Laparoscopic Management of Sonographically Suspicious Ovarian Masses

Original Article

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ABSTRACT

Background: This clinical trial was done to evaluate the role of laparoscopy in management of sonographically suspicious adnexal masses. This study was conducted in the obstetrics and gynecology outpatient's clinics of Maadi military hospital, Cairo. This study was conducted on 54 Patients suspected to have ovarian mass by ultrasound imaging.

Objective: To evaluate the role of laparoscopy in management of sonographically suspicious adenexal masses.

Patients and Methods: Patients who are diagnosed with an ovarian mass that appear suspicious by 2D ultrasound imaging, who seek medical advice in the Obstetrics and Gynecology outpatient's clinics of Maadi military hospital, Cairo; from January 2022 till November 2022.

Results: Serum Ca-125 level had a sensitivity of 76.4 % (52.74–90.44), a specificity of 85.3 % (71.56–93.12), a positive predictive value of 68.4 %, and a negative predictive value of 89.7 %. Indicating the RMI was superior than CA-125 in discriminating between benign from malignant tumors which agree with our results.

Conclusion: In our study; suspicious ovarian masses can be managed laparoscopically as a diagnostic and therapeutic tool especially if the facility of Frozen Section Biopsy can be offered. Laparoscopic surgery seems to offer significant advantages such as reduced hospital stay, less adverse effects as decreased post-operative pain, lesser de-novo adhesions formation, better cosmetic result and faster recovery.

Key Words: Laparoscopy, sonographic 2D ultrasound, suspicious ovarian masses.

INTRODUCTION

Ovarian masses or cysts are commonly occurring, and studies had showed that 10% of women undergo an operation during their life for investigation or treatment of an ovarian mass. These masses are usually asymptomatic; however, it is diagnosed as an incidental finding during imaging for another reason, or for investigation of non-specific abdominal or pelvic pain[1].

The discrimination between benign and malignant adnexal masses is central to decisions regarding clinical management and surgical planning in such patients. A standardized method for preoperative identification of probable malignant masses would allow optimization of first-line treatment for women with ovarian cancer[2].

Laparoscopic surgery is an accepted gold standard in the management of adnexal masses in gynecologic surgery through different age group. Between 12 and 21years, of 47 ovarian masses, 49% were non-neoplastic and 51 were neoplastic. Of the neoplastic lesions 62 (5%) were germ-cell tumors, 20.8% were epithelial, and 16.7% were sex-cord-stromal tumors. Overall, 95 (8%) were benign, whereas 4 (2%) were malignant[3].

The present evidence in literature don't offer a comprehensive consensus on the role of laparoscopy in management and diagnosis of ovarian neoplasms, further studies are needed in this aspect to assess the role of laparoscopy in managing and diagnosing ovarian masses[4].

The aim of this study was to evaluate the role of laparoscopy in management of sonographically suspicious adenexal masses.

PATIENTS AND METHODS

Study design & setting

A prospective cohort study was conducted at Gynecology Outpatient's Clinics of Maadi Military Hospital, Cairo; from January 2022 till November 2022.

Study population

Patients who were diagnosed with an ovarian mass that appear suspicious by ultrasound imaging, who seek medical advice during the study period.

Sample size

Sample size was calculated Roasoft online sample size calculator: At a confidence level of 95%, margin of error=5%, and 3.6% ovarian malignancy among patients of ovarian cyst according to previous study by Khoiria *et al*. (2020) Accordingly, we recruited 54 women with ovarian masses.

Inclusion criteria

Female of any age with high risk of malignancy index who were complaining of adnexal masses diagnosed by ultrasound.

Exclusion criteria

Any woman with one or more of the following criteria was excluded; pregnancy, refusal of patients (study, examination and procedure and unfit for anesthesia.

Methodology

All included patients were subject to the following steps after signing an informed consent containing all procedures that were done. Through medical history with full clinical evaluation were done. Local examination: palpation for masses, lower abdominal tenderness, shifting dullness for ascetic, and PV for adnexal masses.

Also, laboratory investigations were done included: complete blood picture, kidney function tests, liver function tests, coagulation profile and CA-125

Ultrasound protocol for ovaries

Either trans-abdominal 2D US examination with fully distended urinary bladder or trans-vaginal US exam. After UB evacuation was done using Semen's Acuson x300 machine with transducer frequencies ranged from 2.5-8 MHz while patient lying supine and multi-directional sonograms were taken through the area of interest. Each adnexal lesion was categorized according to its size, location, internal consistency, and definition of borders.

The discrimination between benign and malignant adnexal masses is central to decisions regarding clinical management and surgical planning in such patients. A standardized method for preoperative identification of probable malignant masses would allow optimization of first-line treatment for women with ovarian cancer.

Laparoscopy

Patients were put in supine position. Abdominal insufflation, usually with carbon dioxide at a pressure of 15-20 mm Hg, has significant physiologic effects. Transperitoneal absorption of carbon dioxide results in a relative acidosis that plateaus after approximately 15 minutes of insufflation.

A small incision is made in the belly button and a tiny camera is inserted. The surgeon watches the image from this camera on a TV screen and performs the operative procedure. Two or three other tiny incisions are made in the mid pulmar point (mid calvicular).

Specialized instruments are inserted and used for the evaluation process such as; woolf laparoscopy in addition to its tools like endoscope, camera, insufflator, trocars and surgical instruments like Harmonic, LigaSure, Scalples, scissor, Graspers (surgical, Maryland..etc).

Pathology examinations

Histopathological assessment was conducted by taking biopsies from suspicious lesions then sent for frozen section. Each specimen was evaluated for features of malignancy and pathological subtype of ovarian cancers.

Statistical analysis

Data was collected and analyzed by using SPSS (Statistical Package for the Social Science, version 20, IBM, and Armonk, New York). The Shapiro test was used to determine compliance of the data to normal distribution. Quantitative data were expressed as mean (SD) and minimum-maximum and compared by Student t test was used in case of two different groups

Nominal data are given as number (n) and percentage (%). Chi2 was used to compare between nominal data. Accuracy of CA125 and RMI in prediction malignant ovarian masses in the studied patients was determined by receiver operator characteristics (ROC) curve. Level of confidence was kept at 95% and hence, *P value* was considered significant if < 0.05

RESULTS

Age, BMI and ultrasound findings in the studied cases (Table 1)

Table 1: Age, BMI and ultrasound findings in the studied cases

Variables	N= 54	
Age (years)	45.5±10.2	23.0–60.0
BMI (kg/m2)	26.7±2.3	22.5–31.5
Ultrasound data		
Multiloculated	42	77.8%
Solid area	34	63.0%
Bilaterality	32	59.3%
Ascites	13	24.1%
Metastasis	4	7.4%

Data expressed as frequency (percentage), mean (SD), range. BMI: Body mass index.

Mean of age was 45.5±10.2 years and of BMI was 26.7±2.3 kg/m2. Multiloculated was the most frequent US findings (77.8%), followed by solid area (63.0%).

Risk Malignancy Index among the studied cases (Table 2)

More than three quarters of cases (79.6%) had two or

more Ultrasonic feature. More than two thirds of cases were postmenopausal. Mean of CA125 was 321.9±346.5 U/mL, while that of RMI score was 2383.6±2988.2

Table 2: Risk Malignancy Index among the studied cases

Criteria		n	%
Ultrasonic features	One	11	20.4%
	Two or more	43	79.6%
Menopause	Postmenopausal	37	68.5%
	Premenopausal	17	31.5%
		Mean±SD	Range
CA125 (U/mL)		321.9±346.5	3.0–937.0
RMI score		2383.6±2988.2	3.0–8433.0

Data expressed as frequency (percentage), mean (SD). RMI:risk malignancy index; CA: carcino-embryonic antigen

Final diagnosis among the studied cases (Table 3)

Serous cyst was the most frequent benign findings (5.6%), while epithelial ovarian cancer was the most frequent malignant findings. Malignancy was in 83.3% of the studied cases.

Table 3: Final diagnosis among the studied cases

Criteria		n	%
Histopathology	Endometriosis	2	3.7%
	Serous cyst	3	5.6%
	TOC	1	1.9%
	Dermoid cyst	2	3.7%
	Fibroid	1	1.9%
	Ovarian cancer	45	83.3%
Malignancy	Malignant	45	83.3%
	Benign	9	16.7%

Data expressed as frequency (percentage)

Comparison between groups of patients according to final diagnosis (Table 4)

Cases with malignancy significantly had more frequent two or more Ultrasonic features and postmenopausal status as well as significant higher CA125 and risk malignancy index (RMI) score.

Table 4: Comparison according to final diagnosis

Criteria		Malignant (Total=45)	Benign (Total=9)	*p-value*
Age (years)		46.2±10.6	42.3±7.3	ˆ0.304
BMI (years)		26.6±2.2	27.1±2.7	ˆ0.562
Ultrasonography findings	Multiloculated	35 (77.8%)	7 (77.8%)	§0.999
	Solid area	28 (62.2%)	6 (66.7%)	§0.999
	Bilaterality	28 (62.2%)	4 (44.4%)	§0.461
	Ascites	13 (28.9%)	0 (0.0%)	§0.094
	Metastasis	4 (8.9%)	0 (0.0%)	§0.999
Ultrasonic features	One	6 (13.3%)	5 (55.6%)	§0.012*
	Two or more	39 (86.7%)	4 (44.4%)	
Menopause	Postmenopausal	35 (77.8%)	2 (22.2%)	§0.003*
	Premenopausal	10 (22.2%)	7 (77.8%)	
CA125 (U/mL)		376.4±355.0	49.3±43.4	˜0.001*
RMI score		2835.3±3082.2	125.1±135.9	˜0.001*

Data expressed as frequency (percentage), mean (SD). *P value* was significant if < 0.05

Diagnostic performance of CA125 and Risk of Malignancy Index (RMI) in diagnosing malignancy (Table 5, Figure 1)

At cutoff point ≥67.0 (U/mL), CA125 had 70.4% accuracy in diagnosing the malignant ovarian mass with area under curve was 0.791. Meanwhile, RMI at cutoff point ≥205 had 83.3% accuracy in diagnosing the malignant ovarian mass with area under curve was 0.916

Table 5: Diagnostic characteristics of CA125 and Risk of Malignancy Index (RMI) in diagnosing malignancy

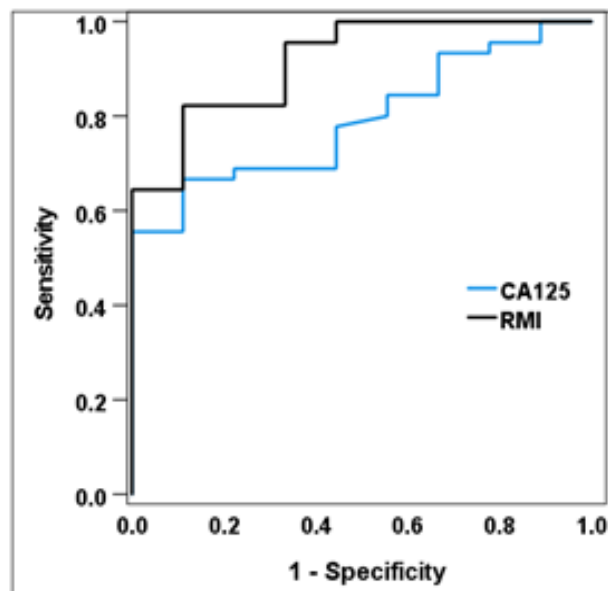| Characteristics	CA125	RMI
Area under curve	0.791	0.916
Standard error	0.066	0.046
p-value	0.006*	<0.001*
95% confidence interval	0.663−0.920	0.826−1.000
Cutoff point	≥67.0 (U/mL)	≥205.0
Sensitivity	66.7%	82.2%
Specificity	88.9%	88.9%
Diagnostic accuracy	70.4%	83.3%
Youden's index	55.6%	71.1%
Positive predictive value	96.8%	97.4%
Negative predictive value	34.8%	50.0%

Fig. 1: Receiver operating characteristics (ROC) curve for CA125 and Risk of Malignancy Index (RMI) in diagnosing malignancy

DISCUSSION

This clinical trial was done to evaluate the role of laparoscopy in management of sonographically suspicious adnexal masses. This study conducted in the obstetrics and gynecology outpatient's clinics of Maadi military hospital, Cairo. This study was conducted on 54 Patients suspected to have ovarian mass by ultrasound imaging.

The current study included 54 women, with mean age of 45.5±10.2 years and mean BMI of 26.7±2.3 kg/m². Based on the histopathologic findings we found that 45 (83.3%) cases were malignant and 9 cases were benign. Serous cyst was the most frequent benign findings (5.6%), while ovarian cancer was the most frequent malignant findings.

Adnexal masses were evaluated for sonographic morphological criteria: bilaterality, solid areas, multilocularity, ascites, and metastases[5]. As regard ultrasonography findings among the studied cases, we found that multiloculated was the most frequent US findings (77.8%), followed by solid area (63.0%), then bilaterality (59.3%), ascites (24.1%) while ascites was the least frequent (7.4%). There was no statistically significant difference between benign and malignant groups as regard US findings.

In disagreement with the current study Terzic *et al.*, (2015) included 609 women out of which 20.7% had malignant, 73.7% benign, and 5.6% borderline tumors. Women with malignant tumors were the oldest with mean age of 57.40 years ($p<0.001$)[6].

Also, Terzic *et al.*, 2015 revealed that the most frequent US findings were solid parts followed by multilocularity then Bilaterality. there were significant differences between malignant, benign and borderline tumors regarding all examined parameters except tumor multilocularity. Malignant tumors usually were of mixed consistency or had solid parts and with diameter greater than 5cm[6].

RMI was more accurate than any individual criterion in distinguishing malignant from benign masses. The high false-positive rate of ultrasound, especially in premenopausal women, is often cited as the main limitation of its use in screening for ovarian cancer[7].

Raised serum CA 125 levels are also found in association with benign ovarian cysts, endometriosis, and pelvic infection in addition to cancers of the endometrium, fallopian tube, breast, and colon.

In the current study as regard RMI among the studied cases, we found that more than three quarters of cases (79.6%) had two or more Ultrasonic feature. More than two thirds of cases were postmenopausal. Mean±SD of CA125 was 321.9±346.5 U/mL, while that of RMI score was 2383.6±2988.2.

The comparison between benign and malignant patients revealed that cases with malignancy significantly had more frequent two or more ultrasonic features and postmenopausal status as well as significant higher CA125 and RMI score.

In agreement with our results Qian *et al.*, 2021 revealed that patients with malignancy significantly had higher prevalence of postmenopausal status as well as significantly higher CA125 and RMI score[8].

Also, Javdekar & Maitra, 2015 reported that CA125 level was significantly higher among patients with malignancy than benign (33 vs. 395 $p<0.001$). Also, they revealed that RMI is a reliable tool in differentiating

benign from malignant adnexal masses. But in contrast to our results, they reported that there was no statistically significant difference between benign and malignant groups as regard Menopausal status[5]. The disagreement may be due to the difference in inclusion criteria.

Our results were comparable with Javdekar & Maitra, 2015 who reported that in differentiating benign from malignant adnexal masses RMI >200 had a sensitivity of 70.5 %, a specificity of 87.8 %. ROC showed that cut off value of 25 achieved a sensitivity and specificity of 82.35 and 43.9 %, respectively[5].

As well, Oranratanaphan *et al.*, 2018 enrolled 281 participants. 19.9% of them were malignant. For CA-125 (>35 IU/mL) the AUC of (0.81), sensitivity (87.9%) and specificity (46.2%). At RMI (>250) the AUC of (0.87), sensitivity (64%) and specificity (89%). Indicating the RMI was superior than CA-125 in discriminating between benign from malignant tumors which agree with our results[9].

Also, Al Musalhi *et al.*, 2016 enrolled 213 cases of various types of benign (77%) and malignant (23%) ovarian tumors. At cutoff point of CA125 ≥35 U/mL the AUC, sensitivity, specificity, NPV and PPV were 0.809, 79%, 62%, 91% and 38% respectively. At cutoff point of RMI ≥200 the AUC, sensitivity, specificity. Indicating the RMI was superior than CA-125 in discriminating between benign from malignant tumors which agree with our results[10].

Moreover, Terzic *et al.*, 2013 revealed that the sensitivity of the RMI in the overall population was 83.81%; the specificity was 77.24%; the positive predictive value (PPV) was 47.06%, and the negative predictive value (NPV) was 95.18%. In premenopausal women, the RMI sensitivity was 83.87%; specificity, 80.31%In postmenopausal women the RMI sensitivity was 83.78%; specificity, 68.18%; PPV, 63.92%; and NPV, 74.71%[11].

Finally, the current study showed that laparoscopy was safe and effective for the management of adnexal mass, this comes in agreement with Eltabbakh *et al.*, 2008 who concluded that Laparoscopy is feasible and safe for women with large ovarian cysts with benign features and results in a short hospital stay[11].

Also, Sarbhai & Yadav, 2020 confirms that laparoscopy can be safely performed for management of benign adnexal masses after proper selection of cases by using ultrasonography and markers like CA-125[12].

Furthermore, Barreta *et al.*, 2014 showed that that laparoscopy for the diagnosis and treatment of adnexal masses is safe and does not increase complication rates even in patients who need conversion to laparotomy[12].

CONCLUSION

In our study; suspicious ovarian masses can be managed laparoscopically as a diagnostic and therapeutic tool especially if the facility of Frozen Section Biopsy can be offered.

Laparoscopic surgery seems to offer significant advantages such as reduced hospital stay, less adverse effects as decreased post-operative pain, lesser de-novo adhesions formation, better cosmetic result, faster recovery.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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