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Study of Diagnostic Efficacy of Risk of Malignancy Index(RMI-II), Neutrophil Lymphocyte Ratio(NLR) and Platelet Lymphocyte Ratio(PLR) in Preoperative Assessment of Adnexal Masses in Females and Its Histopathological Correlation

Running title – Comparison of different preoperative test to differentiate malignant and benign adnexal masses

Authors-

1.Dr. Shikha Seth, MD,Professor, Obs and Gynae , GIMS,Noida, Uttar Pradesh ,India

2.Dr. Shipra Saxena, MD, Assistant Prof., Obs and Gynae, KM Medical College Mathura, Uttar Pradesh , India

3 .Dr.Vandana Verma, Assistant Prof., Obs and Gynae, UPUMS ,Saifai, Etawah, Uttar Pradesh , India

4. Dr. Vaibhav Kanti, Associate prof, Obs and Gynae, UPUMS ,Saifai, Etawah, Uttar Pradesh , India

5. Dr. Umesh Kumar Gupta, Assistant Prof., Peadiatric surgery, UPUMS ,Saifai, Etawah, Uttar Pradesh , India

Abstract-

Introduction-

Inflammatory cells may reach significant levels in blood in different type of cancers.Neutrophil Lymphocyte Ratio(NLR) and Platelet Lymphocyte Ratio(PLR) arecost-effective and universally available.So this study was planned to assesthe efficacy of NLR and PLR along with Risk of malignancy Index(RMI- II) in differentiating benign and malignant adnexal masses preoperatively.

Aims and objectives- The main aim of the study was to assess diagnostic efficacy of RMI-II ,NLR and PLR in preoperative assessment of adnexal masses taking histopathology as gold standard.

Material and methods-

This study was a prospective study of diagnostic efficacy conducted at the department of Obstetrics and Gynaecology in collaboration with Department of Radiodiagnosis, Department of Biochemistry and Department of Pathology at UPUMS, Saifai, Etawah, over a period of 18 monthson 104 patients.Ethical clearance was taken from the ethical

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committee of the institute. Risk of malignancy index (RMI-II), NLR and PLR were calculated.The diagnostic efficacy wereassessed for all the tests and comparison done by using χ2 test.

Results –

The specificity and positive predictive value of RMI-II was found 100%. NLR above 3.35 was found to have high negative predictive value of 91.9 5% in diagnosing malignancy.

Conclusion-

The sensitivity of CA 125 alone was found to be 76.9 2% which was higher than for any other parameter assessed whereas the specificity of RMI-II was highest among all the parameters. PLR value (more than 300) is highly specific for malignant Adnexal masses.

Key words-cancer, chronic inflammation, ovarian carcinoma,

INTRODUCTION-

Adnexal masses may be of different aetiologies like infective, inflammatory, benign and malignant tumors.[1]All these pathologies require different management plan. Therefore it is important to correctly diagnose the pathology. As ovarian malignancy is second most common gynaecologic malignancy and seventh leading causes of cancer deaths in women worldwide. [2]So need of differentiating benign and malignant masses are really crucial in case of ovarian masses as the delay in management may increase morbidity and mortality. Currently the conventional modalities like clinical examination, ultrasound assessment and tumour marker assays are being used to assess pelvic masses, but none is alone sufficiently sensitive and specific for detecting malignancy in adnexal masses.[3,4] As both imaging and biomarker tests are not individually able to predict the exact malignancy potential. ThereforeRisk of Malignancy Index (RMI) was used to differentiate between benign and malignant masses which is a scoring system including these modalities.[5]

Many studies have also shown that Chronic inflammatory response may lead to development and the progression of any cancer. [6] Inflammation contributes to the response against tumor cells which lead to irreversible DNA damage by inhibiting apoptosis of the cancer cells and trigger angiogenesis. It has been seen that these triggers allow the tumor to grow constantly, invade the nearby tissue and subsequently tumor spread to other sites in the body.[7,8,9] As this process continues growth factors released from platelets, like platelet-derived growth factor, transforming growth factor B and endothelial growth factor which may also contribute to the

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growth and development of the tumor.[10]Thrombocytosis is related with poor prognosis of patient in case of malignancy.[10,11,12] Keeping this in mind apart from cytokins, very basic inflammatory markers and their ratio such as neutrophil-to-lymphocyte ratio(NLR) and platelet to lymphocyte ratio (PLR) have been tried in few studies on various cancer as diagnostic and prognostic markers and it has been found that inflammatory cells or markers may reach significant levels in blood in different type of cancers.[12,13,14,15]but till date we don't have fixed cut-off values of PLR and NLR for reference. [11]Therefore it was hypothesized that NLR and PLR which are known to be cost-effective and universally available, may help to some extent in distinguishing between benign and malignant ovarian masses prior to undergoing surgery,especially in resources limited setting.

So this study was planned to further asses the efficacy of NLR and PLR along with RMI- II in differentiating benign and malignant adnexal masses preoperatively.

Aims and objectives- The main aim of the study was to asses diagnostic efficacy of RMI-II , NLR and PLR in differentiating benign and malignant adnexal masses preoperatively,taking histopathology as gold standard. The secondary objective of the study was also to estimateprevalence of adnexal masses and their pathological distribution in rural females of Western Uttar Pradesh.

Material and methods-

Study Design-This study was a prospective study of diagnostic efficacy .

Setting – This was a hospital based study including 104 cases with clinical and sonographically confirmed adnexal masses in age group of 15 to 65 years.This study was conducted at the department of Obstetrics and Gynaecology in collaboration with Department of Radiodiagnosis,Department of Biochemistry and Department of Pathology at Uttar Pradesh University of Medical Sciences Saifai, Etawah,which is a rural tertiary care centre.

Interventions-

104 cases with clinical and sonographically confirmed adnexal masses in age group of 15 to 65 years, admitted from January 2017 to June 2018, who were planned for surgical exploration were included in the study after taking proper consent. Adnexal mass cases with pregnancy, females with inadequate documentation, females who are planned for conservative management and ectopic pregnancy cases were excluded from the study.All the includedpatientswere worked up thoroughly by taking proper history and complete physical examination. Based on the clinical impression masses were categorised as benign or malignant. Further investigations were done as per the requirement including adenosine

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deaminase, CA 125, pelvic sonography for morphological scoring of masses. CT scan and MRI was done only if sonography and clinical findings are doubtful and are not corresponding with each other.

Data collection-

According to clinical finding and investigation basis RMI-II scoring was calculated and each case was categorised in benign and malignant respectively. Calculation of Risk of malignancy index (RMI-II)[5] was done by using formula U x M x CA-125 where U is ultrasonographic morphological score, 1 scoring was given if oneUltrasound findings was present and 4 score denoted ≥ 2 ultrasonographic findingsuggestive of malignancy were present.Ultrasonographic finding suggestive of malignancy were presence of multilocular cystic lesion, solid areas, bilateral lesion, ascites, intraabdominal metastatic lesions. M was menopausal score,1 score was given if female is premenopausal and 4 score was given for postmenopausal status. CA-125 is direct level of CA125.Cut-off values of RMI-II was taken as 200 to differentiate between benign and malignant masses.[5,16]

NLR and PLR were calculated.Cut off values for NLR and PLR to differentiate benign and malignant adnexal masses was taken as 3.35 and 572.9 respectively andcategorisation of adnexal masses in benign and malignant was done(cut offs were based on review of literature).[7,17]

Laparotomy was done and details were noted and the tissue obtained from surgery was sent for histopathologic examination. Histopathology reports were collected.

Statistical analysis-

Taking histopathology as the gold standard final test, findings of preoperative diagnostic tests were analysed. The diagnostic efficacy wereassessed in terms of sensitivity, specificity, positive predictive value and negative predictive value of all the three tests i.e. Risk of malignancy index, neutrophil lymphocyte ratio and platelet lymphocyte ratio. Kruskal Wallis test was used for finding significance among all the diagnostic tests.

Ethical consideration- Ethical clearance for this study was taken by the ethical committee of the institute.

Results –

During this study period of 18 months the total number of admissions in gynaecology ward were 2017. Out of which total number of admissions with adnexal mass pathology were115 therefore the burden of adnexal masses in our study came out to be 5.7%. Out of these 115 adnexal mass cases 11 cases (9.57 %) were managed conservatively and rest 104(90.4 3%)

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cases were planned for laparotomy. Figure 1A and B showed the distribution of adnexal masses based on Histology. Out of 104 cases of masses 37(36.5 4%) were functional / inflammatory, 54(50.9 6%) benign and 13 (12.5%) were malignant adnexal masses. (Fig.-1A) Clear histological evidence of tuberculosis was found in 6 cases that is 5.6 %.Table 1 showed the distribution of adnexal mass based on the demographic features.

Adnexal masses were found most prevalent among the reproductive age group (15 to 45 years age) i.e. in 77.8 % cases and the peak prevalence was in 35 to 45 years of age. In this study only 17 cases (16.3 5%) cases were found in postmenopausal women. Maximum incidence of adnexal masses were noticed in women with high parity ≥ 3 compared to primipara or nullipara cases (Table 1).Taking a cut off value of CA- 125, 35 units/litre, sensitivity, specificity, positive predictive value and negative predictive value of CA -125 for predicting malignancy was found 76.9 2%, 9.2 2%, 47.3 7%, and 96.4 7% respectively (Table 3).

This study showed that morphological sonographic scoring was quite specific test (specificity- 91.2 1%) to diagnose malignancy but it has poor sensitivity and positive predictive values which was found 23.0 8% and 27.27% respectively whereas negative predictive value was found 89.24 % therefore it can't be relied alone for work up of adnexal masses. Table 5 showed the categorisation of mass based on RMI-II scoring. Only 8cases(61.5%) had R MI-II score of greater than 200 while all benign, inflammatory and functional masses had RMI-II value of less than 200. Sensitivity, specificity, positive predictive value and negative predictive value of RMI-II was found 61.54%, 100%, 100% and 94.7 9% respectively. So RMI-II score with cut off value above 200 is highly specific test for detecting malignancy. Mean RMI-II score was found to be significantly high(>1500) in malignant adnexal masses.Table 4 showed that maximum i.e. 90.7 4% benign and 94.5 9% inflammatory masses had NLR values less than 3.35 however only 46.15% of malignant masses had NLR value above 3.35. So high NLR value can be utilised in addition to other test for differentiating adnexal massetiology with better accuracy preoperatively. Sensitivity of NLR was found 46.1 5%, specificity was 7.91 %, positive predictive value was 35.2 9% and negative predictive value was found 29 5%(table 3). NLR cut off value of 3.35 and above was found to have high negative predictive value of 91.9 5% in diagnosing malignancy among adnexal mass pathologies.

Since no values of PLR≥ 572.9 was found in our study as taken from previous study done by Melahat Yildirim et.al.[7] therefore a new cut off value was evaluated to help out in discriminating benign and malignant masses. Based on our own result an arbitrary cut off of 300 was taken, based on which the distribution found to be in table 4.

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Out of 13 malignant cases 15.3 8% cases had a PLR value greater than 300 whereas most of the benign tumors(98.1 5%) and all the functional and inflammatory mass were found to have PLR value of less than 300 in our study. As per the results, in our study sensitivity,specificity, positive predictive value and negative predictive value of PLR was found 15.3 8%, 98.9%, 66.67%, and 89.1 % respectively.

Discussion-

In this studyamong all the adnexal masses pathologies identified by histopathology, the most common was dermoid cyst (19.12%) followed by simple cyst whereas in study done by S.H. Shukri et. al. most common adnexal mass pathology was teratoma (26%) followed by corpus luteal cyst.[17]

Maximum incidence of adnexal mass was seen among age group15 to 45 years in which 81 (77.8 8%)patients were registered (Table1).Prevalence of malignant tumors increased sharply (23.5 3%)beyond 45 yrsas compared to reproductive age group (10.34%) which is comparable to an incidence of ovarian malignancy in postmenopausal women(30%) in a study by J.A.Benett and E.Olivaand to the study done byR. Rai, P.C. Bhutia and Tshomo U. where57.9% of adnexal masses were malignant in postmenopausal women whereas this percentage was only 42.1% in premenopausal women.[18,9]

Maximum incidence of adnexal masses were noticed in multipara with parity≥ 3 in our study whereas on comparing adnexal masses pathology on the basis of parity of females, maximum prevalence of ovarian tumors both benign (58.3%) and malignant(16.67%) were seen in nulliparous female which further supported the theory of instant ovulation as a risk factor for carcinogenesis.

Study of distribution of adnexal masses on the base of CA 125 indicated that taking a cutoff value of 35 U/litre, sensitivity to correctly identify malignancy preoperatively was found to be 76.92% whereas specificity to correctly rule out malignancy was 90.11% which was statistically significant.The poor sensitivity of CA 125 is the reason why this test is not used as routine screening of population for ovarian malignancy.

The sensitivity, specificity positive predictive value and negative predictive value of RMI-II in our study was 61.5 4%, 100% ,100% and 94.7 9%(Table 4) which was comparable to another study done by M.Terzic et.al. in 2015 where sensitivity, specificity, positive predictive value and negative predictive value of RMI-II was calculated to be 83.33% 94.1 2% 89.2 9% and 90.5 7% respectively.[16]CA-125 was found to be more sensitive than RMI-II in differentiating benign and malignant tumors however RMI-II score was more specific in

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diagnosing malignant ovarian tumors as compared to CA 125 alone. It is similar to study by Khawla Al-Musalhi, ManalAl Kindi et alWhere in the CA 125 test was found to be more sensitive (69% vs %&%)in detecting the majority of malignant ovarian tumors compared to RMI -II.[20]

The study of trends of NLR in differentiation of benign and malignant tumors showed arise in mean value ofNLR from 2.42 in functional masses to 3.12 in benigntumors which further rose to 3.56 in malignant masses and it is corresponding to the suggested cutoff of 3.35 to differentiate benign and malignant tumors the sensitivity and specificity of NLR indifferentiation of benign and malignant tumors was 46.1 5% and 87.91% respectively in this study which was compared to those found in the study by MelahatYilidirim where sensitivity and specificity ofNLR was calculated to be 55% and 81 per cent respectively .[7]

However the suggested cut-off value of PLR adopted from the study by MelahatYilidirim was 572.9 which could not found in any of the case reported in our study.[7]It may be due to lower values of mean platelet count which ranged between 2.01 in functional masses 2.42 in malignant tumor(mean value 2.24 lakhs).Thus though phenomena of increased thrombocytes could be appreciated among malignant tumors it was not found to be statistically significant .As a result of thrombocytosis and reducing trend of lymphocytes in tumors the mean value of the PLR was also found increased from 95.26 in functional masses to 133.42 in benign tumor and further increase to 149.53 in malignant tumors which was also found to be statistically significant.Therefore a new cutoff value of PLR that was 300, was consideredfor calculations done in our study and sensitivity, specificity, positive predictive value and negative predictive value of PLR was found to be 15.3 8% 98.9 %, 66.67% and 89.1 % respectively so above 300 PLR is highly specific to identify malignant tumors.

Conclusion-

The overall burden of adnexal mass in population was 5.7 %. The incidence of malignancy was higher with older age, postmenopausal status and nulliparityThe sensitivity of CA 125 alone was found to be 76.9 2% which was higher than any other parameter that is RMI-II, NLR and PLR however the specificity of RMI-II was highest among all the parameters compared and comparing RMI-II, NLR and PLR it was found that sensitivity and specificity of NLR was comparable to that of RMI-II score. No test was found to be sensitive enough to be suggested as a screening tool for ovarian tumors. Apart from the well-known RMI-II which was found to be highly specific in our study also, we observed that high PLR value (more than 300) is highly specific for malignancy in Adnexal masses.

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The result of this study was comparable to those of various other studies conducted elsewhere in the world however the results can be affected by a small sample size and exclusion of the conservatively managed patients.Thus larger study may be helpful for further evaluation.

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Figure 1: Distribution of adnexal masses on the basis of histopathology-

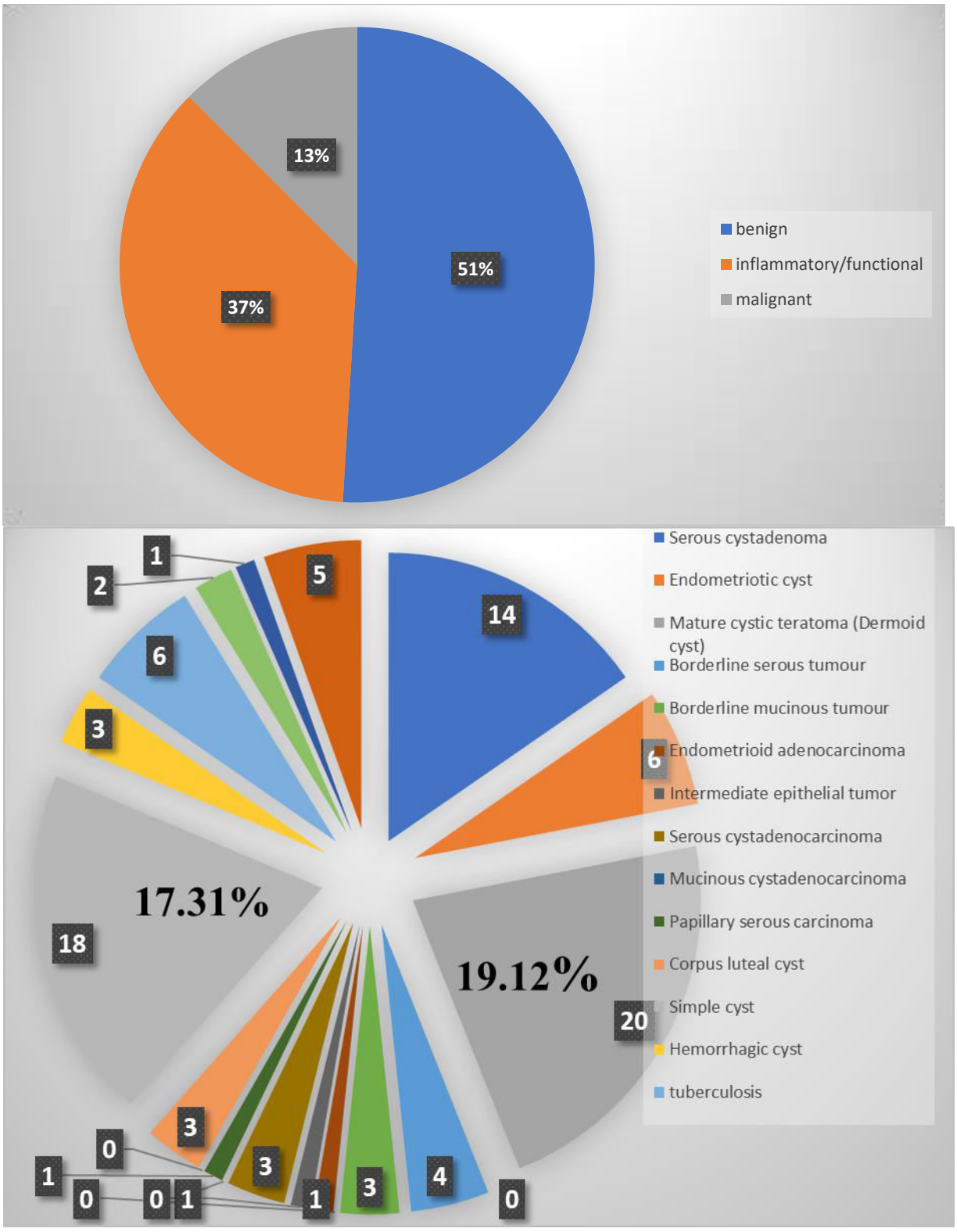

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Table 1: Distribution of adnexal masses on the basis of demographic profile-

Demographic parameter		Number of patients	Percentage
Age	<15 years	1	0.96
	15-25 years	21	20.19
	25-35 years	29	27.80
	35-45 years	31	29.81
	>45 years	22	21.15
Reproductive status			
Reproductive age		87	83.60
Postmenopausal age		17	16.35
Parity			
0		12	11.54
1		10	9.62
2		25	24.03
≥ 3		57	54.8 1

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Table 2Distribution of adnexal mass histopathologyaccording to demographic profile

Demographic parameter		Benign Pathology		Malignant Pathology		Inflammatory / functional	
Age	< 15 years	1	100	-	-	-	-
	15 to 25 years	10	47.62	3	14.28	8	38.10
	25 to 35 years	14	48.27	1	3.46	14	48.27
	35 to 45 years	21	67.74	2	6.46	8	25.81
	45 to 55 years	4	40.00	4	40.00	2	20.00
	> 55 years	4	33.33	3	25.00	5	41.67
Reproductive status							
	Reproductive (87)	48	55.17	9	10.34	30	34.49
	Postmenopausal(17)	6	35.92	4	23.5 3	7	41.18
Parity							
	0(12)	7	58.33	2	16.67	3	25.00
	1(10)	5	50.00	--		5	50.00
	2(25)	15	60.00	2	8.00	8	32.00
	≥3(57)	27	47.37	9	15 .79	21	36.84

Table 3 Diagnostic efficiency of different test used to differentiate Benign and Malignant ovarian Masses

	CA-125	USG Score	RMI-II	NLR	PLR
SENSITIVITY	76.92%	23.08%	61.54%	46.15%	15.38%
SPECIFICITY	90.11%	91.21%	100%	87.91%	98.9%
POSITIVE PREDICTIVE VALUE	47.37%	27.27%	100%	35.29%	66.67%
NEGATIVE PREDICTIVE VALUE	96.47%	89.24%	94.79%	91.95%	89.1%

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Table 4: Comparison of significant values in different diagnostic tests with histopathology of adnexal masses

Diagnostic test	Benign		Malignant		Others	
	Number	Percentage	Number	Percentage	Number	Percentage
CA 125						
< 35 u/l	47	8 7.4	3	23.08	35	94.59
>35u/l	7	12.96	10	76.92	2	5.41
Ultrasonography Score						
Score 0-1	49	90.74	10	76.92	34	91.89
Score >2	5	9.26	3	23.08	3	8.11
RMI-II SCORE						
<200	54	100	5	38.46	37	100
>200	-		8	61.54	-	
NLR						
<3.35	45	90.74	7	53.85	35	94.59
>3.35	9	16.67	6	46.15	2	5.41
PLR						
<300	45	90.74	7	53.85	35	94.59
>300	9	16.67	6	46.15	2	5.41

Table 5: Comparative statistics of different diagnostic tests

Outcome CA 125	Number	Means	standard deviation	P value
Benign	54	21.7 3	23.7 3	
Functional	24	12.83	8.67	<0.001
Inflammatory	13	31.8 4	5 1.35	
Malignant	13	241.06	317.17	
REMI-II				
Benign	54	31.43	31.61	

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Functional	24	25.29	35.84	
Inflammatory	13	37.17	50.8 9	**<.001**
Malignant	13	1507.3	275 6.5 9	
NLR (cut off 3.35)				
Benign	54	3.12	3.27	
Functional	24	2.42	1.67	**0.013**
Inflammatory	13	1.76	0.81	
Malignant	13	3.56	1.80	
PLR (CUT OFF 300)				
Benign	54	133.42	71.85	
Functional	24	95.26	33.92	**0.007**
Inflammatory	13	81.61	33.71	
Malignant	13	149.53	113.55	