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Original Research Paper

Radio-Diagnosis

"UTILITY OF IOTA ADNEX MODEL IN PRE-OPERATIVE EVALUATION OF ADNEXAL MASSES WITH HPE CO-RELATION IN FEMALES BETWEEN 30-70 YEARS IN TERTIARY CARE CENTRE OF CENTRAL INDIA"

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ABSTRACT

1. Objectives:

- To prove that there is a role of IOTA ADNEX model in preoperative evaluation of adnexal masses.

2. Conclusion And Results:

- In our study, out of 65 patients, most of the patients were ≤50 years of age. Age was statistically significant with HPE (p-0.032).
- We found that, most of the patients had family history in Malignant group compared to Benign group but this was not statistically significant (p-0.951).
- Our study showed that, a greater number of patients had more than 10 locules in Malignant group compared to Benign group though it was not statistically significant (p-0.87).
- Higher number of patients had Ascites in Malignant group compared to Benign group which was statistically significant (p<0.001).
- More number of patients had Post Acoustic Shadowing in Malignant group compared to Benign group which was statistically significant (p<0.001).
- It was found that, the mean CA 125 U/mL was higher in Malignant group compared to Benign group it was statistically significant (p<0.001).
- The mean Lesion Diameter (mm) was more in Malignant group compared to Benign group but this was not statistically significant (p-0.701).
- We showed that, the mean Solid Component Size (mm) was more in Malignant group compared to Benign group which was statistically significant (p<0.001).
- The mean number of Papillary Projections was more in Malignant group compared to Benign group which was statistically significant (p-0.005).
- We observed that, majority of lesions which were categorized as malignant by IOTA ADNEX model turned out to be malignant and benign lesions turned out to be benign on HPE, it was statistically significant (p-0.0001).

3. Inference:

IOTA ADNEX MODEL proved to be a useful tool in early detection of adnexal lesions and differentiating them into beningn and malignant groups. The discriminating performance of ovarian tumors with the IOTA-ADNEX model has been better than other existing models. In 2014, ADNEX model was developed. The ADNEX model helps in differentiation of benign from malignant by using 9 predictors, 3 of them are clinical (age, CA 125 and type of centre) and rest 6 are sonographic variables (maximal diameter of lesion, proportion of solid tissue, more than 10 cyst locules, no. of papillary projections, acoustic shadow and ascites. This study aimed to test reliability of these risks prediction models to improve the performance of pelvic ultrasound and discriminate between benign and malignant lesions. Association of results of IOTA ADNEX model with HPE was statistically significant (p<0.0001).

KEYWORDS : IOTA ADNEX, HPE, USG

INTRODUCTION:

Ovarian cancer has become the most common cause of morbidity and mortality in middle aged women. Nearly all benign and malignant ovarian tumors originate from one of three cell types: epithelial cells, stromal cells, and germ cells. In developed countries, more than 90% of malignant ovarian tumors are epithelial in origin, 5%–6% of tumors constitute sex cord-stromal tumors (e.g., granulosa cell tumors, thecomas, etc.) and 2%–3% are germ cell tumors (e.g., teratomas, dysgerminomas, etc). Gynaecologic USG is useful tool for identifying the presence of ovarian mass, differentiating between benign and malignant tumors and determining the treatment plan of ovarian tumor. There are two important reasons to use USG in differentiating ovarian tumors. [1]. It helps clinicians to decide the plan of treatment either observation or surgery.[2]Ovarian tumor is not so common among gynaecologic tumors, but it is a fatal disease with high recurrence rate. Most patients with ovarian tumors are diagnosed at an advanced stage. The analysis by period showed an increasing trend in incidence rate of ovarian cancer in most registries with a mean annual % increase in ASR ranging from 0.7 – 2.4 %. In 2014, ADNEX model was developed. The ADNEX model helps in differentiation of benign from malignant by using 9 predictors, 3 of them are clinical (age, CA 125 and type of centre) and rest 6 are sonographic variables (maximal diameter of lesion, proportion of solid tissue, more than 10 cyst locules, number of papillary projections, acoustic shadow and ascites. This study aimed to test reliability of these risks prediction models to improve the performance of pelvic ultrasound and discriminate between benign and malignant lesions.

Several scoring models, such as the risk of malignancy index (RMI) and the risk of ovarian malignancy algorithm (ROMA), have been developed for the differentiation of adnexal masses. Since 2005, the international ovarian tumor analysis (IOTA) group has presented other risk predictive models with logistic regression (LR1, LR2) and sonographic characteristics (simple rules). The IOTA group demonstrated that these predictive models have better diagnostic performance than pre-existing systems. In 2014, a new model with better performance, the assessment of different neoplasias in the

adnexa (ADNEX) model, was developed in this group. This model uses three clinical features and six US features to predict the malignancy risk of adnexal masses. Through various external validation studies, the discriminating performance of ovarian tumors with the IOTA-ADNEX model has been better than other existing models [5]. Our hypothesis is that the IOTA-ADNEX model is not different from the subjective analysis of experienced experts in differentiating benign and malignant ovary disease

MATERIALS AND METHODS:

Inculsion Criteria:

All females between 30-70 years, who complains of menstrual irregularities, lower abdominal fullness and PV bleeding.

Exclusion Criteria:

1. Pre-pubertal females.
2. Post-operative cases
3. Females with PCOS
4. Patient not willing to participate in study
5. Pregnant females

Adnex Model:

CLINICAL PARAMETERS

1. AGE
2. CA125 levels
3. Type of centre (oncology or other centre)

Sonographic Parameters

1. Maximal diameter of the lesion
2. Proportion of solid component
3. More than 10 cyst locules
4. Number of papillary projections.
5. Ascites
6. Acoustic shadow

WRITTEN INFORMED CONSENT was obtained from the patients.

Source Of Data:

Cases from obstetrics and gynaecology department of tertiary care centre.

Method Of Collection Of Data:

Data was collected from all the females coming to radiology department with complaints of pain and mass per abdomen or per vaginal bleeding.

Place Of Study: GMCH Nagpur

Duration Of Study: 2 YEARS

Sample Size: 65

Source Of Cases: OBSTETRICS AND GYNAECOLOGY DEPT

Type Of Study- ANALYTICAL STUDY

USG Imaging Protocols

Pt was subjected to US after clinical evaluation either transabdominal or else transvaginal.

Equipments: PHILIPS GE LOGIQ S8
Transducer for transvaginal imaging: iC5-9-D (3.3-8.6 MHz)
Transducer for transabdominal imaging: C1-5-D (2-5 MHz)

Imaging Criteria:

1. Maximal diameter of the lesion
2. Proportion of solid component
3. More than 10 cyst locules
4. Ascites
5. Number of papillary projections
6. Acoustic shadow

DISCUSSION:

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version 5. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test (□2 test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate.

P-value ≤ 0.05 was considered for statistically significant.

Table: Association between Age: HPE

Age (Years)	HPE		Total
	Malignant	Benign	
<50	14	21	35
>=50	20	10	30
Total	34	31	65

Chi-square value: 4.6046; **p-value:** 0.032
In Malignant group, 14 patients were ≤50 age in years and 20 patients were ≥50 age in years.

In Benign group, 21 patients were ≤50 age in years and 10 patients were ≥50 age in years.

Association of Age in Years with HPE was statistically significant (p=0.032).

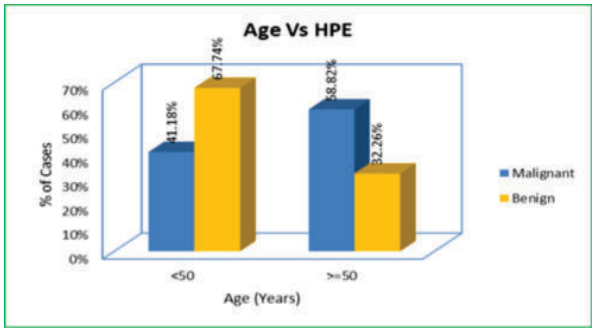


Table: Association between Family History: HPE

Family History	HPE		Total
	Malignant	Benign	
Yes	9	8	17
No	25	23	48
Total	34	31	65

Chi-square value: 0.0037; **p-value:** 0.951

In Malignant group, 9 patients had family history.
In Benign group, 8 patients had family history.

Association of Family History with HPE was not statistically significant (p=0.951).

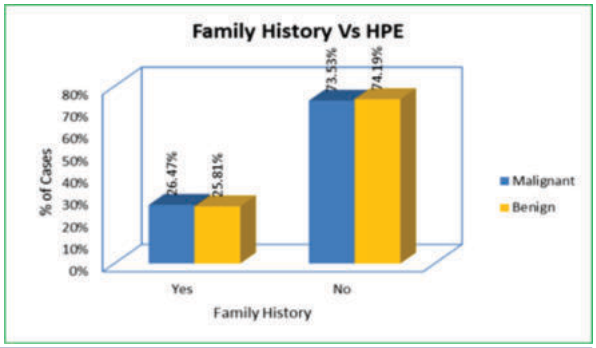


Table: Association between More than 10 Locules : HPE

More than 10 Locules	HPE		Total
	Malignant	Benign	
Yes	6	5	11
No	28	26	54
Total	34	31	65

Chi-square value: 0.0265; **p-value:** 0.87

In Malignant group, 6 patients had more than 10 locules.
In Benign group, 5 patients had more than 10 locules.

Association of More than 10 Locules with HPE was not statistically significant (p=0.87).

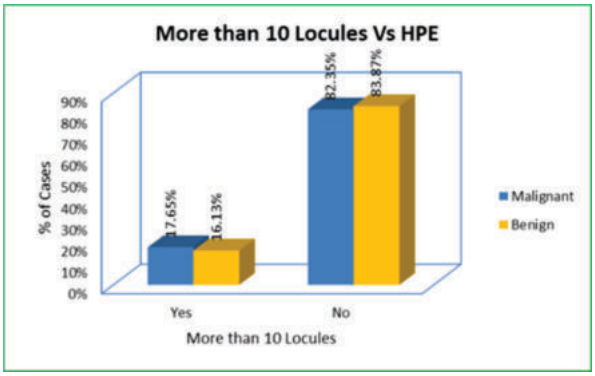


Table: Association between Ascites: HPE

Ascites	HPE		Total
	Malignant	Benign	
Yes	28	6	34
No	6	25	31
Total	34	31	65

Chi-square value: 25.7969; **p-value:** <0.001

In Malignant group, 28 patients had Ascites.
In Benign group, 5 patients had Ascites.

Association of **Ascites** with HPE was statistically significant (p<0.001).

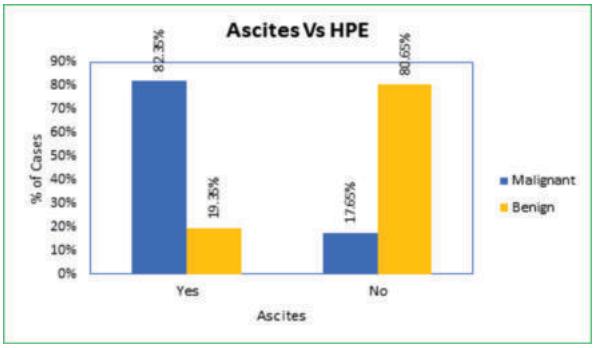


Table: Association between Post Acoustic Shadowing: HPE

Post Acoustic Shadowing	HPE		Total
	Malignant	Benign	
Yes	25	5	30
No	9	26	35
Total	34	31	65

Chi-square value: 21.4978; **p-value:** <0.001

In Malignant group, 25 patients had Post Acoustic Shadowing., In Benign group, 5 patients had Post Acoustic Shadowing.

Association of Post Acoustic Shadowing with HPE was statistically significant (p=<0.001).

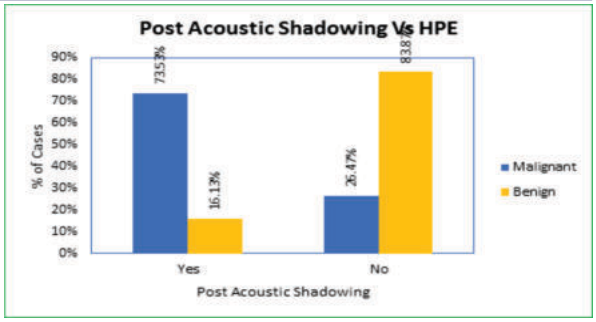


Table: Distribution of mean CA 125 U/mL with HPE

HPE	CA 125 U/mL		P Value (t-test)
	Mean	Std. Deviation	
Malignant	1211.06	1117.195	<0.001
Benign	150.35	265.637	

Chi-square value: 35.5699; **p-value:** <0.001

In Malignant, the mean CA 125 U/mL (mean± SD.) of patients was 1211.06±1117.195.

In Benign, the mean CA 125 U/mL (mean± SD.) of patients was 150.35±265.637.

Distribution of mean CA 125 U/mL with HPE was statistically significant (p=<0.001).

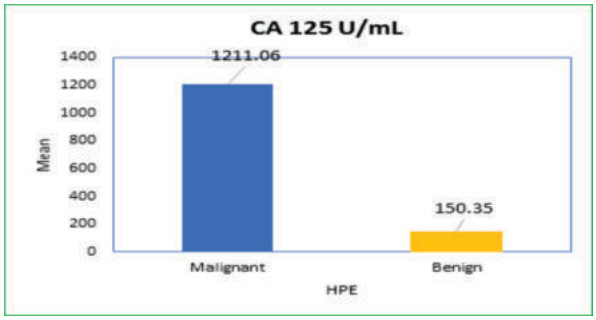


Table: Distribution of mean Lesion Diameter (mm) with HPE

HPE	Lesion Diameter (mm)		P Value (t-test)
	Mean	Std. Deviation	
Malignant	121.18	6.860	0.701
Benign	120.65	3.592	

Chi-square value: 0.9660; **p-value:** 0.701

In Malignant, the mean Lesion Diameter (mm) (mean± SD) of patients was 121.18±6.860.

In Benign, the mean Lesion Diameter (mm) (mean± SD) of patients was 120.65±3.592.

Distribution of mean Lesion Diameter (mm) with HPE was not statistically significant (p=0.701).

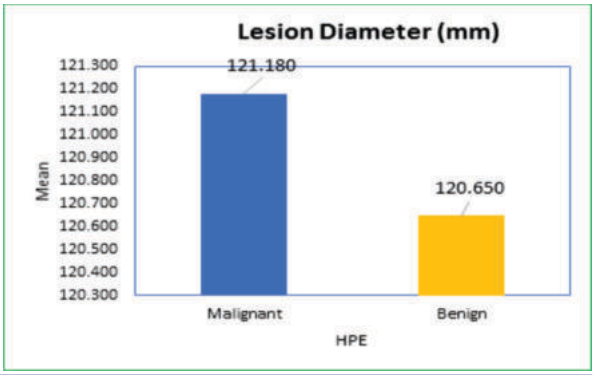


Table: Distribution of mean Solid Component Size (mm) with HPE

HPE	Solid Component Size (mm)		P Value (t-test)
	Mean	Std. Deviation	
Malignant	93.18	51.477	<0.001
Benign	31.61	57.352	

Chi-square value: 18.4669; **p-value:** <0.001

In Malignant, the mean Solid Component Size (mm) (mean± SD) of patients was 93.18±51.477.

In Benign, the mean Solid Component Size (mm) (mean± SD) of patients was 31.61±57.352.

Distribution of mean Solid Component Size (mm) with HPE was statistically significant (p=<0.001).

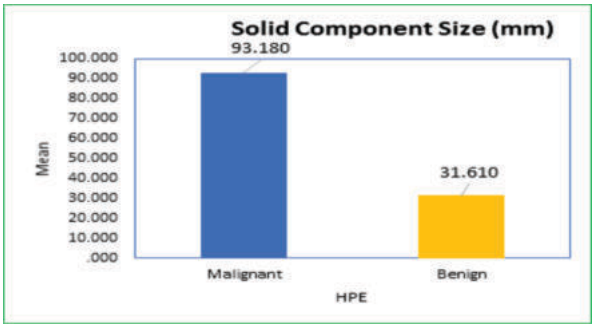


Table: Distribution of mean No. of Papillary Projections with HPE

HPE	No. of Papillary Projections		P Value (t-test)
	Mean	Std. Deviation	
Malignant	0.56	1.078	0.005
Benign	0.00	0.000	

Chi-square value: NA; **p-value:** 0.005

In Malignant, the mean No. of Papillary Projections (mean± SD) of patients was 0.56±1.078.

In Benign, the mean No. of Papillary Projections (mean± SD) of patients was 0.00±0.000.

Distribution of mean No. of Papillary Projections with HPE was statistically significant (p=0.005).

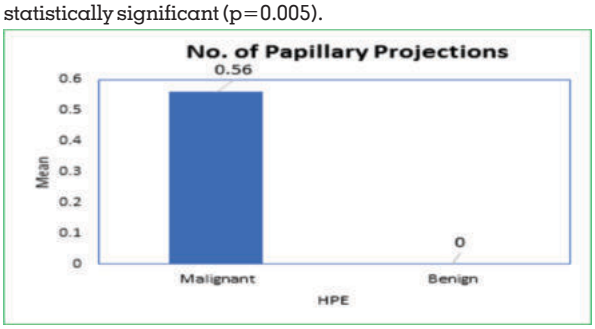


Table: Association between IOTA: HPE

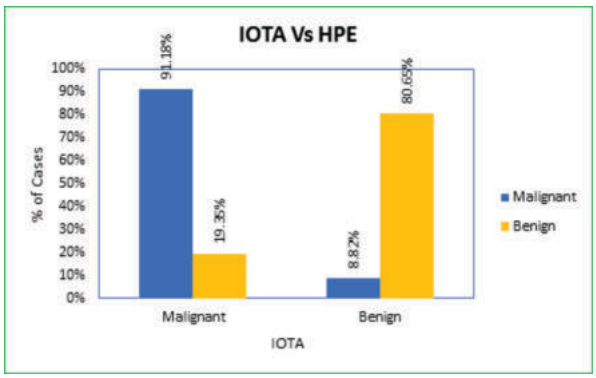
IOTA	HPE		Total
	Malignant	Benign	
Malignant	31	6	37
Benign	3	25	28
Total	34	31	65

Chi-square value: 34.1118; **p-value:** <0.001

In Malignant group, 31 patients had IOTA Malignant and 3 patients had IOTA Benign.

In Benign group, 6 patients had IOTA Malignant and 25 patients had IOTA Benign.

Association of IOTA with HPE was statistically significant (p<0.0001).



The present study was an Analytical Study. This Study was conducted for 2 Years at GMCH Nagpur. Total 65 patients were included in this study.

In our study, out of 65 patients, most of the patients were [35] ≤50 years of age. Age was statistically significant with HPE (p=0.032).

Szubert S et al [23](2016) found that the external, two-centre validation of the IOTA ADNEX model for differential diagnosis of adnexal tumors. A total of 204 patients with adnexal masses (134 benign and 70 malignant) treated at the Division of Gynaecologic Surgery, Poznan University of Medical Sciences, Poland (Centre I), and 123 patients (89 benign and 34 malignant) from the Department of Obstetrics and Gynaecology, Clinica Universidad de Navarra, University of Navarra School of Medicine, Pamplona, Spain (Center II), were enrolled into the study. ADNEX achieved high accuracy in discriminating between malignant and benign ovarian tumors in both centres (79.9% and 81.3% in Centres I and II, respectively).

Ruiz M et al [25] (2016) showed that to investigate the prognostic value of ADNEX Magnetic Resonance Imaging Scoring in the preoperative management of adnexal masses. They performed a retrospective study on patients who underwent surgery for an adnexal mass, with prior exploration by Magnetic Resonance Imaging (MRI), at the Gynaecology Department of the Poissy Teaching Hospital between May 2012 and August 2014. MRI data were retrospectively read by radiologists, without knowledge of the histology, and classified according to the criteria of the ADNEX MR score. The radiological presumption of benign or malignant mass was compared with the final histological diagnosis. They calculated the sensitivity, specificity, positive and negative likelihood ratios and ROC curve of the ADNEX MR score with their 95% confidence intervals (95%CI). One-hundred-and-forty-eight patients were included in the study of which 24 had malignant or borderline ovarian tumors.

We found that, most of the patients had family history [9] in Malignant group compared to Benign group [8] but this was not statistically significant (p=0.951).

Meys EM et al [28](2017) validated externally the performance of the Assessment of Different NEoplasias in the adneXa (ADNEX) model and compared this model with other frequently used models in the differentiation between benign and malignant adnexal masses. In this retrospective diagnostic accuracy study, they assessed data collected prospectively from patients with adnexal pathology who underwent real-time transvaginal ultrasound by a single expert ultra-sonographer in a tertiary care hospital between July 2011 and July 2015. The presence of a malignancy was determined by subjective assessment and use of four

prediction models: the ADNEX model, simple ultrasound-based rules (simple rules), Logistic Regression model 2 (LR2) and the Risk of Malignancy Index (RMI), of which three different variants were assessed.

Our study showed that, more number of patients had [6] more than 10 locules in Malignant group compared to Benign group [5] though it was not statistically significant (p=0.87). Higher number of patients had [28] Ascites in Malignant group compared to Benign group [5] which was statistically significant (p<0.001). More number of patients had [25] Post Acoustic Shadowing in Malignant group compared to Benign group [5] which was statistically significant (p<0.001).

Araujo KG et al [29](2017) showed that to evaluate the performance of the International Ovarian Tumor Analysis (IOTA) ADNEX model in the preoperative discrimination between benign ovarian (including tubal and para-ovarian) tumors, borderline ovarian tumors (BOT), Stage I ovarian cancer (OC), Stage II–IV OC and ovarian metastasis in a gynecological oncology centre in Brazil.

Receiver–operating characteristics (ROC) curve analysis was used to determine the diagnostic accuracy of the model to classify tumors into different histological types. Of 131 women, 63 (48.1%) had a benign ovarian tumor, 16 (12.2%) had a BOT, 17 (13.0%) had Stage I OC, 24 (18.3%) had Stage II–IV OC and 11 (8.4%) had ovarian metastasis. The area under the ROC curve (AUC) was 0.92 (95% CI, 0.88–0.97) for the basic discrimination between benign vs malignant tumors using the IOTA ADNEX model.

Performance was high for the discrimination between benign vs Stage II–IV OC, BOT vs Stage II–IV OC and Stage I OC vs Stage II–IV OC, with AUCs of 0.99, 0.97 and 0.94, respectively.

It was found that, the mean CA 125 U/mL was higher [1211.06±1117.195] in Malignant group compared to Benign group [150.35±265.637] it was statistically significant (p<0.001). The mean Lesion Diameter (mm) was more [121.18±6.860] in Malignant group compared to Benign group [120.65±3.592] but this was not statistically significant (p=0.701).

We showed that, the mean Solid Component Size (mm) was more [93.18±51.477] in Malignant group compared to Benign group [31.61±57.352] which was statistically significant (p<0.001) and the mean number of Papillary Projections were more [0.56±1.078] in Malignant group compared to Benign group [0.00±0.000] which was statistically significant (p=0.005).

Froyman W et al [32](2019) there are many diagnostic methods to assist clinicians in assessing adnexal masses on ultrasound. After suggesting a standardized terminology and measurement technique to evaluate adnexal masses, the International Ovarian Tumor Analysis (IOTA) group has developed different strategies such as the Simple Rules and Assessment of Different Neoplasias in the adneXa (ADNEX) model, which have been shown to outperform other available methods.

Besides differentiating between benign neoplasms and malignancies, the ADNEX model can also give the predicted risk for different subtypes of malignant adnexal masses, which is clinically very relevant for guiding patient management.

Nohuz E et al [31](2019) found that the IOTA (International Ovarian Tumor Analysis) group has developed the ADNEX (Assessment of Different NEoplasias in the adneXa) model to predict the risk that an ovarian mass is benign, borderline or malignant. This study aimed to test reliability of these risks prediction models to improve the performance of pelvic ultrasound and discriminate between benign and malignant cysts. Postmenopausal women with an adnexal mass (including ovarian, para-ovarian and tubal) and who underwent a standardized ultrasound examination before surgery were included.

Prospectively and retrospectively collected data and ultrasound appearances of the tumors were described using the terms and definitions of the IOTA group and tested in accordance with the ADNEX model and were compared to the final histological diagnosis. Of the 107 menopausal patients recruited between 2011 and 2016, 14 were excluded (incomplete inclusion criteria).

Thus, 93 patients constituted a cohort in whom 89 had benign cysts (83 ovarian and 6 tubal or para-ovarian cysts), 1 had border line tumor and 3 had invasive ovarian cancers (1 at first stage, 1 at advanced stage and 1 metastatic tumor in the ovary). The overall prevalence of malignancy was 4.3%. Every benign ovarian cyst was classified as probably benign by IOTA score which showed a high specificity with the probably malignant lesion proved malignant by histological exam.

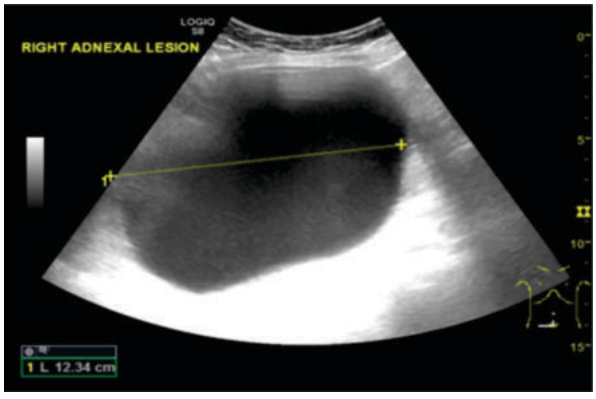
We observed that, majority number of patients had [31] IOTA Malignant in Malignant group compared to Benign group [25] it was statistically significant (p<0.0001)

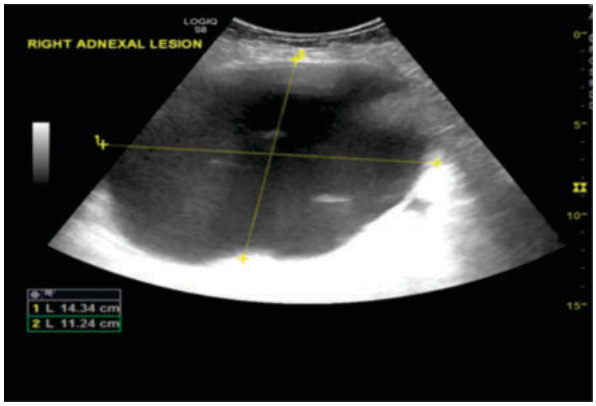
FEW REPRESENTATIVE CASES

Case 1

A 49 years old female patient came with the complaints mass in lower abdomen since 2month.

Patient underwent transvaginal ultrasound and following results were obtained:

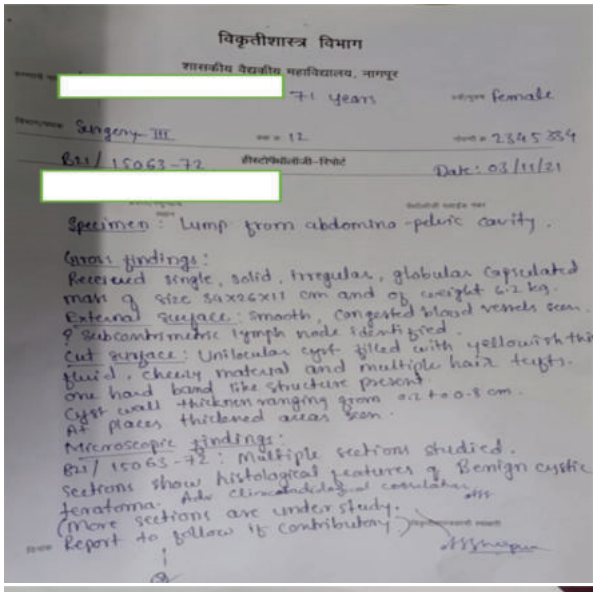




CA 125-7
Diameter of the lesion-140mm
Size of solid component- 0mm
More than 10 locules- no
Number of papillary projections- 0

Ascites- no
Post acoustic shadowing- no
IOTA ADNEX CATEGORY- Benign

HPE



विकृतीशास्त्र विभाग

शासकीय वैद्यकीय महाविद्यालय, नागपूर

[redacted] 71 years female

Surgery- III

Reg/ 15063-72

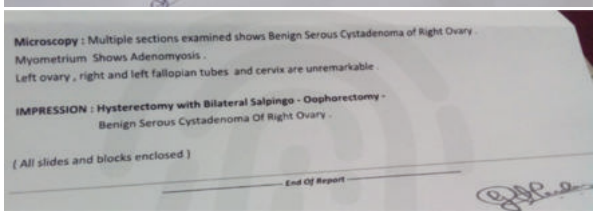
Date: 03/11/21

[redacted]

Specimen : Lump from abdomino-pelvic cavity.

Gross findings:
Received single, solid, irregular, globular encapsulated mass of size 24x26x11 cm and of weight 6.2 kg.
External surface: Smooth, congested blood vessels seen.
? Subcentimetric lymph node identified.
Cut surface: Unilocular cyst filled with yellowish thick fluid, cheesy material and multiple hair tufts. One hard band like structure present.
Cyst wall thickness ranging from 0.2 to 0.8 cm.
At places thickened areas seen.

Microscopic findings:
Reg/ 15063-72: Multiple sections studied.
Sections show histological features of Benign cystic teratoma. Adv clinical findings correlation.
(More sections are under study.
Report to follow if contributory)



Microscopy : Multiple sections examined shows Benign Serous Cystadenoma of Right Ovary .
Myometrium Shows Adenomyosis .
Left ovary , right and left fallopian tubes and cervix are unremarkable .

IMPRESSION : Hysterectomy with Bilateral Salpingo - Oophorectomy -
Benign Serous Cystadenoma Of Right Ovary .

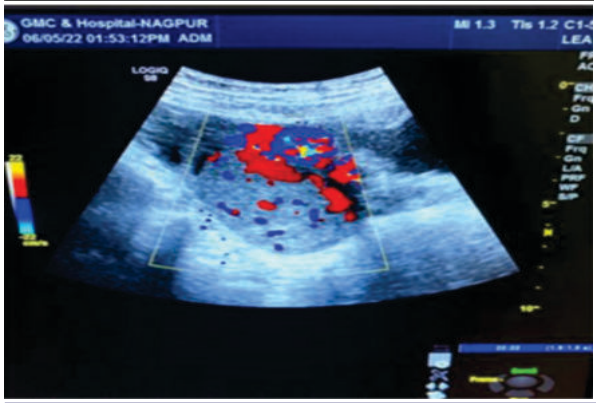
(All slides and blocks enclosed)

End Of Report

Case 2

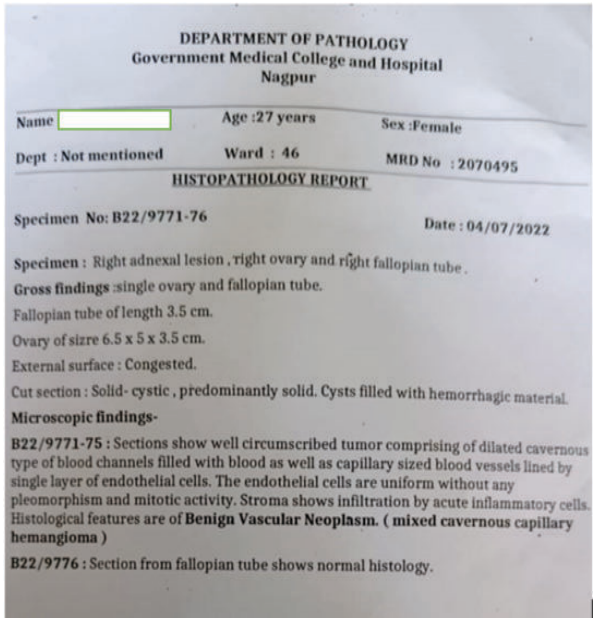
A 30-year-old female patient came with the complaint of mass in lower abdomen with excessive per veginal bleeding.

Patient underwent diagnostic transabdominal ultrasound



CA 125-38
Diameter of the lesion-65mm
Size of solid component- 65 mm
More than 10 locules- no
Number of papillary projections- 0
Ascites- no
Post acoustic shadowing- no
IOTA ADNEX CATEGORY- Benign

HPE



DEPARTMENT OF PATHOLOGY
Government Medical College and Hospital
Nagpur

Name [redacted] Age :27 years Sex :Female

Dept : Not mentioned Ward : 46 MRD No : 2070495

HISTOPATHOLOGY REPORT

Specimen No: B22/9771-76 Date : 04/07/2022

Specimen : Right adnexal lesion , right ovary and right fallopian tube .

Gross findings :single ovary and fallopian tube.

Fallopian tube of length 3.5 cm.

Ovary of sizre 6.5 x 5 x 3.5 cm.

External surface : Congested.

Cut section : Solid- cystic , predominantly solid. Cysts filled with hemorrhagic material.

Microscopic findings-

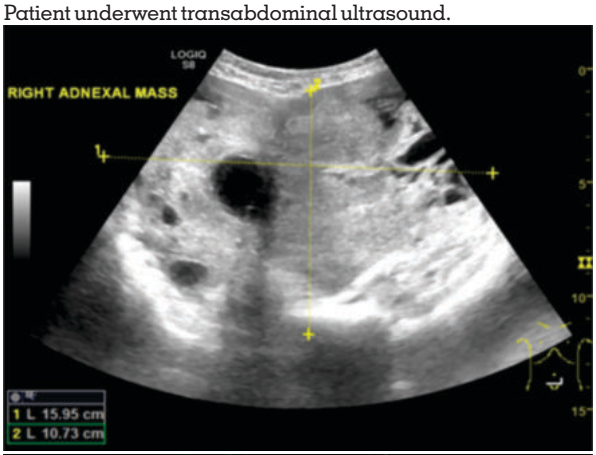
B22/9771-75 : Sections show well circumscribed tumor comprising of dilated cavernous type of blood channels filled with blood as well as capillary sized blood vessels lined by single layer of endothelial cells. The endothelial cells are uniform without any pleomorphism and mitotic activity. Stroma shows infiltration by acute inflammatory cells. Histological features are of **Benign Vascular Neoplasm. (mixed cavernous capillary hemangioma)**

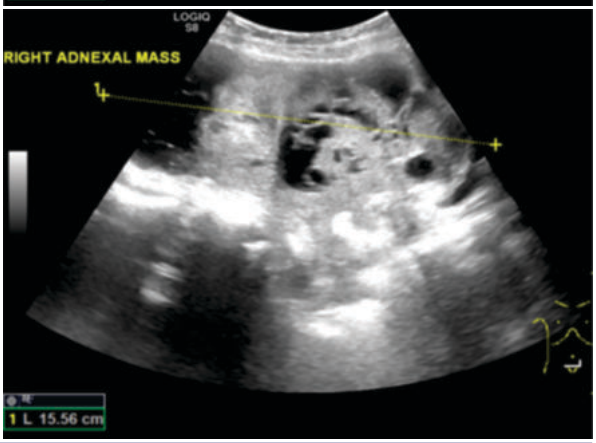
B22/9776 : Section from fallopian tube shows normal histology.

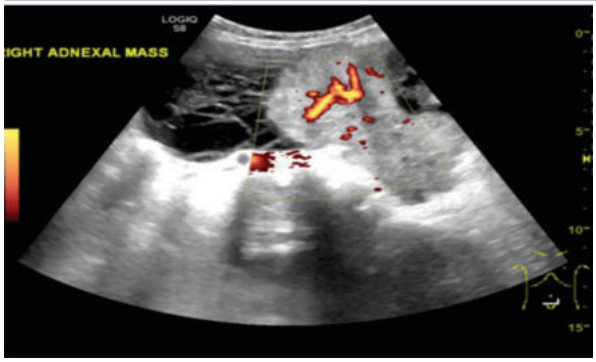
Case 3:

A 64-year-old female patient came with the complaints of mass in lower abdomen since 5 months

Patient underwent transabdominal ultrasound.

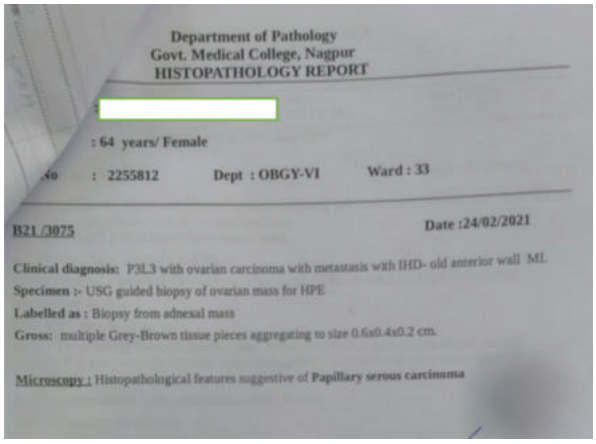






CA 125- 869
Diameter of the lesion-160mm
Size of solid component- 150mm
More than 10 locules- no
Number of papillary projections- >3
Ascites- yes
Post acoustic shadowing- yes
IOTA ADNEX CATEGORY- STAGE II-IV

HPE


Department of Pathology
Govt. Medical College, Nagpur
HISTOPATHOLOGY REPORT

: 64 years/ Female

: 2255812 Dept : OBGY-VI Ward : 33

B21 /3075 Date :24/02/2021

Clinical diagnosis: P3L3 with ovarian carcinoma with metastasis with IHD- old anterior wall MI.
Specimen :- USG guided biopsy of ovarian mass for HPE
Labelled as : Biopsy from adnexal mass
Gross: multiple Grey-Brown tissue pieces aggregating to size 0.6x0.4x0.2 cm.

Microscopy : Histopathological features suggestive of Papillary serous carcinoma

Conflicts Of Interest Statement: None

Funding: None

ABBREVIATIONS:

IOTA -INTERNATIONAL OVARIAN TUMOR ANALYSIS
ADNEX- ASSESSMENT OF DIFFERENT NEOPLASIAS IN ADNEXA
HPE- HISTOPATHOLOGICAL EXAMINATION
USG-ULTRASONOGRAPHY

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