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RESEARCH ARTICLE

TO STUDY AND ASSESS THE VALIDITY OF THE RISK OF MALIGNANCY INDEX(RMI-4) IN DISCRIMINATING BETWEEN BENIGN AND MALIGNANT OVARIAN MASSES

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Abstract

Introduction: The most fatal of all gynecological cancers is ovarian cancer. Of all gynecological cancers, it has the greatest fatality-to-case ratio. It is the 4th most prevalent cancer among women. The lifetime risk of being diagnosed with ovarian carcinoma is 1% to 1.5 %, with a nearly 0.5% chance of dying from it. Suboptimal primary cytoreductive surgery has great prognostic significance. The reason was because of inappropriate preoperative evaluation, which decides the kind of surgery being performed and the surgeon's expertise of the surgeon in performing staging laparotomy if indicated. Hence, a gynecologist must be able to differentiate benign from the malignant ovarian mass. Several studies have revealed that the diagnosis of ovarian mass by investigations like Ultrasonogram, Doppler, MRI, CT has been proved to be uncertain despite the need for expertise. The goal of this study was to assess the ability of the Risk of Malignancy Index Scoring System (RMI- 4) in differentiating benign from malignant ovarian masses and to compare the scoring patterns to histopathological findings.

Objectives: To validate the efficiency of the Risk of Malignancy Index(RMI-4) in discriminating benign and malignant ovarian tumors.To correlate the calculated value of the Risk of Malignancy Index(RMI-4) to the histopathological report.To evaluate the performance of individual parameters and the Risk of Malignancy Index(RMI-4) in differentiating benign and malignant ovarian tumors.

Materials and methods: A prospective observational study in one year from date of approval from institutional ethical committee i. e from 2019 to 2021on women attending Gynecology outpatient and inpatient department diagnosed with an ovarian mass at Government Maternity Hospital, Tirupati.

Results : 50 women with ovarian mass were selected for the study. Patients with endometriosis, fibroid uterus, Pelvic inflammatory disease, menstruation, pregnancy, ectopic pregnancy, and other non-gynecological conditions like peritonitis, diverticulitis, inflammatory bowel disease, tuberculosis, liver disease, recent surgery, are excluded. General and gynecological examinations were done for all cases. Ultrasound pelvis was done for all the patients and the presence of bilateral ovarian mass, multiloculated tumor, presence of solid areas, ascites, and extra ovarian metastasis was noted. An ultrasound score (U) of 1 was given if none or one of the features are found, and a score

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of 4 was given if two or more of these features were noted. Size of the tumor measured. A score of 1 was given for a tumor less than 7 cm and a score of 2 for a tumor size more than or equal to 7 cm size. Postmenopausal status was defined as more than one year of amenorrhea or age older than 50 years for women who had undergone hysterectomy; they were scored as M=4. All other patients who did not meet these criteria were defined in a premenopausal status which scored M=1. The Risk of Malignancy Index (RMI-4) was calculated by using the formula: RMI-4 = U x M x S x CA 125. Laparotomy was done for all cases and the specimen was sent for histopathological examination which is the gold standard.90% of the tumors were benign and 10% were malignant.Prediction of malignancy by CA 125, ultrasound, and RMI-4 was analyzed.The optimal cut-off value of RMI-4 was 450 with a sensitivity of 95.56%, specificity of 100%, PPV of 100%, and NPV of 71.43%.Though the Specificity and PPV of CA125 were high, Sensitivity was less (86.67%).This study showed that RMI-4 had better performance than CA 125, USG score, and menopausal score in predicting malignancy.

Conclusion:RMI-4 is a multimodal approach that is simple and easily applicable in the preoperative evaluation of a patient with an ovarian mass.Risk of Malignancy Index -4 (RMI-4) is a reliable method in discriminating benign and malignant ovarian mass preoperatively.Risk of Malignancy Index -4 (RMI-4) is a better scoring index in differentiating benign and malignant ovarian mass when compared to individual tests of ultrasonogram or CA125 level.The optimal cut-off point of Risk of Malignancy Index -4 (RMI-4) at which benign and malignant tumors can be discriminated was 450 in the present study.RMI-4 is the most useful scoring system in the proper selection of patient.Since the specificity of Risk of Malignancy Index -4 (RMI-4) was high, there is a potential role for this index in the selection of cases for conservative management or minimally invasive surgery in case of benign ovarian masses.

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Introduction:-

The most fatal of all gynecological cancers is ovarian cancer. Of all gynecological cancers, it has the greatest fatality-to-case ratio.It is the 4th most prevalent cancer among women.The lifetime risk of being diagnosed with ovarian carcinoma is 1% to 1.5 %, with a nearly 0.5% chance of dying from it[1].

Suboptimal primary cytoreductive surgery has great prognostic significance. The reason was because of inappropriate preoperative evaluation, which decides the kind of surgery being performed and the surgeon's expertise of the surgeon in performing staging laparotomy if indicated. Hence, a gynecologist must be able to differentiatebenign from the malignant ovarian mass.Several studies have revealed that the diagnosis of ovarian mass by investigations like Ultrasonogram, Doppler, MRI, CT has been proved to be uncertain despite the need for expertise.

In 1990, Jacob et al[1] developed a simple scoring index, Risk of Malignancy Index (RMI)according to MENO Score, Ultrasound score, and CA-125 which were obtained preoperatively. They concluded thatRMI was effective indifferentiating benign from the malignant ovarian mass.

Later in 1996, Tingulstad et al[2] modified RMI and named as RMI 2 and further, it was modified as RMI-3[3] in 1999. Yamamoto et al[4] developed a new RMI and named as RMI- 4 in 2009 where they included tumor size score.

The goal of this study was to assess the ability of the Risk of Malignancy Index Scoring System (RMI- 4) in differentiating benign from malignant ovarian massesand to compare the scoring patterns to histopathological findings.

Aim Of The Study

1. To study and assess the validity of the Risk of Malignancy Index(RMI-4) in discriminating between benign and malignant ovarian masses.

Objectives:-

1. To validate the efficiency of the Risk of Malignancy Index(RMI-4) in discriminating benign and malignant ovarian tumors.
2. To correlate the calculated value of the Risk of Malignancy Index(RMI-4) to the histopathological report.
3. To evaluate the performance of individual parameters and the Risk of Malignancy Index(RMI-4) in differentiating benign and malignant ovarian tumors.

Review Of Literature

Among all gynecological cancers, ovarian cancer poses the greatest clinical challenge.According to **7thGLOBOCON,** the incidence of ovarian cancer is 6.6 per 1,00,000 population. Mortality is 4.2 per 1,00,000 population. About 30% of ovarian tumors in women are malignant, whereas only about 7% of ovarian epithelial tumors in premenopausal patients are malignant.

Ovarian carcinoma is the fifth most common cancer-related cause of death.To plan whether the ovarian tumor requires a minimally invasive procedure or extensive staging procedures, a gynecologist should predict the presence of malignancy before surgery. In women with ovarian masses, the optimal intervention dependsupon the evidence of malignancy.ovarian cancer is portrayed as a silent killer that lacks appreciable signs and symptoms.

The ovary is composed of coelomic epithelial layer, germ celllayer, andstromallayer. Epithelial lesions accountfor 80% ofovariantumorsandrepresentover90%ofovariancarcinoma.Serous lesion accounts for 70% of epithelial tumors and mucinous20%,endometroid2%,clearcell,Brennerandundifferentiatedcarcinoma each represent <1% of epithelial lesions. Serouspapillary cystadenocarcinoma is the dominant cell type in malignanttumors. Non-epithelial malignancy accounts for 10% of all ovariantumors and varies widely with age. The most significant limiting component indiagnosticspecificityis theoverlapofUSG features.

In the early stage of malignancy, the majority of women who haveovarianmassareasymptomatic,usuallyhavevagueandnonspecific symptoms. Thepresenceofvague symptoms like dyspepsia,early satiety,loss ofappetite, urinary urgency and/orfrequency, altered bowel habits that have been therefor less than one-yearduration, or their persistence for more than 12 days per monthshouldalertthetreatingphysician.

Acarefulhistorytakingregardingthepresentingcomplaints,thenature,onset, andprogressionshould be sought. The family history of malignancy suchas breast cancer, colon cancer, ovarian cancer shouldbeelicited, as10% of ovarian tumors runs in families. These familial carcinomas areassociated with the presence of the BRCA gene. Hereditary ovarian cancers are associatedwith Hereditary Nonpolyposis Colorectal Cancer(HNPCC),Breastovariancancersyndromes.

To arrive at a clinical diagnosis, a thorough physical examination is required.If there is any suspicion of pelvic masses, imaging studiesare advocated. The Ultrasonogram is the preliminary study in womenwith adnexal masses. Ultrasonogram is more commonly usedtodifferentiatebetweenbenign andmalignantovarian tumors.

The ultrasonographicfeaturethat is suggestiveofmalignancyarethefollowing :

1. Multiloculatedlesion
2. Bilaterallesion
3. Ovarianvolumemorethan10cm^3
4. Septalthicknessmorethan2mm
5. Cystwallthicknessmorethan3mm
6. Solidcomponent/complexmass(Solid&Cystic)

7. Papillaryexcrescences
8. Increaseinvascularity
9. Doppler resistance index less than 0.40(RI < 0.40)
10. Presenceofascites
11. Presenceofintrabdominalmetastasis

The sensitivity of USG is high but the specificity is low fordiagnosisofearlyovarian malignancy.

Ferrazzi et al[8] (1997) in prospective comparison of themorphologicalscoringsystem,anewmulticenterscoredemonstrateda statistically significant diagnostic accuracy. This was due to the additionoftwonewcriteriathatallowedcorrectionfortypicaldermoidand endohemorrhagic corpora lutea.The scores were sensitive but notspecific with the best diagnostic accuracy of 72% obtained with asensitivity of 87%and specificity o f 67%. This study gave a better resultthan other previous scoring systems (Sassone et al[6] 1991, Granberg etal[5]1993,etc)inpredictingthemalignancy.

None of these scoring systems have very high accuracy. Theparameterusedindifferentultrasonographymorphologicalscoringsystems needs specificexpertiseskillsofthesonologist.

CA125isthemostcommonlyusedtumormarkerinscreening high-riskpatientswith ovarian tumors. CA 125 alsocalled cancer Antigen 125, was so namedbecauseit was the125thantibodyfoundwhiletestingvariousantibodies againstan ovariantumor. The normal level is 0-35 U/ml. CA 125 was first describedbyBastand colleaguesin1983.

CA 125isproducedinlowquantitiesbynormal ovarianepithelial cells, peritoneallliningcells, lining cells ofGIT, pancreas,breast, andlung.Thusanelevated level ofCA 125 is not veryspecific.Elevated levels of CA 125 are frequently associated with ovarianmalignancy. However, due to low sensitivity and specificity, CA-125wasnotuseful as ascreening method.

CA 125 is found to be elevated besides in ovarian malignancylike breast cancer, lung cancer, GIT Carcinomas, pancreatic cancer,Endometrial cancer, fallopian tube cancer, etc. The benign conditionsassociatedwithelevatedCA125valuesareendometriosis,fibroiduterus, Pelvic inflammatory disease, menstruation, pregnancy, ectopicpregnancy, andothernon-gynecologicalconditionslikeperitonitis,diverticulitis, inflammatory bowel disease, tuberculosis, liver disease,recent surgery, etc.
The various other tumor markers that can be used for screening ofovarian cancer are CA 19-9, CA 15-3, lipid-associatedsialic acid,osteopontin, etc.,Noneofthesetumormarkers havediagnosticpotential.

Anewapproachindiagnosingovariancarcinomaistheproteomicpatternwhichdetectstheproteins&proteinfragmentscirculating in the blood. The sensitivity of proteomic pattern is 100%and specificity is 95% with a PPVof 94%. But itsefficacyandvalidationare yettobestudiedin a largepopulation.

Genetic testing is advised in women with a family history ofepithelialovarian carcinoma.

Numerous investigational modalities are beingused and studied. None of them proved to be the best in differentiatingbenignfrommalignantovariantumors.Hencewasintroducedmultimodal screening modalities, which combine various parametersto improve the Sensitivity and Specificity of the test in predicting thepresenceofmalignancy.

In 1990, Jacob et al[1] designed a new scoring system calledthe Risk of Malignancy Index(RMI). RMI is based on the following 3parameters.
1. SerumCA125 level(U/ml).
2. Ultrasound score. The various parameters are multilocular cyst,presence of solid mass, bilateral lesions, evidence of metastasis,presenceofascites.Eachparameterisgiven1point.Theultrasoundscore (U)of 0 is given if the total point is 0,a score of1ifthetotalpoint is 1, and a score of 3 if the totalpointisbetween2-5.
3. The menopausal status (M) M=1 if premenopausal and M-3 ifpostmenopausal.

RMI was calculated using these 3 criteria. It was the product of the CA125level (absolute value in U/ml),MENO score, and USGscore.Itis expressedas,
RMI=CA125 x M x U
Using the RMI cut-off level of 200, the sensitivity is reported as85%and specificityas 97%fordiagnosingovarian cancer.

In 1993, Davis et al[9] performed a study on 124 patients to evaluate thevalidity of RMI. The study confirmed that theRMIismoreappropriateindifferentiatingbenignandmalignanttumors than the individual criteria and the results were compared withtheotherscoringsystems.Inthisstudy,theSensitivityofRMIwas 87% and Specificity was 89%. It was revealed that RMI wasa simple scoring system that could be employed in clinical practice for discriminating benign ovarian mass from the malignant lesion and providesan opportunity for appropriate selection of cases that can be referred toa tertiarycenter,whereappropriatesurgerybyexpertsurgeonsareavailable.

Tingulstad et al[2]in 1996 modified the RMI proposed by Jacob et al[1] in 1990 now called RMI 1. TheRMI2ofTingulstadetal[2]wascalculatedbasedonthesameparametersas Jacobet al[1]butthescoringvaluewasaltered.

1. CA125level(valueinU/ml)
2. menopausalscoreM(M=1ifpremenopausalbutM=4ifpostmenopausal)
3. UltrasoundscoreU (basedon5USGfeatureslikebilaterallesion, multiloculation, solid lesion, ascites, and extra ovarianmetastasis. Each parameter was given 1 point and U=1 if thepoints were 0 or 1 and U = 4 if two or more parameters werepresent).

RMIistheproductofCA125,Ultrasoundscore, andmenopausal status. The Sensitivity of RMI-2 was 71%, specificity was96%, PPV value was 89% and NPVwas 88%. They concluded that RMI-2 has better performance thanRMI-1andrecommendedthatRMI-2wasbetterthanRMI-1indifferentiatingbenignfrommalignantovarian tumors.

In 1999, Tingulstad et al[3]further modified RMI-2 which was previouslymodified from RMI-1 by altering the scoring values and it wastermed as RMI-3. The RMI-3 was the product of ultrasound score, CA125value, andMENO score,butthescoringwasdifferentfromRMI-1andRMI-2.TheCA125valuewastheabsolutevalue.Themenopausal score is like RMI-2, that is M=1 if premenopausal andM=3 if postmenopausal. The ultrasound score U is based on the samefive criteria like bilateral lesion, multiloculations, presence of solidareas, ascites, and intraabdominal metastasis. U=1 if no or one criteriaispresent and U=3 iftwo ormorecriteriaare present.

RMIwasfurther modified by Yamomotoet al[4], in 2009.They introduced new criteria in the RMI score. It was thetumor size score. According to them, RMI-4 was the product of CA 125value,USG score,MENO Score, andtumorsizescore.

RMI4 =CA125 x Ux Mx S.
Where,CA125level–theabsolutevalueinU/ml

U is the ultrasound score based on the 5 parameters- bilaterallesions,multilocularity,solidareas,ascites, andextraovariantumor. U=1ifnooroneparameterispresentandU=4if2ormoreparameteris present.

In2001,Manjunathetal[11]conductedastudythatcomparedthe ability of the Risk of Malignancy indices RMI-1, 2, and RMI-3 indifferentiating benign from the malignant ovarian tumor. This study showedthat there was no statistical difference amongthem indifferentiating benign from malignant ovarian tumors. They concludedthat the diagnostic performance of the RMI indices RMI-1, RMI-2, andRMI-3 was reliable.

Ma et al (2003) performed a study with 140 patients to evaluatetheRMIpreoperativelyinwomenwitha pelvic mass. The Sensitivity of RMI studied was 87.3%, specificity was84.4%, PPV was 82.17% and NPV was89%.Theyconcludedthattherewasnosignificant difference among RMI 1, 2, 3 statistically in differentiating benign from malignant ovarian tumor and showed that RMI is reliable in predictingmalignancy.

Ulusoy et al[14] (2007) assessed 296 patients with RMI. The cut-off valueof RMI was 200. The sensitivity was 71.7% specificity was80.5%,thePPVwas67.3%andNPV was 83.6%.

In2010,vandenAkkeretal[15]analyzed Gynecologic oncology in 548 patients to evaluate the RMI on dailybasis. They showed, with a cut-off value of 200, RMI had a Sensitivityof 81%, Specificity of 85%, PPV of 48%, and NPV of 96%.TheyconcludedthatRMIwasasimplescoring systemin diagnosing ovarian cancer during the preoperative evaluation.

RachmasariPutrietal(2010)analyzed90patientsretrospectively and calculated the RMI score. 70patientshadmalignancyand20patientshadbenigntumors.TheSensitivity of RMI in the study was 70%, specificity was 75%, PPV was 90.74% and NPV was 41.67% whenthe cut-off value of RMI was 200. They concluded that RMI is a veryusefulmethod indiagnosing malignancy.

In 2011, Milan Terzic et al analyzed the ability of the RMI scoringsystem to detect malignancy. The study involved 81 patients, out ofwhich 51 had benign tumors and 30 had malignancy. With a cut-offvalueofRMI200,thesensitivitywas83.33%,specificitywas94.12%, PPV was 89.29% and NPV was 90.57%.

The 4RiskofMalignancyIndexscoringsystem:

	Parameters	**RMI1**	**RMI2**	**RMI3**	**RMI4**
1.	CA125	U/ml	U/ml	U/ml	U/ml
2.	MenopausalStatus - Premenopausal - Postmenopausal	 1 3	 1 4	 1 3	 1 4
3.	UltrasonogramscoreIf no parameter present If1 parameter If2 ormoreparameters	 U= 0 U= 1 U= 3	 U=1 U=1 U=4	 U=1 U=1U=3	 U=1 U-1U=4
4.	Tumor size score size<7cm size>7cm	 - -	 - -	 - -	 S= 1 S= 2

Monirath Hav et al [16] (2011) studied the effectiveness of RMIin the primary evaluation of patients with adnexal masses. 151 patientswereincludedinthestudy.132patientswerediagnosedtohave benignmassand19were diagnosedtohavemalignantmass.Thestudyshowedthatthebestcut-offvalueofRMI3was238atwhichtheperformanceofRMIwasgood.Thesensitivitywas89.5%,specificity was 96.2%, the PPV was 77.3% andNPV was98.4%.

In 2011, Bouzari Z et al studied the RMI Scoring in 182 patientsto evaluate its ability to diagnose malignancy in patients with an ovarianmass. The study showed at a cut-off value of 200, sensitivity,specificity,PPV, and NPV oftheRMIwere91.3%,88%,52%, and98.5%respectively.Theyconcluded that the Sensitivity, Specificity, PPV, andNPV were highatacut-offpointof265indifferentiating benign from malignant ovarian tumors. The cut-off pointof 265 for the RMI was based on the Receiver operating characteristiccurve evaluation at which the Sensitivity was 91.3% and Specificitywas96.2%.

In 2012, Erfan Akturk[17] et al conducted a study to comparethe four risk malignancy indices RMI-1, RMI-2, RMI-3, andRMI- 4.Thestudyincluded100patientswithan ovarianmass.Theyproposed that the performance of RMI-1, RMI-2, and RMI-3 at a cut-offvalueof200andRMI-4atacut-offvalueof500hadbetterperformance and there was no statistical difference. The Sensitivity,Specificity, PPV, and NPV of RMI1, RMI-2, RMI-3, RMI-4 were obtained and there was no statisticaldifferenceandtheirdiagnosticperformancewas thesame.Theyconcluded that RMI was a simple index and any of the four RMIindices could be used in low resource units. RMI is the most usefuldiagnostic index in the proper selection of patients who require referral totertiarycenter andalsodifferentiatesbenigndiseasethatneedsconservative line of management or minimally invasive procedures, thushelping in the reduction of unnecessary surgical exploration of a patientwithbenigndiseases.Thestudyshowedthatinpreoperativeevaluation of patients with ovarian tumors, the RMI should be the testofchoiceindifferentiatingbenign frommalignancy.

Wang et al [11] (2012) studied an improved RMI on180womenwithovariantumors.HemodifiedtheRMIdeveloped by Jacob et al [18] by introducing a color doppler study and a new tumor marker (Tumor-specific growth factor). He redesigned theRMIbyincludingultrasoundsoundscore,Tumor-specificgrowthfactor levels, and color doppler flow imaging result and calculated theimproved RMI. The study concluded that improved RMI has highSensitivity,Specificity,PPV, and NPV whencomparedtoRMI.ThestudyshowedthatImproved RMI has better performance than the RMI of Jacob et al [18]in discriminating benign from the malignant ovarian tumor. He showedthat in comparison to classic Jacob's model the improved RMI wasaccurateinpredictinggermcelltumor,granulosacelltumor, andovarianmalignanciesin the

earlystage.Thuswiththe inventionofsophisticateddopplermethodswhichrequiresa highlevelofexpertiseinultrasonogrammaybeapplicablein a tertiarycenter.

In2012,HakanssonFetalconductedaprospectiveobservationalstudyinthetertiary oncology center including1159women with pelvic masses. The main objective was torecalculatetheRMI ata tertiary center and toassessthe diagnosticability of RMI with a cut-off value of 200 for preoperative diagnosis ofovarian carcinoma. The Sensitivity of the RMI was 92% and Specificitywas 82%, PPV was 62% and NPV was97%.Basedonthestudy,heconcludedthatthe RMI hashighdiagnosticperformanceindifferentiatingbenign froma malignant tumor whichenables the malignantpatients tofurtherpreoperativeinvestigationsifneeded.

A retrospective study was carried out by Kulkarni KA et al (2016), among 71 women with an adnexal mass. This study aimed at evaluating the ability of RMI-4 to predict the nature of adnexal mass and to compare it with RMI 2. They concluded that RMI 2 was marginally more sensitive however less specific than RMI 4.

In 2018, smrutishree et al, performed a study among 124 women with adnexal mass to analyze the ability of RMI-4 for discriminating benign from malignant adnexal mass and compared it with RMI-1, RMI-2, and RMI-3. It was found that RMI-4 was statistically significant as a screening agent for discriminating benign from the malignant adnexal mass. The cut-off value for RMI-4 was found to be 450 with a Sensitivity of 68.3%, Specificity of 84.4%, PPV of 80.4%.

A prospective study was conducted by amarjeet Kaur et al in 2020, in which 30 women with adnexal mass were included to determine if the RMI-4 can distinguish benign from the malignant adnexal mass. The cut-off value was 450 with a Sensitivity of 72.73% and Specificity of 89.47%, PPV of 80%, and NPV of 85%. They concluded that RMI is a reliable, simple,easy to use, and cost-effective method in differentiating benign from malignant adnexal mass.

The adnexa refers to the ovaries and fallopian tubes. The humanfemale gonads are the ovaries. The site of the location of ovaries is oneither side of the uterine cornua attached to the uterus through the ovarianligament.Thebloodvesselsandnervesreachthe ovariesviatheInfundibulopelvic ligaments which extend from the ovary to the lateralpelvicwall.Theyarealsoknownasthe suspensoryligamentof the ovary.Theovariesareattachedtothebroadligamentviathemesovarium.

The cut section of the ovary shows the outer cortex and inner medulla.The outer cortex has a specialized stroma and follicles. It is linedby cuboidal surface epithelium derived from the mesothelium of the ovary.The ovarian medulla is composed of blood vessels and the fibromuscularlayer.

The ovary is pearly white due to the presence of tunicaalbuginea.Beforemenopause,eachovarymeasuresabout3.5X2X1.5cm.In earlymenopause,thedimensionsofeach ovaryis 2X1.5 X0.5cmwhereasinlatemenopauseitmeasureabout1.5X0.75X5cm.After menopause, the ovary shrinks and is reduced in size andvolume.Thetunicaalbugeniathickens.Inearlymenopause, thevolumeis8mlwhereasinlatemenopausethevolumeislessthan2ml.

Due to the complexity in the development, embryology, andhistology, the ovary is the potential to develop a malignancy. Due to itsanatomiclocation deep in the pelvis, it is not easily accessible clinicallyforanyscreeningprocedures.

Ovarian tumors can arise from epithelial cells, germ cells,stromal cells, and connective tissue. About 80% of ovarian tumors areepithelialinorigin. Amongepithelialtumors,80% arebenignand20%aremalignant.Amongmalignantovariantumors,90%areepithelial in origin.Also, malignant ovarian neoplasms are primarytumors in 80% of cases, and 20%, are secondary from GIT,breast,and colon.

Materialsandmethods:-

Study Design:
A prospective observational study.

Study Period:
one year from date of approval from institutional ethical committee i. e from 2019 to 2021.

Study Subject:
women attending Gynecology outpatient and inpatient department diagnosed with an ovarian mass.

Study Setting:
outpatient and inpatient department at Government Maternity Hospital, Tirupati.

Sample Size:
50 women were selected for the study.

Inclusioncriteria
1. Women diagnosed with an ovarian mass.
2. Women who gaveinformed written consent to participate in the study.

Exclusioncriteria
1. Women with endometriosis, acute pelvic inflammatory disease, hydrosalpinx, uterine leiomyoma, cirrhosis of the liver as CA 125 levels will be elevated in these conditions.
2. Ovarianmassinpregnantwomenwa s excludedbecause CA 125 levels will be elevated in pregnant women and hence may give afalse-positiveresult.
3. Women with ovarian mass with other malignancies are excluded.
4. Women with previous major pelvic surgery other than hysterectomy.

Methodology:-
1. This study was conducted after the approval of the institutional ethical committee.
2. The study procedure and objectives of the study were explained to the study subjects in detail.
3. Written and informed consent was taken.
4. Demographic data and detailed history were taken from the patient.
5. Serum CA 125 and ultrasound examination were done at the time of preoperative laboratory assessment which was done within 1 week before surgery. SerumCA125wasdeterminedbyradioimmunoassay.
6. Ultrasoundexaminationwasperformedusinga3.5-MHzabdominalconvextransducer in patients with a full bladder or a 7.5-MHz vaginal probe inpatients after emptying the bladder. USG score was allocated forthefollowing features
7. Multiloculation,
8. Presenceofsolidelements,
9. Bilaterality,
10. Presenceofascites,
11. Evidenceofmetastases.

An ultrasound score (U) of 1 was given if none or one of thefeatures was found, and a score of 4 was given if two or more of thesefeatureswereshown.

Postmenopausal status was defined as “more than one year ofamenorrheaor age older than 50 years for women who had undergonehysterectomy”,theywerescoredasM=4.Allotherpatientswhodidnot meet the above criteria were defined in a premenopausal status whichscored M=1.

Size of the tumor measured. A score of 1 was given for tumors less than 7cm and a score of 2 for tumor size more than or equal to 7cm size.

USG pelvis was done for all the patients and the presence of bilateral ovarian mass, Multiloculated tumor, presence of solid areas,ascites, and extra ovarian metastasis was noted. An ultrasound score(U) of 1 was given if none or one of the features are found, and a score of 4 was given if two or more of these features were noted.

The absolute values of serum CA-125 were entered inthe formula as such.

Ultrasonographicexamination of pelvic organs was performed,menopausalstatus,levelofcancerantigen125(CA125)wereassessed, size of the tumor noted, and finally, RMI-4 was calculated for all the patients. RMI-4 wascalculatedusingtheformula:

RMI-4 SCORE = *Ultrasound score x Menopausal score x CA125level in U/ ml x Tumor size score*

Aftersurgery,histopathological(HPE)findingsofexcisedtumors were analyzed to determine the final diagnosis. Thehistopathologicaldiagnosisisconsideredthegoldstandardfordefiningtheoutcomes.

Finally, based on the standard formulas, Sensitivity, Specificity,PPV, and NPV of the RMI-4 wecalculated,asRMI-4isanindex that indicatesmalignancy regarding theactualpresenceorabsenceofmalignant ovarianmass.

Sensitivity:
Sensitivity wasdefined as the percentage of patients withmalignantovarian masshavingapositivetestresult.
Sensitivity= [(truepositive/truepositive+falsenegative)×100]

Specificity:
The Specificity was defined as the percentage with benign ovarianmassshowingnegativeresults.
Specificity=[(truenegative/ truenegative+falsepositive)×100]

Positivepredictivevalue(PPV):
The PPV was defined as the percentage ofpatientswithapositivetestresulthavingmalignantovarianmass.
PPV = [(true positive / true positive + falsepositive)×100]

Negativepredictivevalue(NPV):
The NPV is defined as the percentage ofpatientswithanegativetestresulthaving benignovarianmass.
NPV=[(truenegative/truenegative +falsenegative)×100]

Statisticalanalysis:
Data were analyzed using SPSS v21. Data were entered in an MS Excel spreadsheet.
Categorical data were expressed in frequencies and percentages.
Continuous data were expressed as mean and standard deviation.
The Chi-square test was used as a test of significance for categorical data.
ROC curve analysis was done to obtain the optimum cut-off at a given sensitivity and specificity.
A P-value less than 0.05 was considered statistically significant.
Bar charts and pie charts were made for pictorial representation of data wherever suitable.

Observation And Results:-

Table 1:-

HISTOPATHOLOGY	NO. OF PATIENTS	PERCENTAGE
BENIGN	45	90%
MALIGNANT	5	10%

The study included 50 patients with ovarian mass, out of which 45 are benign comprising 90% and 5 are malignant comprising 10%.

Table 2:-

AGE IN YEARS	BENIGN n (%)	MALIGNANT n (%)	TOTAL n(%)
< 30	13 (28.9%)	0 (0%)	13 (26%)
31-40	12 (26.7%)	0 (0%)	12 (24%)
41-50	16 (35.6%)	1(20%)	17 (34%)
51-60	3 (6.6%)	2(40%)	5 (10%)
>61	1 (2.2%)	2(40%)	3 (6%)

Malignancy was noted in 10% of the cases, 20% of which are seen in the age group of 41-50 years, 40 % in the age group of 51-60 years, 40% in the age group of more than 61 years.In this study, it is noted that the percentage of malignant masses increases as age increases.

Table 3:-

HPE	<30 YEARS	31-40 YEARS	41-50 YEARS	51-60 YEARS	>60 YEARS
BENIGN	13 (28.9%)	12 (26.7%)	16 (35.6%)	3 (6.6%)	1 (2.2%)
MALIGNANT	0 (0%)	0 (0%)	1 (20%)	2 (40%)	2 (40%)

Among 45 benign masses, 35.6% are seen in the age group of 41-50 years, 28.9 % are seen in the age group of fewer than 30 years, 26.7% are seen in the age group of 31-40 years, 6.6 % are seen in the age group of 51-60 years and only 2.2 % are seen in the age group more than 61 years.

Among 5 malignant masses, 40% of cases are seen in the age group of 51-60 years, 40% cases are seen in the age group of more than 61 years, and no cases are seen in the age group of 31-40 and less than 30 years.

Table 4:- Menstrual History.

MENSTRUAL PATTERN	BENIGN n (%)	MALIGNANT n (%)	TOTAL n (%)
REGULAR	34(97.1%)	1(2.9%)	35(70%)
IRREGULAR	3(75%)	1(25%)	4(8%)
POST MENOPAUSAL	8(72.7%)	3(27.3%)	11(22%)

In our study, among postmenopausal women, 27.3% had a malignant tumor, 2.9% of women with regular cycles, and 25% of women with irregular cycles had a malignant ovarian tumor.

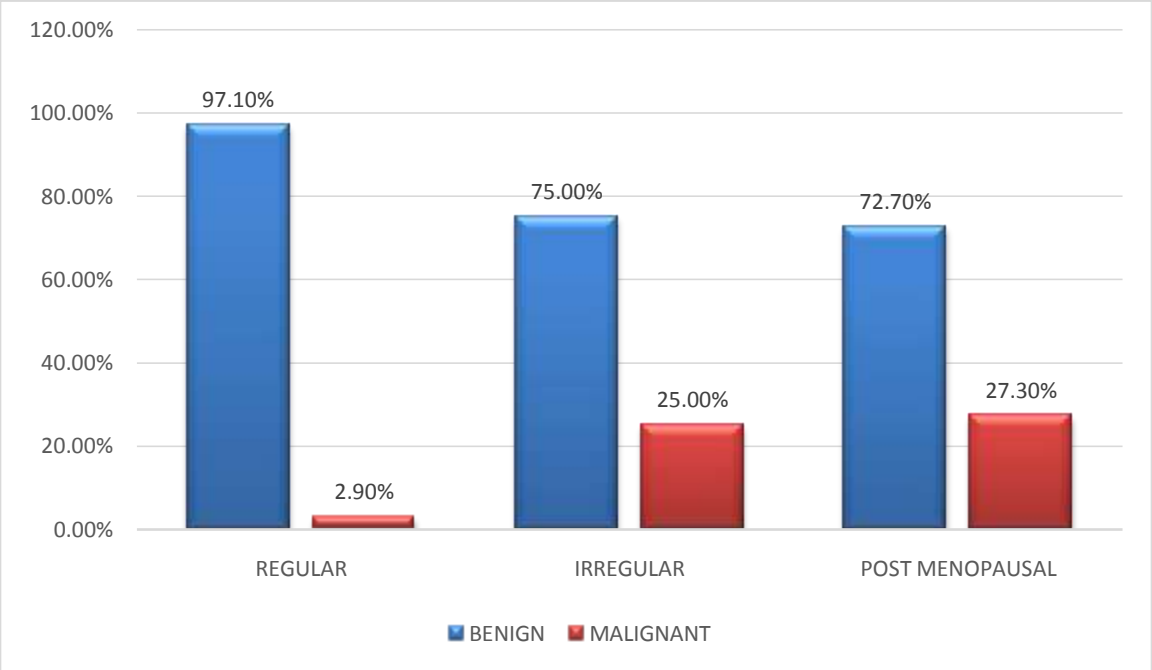


Table 5:-

HPE	REGULAR	IRREGULAR	POST MENOPAUSAL	P-value
BENIGN	75.6%	6.7%	17.8%	0.036
MALIGNANT	20%	20%	60%	

Among the women with malignant mass (n= 5), 60% belong to the postmenopausal age group, whereas 17.8% with benign tumors belong to the post-menopausal age group.

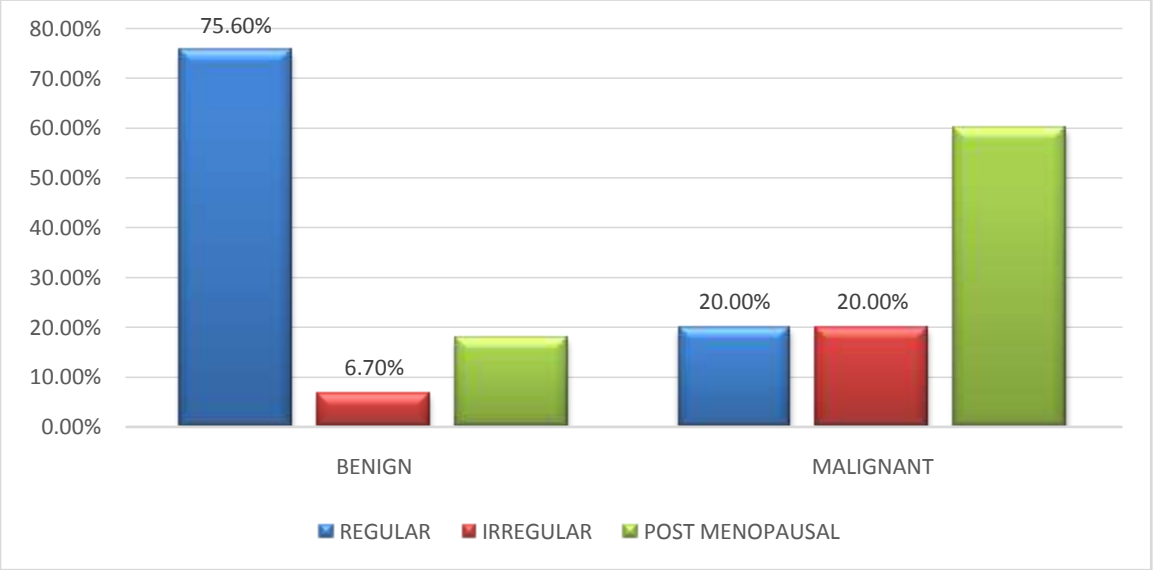


Table 6:- Pre Menopausal Age Group.

HPE	REGULAR	IRREGULAR
BENIGN	91.9%	8.1%
MALIGNANT	50%	50%

Among the 39 women with a benign tumor in the premenopausal age group, 91.9% of women have regular cycles, whereas the remaining 8.1% have irregular cycles. Among 2 women in the premenopausal age group with a malignant tumor, 50% have regular cycles and 50% have irregular cycles.

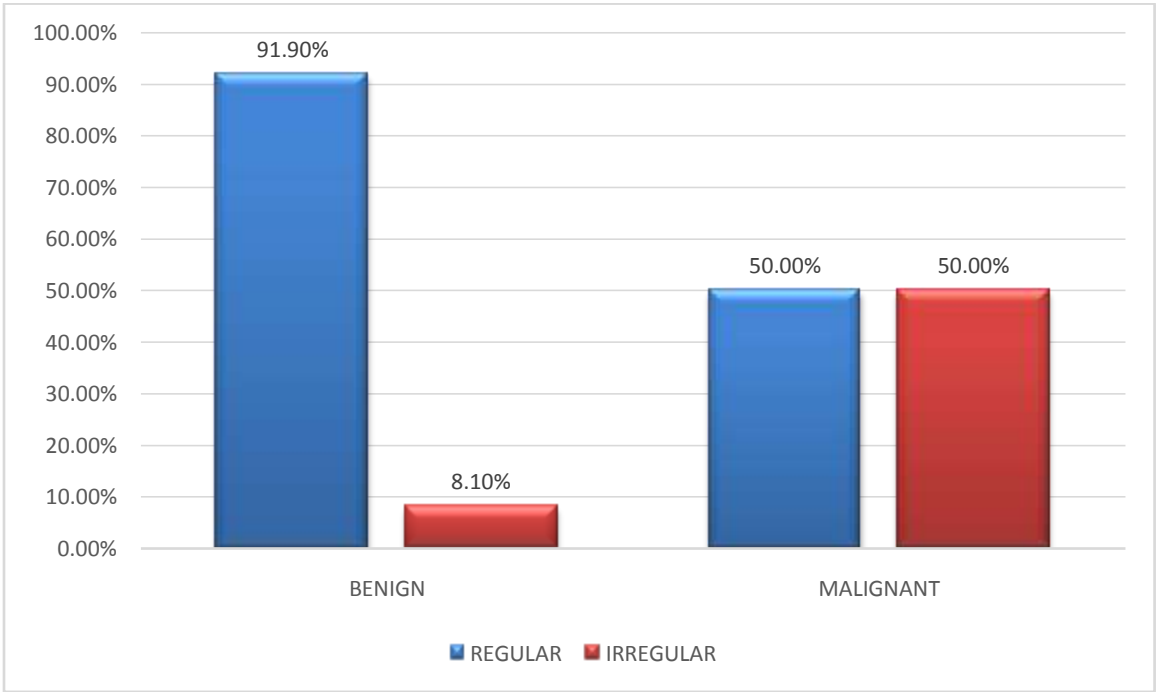


Table 7:-

HPE	PRE MENOPAUSAL	POST MENOPAUSAL	TOTAL n (%)	P value
BENIGN	37 (82.2%)	8 (17.8%)	45 (90%)	0.031

MALIGNANT	2 (40%)	3 (60%)	5 (10%)	

Among 45 patients with benign masses, 82.2% of them are premenopausal and 17.8% are postmenopausal women.Among 5 cases of malignant masses, 60 % of the women belong to the postmenopausal age group and 40% belong to the premenopausal age group.

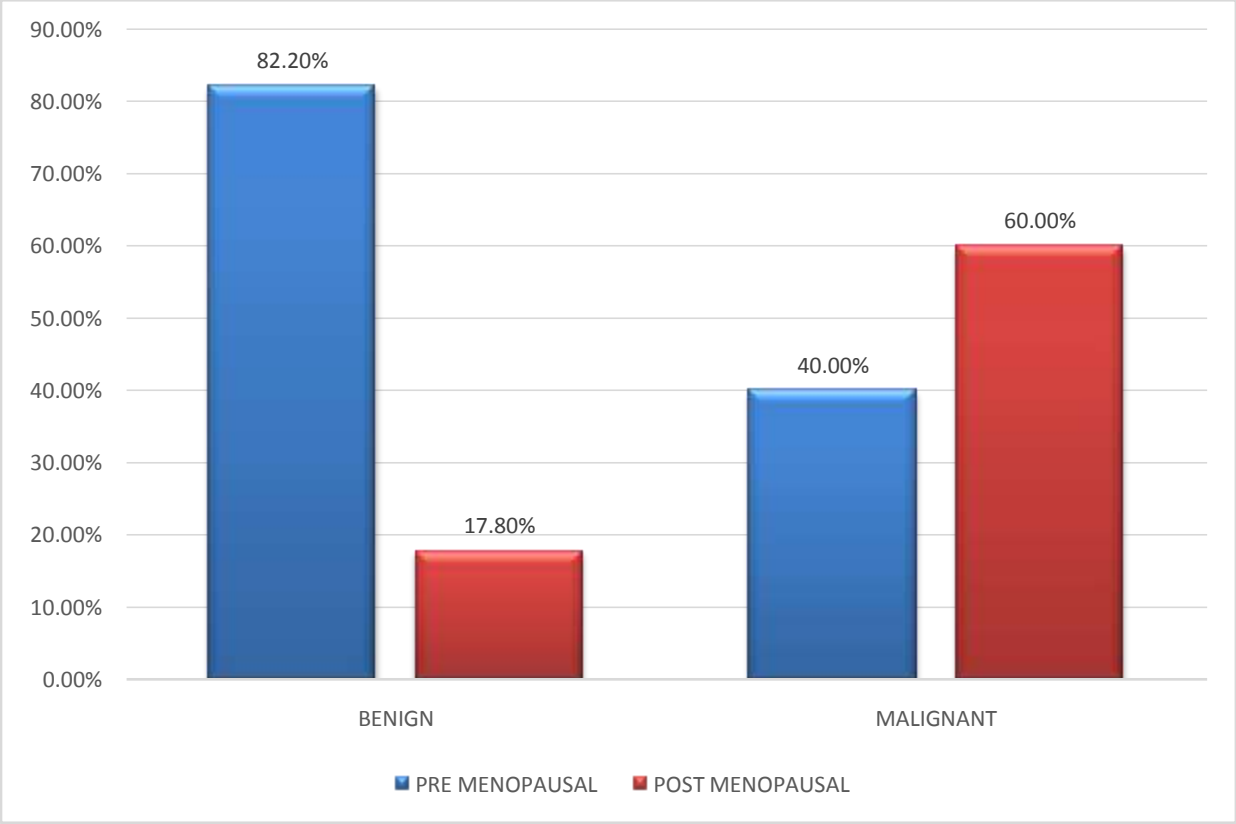


Table 8:- Parity Distribution.

PARITY INDEX	BENIGN n (%)	MALIGNANT n (%)	TOTAL n (%)	P value
NULLIPAROUS	6 (100%)	0 (0%)	6 (12%)	0.384
MULTIPAROUS	39 (88.6%)	5 (11.4%)	44 (88%)	

In our study, 6 patients are nulliparous and 44 patients are multiparous women. All the nulliparous women had benign tumors whereas 88.6% of multiparous women had benign and 11.4% of multiparous women had a malignant tumor. In this study, parity has no statistical significance and has a P-value of 0.384.

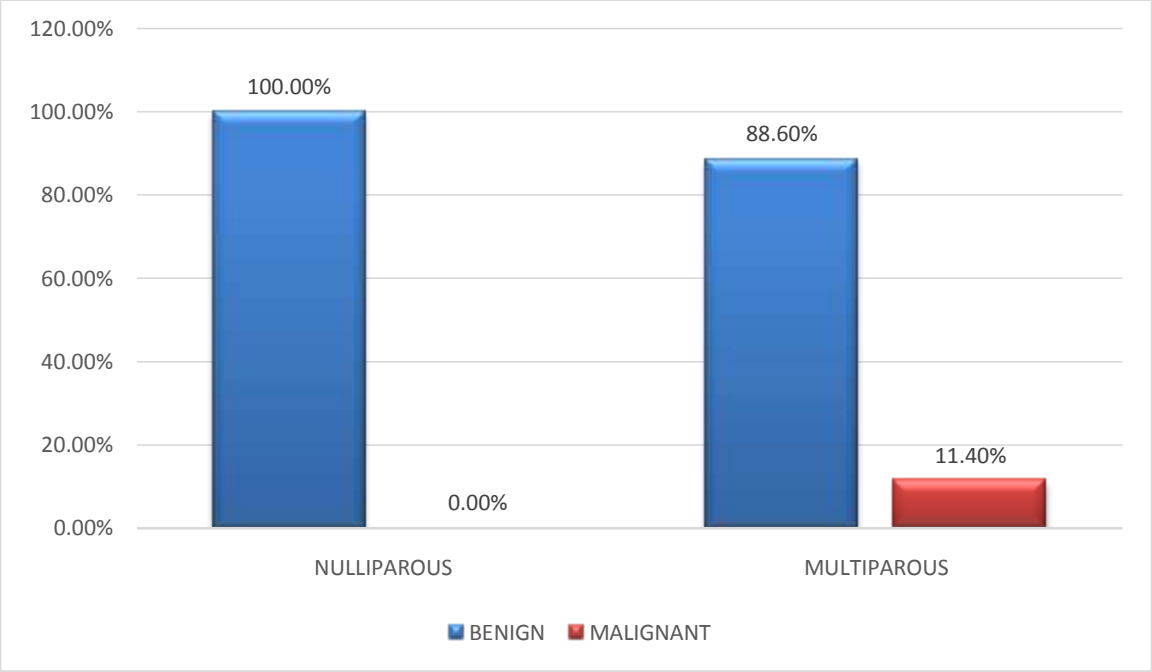


Table 9:- Parity Distribution.

HPE	NULLIPAROUS	MULTIPAROUS
BENIGN	13.3%	86.7%
MALIGNANT	0	100%

Among 45 patients with benign masses, 13.3% of patients with benign masses are nulliparous and 86.7% are multiparous women.

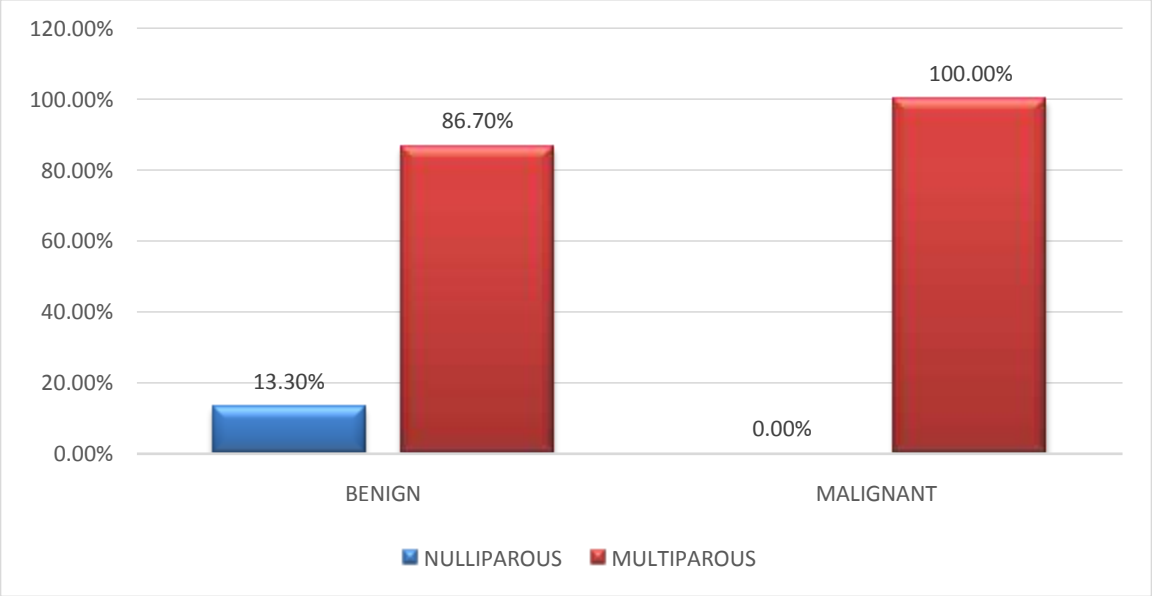


Table 10:- Tumor Size Score.

TUMOR SIZE SCORE	BENIGN n(%)	MALIGNANT n (%)	TOTAL n (%)	P-value
1	4 (100%)	0 (0%)	4 (8%)	0.487
2	41 (89.1%)	5 (10.9%)	46 (92%)	

In our study, among 46 patients with a tumor size score of 2, 89.1% of them have benign masses and 10.9% of them have malignant masses. There is no statistical significance of tumor size score with a P-value of 0.487.

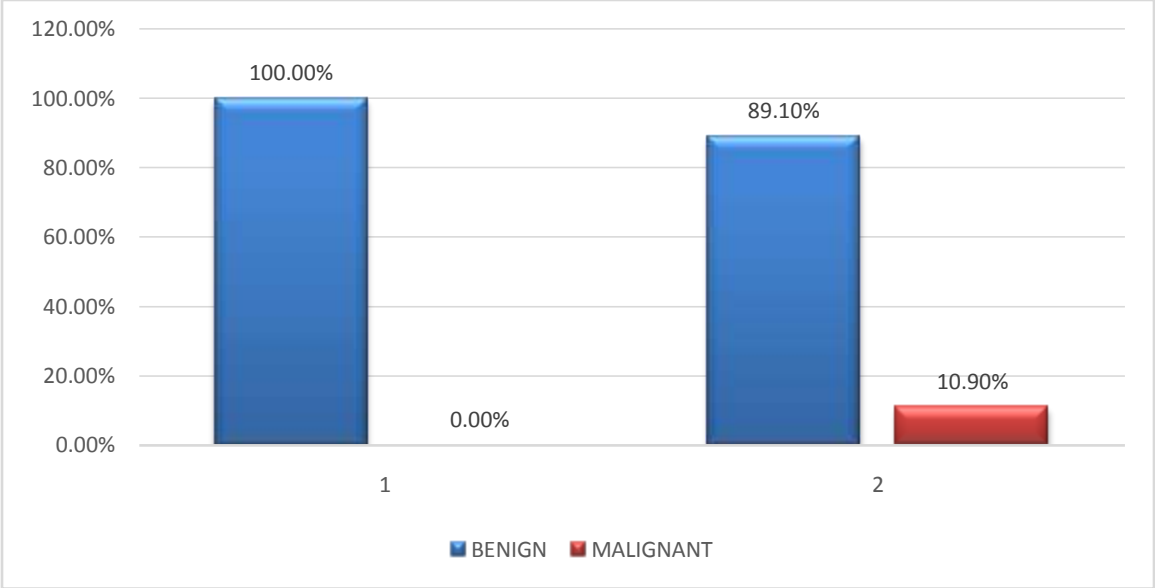


Table 11:- Ultrasound Score.

ULTRASOUND SCORE	BENIGN n(%)	MALIGNANT n (%)	TOTAL n (%)	P-value
1	34 (97.1%)	1 (2.9%)	35 (70%)	0.01
4	11 (73.3%)	4 (26.7%)	15 (30%)	

In this study, 35 patients had an ultrasound score of 1, indicating the presence of one or none of the parameters of ultrasound criteria. Among 35 patients, 34 patients (97.1%) had benign masses and 1 patient (2.9%) had malignant mass. 16 patients had an ultrasound score of 4, indicating the presence of ≥2 parameters of ultrasound criteria. Among 16 patients, 11 patients (73.3%) had benign tumors and 4 patients (26.7%) had malignant tumors. The ultrasound score was found to be statistically significant with a P-value of 0.01.

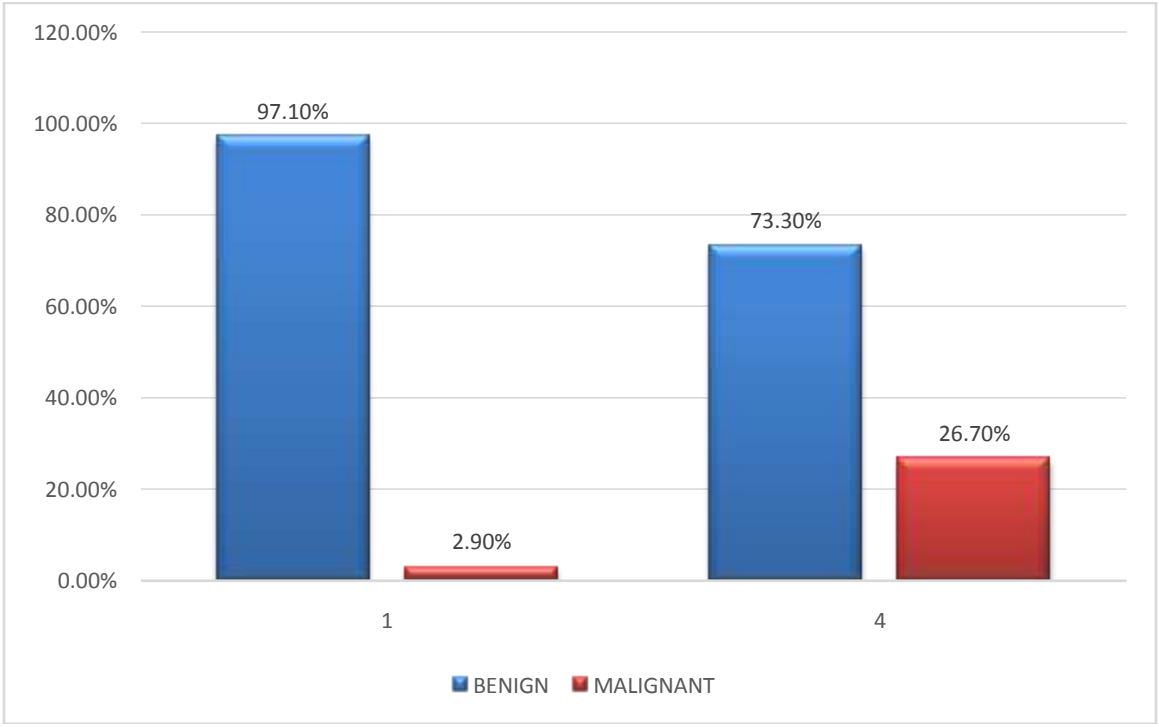


Table 12:- Ultrasound Score.

ULTRASOUND SCORE	U=1	U=4
BENIGN	34 (75.6%)	11 (24.4%)
MALIGNANT	1 (20%)	4 (80%)

SENSITIVITY – 75.56%
SPECIFICITY – 80%
POSITIVE PREDICTIVE VALUE – 97.14%
NEGATIVE PREDICTIVE VALUE – 26.67%

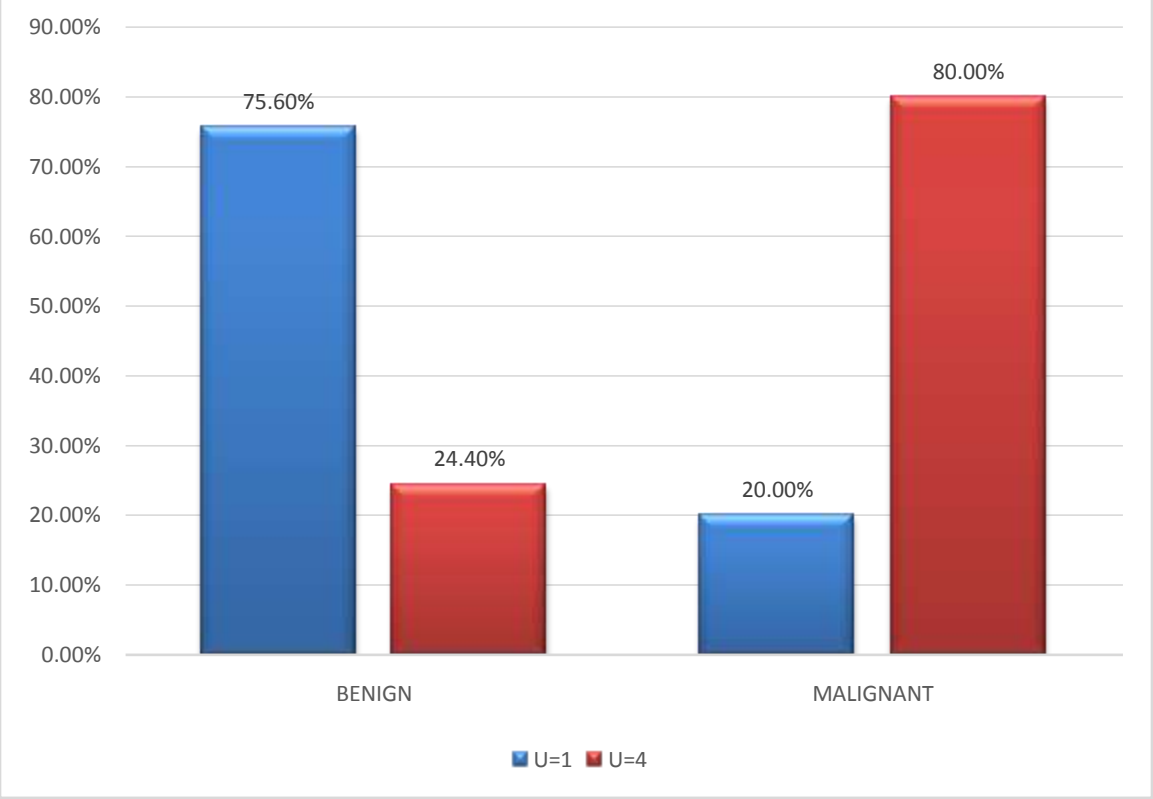


Table 13:- CA 125.

CA 125	BENIGN n (%)	MALIGNANT n (%)	TOTAL n (%)	P value
< 35 U/ml	39 (100%)	0 (0%)	39 (78%)	0.001
> 35 U/ml	6 (54.5%)	5 (45.5%)	11 (22%)	

The CA 125 value was analyzed with a cut-off value of 35U/ml. The normal range is 0-35U/ml. In this study, 39 patients had less than 35U/ml and 11 patients had more than 35U/ml. All the 39 patients with CA125 less than 35U/ml had benign masses. Among patients with CA125 more than 35U/ml, 54.5% had benign masses and 45.5% had malignant masses.

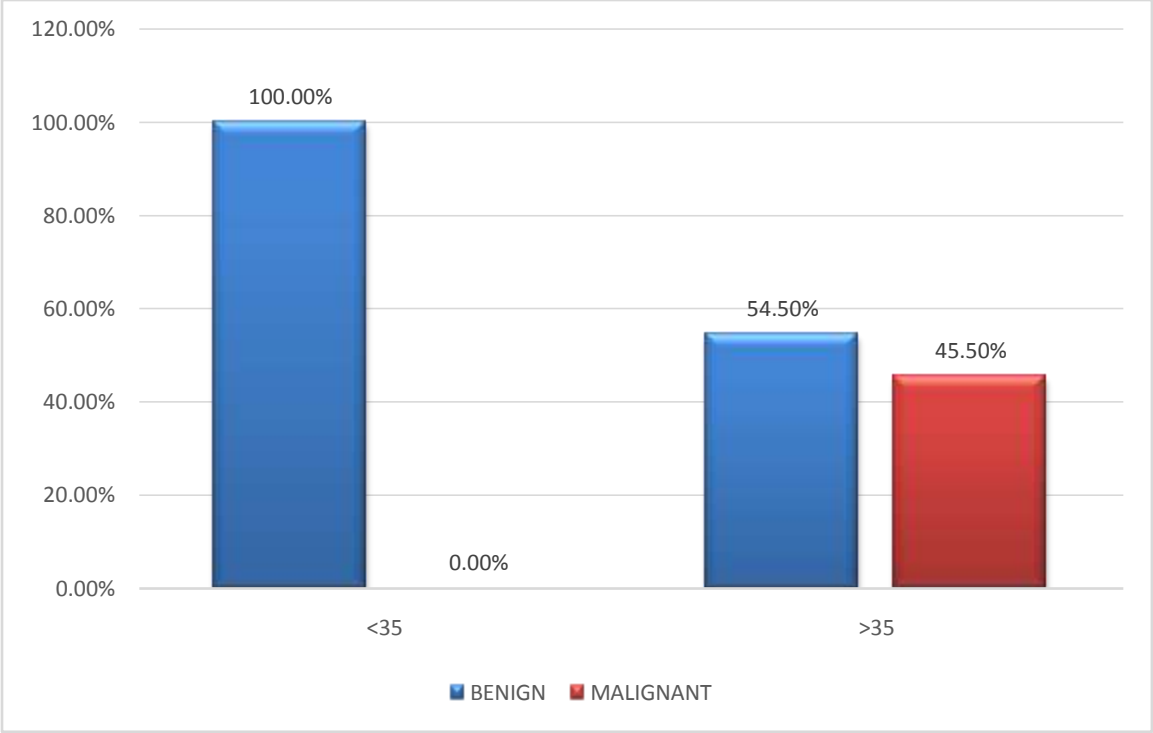


Table 14:-

HPE	CA 125	
	< 35 U/ml	> 35 U/ml
BENIGN	86.7%	13.3%
MALIGNANT	0	100%

Among the patients with a benign tumor, 86.7% had CA 125 less than 35U/ml and 13.3% had CA 125 more than 35U/ml, whereas the patients with a malignant tumor, 100% o them had CA 125 value more than 35U/ml. The Sensitivity of CA 125 in discriminating benign from the malignant tumor is 86.67%, the Specificity is 100%, the PPV was 100% and NPV was 45.45%.

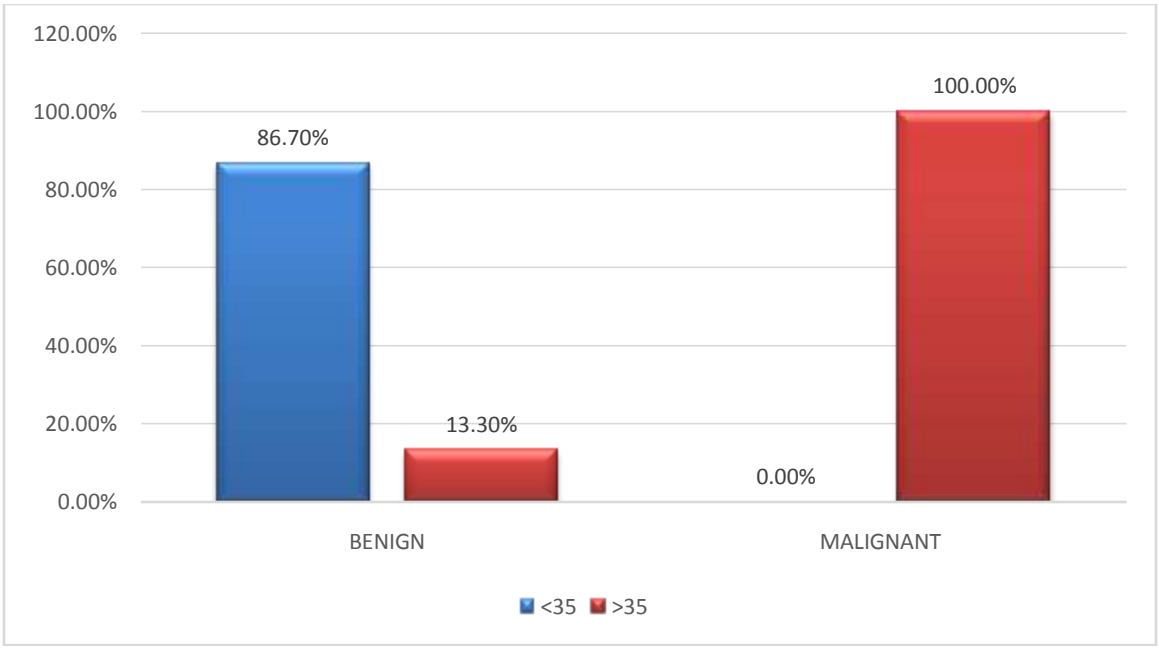
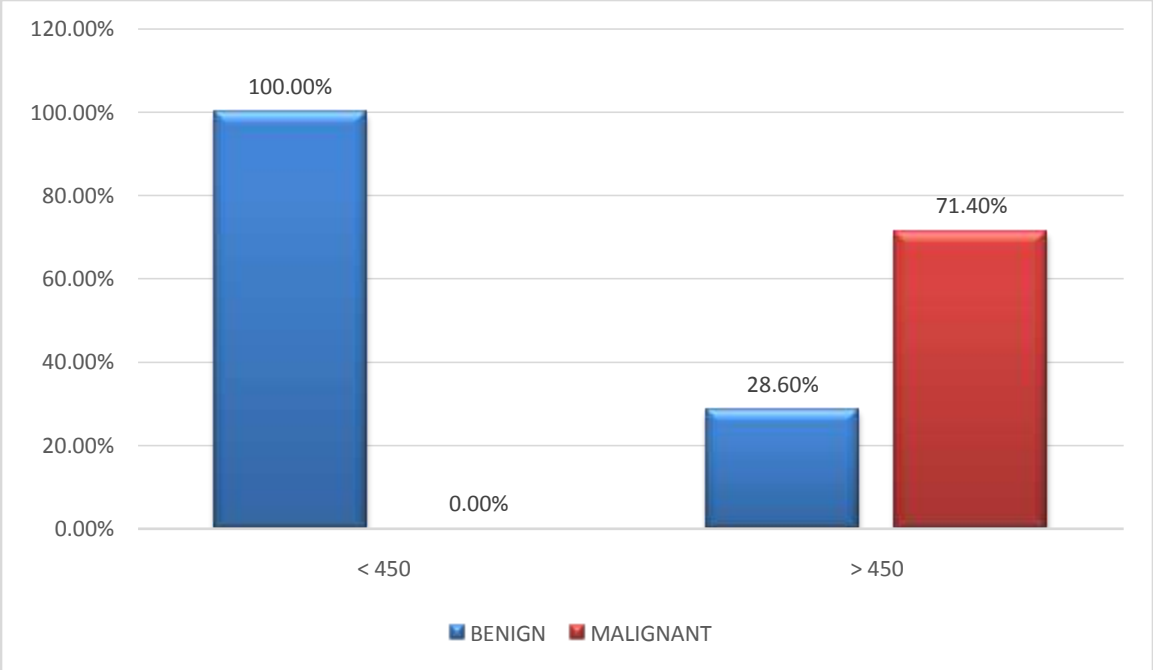


Table 15:-

RMI	BENIGN n(%)	MALIGNANT n (%)	TOTAL n (%)	P value
< 450	43 (100%)	0	43 (86%)	0.01
> 450	2 (28.6%)	5 (71.4%)	7 (14%)	

SENSITIVITY – 95.56%
SPECIFICITY – 100%
POSITIVE PREDICTIVE VALUE – 100%
NEGATIVE PREDICTIVE VALUE – 71.43%



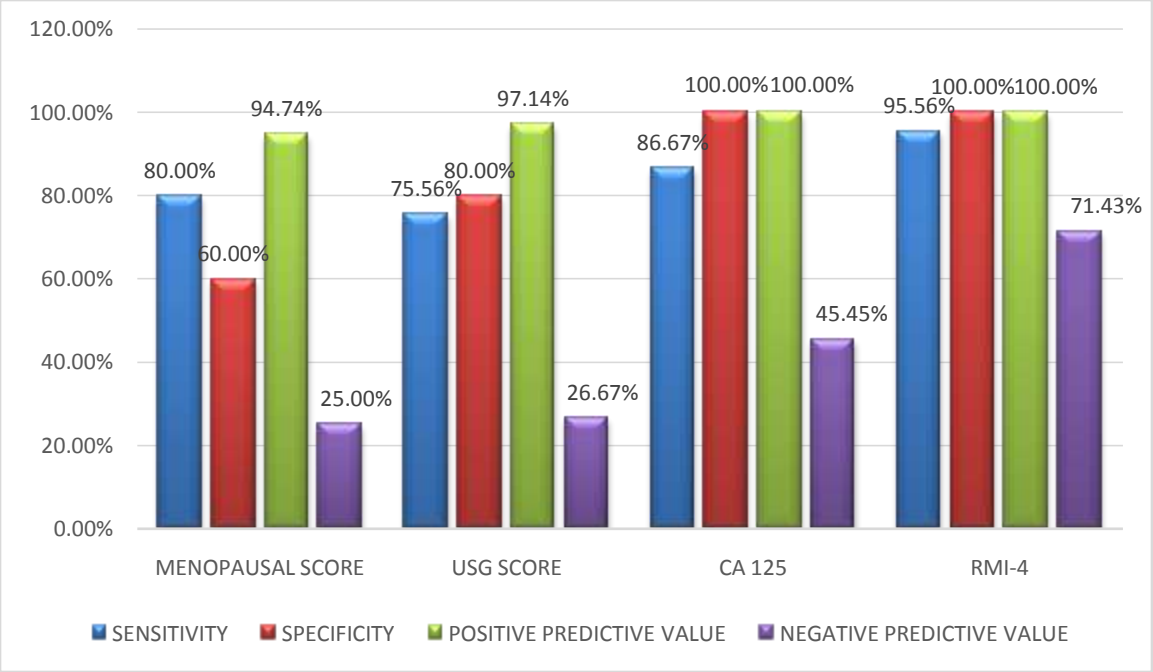
The RMI-4 was calculated using USG score, CA 125 level, MENO score, and tumor size score preoperatively. With the cut-off value of 450 , 43 patients(86%) had RMI-4 score of <450 and 7 patients(14%) had more than 450. Among 43 patients, all of them had benign masses and among 7 patients, 2 patients (28.6%) had benign masses and 5 patients (71.4%) had malignant masses.

RMI-4 score with a cut-off value of 450 was found to be statistically significant in differentiating benign from malignant masses with a P-value of 0.001.

Table 16:- Comparision Of Sensitivity, Specificity, Ppv, And Npv Of Various Parameters.

	SENSITIVITY	**SPECIFICITY**	**PPV**	**NPV**
MENO SCORE	80%	60%	94.74%	25%
USG SCORE	75.56%	80%	97.14%	26.67%
CA 125	86.67%	100%	100%	45.45%
RMI-4	95.56%	100%	100%	71.43%

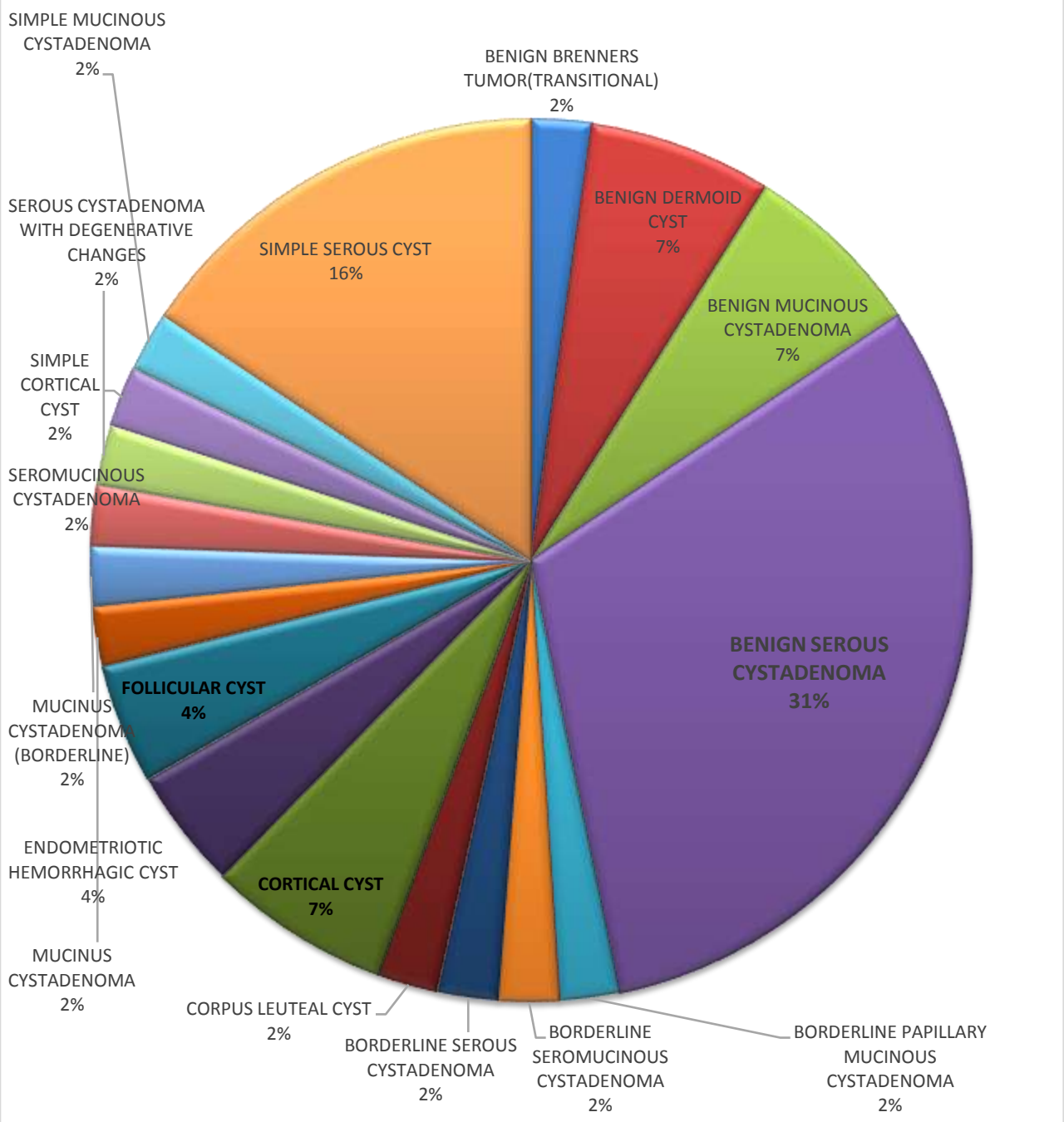
When compared to individual parameters in the RMI-4 formula, RMI-4 had better sensitivity of 95.56%, specificity of 100%, PPV of 100%, and NPV of 71.43%. CA 125 also had 100% specificity and 100% PPV with a cut-off of 35U/ml like RMI-4 with a cut-off score of 450.



Histopathology

Benign Tumors

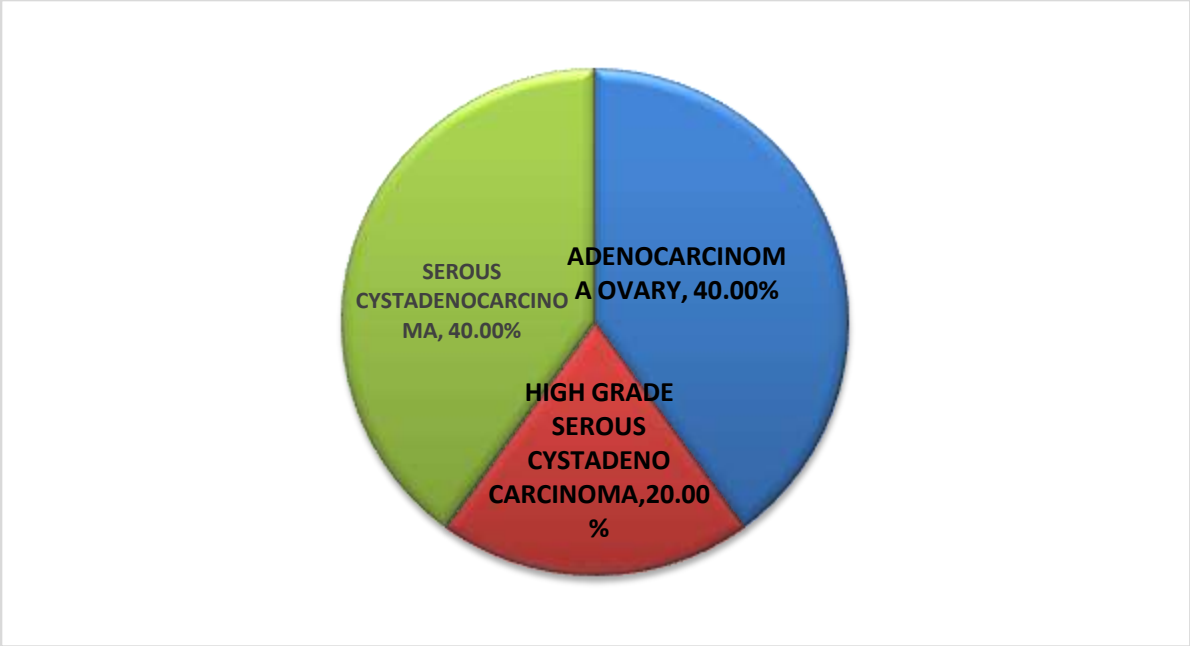
HISTOPATHOLOGY	NO. OF PATIENTS	% OF BENIGN TUMORS	% OF TOTAL
BENIGN BRENNERS TUMOR(TRANSITIONAL)	1	2.2	2.0
BENIGN DERMOID CYST	3	6.7	6.0
BENIGN MUCINOUS CYSTADENOMA	3	6.7	6.0
BENIGN SEROUS CYSTADENOMA	14	31.1	28.0
BORDERLINE PAPILLARY MUCINOUS CYSTADENOMA	1	2.2	2.0
BORDERLINE SEROMUCINOUS CYSTADENOMA	1	2.2	2.0
BORDERLINE SEROUS CYSTADENOMA	1	2.2	2.0
CORPUS LUTEAL CYST	1	2.2	2.0
CORTICAL CYST	3	6.7	6.0
ENDOMETRIOTIC HEMORRHAGIC CYST	2	4.4	4.0
FOLLICULAR CYST	2	4.4	4.0
MUCINOUS CYSTADENOMA	1	2.2	2.0
MUCINOUS CYSTADENOMA (BORDERLINE)	1	2.2	2.0
SEROMUCINOUS CYSTADENOMA	1	2.2	2.0
SEROUS CYSTADENOMA WITH DEGENERATIVE CHANGES	1	2.2	2.0
SIMPLE CORTICAL CYST	1	2.2	2.0
SIMPLE MUCINOUS CYSTADENOMA	1	2.2	2.0
SIMPLE SEROUS CYST	7	15.6	14.0



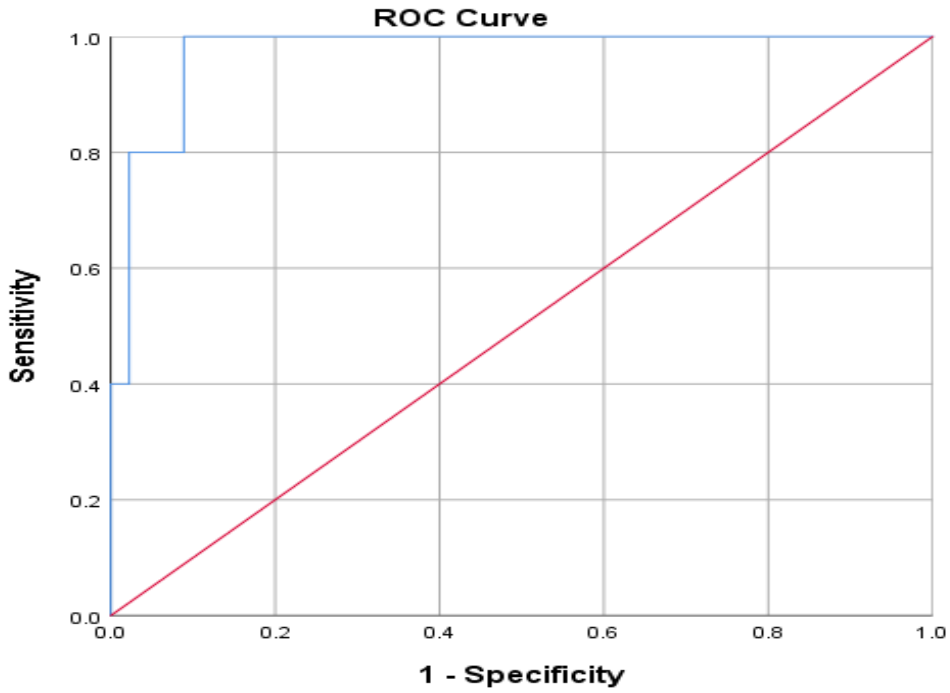
Malignant TUMORS

HISTOPATHOLOGY	NO. OF PATIENTS	% OF MALIGNANT	% OF TOTAL
ADENOCARCINOMA OVARY	2	40.0 %	4.0%
HIGH-GRADE SEROUS CYSTADENOCARCINOMA	1	20.0%	2.0%
SEROUS CYSTADENOCARCINOMA	2	40.0%	4.0%

In our study, serouscystadeno carcinoma was the most common malignant tumor comprising 60% of the malignant tumors in which 20% were high grade. 40% of the malignant tumors were Adenocarcinoma.

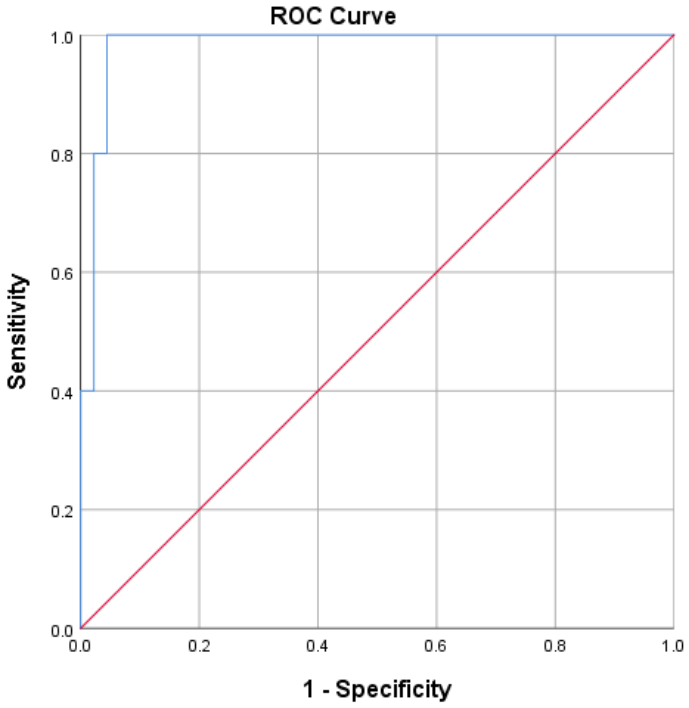


Receiver Operating Characteristic Curves



Area Under the Curve				
Test Result Variable(s): CA-125 VALUE(U/ML)				
Area	Std. Error	P-VALUE	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.973	.022	.001	.929	1.001

CUT OFF: 67.74
SENSITIVITY: 100%
SPECIFICITY: 91.1%



Area Under the Curve				
Test Result Variable(s): RMI				
Area	Std. Error	P-VALUE	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.982	.017	.001	.949	1.001

CUT OFF: 447.12
SENSITIVITY: 100%
SPECIFICITY: 95.6%

Discussion:-

This study was aimed at the use of RMI-4 in differentiating benign from the malignant adnexal mass. Sensitivity, Specificity, PPV, NPV of RMI-4 in differentiating benign from malignant tumors were calculated.

In this study, 50 patients having adnexal mass were divided into five age groups. 28.9% of benign masses were noted in less than 30 years of age. 26.7% and 35.6% benign masses were noted in the age group of 31-40 and 41-50 years of age respectively. 6.6% and 2.2% of benign masses were noted in 51-60 and more than 60 years respectively. 40% o the malignant masses were noted in the age group more than 61 years, 40% of the malignant masses were noted in the age group 51-60 years. The mean age of malignant masses was 57.8 +/- 9.28 and the mean age at which benign masses were noted was 38.36+/-11.017. This shows there is more incidence of malignant masses as age increase. There was a statistically significant correlation noted between age and the occurrence of benign and malignant masses, with a P-value of 0.001.
Various case-control studies have shown that pregnancy reduces the risk of ovarian cancer. One pregnancy reduces the risk of ovarian cancer by as much as one-third and with subsequent pregnancies, the risk lowers further. In this study, parity was not statistically significant in determining benign and malignant masses with a P-value of 0.384.

In our study, 60% of the patients with malignant ovarian mass were postmenopausal when compared to premenopausal women 40%. Hence, malignant ovarian masses are most common in postmenopausal women. The sensitivity of the menopausal score in diagnosing malignancy was 80% and specificity was 60%. The PPV was 94.74%, NPVwas 25%, and found that statistically significant with a P-value of 0.031. In a study conducted by Singhal S et al[5] (2018), they found that 40% with malignant tumors were postmenopausal as compared to 15.6% with benign ovarian mass and it was statistically significant with a P-value of 0.0006.

Dora et al[3] observed that among the postmenopausal patients,81.6% had malignant masses compared to premenopausal women.

Arun-Muthuvel V et[4] al, observed that 61% of the ovarian tumors in postmenopausal women were malignant which is similar to this study.

This study found that the size of the tumor individually has no statistical significance in discriminating benign from the malignant tumor with a P-value of 0.487 as found in the study conducted by Smrutishree Sahoo et al in 2018 with a P-value o 0.40. The adnexal mass of size more than 8cm and more than 5cm in pre and post-menopausal women respectively should be considered for intervention [1].

In this study, ultrasound score had a sensitivity of 75.56%, specificity of 80%, PPV of 97.14%, and NPVof 26.67%. Individually, the ultrasound score was statistically significant with a P-value of 0.01.

In a study conducted by Kaur A et al[6] (2020), the sensitivity of the USG Score was 90.91%, specificity was 52.63%, PPV was 52.63% and NPV value was 90.91% with a P-value of 0.01.

Rachmasari putrid et al study showed that CA 125 level at a cut-off value of 35U/ml had a sensitivity of 81.43% and specificity of 60%, PPV of 87.69%, and NPV of 48%.

In our study, CA 125 had a Sensitivity of 86.67%, Specificity of 100%, PPV of 100%, and NPV of 45.45% at a cut-off of 35 U/ml. CA125 at a cut-off of 67.74 U/ml,Sensitivity was 100%, and Specificity of 91.1%. the mean of CA125 at which malignancy was noted was 2091.7 ± 3026 and the Mean of benign masses was 35.2 ± 69.64.
With a cut-off value of CA125 -35 U/ml.
True positive – 39
True negative - 5
False-positive - 0
False-negative – 6
Among the – false-negative cases
Among the false positive cases

When comparing individual parameters, CA125 had better Sensitivity and Specificity than ultrasound score, tumor size score, and MENO score which was similar to the study conducted by Shekar NC et al[2] in 2019 with 80% Sensitivity and 76.9% Specificity.

RMI-4 was calculated for every patient enrolled in the study (n=50). Out of 50 patients with the RMI-4 cut-off value of 450,
True positive - 43
True negative -5
False-positive - 0
False-negative – 2

Among false negatives, Benign mucinous cystadenoma and Benign Brenners tumor were noted.

No patient with RMI-4 less than 450 had malignancy, constituting false negative
The mean RMI was 29978.36 with SD 37844.17 in malignant masses and benign masses mean RMI -4 was 477.90 with SD 2171. This was statistically significant with a P-value of 0.001.

Limitations Of The Study

1. The size of the sample is small.
2. CA125 is more significant in postmenopausal women compared to premenopausal women as it can be raised in various benign inflammatory conditions. In this study, a cut-off value of CA125 was taken as 35U/ml in both pre and postmenopausal women. CA125 more than 35 U/ml is significant in postmenopausal women whereas morethan 200 U/ml in premenopausal women.
3. RMI-4 uses tumor size with a cut-off of 7cm both in pre and postmenopausal women. Adnexal mass of >8cm and >5cm in pre and postmenopausal women respectively should be considered for intervention [1].

Summary

1. 50 women with ovarian mass were selected for the study.
2. Patients with endometriosis,fibroiduterus, Pelvic inflammatory disease, menstruation, pregnancy, ectopicpregnancy, andothernon-gynecologicalconditionslikeperitonitis,diverticulitis, inflammatory bowel disease, tuberculosis, liver disease,recent surgery, are excluded.
3. General and gynecological examinations were done for all cases.
4. Ultrasound pelvis was done for all the patients and the presence of bilateral ovarian mass, Multiloculated tumor, presence of solid areas,ascites, and extra ovarian metastasis was noted. An ultrasound score(U) of 1 was given if none or one of the features are found, and a score of 4 was given if two or more of these features were noted.
5. Size of the tumor measured. A score of 1 was given for a tumor less than 7 cm and a score of 2 for a tumor size more than or equal to 7 cm size.
6. Postmenopausal status was defined as more than one year ofamenorrheaor age older than 50 years for women who had undergonehysterectomy;theywerescoredasM=4.Allotherpatientswhodidnot meet these criteria were defined in a premenopausal status whichscored M=1.
7. The Risk of Malignancy Index (RMI-4) was calculated by using the formula
8. RMI-4 = U x M x S x CA 125
9. Laparotomy was done for all cases and the specimen was sent for histopathological examination which is the gold standard.
10. 90% of the tumors were benign and 10% were malignant.
11. Prediction of malignancy by CA 125, ultrasound, and RMI-4 was analyzed.
12. The optimal cut-off value of RMI-4 was 450 with a sensitivity of 95.56%, specificity of 100%, PPV of 100%, and NPV of 71.43%.
13. Though the Specificity and PPV of CA125 were high, Sensitivity was less (86.67%).
14. This study showed that RMI-4 had better performance than CA 125, USG score, and menopausal score in predicting malignancy.

Conclusion:-

1. RMI-4 is a multimodal approach that is simple and easily applicable in the preoperative evaluation of a patient with an ovarian mass.
2. Risk of Malignancy Index -4 (RMI-4) is a reliable method in discriminating benign and malignant ovarian mass preoperatively.
3. Risk of Malignancy Index -4 (RMI-4) is a better scoring index in differentiating benign and malignant ovarian mass when compared to individual tests of Ultrasonogram or CA125 level.
4. The optimal cut-off point of Risk of Malignancy Index -4 (RMI-4) at which benign and malignant tumors can be discriminated was 450 in the present study.
5. RMI-4 is the most useful scoring system in the proper selection of patient
6. Since the specificity of Risk of Malignancy Index -4 (RMI-4) was high, there is a potential role for this index in the selection of cases for conservative management or minimally invasive surgery in case of benign ovarian masses.