15, 17] and feature the possible performance of sonographic imaging of ovarian lesions when closely rooted in the clinical triage of patients in a busy gynecological surgical department. Nonetheless an easy sonographic descriptive scoring system is not significantly lower in accuracy than the expertise achieved by gynecological surgeons who combine laparoscopic and sonographic skills.

## References

- [1] Van Nagell J.R., Higgins R.V., Donaldson E.S., Gallion H.H., Powell D.E., Pavlik E.J. *et al.*: "Transvaginal sonography as a screening method for ovarian cancer: a report of the first 1000 cases screened". *Cancer*, 1990, 65, 573.
- [2] Granberg S., Norstrom A., Wikland M.: "Tumors in the lower pelvis as imaged by vaginal sonography". *Gynecol. Oncol.*, 1990, 37, 224.
- [3] Valentin L.: "Pattern recognition of pelvic masses by gray-scale ultrasound imaging: the contribution of Doppler ultrasound". *Ultrasound Obstet. Gynecol.*, 1999, 14, 338.
- [4] Timmerman D., Schwärzler P., Collins W.P., Clarehout F., Coenen M., Amant F. *et al.*: "Subjective assessment of adnexal masses with the use of ultrasonography: an analysis of interobserver variability and experience". *Ultrasound Obstet. Gynecol.*, 1999, 13, 11.
- [5] Sassone A.M., Timor-Tritsch I.E., Artner A., Carolyn W., Warren W.B.: "Transvaginal sonographic characterization of ovarian disease: evaluation of a new scoring system to predict ovarian malignancy". *Obstet. Gynecol.*, 1991, 78, 70.
- [6] Lerner J.P., Timor-Tritsch I.E., Federman A., Abramovich G.: "Transvaginal ultrasonographic characterization of ovarian masses with an improved, weighted scoring system". *Am.J. Obstet. Gynecol.*, 1994, 170, 81.
- [7] De Priest P.D., Shenson D., Fried A., Hunter J.E., Andrews S.J., Gallion H.H. *et al.*: "A morphology index based on sonographic findings in ovarian cancer". *Gynecol. Oncol.*, 1993, 51, 7.
- [8] Ferrazzi E., Zanetta G., Dordoni D., Berlanda N., Mezzopane R., Lissoni G.: "Transvaginal ultrasonographic characterization of ovarian masses: comparison of five scoring systems in a multicenter study". *Ultrasound Obstet. Gynecol.*, 1997, 10, 192.
- [9] Tailor A., Jurkovic D., Bourne T.H., Collins W.P., Campbell S.: "Sonographic prediction of malignancy in adnexal masses using multivariate logistic regression analysis". *Ultrasound Obstet. Gynecol.*, 1997, 10, 41.
- [10] Alcazar J.L., Jurado M.: "Using a logistic model to predict malignancy of adnexal masses based on menopausal status, ultrasound morphology, and color Doppler findings". *Gynecol. Oncol.*, 1998, 69, 146.
- [11] Biagiotti R., Desii C., Vanzi E., Gacci G.: "Predicting ovarian malignancy: application of artificial neural networks to transvaginal and color doppler flow US". *Radiology*, 1999, 210, 399.
- [12] Berlanda N., Ferrari M.M., Mezzopane R., Boero V., Grijuela B., Ferrazzi E., Pardi G.: "The impact of a multiparameter, ultrasound based triage on surgical management of adnexal masses". *Ultrasound Obstet. Gynecol.*, 2002, 20, 181.
- [13] Maggino T., Gadducci A., D'Addario V., Pecorelli S., Lissoni A., Stella M. *et al.*: "Prospective multicentric study on CA125 postmenopausal pelvic masses". *Gynecol. Oncol.*, 1994, 54, 117.
- [14] Strigini F.A.L., Gadducci A., Del Bravo B., Ferdegini M., Genazzani A.: "Differential diagnosis of adnexal masses with transvaginal sonography, color flow imaging, and serum CA125 assay in pre- and postmenopausal women". *Gynecol. Oncol.*, 1996, 61, 68.
- [15] Valentin L.: "Comparison of Lerner score, Doppler ultrasound examination, and their combination for discrimination between benign and malignant adnexal masses". *Ultrasound Obstet. Gynecol.*, 2000, 15, 143.
- [16] Romagnolo C., Maggino T., Zola P., Sartori E., Gadducci A., Landoni F.: "An analysis of different approaches to ovarian cysts in Italy". *Eur. J. Obstet. Gynecol. Reprod. Biol.*, 2004, 25, 183.
- [17] Ueland F.R., DePriest P.D., Pavlik E.J., Kryscio R.J., van Nagell J.R., Jr.: "Preoperative differentiation of malignant from benign ovarian tumors: the efficacy of morphology indexing and Doppler flow sonography". *Gynecol. Oncol.*, 2003, 91, 46.

Address reprint requests to:

C. ROMAGNOLO, M.D.

Department of Obstetrics and Gynecology

Sacro Cuore Hospital

Viale Sempredoni, 22

37024 Negrar (Verona) Italy