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Research Article

Comparison of CA-125, conventional ultrasound and CT imaging in diagnosis and staging of ovarian cancer correlated with surgico-pathological findings

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ABSTRACT

Background: Preoperative evaluation of suspected ovarian malignancy is of paramount importance and a diagnostic tool with high degree of precision helps treating physician in planning appropriate surgery and also neoadjuvant chemo therapy in candidates who are not currently fit for extensive surgical procedure. Though the ultrasound examination of abdomen and pelvis helps one in detection and characterization of adnexal lesion to some extent, its diagnostic ability is further improved by addition of advanced imaging techniques such as computed tomography, magnetic resonance imaging and thus can prove beneficial in choosing patient for right surgery, there by optimising the treatment outcome. Objective of current study was to compare ultrasonography imaging, CT imaging, CA-125 values, RMI 3 score, surgical staging and histopathological findings in carcinoma ovary.

Methods: The study is a prospective observational study, carried out between September 2011 and July 2013, in the department of obstetrics and gynaecology, Kasturba hospital, Manipal. All cases of carcinoma ovary who underwent imaging (USG, CT/ MRI) were followed by staging laparotomy during the course of study. All cases of carcinoma ovary who has undergone neoadjuvant chemotherapy were excluded. All patients included in the study underwent CA-125 estimation, conventional ultrasound, CT scan (Sixty four slice with contrast) followed by staging laparotomy and histopathological examination of the specimen. RMI-3 (Risk Malignancy Index Score-3) was calculated in all cases.

Results: 54 patients were included in the evaluation. The efficacy of CT (Sensitivity 95.1%, specificity 46.2%) and Ultrasound (Sensitivity 90.2%, specificity 53.8%) were comparable in detection of ovarian malignancy. Combination of CT and USG (Sensitivity 95%, specificity 78.6%) gave the best result in non-invasive investigations whereas combination of CT and surgical staging (Sensitivity 95.1%, specificity 84.6%) gave a better result when invasive modalities were considered. RMI-3 score had sensitivity of 82% and specificity of 64% and did not improve the accuracy.

Conclusions: Optimal preoperative evaluation was achieved with combination of USG and CT. Additional of CA-125 further improved the precision. All the three modes had good diagnostic performances, and complimented each other in further refining the characterization of the mass, local spread and distant tumour dissemination.

Keywords: Ovarian cancer, Ultrasound, CT, RMI-3, Surgical staging

INTRODUCTION

Ovarian cancer is one of the leading cancers in Indian women.¹ In year 2012, ovarian cancer occurred in 239000 women worldwide (new 26834 cases in India) and

resulted in 152000 deaths (GLOBOCAN 2012).² Ovarian cancer is more lethal than endometrial and cervical cancer combined due to delayed diagnosis. Owing to the lack of symptoms and early peritoneal dissemination, the tumour has spread outside the pelvis in approximately

70% of cases at the time of diagnosis.³The stage at diagnosis is the most important prognostic factor. The 5-year survival rates drop from 93% in patients with localized disease to 28% in those with distant metastases.

CA-125 which has been found to be elevated in epithelial cancer is more often nonspecific, and gynaecological examination and ultrasound evaluation too have low sensitivity, CT and MRI imaging have become the popular method of detection and preoperative assessment of ovarian tumours.⁴

Proper pre-operative staging by imaging can prevent unnecessary surgeries in case of advanced cases of ovarian carcinoma which leads to morbidity which is preventable. Accurate staging using imaging helps to decide on neoadjuvant chemotherapy which will be ideal for patients with advanced carcinoma which helps in optimal tumour debulking during interval cytoreductive surgeries.

Whenever an ovarian mass is detected by clinical examination, the next task is to determine the malignant nature of the disease and its spread within pelvis and abdominal cavity. Establishing benign nature of the lesion preoperatively may reduce unnecessary ultra-radical surgery, thereby reducing morbidity and mortality related to prolonged and extensive staging procedure. Hence it is important that diagnostic studies should assist the gynae oncologist in planning appropriate surgery and chemotherapeutic planning.

Introduction of high frequency transvaginal probe (more than 5 MHz) has greatly improved the ultrasound capability in characterization of adnexal masses, as the images obtained are of high resolution and clarity. Preoperative evaluation by Computed Tomography (CT) with contrast enhancement, till today is one of the best method available to characterize the ovarian mass and to determine its extent of spread and CT findings match with surgico-pathological staging in 70 to 90% of cases.⁵

Only one study has compared the efficiency of all the three imaging modalities in the staging of ovarian cancer, the study was conducted by the RDOG (Radiology Diagnostic Oncology Group).⁶ Though ultrasound is an important tool in evaluating nature of the tumour, it cannot assess tumour spread. CT and MRI imaging modalities score over ultrasound in this aspect, especially for assessing the lesions underneath diaphragm, on hepatic surfaces and evaluation of intrahepatic small lesions and involvement of lesser sac. Also lymph node metastasis (smaller than 1 cm) are easily picked by CT and even better by MRI.⁷

According to American College of Radiology (ACR) appropriateness criteria reviewed in 2012 for staging and follow-up of ovarian cancer in pre-treatment staging of ovarian cancer as well as to rule out recurrent ovarian cancer, CT abdomen and pelvis with contrast again holds

the highest ranking followed by MRI with or without contrast.⁸

The aim of our study was to compare ultrasonography imaging, CT imaging, CA-125 values, RMI 3 score, surgical staging and histopathological findings in carcinoma ovary.

METHODS

The present study is a prospective observational study, carried out between September 2011 and July 2013, in the department of obstetrics and gynaecology, Kasturba hospital, Manipal, after obtaining the institutional ethical committee clearance (IEC 242/2011, dated 15-09-2011).

Inclusion criteria

All cases of Carcinoma ovary who underwent imaging (USG, CT/MRI) followed by staging laparotomy during the course of study.

Exclusion criteria

All cases of carcinoma ovary who have undergone neoadjuvant chemotherapy.

Sample size calculation

Calculated sensitivity of the ultrasound for the detection of ovarian carcinoma is around 85% (Jung et al. 2002).⁹ The minimum required sample size is determined by Buderer's formula;

$$N = [Z^2_{1-\alpha/2} \times P \times (1-P)]/L^2$$

Where; in: n = number of patients, $Z_{1-\alpha/2} = 1.96$ (standard normal deviate value that divides the central 95% of z distribution from 5% in the tails), P = the reported sensitivity (85%, i.e., 0.85), L= absolute precision desired on either side (half width of the confidence interval of the confidence interval) of sensitivity (10% i.e., 0.1).

Accordingly we got the minimum sample size as 49 and we have recruited 54 cases taking into consideration some dropouts.

All patients included in the study underwent cancer antigen-125 estimation (CA-125 Detected by Immunohistochemistry), conventional ultrasound (Toshiba Nimio ultrasound machine with frequency 6.5MHz transvaginal transducer and 5 MHz transabdominal transducer), CT scan (Brilliance 64 by Philips, sixty four slice CT with contrast) followed by staging laparotomy (same standard technique in all cases) and histopathological examination of the specimen. RMI-3 was calculated in all cases, which was given by the equation;

$$RMI\ 3 = U \times M \times CA-125$$

Where; a total ultrasound score of 0 or 1 made U=1, and a score of ≥ 2 made U=3; premenopausal status made M=1 and postmenopausal M=3. The score for CA-125 remains unchanged (corresponds to actual level of serum concentration in units/mL). Ultrasound features (one point for each finding) suggesting malignancy were multilocular cyst, solid areas, bilateral lesions, ascites, intra-abdominal metastases. RMI score of more than 200 was considered to represent malignancy.¹⁰

Statistical analysis

Statistical Package for the Social Sciences (SPSS-16) was used for statistical compilation and analysis.

Table 1: Parity and menopausal status of patients studied.

Parity	Number (%)	Pre-menopausal n (%)	Menopausal ≤ 5 years n (%)	Menopausal 6-10 years n (%)	Menopausal ≥ 11 years n (%)
Nulliparous	10 (18.5)	6 (11.1)	3(5.5)	-	1 (0.18)
Multiparous	38 (70.3)	16 (29.6)	6 (11.1)	9 (16.6)	7 (12.9)
Grand multi	6 (11.1)	-	2 (3.7)	1 (0.18)	3 (5.5)

Majority of patients were multiparous (38 cases) and were in surprisingly in premenopausal age group (16 cases) with commonest presenting complain being abdominal complaints including post meal distention of abdomen, loss of appetite and lower abdomen pain (Table 2).

Table 2: Presenting complaints of patients in the study.

Chief complaints	n (%)
Abdominal complaints (post meal distension, loss of appetite, lower abdomen pain)	42 (77.7)
Post-menopausal bleeding	7 (12.9)
Menstrual complaints	2 (3.7)
No complaints (incidental finding)	3 (5.5)

Ca 125 levels were low (<35 U/ml) in 15 (27.7%), mildly elevated (35-200 U/ml) in 18 (33.3%), significantly elevated in (201 - 1000 U/ml) in 18 (33.3%) and were very high (>1001 U/ml) in 3 (5.5%) cases.

The histopathological analysis of surgical resected specimens was considered as gold standard for comparison of diagnostic values of various investigative modalities (Table 3).

Diagnostic comparison was done (Table 4) for different modes of evaluation using sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV) and accuracy.

RESULTS

Total of 68 patients were included in the study of which 11 underwent neoadjuvant chemotherapy and 3 deferred treatment.

Remaining 54 patients were included in the study.

The youngest patient was 11 years and the most elderly patient was 73 years, mean age \pm standard deviation was calculated which $47.5 \pm$ was 15.5 years.

Majority of patients included were above 40 years. Only 9 patients were in the less than 40 years group. Table 1 shows patient demographic details.

Table 3: Histopathological findings in 54 patients who underwent surgery with suspicion of ovarian tumour.

Nature of the disease	WHO group	Histopathology	N
Benign	Epithelial	Serous cystadenoma	1
		Mucinous cystadenoma	7
		Mucinouscystadenoma with Brenner	1
Border-line	Epithelial	Borderline mucinous	5
		Borderline serous	1
Malignant	Epithelial	Serous cystadeno carcinoma	12
		Mucinous cystadeno carcinoma	1
		Clear cell Carcinoma	3
		Endometrioid adenocarcinoma	5
		Adenocarcinoma	2
		Adenofibroma	1
	Germ cell	Yolk sactumor (1 with hepatoid differentiation)	3
		Ovarian dysgerminoma	2
		Immature teratoma	1
		Malignant mixed Mullerian tumour	2
Metastatic	Krukenberg tumor	2	
	Fallopian tube Ca	1	
Transition-al cell	Transition cell carcinoma	1	
Others	Endometriotic cyst	1	
	Pendunculated fibroid	1	
	Paraovarian cyst	1	

Table 4: Diagnostic performance of USG, CT and surgical staging in evaluation of ovarian tumours.

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
A. Detection unilaterality/bilaterality					
USG	55.5	55.58	55.5	44.4	55
CT	81.4	51.8	62.85	73.6	67
Surgical staging	85.1	85.1	85.1	14.81	85
B. Detection of malignant ascites					
USG	66.6	64.1	35.7	16.6	60
CT	87.5	50	42.4	90.4	61
Surgical staging	80	46.1	36.3	85.7	56
C. Detection of lymph node metastasis*					
CT	81.8	67.4	39.1	93.5	70
Surgical staging	83.3	83.3	58.8	94.59	83
D. Detection of Peritoneal Metastasis					
USG	33.3	93.9	77.7	68.8	70
CT	68.1	87.5	78.9	80	80
Surgical staging	100	87.8	84	100	93
*USG did not pick up any lymph node enlargements in any of the 54 patients who were studied & hence omitted for analysis					

CT showed a 67% accuracy compared to 55% by USG in detection of ovarian tumours whether unilateral or bilateral involvement. Accuracy of both USG and CT were similar; 60% and 61% respectively in detection of malignant ascites. CT had a 68% sensitivity in detecting peritoneal metastases than USG (33%) and hence preferred for preoperative staging. Both USG and CT had equal accuracy in detection of hepatic metastasis. Overall accuracy of CT in staging ovarian tumors was 95%

compared to USG which was only 82%. The efficacy of different modalities in detecting a malignant ovarian cancer was better when combined (Table 5). When two parameters were compared the combination of CT and surgical staging gave the highest results, next to combination of USG and surgical staging. The usual investigative modality (USG + CA-125) gave only a comparable result to CT alone in detecting ovarian malignancy.

Table 5: Diagnostic values of single parameter vs. two parameters.

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
A. Single parameter					
CA 125 (>35 u/ml)	87.8	76.9	92.3	66.7	85.2
USG	90.2	53.8	86	63.6	81.5
CT	95.1	46.2	84.8	75	83.3
Surgical staging	92.7	100	100	81.3	94.4
B. Two parameters					
CA 125 & USG	92.7	76.9	92.7	76.9	88.9
CA 125 & CT	92.9	75	92.9	75	88.9
USG & CT	95	78.6	92.7	84.6	90.7
USG & surgical staging	95.1	84.6	95.1	84.6	92.6
CT & surgical staging	97.6	91.7	97.6	91.7	96.3
RMI 3 score*	82	64	87	56	77.7
*RMI 3 scores include menopausal state in addition to CA 125 and USG findings					

In our study, both USG and CT showed remarkable accuracy for detection of extraovarian spread individually and also when combined together.

CT had better specificity in diagnosing malignant ovarian mass and better accuracy in pre-operative staging of the disease compared to ultrasound imaging.

DISCUSSION

This prospective study evaluated various modalities of investigations in ovarian masses mainly to determine malignant nature, extent of local tumour spread and extraovarian dissemination. The diagnostic abilities of each was analysed and correlated with one another, considering final histopathological report as gold standard. The results indicated that combined parameters were superior in detection of ovarian malignancy and its spread than individual modalities taken independently.

The percentage of stage 3 and 4 disease were high, almost 60%. This result was likely due to the referral status of our center which is a tertiary center.

Regarding the role of ultrasound in evaluation of adnexal lesion, our aim was not to evaluate its role for routine screening for malignancy, but to study indicators of malignancy such as thick walls, thick septae, intracystic projections, solid areas, bilaterality, presence of ascites and intra-abdominal metastasis, so that we could estimate RMI scores accurately. We also estimated CA-125 levels in all the cases, though we knew that this marker is primarily meant for tumors of epithelial origin which constitutes the majority of ovarian tumours (up to 80%). However CA-125 is not very specific for ovarian cancer and it is well-known that false positive results may result from several benign conditions such as pelvic inflammation, endometriosis, adenomyosis, uterine fibroids and even normal menstruation.¹¹

We calculated RMI-3 for all our cases and compared it to combined results of USG and Ca-125 and obtained an accuracy of 77.7% for RMI-3 in detection of ovarian malignancy which was far lower than accuracy of combined parameter USG and Ca-125 which was 88.9%.¹² The efficacy of RMI scores alone in detection of a malignant ovarian tumour is less, hence other investigative modalities results should also be considered in addition to RMI.

Table 6: Comparison of studies on USG for detection of ovarian malignancy*.

Studies	Sensitivity (%)	Specificity (%)
Liu J et al. (2007) ¹³	89	84
Fatma Ferda (2007) ¹⁴	83	92
UKCTOS (2009) ¹⁵	89	99
Firoozabadi et al. (2011) ¹⁶	52	88
IOTA (2012) ¹⁷	90	88
Hafeez S et al. (2013) ¹⁸	91	91
Current study (2013)	90	54

Our results of USG compared to other studies in literature (Table 6) showed a comparable sensitivity of 90% especially when compared to the results of international ovarian tumor association and United Kingdom Collaborative Trial of Ovarian Cancer Screening

(UKCTOS) in detection of ovarian malignancy.¹³ Our study showed a very low specificity of 54% in detection of ovarian carcinoma when compared to other studies in literature. This may be because of the inter-observer variation in results of ultrasonography and also the failure of USG in assessment of the involvement of retroperitoneal area.

The results of CT in our study compared to other studies in literature (Table 7) showed a higher sensitivity, comparable to the study by Mubarak et al.¹⁹ Although our study showed a very low specificity of 46% because of the high number of false positives which may be due to non-specific inflammatory changes within the tumour, reactive lymphadenitis appearing as enlarged lymph nodes on CT, which were reported as possible malignancy, which changes the stage of disease. And also lack of extensive retroperitoneal and paraaortic lymph node dissection also would have contributed to the low specificity.

Table 7: Comparison of studies on CT for detection of ovarian malignancy.

Studies	Sensitivity (%)	Specificity (%)
Kurtz et al. (1999) ²⁰	90	88
Kinkel et al. (2005) ²¹	81	87
Liu J et al. (2007) ¹³	85	86
Fatma Ferda (2007) ¹⁴	91	96
Mubarak et al. (2011) ¹⁹	97	91
Firoozabadi et al. (2011) ¹⁶	79	92
Current study	95	46

NICE clinical bulletin (no. 122)¹⁴ states that whenever clinical feature, ultrasound and serum CA-125 prompt the diagnosis of ovarian cancer, then the recommendation is to do abdomino-pelvic CT or MRI to document the pelvic and peritoneal spread and thorax should be included in the imaging if patient has respiratory findings, for example plural effusion, decreased air entry etc.²² In our study, we could get a better sensitivity 95% and specificity 78.6% when ultrasound and CT were combined.

Our study showed that efficacy of different modalities in detecting a malignant ovarian cancer was better when combined. When two parameters were compared the combination of CT and surgical staging gave the highest results, accuracy of 96.3% next to combination of USG and surgical staging 92.3%.

Based on our findings where we had a significant better results in staging laparotomy (Sensitivity 92.7%, specificity 100.0%) in detection of both ovarian carcinoma and its spread to other sites, hepatic metastasis (Sensitivity 100%, specificity 98.03%), lymph node metastasis (Sensitivity 83.3%, Specificity 83.3%), peritoneal metastasis (Sensitivity 100%, specificity

87.8%), which lead us to conclude that patients with negative findings on imaging should continue to undergo staging laparotomy as this procedure add only minimal morbidity and operative time and result in the upstaging of a significant percentage of patients. We believe that comprehensive surgical staging remains a critical aspect in the evaluation of patients with apparent early-stage ovarian cancer, as this procedure aids in identifying patients who may benefit from adjuvant chemotherapy.

CONCLUSION

The results of present study indicate remarkable diagnostic abilities of two different imaging (USG & CT) modalities in detection of extent of malignant spread both individually and in combination. Addition of the third parameter (CA-125) further improves the precision. It is difficult to suggest a single investigative modality for evaluation of women with suspected ovarian malignancy. All the three modes, though not inferior by themselves, are complimentary to each other in their diagnostic performances.

Pre-operative sonography by both routes should be performed, transvaginal ultrasound provides opportunity for characterisation of ovarian mass, transabdominal ultrasound imaging assesses extra pelvic dissemination. CT imaging augments ultrasound findings because of its ability to image the deeper areas and the minimal extra ovarian spread and proves to be important adjunct to assess and treat when surgical staging is not feasible (by neoadjuvant chemotherapy). However, in cases where patient cannot afford CT imaging, a combination of CA 125 and USG can be considered satisfactory in preoperative evaluation of ovarian carcinoma.

Limitations

The reports of ultrasonography and CT were not double blinded during reporting. Detection of distant metastasis was not possible for complete staging as all patients did not undergo CT/USG of chest or brain because of financial constraints. The prognosis, overall survival rate and progression free interval needs to be calculated to comment regarding the benefit of complete pre op staging and laparotomy.

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