CLINICOPATHOLOGICAL FEATURES OF OVARIAN TUMOURS-
A PROSPECTIVE OBSERVATIONAL STUDY

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LIST OF ABBREVIATIONS

M	**-**	**Menopausal status**
RMI	**-**	**Risk of Malignancy Index**
SD	**-**	**Standard deviation**
USG	**-**	**Ultrasonography**
PPV	**-**	**Positive predictive value**
NPV	**-**	**Negative predictive value**
WHO	**-**	**World Health Organisation**
CT	**-**	**Computerised Tomography**
MRI	**-**	**Magnetic Resonance Imaging**
CA 125	**-**	**Cancer Antigen 125**
HE 4	**-**	**Human epididymal 4 protein**
HPR	**-**	**Histopathology Report**
OCP	**-**	**Oral contraceptive pill**
hCG	**-**	**Human chorionic gonadotropin**

ABSTRACT

Introduction

Information from developing countries regarding clinicopathological features for ovarian tumours is lacking. Influence of menarche, menopause, nulliparity, mean age of presentation and type of tumour needs to be identified. This will help develop a analysis for clinicopathological features of ovarian tumour.

Material and Methods

This was a prospective observational study conducted from 1 January 2014 to 31 August 2015 at KLE's Dr. Prabhakar Kore Hospital and MRC which included 119 patients satisfying the inclusion criteria. Incidence of ovarian tumour and clinicopathological features of ovarian tumours was studied .

Statistical analysis

Percentage distribution of clinical and pathological features of ovarian tumours was studied. Categorical outcomes were summarized as rates and Numerical outcomes as mean.

Result

The incidence of ovarian tumours at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre from 1 January 2014 to 31 August 2015 was found to be 6.9% of all gynaecological admissions. In a study of 119 women 92.43% of women presented with pain per abdomen, 83% of women were multiparous. Only 17.64% of women were post menopausal. Amongst 101 patients whose HPR was available, 113.86% (14) of patients had malignant lesions while 86.13% (87) of patients had

benign lesions on histopathological examination. The commonest benign lesion was serous cystadenoma 35.63% (31) followed by simple cyst and mucinous cystadenoma 17.24% (15) each and the commonest malignant lesion being serous papillary adenocarcinoma 50% (07). The sensitivity and specificity of CA 125 in detecting malignant lesions among 70 patients was 70% and 85% respectively. The sensitivity and specificity of RMI in comparison to HPR in 68 patients was found to be 66.6% and 94.64% respectively. Thus, it is concluded that on morphological grounds, tumours originating from surface epithelium are the commonest variant and various modalities will help in early detection of malignant lesions of ovary thereby, reducing the mortality rates.

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INTRODUCTION

Ovarian tumours frequently present as adnexal masses and are frequent reasons for referral to Gynaecologist.

Information from developing countries regarding clinicopathological features for ovarian tumours is lacking. The influence of mean age of presentation, parity, menopause, type of tumour needs to be studied [53]. This will help develop a analysis for clinicopathological features of ovarian tumour. This encouraged us to conduct the present study at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

Ovarian tumours are common form of neoplasia in women. Ovarian tumours constitute 3% of all Gynaecological admissions.[59] Ovarian tumours account for about 30% of all female genital cancers. Asian countries have rate of 2 to 6 new cases per 1,00,000 women per year.[57] Benign ovarian cysts are the commonest constituting about 90% of ovarian tumours. Gynecologists receive the major load due to ovarian lesion not only because of anatomical location but also since these tumours may remain unnoticed for long period of time.[57]

Ovarian tumour is not a single entity, but a complex wide spectrum of neoplasms involving a variety of histological tissues ranging from epithelial tissues, connective tissues, specialized hormone-secreting cells, germinal and embryonal cells. Most common are epithelial tumours constituting 80% of all tumours. 80% are benign tumours and 20% are malignant tumours.[60]

It is very important to determine the histological pattern of ovarian tumours as the prognosis depends upon the degree of differentiation. The histogenetic

classification categorizes ovarian neoplasms with regard to their derivation from coelomic epithelium, germ cell and mesenchyme. The early development of ovary is divided into four major stages- First stage- primordial germ cell get segregated and migrate from their site of origin to settle in genital ridge; bilateral thickening of coelomic epithelium. Second stage- proliferation of coelomic epithelium and underlying mesenchyme. Third stage- ovary get differentiated into inner medulla and peripheral cortex. Fourth stage- development of cortex and involution of medulla.[3]

Amongst benign tumours, 60% of them are epithelial in origin. Among benign epithelial tumour, serous cystadenoma are the most common (30%), occurring most commonly in reproductive age group.[60] They are bilateral in 10% of cases, multiloculated or uniloculated filled with yellowish fluid. Mucinous cystadenoma are second most common epithelial tumour (15- 25%) usually multilocular , filled with mucinous fluid. They can rupture, leading to a condition called pseudomyxoma peritonei. Benign or mature cystic teratoma is the most common germ cell tumour, filled with thick sebaceous material. They account for 40% of all ovarian tumours. In 10% of cases torsion can occur. Fibroma are the most common benign solid tumour, occurring mostly in post menopausal age group. The combination of ovarian fibroma, ascites and hydrothorax is called Meig's syndrome.[3,60]

Mostly benign ovarian tumours are asymptomatic. If symptomatic present with dull aching pain, which may be acute severe pain in torsion, rupture, haemorrhage, infection.[3] They may present with menstrual disturbances in hormone secreting tumour like granulosa cell tumour - amenorrhoea, anovulatory cycles, dysmenorrhea. Pressure symptoms like increased frequency of micturition, bilateral odema of feet due to venous obstruction are encountered with fibroma.[60]

Management of benign ovarian tumours depend upon- age, menopausal status, size of mass, ultrasonographic morphology, tumour marker levels. In premenopausal women with a simple cyst of 5-8 cm, benign morphology, CA 125<200 IU/ml – follow up has to be done for 3-6 months, if it is symptomatic and associated with increase in size then proceed with laparoscopic cystectomy. In post menopausal women with simple cyst of 3-5 cm, benign morphology, CA 125<35 IU/ml, Doppler RI > 0.40 – follow up for 6 weeks, if it is associated with increase in size of cyst or CA 125 is increasing then proceed with laparotomy.[60]

Borderline ovarian tumours or ovarian epithelial tumours of low malignant potential were first described by Taylor in 1929.[3,60] Histologically, these are intermediate between truly benign neoplasms and those with invasive characteristics. They constitute 10-15% of all epithelial tumours, prevalence being 2.5 per 1,00,000 women.[61] Characteristics of Borderline ovarian tumours – Bilateral in 25-50% , Epithelial multilayering of more than 4 cell layers, 4 mitoses per 10 power field, Nuclear atypia, Increased Nuclear to Cytoplasmic ratio, Epithelial budding and cell detachment in lumen, No destructive stromal invasion. Clinically, they have a high survival rate of 90%.[3,61] Tumours have a typical indolent course. Spontaneous regression of peritoneal implants is known to occur. Diagnosis is entirely dependent on histopathological reports. Management is individualized according to age, parity and desire to preserve fertility. Conservative surgery in form of ovarian cystectomy, salpingo-oophorectomy are performed.[60]

Ovarian cancer is the leading cause of death in women with female genital cancers in developing countries. A women's lifetime risk has been estimated to be about 1 in 55 , which represents an increase from the 1970[1] . In the year 2005,

an estimated 22,220 new cases of ovarian cancer were diagnosed in US alone, with 16,210 deaths predicted[2]. Ovarian cancer is the fifth most common cause of cancer death in women. It is the third most common Gynaecological malignancy among women in western world, hence is the most lethal. Almost 2/3rd of patients present in advanced age. Indian cancer registry data project ovary as an important site of cancer in women, comprising upto 8.7% of cancer in different parts of the country.[15]

The American Cancer Society estimated that there would be 21,880 new cases of ovarian cancer in 2010 and 13,850 deaths from disease. Epithelial ovarian cancer is the eight most common cancer in women, and uterine (corpus and endometrial) is fourth most common. The ovaries are the ninth most common site of cancer in women, accounting for 3% of all new cases, but ovarian cancer causes 5% of cancer deaths.[15]

However, during 2001-2005 the incidence of ovarian cancer declined at a rate of 2.4% annually, and the death rate from ovarian cancer has been stable since 1988.[15]

Prior to surgery and histopathological reporting, it is very difficult to differentiate benign from malignant ovarian lesions. 39 – 69 % of the ovarian masses diagnosed after menopause are malignant as compared to 21-24% prior to menopause.[3]

Ovarian cancer is a disease with a poor prognosis. Women commonly have diagnosis of stage II and IV disease , for which 5- year survival rates are around 27% and 16% respectively[3].

The early detection of early stage disease could have a positive impact on the prognosis of this dreaded disease.

Upto 70 % of the ovarian cancer are detected at advanced stages because of its bizarre and atypical behaviour like abdominal bloating, pain, indigestion, urinary frequency and constipation . Thus a high index of suspicion is required for diagnosis of ovarian cancer.[3]

The prognosis worsens with the late diagnosis. With advanced ovarian disease, the mortality rate increases to 70 % within 2 years and 90% within 5 years.[3] Pre-operative assessment of adnexal mass/ovarian lesions is thus a challenge for Gynaecologist. This encouraged us to research on ovarian lesions.

Ovarian tumour staging is always a surgical staging. Guidelines for staging- 4 peritoneal washings which include diaphragm, pelvis, right and left abdomen; careful inspection and palpation of all peritoneal surfaces; biopsy from undersurface of right hemidiaphragm; biopsy of all suspicious lesions; infracolic omentectomy; biopsy of adhesions; random biopsy of normal peritoneum of bladder reflection cul de sac, right and left paracolic recesses, both pelvic side walls; selected lymphadenectomy of pelvic and para aortic nodes; total abdominal hysterectomy with bilateral salpingo-oophorectomy and excision of mass when prudent. Second look surgery- first defined by Owen Wangenstein in late 1940s.[3]

The quality of primary cytoreductive surgery is one of the most important prognostic factors. The discrimination between benign and malignant ovarian masses is thus important in selective referral of relevant patients to specialized cancer centres.[4]

Until currently, there has been no effective screening method for ovarian tumours and because the lesions are usually asymptomatic until they have metastasized, patients have advanced disease at diagnosis in more than two – thirds of

the cases and the prognosis is therefore poor. Several attempts have been made to distinguish benign from malignant conditions.

At present, one clinical feature provides inadequate performance in discriminating benign and malignant ovarian tumour. For ultrasonographic techniques, the sensitivity and specificity in diagnosis of malignant condition were 62% and 73%, respectively[5,6]. Serum CA 125 is another promising tool. Elevation of serum CA 125 concentrations is documented in 85% of epithelial ovarian cancers.[6,7] The sensitivity and specificity of CA 125 is known to be poor. It is only raised in approximately 50% of stage I epithelial ovarian cancer and in 75-90% of patients with advanced stage disease.[3,60] In one study when CA 125 was compared with HE 4 as a tool for detecting ovarian tumour , HE 4 was more sensitive (90% vs 83%) and specific (95% vs 85%) and had higher positive (93.1% vs 80.7%) and negative predictive values (92.7% vs 87.2%) . When both are combined into Risk of Ovarian Malignancy Algorithm combined sensitivity and specificity of detecting ovarian tumour was found to be 76% and 95% respectively[66]. Placental alkaline phosphatase is another tumour marker produced by dysgerminoma. hCG is secreted by choriocarcinoma, embryonal carcinoma and polyembryoma.

The sensitivity of gray scale sonography in the detection of ovarian tumour was superior to that of Doppler sonography (98% vs 67% respectively).[3,62] In the evaluation of 71 patients with ovarian masses, Cohen et al similarly found that the three dimensional power Doppler sonography was more accurate than two dimensional Doppler sonography or three dimensional gray scale sonography. The authors reported that three dimensional power Doppler sonography had a sensitivity of 100%, specificity of 75%, positive predictive value of 50%.[62] Magnetic resonance

imaging helps to distinguish benign from malignant lesions, with accuracy of diagnosis of malignancy of 93%. CT is not indicated for the differential diagnosis of adenexal masses because of poor soft tissue resolution.[67]

At the cut off level of CA 125=35 IU/ml, the sensitivity was 83.1% but specificity was only 39.3%.[7] The risk of malignancy index is a scoring system of the combination of various clinical features. It has been developed to improve diagnostic accuracy for ovarian malignancy. Jacob et al (1990) originally developed the RMI based on ultrasonographic findings, menopausal status and serum levels of CA 125.[8] By using the RMI at a cut off level of 200 to indicate malignancy, so called RMI I, sensitivity and specificity were 85.45 and 96.9% respectively.[8] Tingulstad et al (1996) then developed RMI 2, a direct comparison showed that RMI 2 was significantly better at predicting malignancy than RMI 1 (p value <0.001). The RMI 2 gave sensitivity of 80%, specificity of 92% and positive predictive value (PPV) of 83% while RMI 1 gave sensitivity of 71% , specificity of 96% , and PPV of 89% .[9] It is a simple and cost effective method and can be used by Gynaecologist even at less specialised centres to diagnose benign and malignant ovarian lesions. So, to know the incidence of ovarian tumour at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre and to study the clinicopathological features of ovarian tumours, the present study was planned.

OBJECTIVES

- To know the incidence of ovarian tumours at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
- To know clinicopathological features of ovarian tumors like demographic, reproductive, menstrual factors, clinical features, investigations and pathological features.

REVIEW OF LITERATURE

Ovarian tumors are one of the major Gynaecological disease in India. The highest incidence rates that ranges from 51.1 to 54.0 per 1,00,000 population are clustered in age group 70 to 84 years.[16]

Highest incidence of benign tumour is seen within 20 to 40 years. In a study it was found that 23.5% of ovarian tumours were serous and 24.5% were mucinous ovarian tumours while incidence of dermoid cyst varied from 5 to 25% of all ovarian neoplasms.[17]

Thus, the commonest category of ovarian tumour encountered were epithelial tumours, second commonest germ cell tumour. The majority of benign neoplasm occurred in reproductive age group as against malignant neoplasm which occurred in menopausal age group.[18]

The incidence of ovarian tumour constitutes 3% of all Gynaecological admissions. [59] About 75% of these are benign. Epithelial ovarian tumours account for 50-55% of all ovarian tumours, commonly encountered between 50-60 years of age group (post menopausal women). Amongst ovarian tumours, germ cell tumours account for 20 – 25%, out of which 3% are malignant tumours. Ovarian sex cord stromal tumours account for 5-10% of all ovarian tumour.[3,60]

Protective factors[3,60]	**Risk factors**[3,60]
Use of OCP	Early menarche
Breast feeding	Late menopause
Multiparity	Talc use
Tubal ligation	Family history with BRCA1 and BRCA2
Hysterectomy	Nulliparity

Epithelial tumors can be split into five basic histological groups which resemble normal epithelium present in genitourinary tract. Serous tumours appear similar to epithelium of fallopian tube, mucinous tumours resemble endocervical mucosa and endometrial tumours resemble endometrium.[3,60]

Many of the tumours are mixed in origin. Sex cord stromal tumours are composed of sex cords and stroma of either male or female in origin and occur in all age groups. These contain granulosa, theca, sertoli or leydig cell. It is also called as functioning tumour group since they exhibit sex steroid activity.[3]

Hormonal activity does not reflect likely clinical outcome, but may be used as a useful tumour marker. Germ cell tumour present prior to puberty or in adult life. Teratoma, dysgerminoma account for about 15% of all ovarian tumour at all age groups, contributing for 60-70% of all ovarian tumours under age of 20 yrs and 90% of these tumours occur before puberty.[3] They represent malignant transformation of primordial germ cells at various stages of differentiation.

Most tumours grow in the substance of ovary, covered by a capsule of thinned ovarian tissue. Ordinarily they extend into peritoneal cavity but may involve

mesovarium and by opening up its leaves, ultimately lies extra- peritoneally between layers of broad ligament.

Borderline epithelial tumours are of low malignant potential, seen in younger premenopausal women between 30-50 yrs.[61] Histological criteria include stratification of epithelial lining of papillae; formation of microscopic papillary projections ; epithelial pleomorphism; atypicality; mitotic activity ; absence of stromal invasion.

According to Janovski and Paramanathon, at least two of these features must be present for the tumour to qualify as borderline.

Majority of malignant ovarian tumours [3.60,62] are epithelial. Predominant histologic types being-

- Serous cystadenocarcinoma 42%
- Mucinous cystadenocarcinoma 12%
- Endometrioid carcinoma 15%
- Undifferentiated carcinoma 17%
- Clear cell carcinoma 06%

Familial ovarian cancer[3]- three categories-

1. Site specific familial ovarian cancer
2. Breast ovarian cancer syndrome
3. Lynch syndrome type II which includes colorectal cancer, endometrial and ovarian cancer. True hereditary ovarian cancer is mainly due to mutation in BRCA1 and BRCA2 genes. BRCA 1 is located on chromosome 17q and BRCA2 is located on chromosome 13q12. Lynch syndrome II is due to inherited mutation in a family of DNA repair gene (MSH2, MLH1, PMS1, PMS2).[3]

Most frequently presenting symptoms of ovarian cancer- Abdominal swelling, abdominal pain, dyspepsia, urinary frequency, weight loss (in decreasing order of frequency)[3,62]. Surgical findings to discriminate between benign and malignant ovarian tumours-

FEATURES [60,62]	**BENIGN**	**MALIGNANT**
Surface papilla	Rare	Very common
Intracystic papilla	Uncommon	Very Common
Solid areas	Rare	Common
Bilaterality	Rare	Common
Adhesions	Uncommon	Common
Ascites(100 ml)	Rare	Common
Necrosis	Rare	Common
Peritoneal implants	Rare	Common
Capsule intact	Common	Infrequent
Totally cystic	Common	Rare

Non malignant condition associated with increased CA 125- Acute Pelvic inflammatory disease, adenomyosis, benign ovarian neoplasm, endometriosis, functional ovarian cyst, Meigs syndrome, menstruation, ovarian hyperstimulation, unexplained infertility, uterine myoma.[3,62]

It has been suggested that RMI and other explicit scoring system may be less sensitive than Ultrasound morphological scores, but are more specific. CT of abdomen and pelvis should be performed in secondary care of all patients suspected of having ovarian cancer .

WHO Classification of Ovarian tumours [62]

I. Epithelial Tumours

A. Serous Tumours

1. Benign

a. Cystadenoma and papillary cystadenoma

b. Surface papilloma

c. Adenofibroma and cystadenofibroma

2. *Borderline malignant* (Carcinoma of low malignant potential)

a. Cystadenoma and papillary cystadenoma

b. Surface papilloma

c. Adenofibroma and cystadenofibroma

3. Malignant

a. Adenocarcinoma, papillary adenocarcinoma

b. Surface papillary carcinoma

c. Malignant adenofibroma and cystadenofibroma

B. Mucinous Tumours

1. Benign

a. Cystadenoma and papillary cystadenoma

b. Surface papilloma

c. Adenofibroma and cystadenofibroma

2. *Borderline* and papillary cystadenoma

a. Cystadenoma and papillary cystadenoma

b. Surface papilloma

c. Adenofibroma and cystadenofibroma

3. Malignant

a. Adenocarcinoma and cystadenocarcinoma

b. Malignant adenofibroma and cystadenofibroma

C. Endometrioid Tumours

1. Benign

a. Adenoma and cystadenoma

b. Adenofibroma and cystadenofibroma

2. Borderline malignant

a. Adenoma and cystadenoma

b. Adenofibroma and cystadenofibroma

3. Malignant

a. Carcinoma

i. Adenocarcinoma

ii. Adenocanthoma

iii. Malignant adenofibroma and cystadenofibroma

b. Endometrioid stromal sarcoma

c. Mixed Mullerian mesodermal tumours, homologous and heterologous

D. Clear cell (mesonephroid) tumours

1. *Benign* : adenofibroma

2. Borderline malignant

3. *Malignant* : carcinoma and adenocarcinoma

E. Brenner Tumours

1. Benign

2. Borderline malignant

3. Malignant

F. Mixed epithelial tumour

1. Benign

2. Borderline malignant

3. Malignant

G. Undifferentiated carcinoma

H. Unclassified epithelial tumours

II. Sex cord stromal tumours

A. Granulosa cell tumours

1. Granulosa cell tumours
2. Tumours in the thecoma-fibroma group
    a. Thecoma
    b. Fibroma
    c. Unclassified

B. **Androblastomas** : Sertoli- Leydig cell tumours

1. Well differentiated
    a. Tubular androblastoma and sertoli cell tumour
    b. Tubular androblastoma and sertoli cell tumour with lipid storage
    c. Sertoli- Leydig cell tumour
    d. Leydig cell tumour and Hilus cell tumour
2. Intermediate differentiation
3. Poorly differentiated
4. With heterologous elements

C. Gynadroblastoma

D. Unclassified

III. Lipoid cell tumours

IV. Germ cell tumours

A. Dysgerminoma

B. Endodermal sinus tumour

C. Embryonal carcinoma

D. Polyembryoma

E. Choriocarcinoma

F. Teratomas

1. Immature
2. Mature
    a. Solid
    b. Cystic
        i. Dermoid cyst (Mature cystic teratoma)
        ii. Dermoid cyst with malignant transformation
3. Monodermal and highly specialized
    a. Struma ovarii
    b. Carcinoid
    c. Struma ovarii and carcinoid
    d. Others

G. Mixed forms

V. Gonadoblastoma

A. Pure

B. Mixed with dysgerminoma or other form of germ cell tumour

VI. Soft tissue tumours not specific to ovary

VII. Unclassified tumours

VIII. Secondary (metastatic) tumours

IX. Tumour- like conditions

INCIDENCE OF INDIVIDUAL OVARIAN TUMORS

I. SURFACE EPITHELIAL TUMOURS

In new WHO classification the term “common epithelial tumours” is replaced by “epithelial stromal tumours”. Previously these tumors were grouped into two categories, benign or malignant but after the advent of FIGO and WHO classification a third group has been labelled as tumors of borderline malignancy or carcinoma of low potential.[23]

They are the most common tumors of ovary. Gupta et al in 1986 noted their incidence to be 54 to 70%. In a study conducted by Maheswari et al in 1994 their incidence was recorded as 65.7% of all ovarian tumors. She also reported that the maximum number of cases were found in third decade of life and presented with abdominal lumps (71.9%) and pain abdomen (47.4%).[23]

Classification

The surface epithelial tumors are classified according to the following parameter.

1. Cell type- serous, mucinous, endometrioid, clear cell etc..
2. Pattern of growth- cystic, solid, papillary.
3. Amount of fibrous stroma.
4. Atypia and invasiveness- benign, borderline or malignant.

A. SEROUS TUMOURS

They constitute 30% of all ovarian tumours making them the single most common group of epithelial tumours. They comprise 22% of benign and nearly 50% of malignant primary tumours of ovary.[23]

1. Benign Serous tumours

They commonly present between 20-50 years of age group. Their peak incidence is seen in 3rd & 4th decade of life. Cystadenofibroma occur in perimenopausal and menopausal women.[23,62]

2. Serous cystadenocarcinoma

It is the most common primary malignant ovarian tumor comprising 14.71% of all ovarian tumours.[24]

B. MUCINOUS TUMOURS

Mucinous tumors are defined as tumors in which the epithelial element includes a prominent component of mucus filled cells. They occur less frequently when compared with the serous types. They comprise 6-25% of ovarian neoplasms. On an average 85% of them are benign, 6% are borderline tumours and 9% are malignant.[24]

C. ENDOMETRIOID TUMOURS

Sampson in 1920 was the first to describe the endometrioid tumours in ovary. These tumors have an epithelial component that resembles proliferative, hyperplastic or malignant endometrium.[25]

1. Benign endometrioid tumours

These are rare and comprise about 10% of ovarian adenofibromas.

D. TRANSITIONAL CELL TUMOURS

Transitional tumors comprise Brenner tumor and Non-Brenner type transitional cell carcinoma. Brenner tumour comprise around 2% of all the ovarian tumours.[26]

E. UNDIFFERENTIATED CARCINOMA

Approximately 5% of ovarian cancers are poorly differentiated to classify and are designated as undifferentiated carcinoma and they have the worst prognosis of any type of surface epithelial carcinoma.[27]

II. SEX CORD- STROMAL TUMOURS

This group includes those tumors originating from sex cords, mesenchyme or both of the embryonic gonads. These comprise 5-12% of ovarian neoplasms.

A. GRANULOSA CELL TUMOURS

Rokitansky first described them. The tumor shows differentiation towards follicular granulosa cells.[28] They comprise 1-2% of all ovarian tumors and the most common malignant sex-cord stromal tumors. There are two types of granulosa cell tumors: an adult type that occurs mainly in menopausal women and a juvenile type that occurs mainly in children.[28]

B. THECOMA-FIBROMA GROUP

They account for 4% of all ovarian tumour and comprise 7% of sex sord-stromal neoplasm. The average age is between 50 and 55 years.[29]

i. Fibroma : Fibroma is a benign tumor composed of fibroblasts and collagen fibres.[28] It is the most common sex-cord-stromal tumour, accounting for 1-5% of ovarian tumor. Fibromas occur invariably after puberty, in peri or postmenopausal age group.[28]

ii. Sclerosing stromal tumour : It is an uncommon benign tumour that occurs mainly in teenagers and young woman in their 20's.

C. SERTOLI-LEYDIG CELL TUMOUR

This tumour was first described by Pick in 1905. And it constitutes less than 1% of all ovarian tumours. These tumours occur mainly in young patient but arise occasionally in children and postmenopausal women.[30]

a. Well differentiated (Mayer type1)

These tumours constitute about 11% of sertoli-leydig cell tumours.

b. Intermediately differentiated (Mayer type2)

These tumors constitute about 54% of sertoli-leydig cell tumours.

c. Poorly differentiated (sarcomatoid, undifferentiated, Mayer type 3)

They form 13% of sertoli- leydig cell tumours.

III. GERM CELL TUMOUR

They constitute 15 to 20% of all ovarian tumours.[31]

A. Teratoma

They form the commonest group of germ cell tumour in ovarian neoplasm. They constitute 25 to 96% of all ovarian tumours. Benign teratoma occur in patients of all age group. Peak incidence is between 20 and 29 yearsof age group.[31]

i. Mature solid teratoma

This is a benign tumour common in adolescent and younger age group (2^{nd} decade).

ii. Immature teratoma

It is one of the most common malignant germ cell tumours of the ovary. 20-30% of patients with such tumour present at the cancer centres.[31] They occur predominantly in children and in younger women. The average age of presentation is 20 years.

B.Dysgerminoma

Chevot identified the tumour in 1911. It is the most common malignant germ cell tumour of ovary.[31] It is a tumour of children and young women. 90% of patients are under 30 years of age group.

C. Yolk sac tumour or Endodermal sinus tumour

Schiller in 1939 first described this tumour along with clear cell carcinoma under the heading 'mesonephroma ovarii'.[27] Telum in 1949 proposed the name endodermal sinus tumour. It is a malignant germ cell tumour where there is differentiation into yolk sac structures.[27] It occurs principally in children and younger women.

D.Choriocarcinoma

Primary ovarian carcinoma is very rare. It is divided into gestational type that is developing from an ovarian pregnancy and non gestational type as a form of germ cell neoplasm[33] and usually occur between third and fourth decade of life.

Ultrasonographic features of Benign and Malignant ovarian tumours

Ultrasonography is an easily available, accessible, non invasive, invaluable diagnostic tool. Its cost is also relatively much less as compared to other imaging modalities like CT scan or MRI. Ultrasonography can therefore be of immense help in detecting and evaluating different types of ovarian tumours.

Ovarian tumour may be cystic or solid and can be benign or malignant.[40] Cystic ovarian masses have a smooth wall with no internal echoes. But they often contain low level echoes representing blood, pus or cellular debris.[41] Solid tumours are irregularly, echogenic masses, with varied pictures of solid-cystic areas, complex masses or truly solid tumours. Presence of papillary excrescences, thick and irregular septae or solid areas are regarded as features suggesting malignant ovarian masses. On the other hand, features like thin wall of lesion, low echogenicity and smooth inner wall structure were more reliable characteristics in predicting benign tumours.

A specific pathologic diagnosis of teratoma can be made from USG when a highly echogenic focus is demonstrated within the tumour mass. This corresponds to the fat and hair containing semisolid material that fills many of these teratomas. These lesions are virtually always benign, although in the pathologic literature there are reports that 0.3% to 2% may undergo malignant degeneration.

Therefore, it would be valuable to identify a particular sonographic characteristic that would better distinguish teratoma from malignant disease.[42] Complex ovarian masses are lesions that contain both cystic and solid components and the most common are dermoid cysts.[43,44]

The ultrasound appearance is that of an hyperechoic nodular structure, usually with distal acoustic shadow, situated near the cyst wall.[45,46,47,48]

The shadowing may be caused by a calcification or by a sebum and hair conglomerate. After puberty both Rokitansky nodule and the acoustic shadow appear in over 70% cases. Before puberty the echoic nodule appears in about 40% of cases and the acoustic shadow in 15% of dermoid cysts. [48] Dermoid mesh corresponds to the presence of hair inside the cyst that appears as long echoic line on

ultrasonography. In some cases only the contour of the cyst may be seen because of the distal acoustic shadow known as tip of ice berg sign.[45,47,48,49] In 1998 Patel et al. described the following ultra-sonographic features as being specific for dermoid cysts: a) The presence of an echogenicity with acoustic shadow, b) Diffuse or regional shining echoes c) Hyperechoic lines and dots, and d) The presence of a fluid-filled level. [50]

Ovarian crescent sign

It is the healthy ovarian tissue adjacent to the tumor, visible as a hypoechogenic tissue with or without ovarian follicle enclosed within ovarian capsule encircling the tumou r.[63] The presence of normal ovarian tissue adjacent to an ovarian cyst is a useful morphological feature in the pre-operative differential diagnosis of adenexal lesions.

Ovarian crescent sign was found to be a better discriminator of malignancy in adenexal mass than tumour morphology (tumour volume and papillary proliferations), Doppler indices and CA 125 estimations leading to conclusion that presence of ovarian crescent sign with a sensitivity of 96% and specificity of 76% may help to exclude an invasive ovarian malignancy. [63]

Tumour markers in ovarian tumours

They are biochemical indicators for the presence of tumour. None of the tumour markers for ovarian tumours are 100% specific or 100% sensitive.[34]

a. Tumour markers for epithelial ovarian tumour-

Bast and colleagues in 1981 described Ca-125 as a 200 Kd glycoprotein recognized by the murine monoclonal, antibody OC 125 as a marker for epithelial malignancies. A raised level of antigen was detected in 82% of women with epithelial

ovarian cancer[35]. None of the antigen is specific to ovarian cancer, as raised serum levels may be found in 29% of other cancers (lung, breast, pancreas, colorectal) and in 6 % of women with non malignant conditions such as cirrhosis with ascites, acute pancreatitis, ovarian cysts, endometriosis, pelvic inflammatory disease.[36]

Jacob and Bast found that 50% of patients with stage I disease had elevated levels of CA-125[37].

CA-125 levels were raised above 35 IU/ml in 78% of women with malignant masses. The predictive value of CA-125 measurements in post menopausal women is little greater and using cut off value of 65IU/ml for which false positive rate is 8%[35].The use of CA-125 in monitoring response to treatment is very helpful as there is always lack in detecting the disease clinically or radiologically. It is a good prognostic marker for stage I disease where there is doubt about the need for adjuvant therapy.[35]

b. Tumour markers in non- epithelial ovarian tumour-

Alpha fetoprotein and human beta chorionic gonadotropin are the best known tumour markers in clinical practise and are invaluable in the diagnosis, treatment and follow up of ovarian germ cell tumours.[38]

Serum placental alkaline phosphatase and lactate dehydrogenase are also sometimes helpful as markers of dysgerminoma.[39]

Inhibin, a polypeptide produced by granulosa cells of ovary is elevated in granulosa cell tumours.[3]

c. HE4 –

Human epididymal 4 protein , was identified in males in the distal epithelium of the epididymis. It functions as a protease inhibitor essential for sperm maturation.

It has since been found in other healthy epithelial tissues such as respiratory tract and female reproductive organs, including ovaries and uterus, where its function is not fully elucidated. It is normally secreted in very low concentration by healthy ovaries.

HE 4 is found in high levels in serum of women with serous epithelial ovarian cancer. Serum levels are less affected by menstruation, ovulation and other benign ovarian conditions.

In pre menopausal, HE 4 is more sensitive and specific marker of ovarian malignancy, including early stage ovarian cancer.[14]

In a study evaluating multiple biomarkers for ovarian cancer, the combination of CA 125 and HE 4 was superior compared with any other tumour marker.

Risk of Malignancy Index

Up to 70% ovarian tumours are detected at advanced stages, with increased ovarian disease, in which the mortality rate reaches 70% within two years and 90% within five years, which has encouraged research into ovarian cancer screening methods.[3] However, these are costly methods and, because of their elevated false-positive results, they have been ineffective. Ovarian tumours present as adnexal masses which give rise to a number of different benign and malignant conditions. The accurate diagnosis of an adnexal mass is a challenge for the Gynaecologist, because of its bizarre and atypical behaviour. Preoperative diagnostic procedures that are able to distinguish whether an ovarian neoplasm is malignant or benign, could be useful in planning optimized treatment. Until now, the standard strategy for differential diagnosis has been exploratory laparotomy. On the other hand, detailed analysis of the origin of the pelvic mass has encouraged the use of minimal invasive surgery, such as laparoscopy or mini-laparotomy, in selected cases. A preoperative suggestion of

malignancy can guide the Gynaecologist to refer women with suspected pelvic masses to an oncology unit for appropriate therapy and optimized debulking.

Several diagnostic methods of pelvic masses have reported, such as abdominal and transvaginal ultrasonography, three-dimensional ultrasound, colour Doppler ultrasonography and tumor markers. However, none of these methods used individually has shown significantly better performance in detecting malignant tumors from clinically restricted ovarian masses. The development of a mathematical formula using a logistic model, incorporating menopausal status, the serum level of a glycoprotein called CA 125 (which is considered to be a tumor marker) and ultrasound findings in a score system, has been described in the literature in the form of different malignancy indices. These indices are calculated using a simplified regression equation obtained from the product of ultrasound findings score, menopausal status score and the absolute value of serum Ca 125 levels.

Jacob et al originally developed the risk of malignancy index in 1990 and it is termed as RMI 1[8]. Tingulstad et al. developed a risk of malignancy index in 1996, known as RMI 2 and in 1990 they modified in to form RMI 3. The difference between the three indices lies in the different scoring of ultrasound findings and menopausal status.[9]

The Risk of malignancy index has been evaluated in 16 studies.[51,52,53,54,55] The Risk of malignancy Index also referred to as RMI I, uses the product of serum CA 125 level (IU/ml), the ultrasound scan result (expressed as a score of 0,1,or 3), and menopausal state(1 if premenopausal, 3 if postmenopausal). The test results vary between 0 and infinity. Jacobs described a cutoff level of 200, within a sensitivity of 85% and a specificity of 97%.

However, most studies evaluated a range of cutoff levels varying between 25 and 250. When 200 was used as cutoff level, the pooled estimate for sensitivity was 78% for a specificity of 87% At a cutoff level of 50, the pooled estimate for sensitivity was 79% for a specificity of 81%.[56,57,58,59]

Finally, an RMI III and RMI IV also have been developed.[9] RMI III and RMI IV both apply different ultrasound scores compared with RMI I and RMI II. RMI III is evaluated in one study and showed at validation a sensitivity and specificity of 74% and 91% respectively. RMI IV has not been validated in other studies. Tailor's model is based on logistic regression analysis and integrates age, Doppler (i.e, time-averaged maximum mean velocity), and a papillary projections score as variables. This model has been evaluated in six publications.[52,63] The score varies between 0 and 100%, and the cut off level is set at 50%. When 50 was used as cut off level, the pooled estimate for sensitivity was 60% (95% CI 20-100%) for a specificity of 93% (95% CI 82-100). When 25 was used as cutoff, the pooled estimate for sensitivity was 78% (95% CI 33-100%) for a specificity of 77 % (95% CI 35-100%).[52]

All Indices presented a significantly better performance in diagnosing malignancy than did each predictor when taken separately. These indices were tested by Morgante et al[5] on another population with evident malignant criteria in the ultrasonography, such as hepatic or distant metastasis, and they found that the RMI 2 was better for detecting ovarian malignancy.

RMI combines three pre-surgical features: serum CA125 (CA125), menopausal status (M) and ultrasound score (U).[8] The RMI is product of the ultrasound scan score, the menopausal status and the serum CA125 level (IU/ml).

RMI = U x M x CA125

The ultrasound result is scored 1 point for each of the following characteristics: multilocular cysts, solid areas, metastases, ascites and bilateral lesions. U=0 (for an ultrasound score of 0), U=1 (for an ultrasound score of 1), U=3 (for an ultrasound score of >2)

The menopausal status is scored as 1=pre-menopausal and 3=post-menopausal.

The classification of 'post-menopausal' is a woman who has had no menstrual cycle for a period of more than 1 year or a woman who has undergone hysterectomy.

Serum CA125 is measured in IU/ml and can vary between zero and hundreds or even thousands of units.

RMI 1

Ultrasound score of 0 considered as U=0, a score of 1 considered as U=1, and a score of 2 considered as U=3.

Premenopausal status considered as M=1 and postmenopausal status is considered as M=3.

The serum level of CA125 was used directly in the calculation.[8]

RMI 2

Ultrasound score of 0 or 1 considered as U=1, and a score of 2 is considered as U=4.

Premenopausal status considered as M=1 and postmenopausal status considered as M=4

The serum level of CA125 was used directly in the calculation.[9]

RMI 3

Ultrasound score of 0 or 1 considered as U=1, and score of 2 considered as U=3. Premenopausal status considered as M=1 and postmenopausal status considered as M=3.[9]

RMI 4

Ultrasound score of 0 or 1 considered as U=1, score >2 considered as U=4. Premenopausal status considered as M=1, Postmenopausal status considered as M=4. A tumour size (single greatest dimension) < 7 cm considered as S=1 and >7 cm considered as S=2.

The serum CA125 level was used directly in the calculation.

The risk of malignancy index is apparently able to identify the probability of malignant and menopausal status, performed individually in woman with ovarian masses. This index is a simple scoring system which can be applied directly to clinical practice and might be of value in the preoperative assessment of the adnexal mass. It showed itself useful in referring patients with advanced neoplasm to a more complex healthcare unit, although it does not show prognostic value. However, the performance of the present index must be evaluated in other studies, using a validation sample from a similar population.

In women without evidence of advanced-stage of ovarian cancer, the current Risk of malignancy index is useful in clinical practice for differentiating malignant from benign pelvic masses, as compared to each individual comparison measured separately. In the present population, this index was more accurate in comparison with best individual predictor and CA125 serum level. No increase in the accuracy was

observed when analysed with patients age, tumor measurements or bilaterality. The validity of the index depends on the properties of malignant neoplasm and the properties of initial and advanced stages.

A prospective study was conducted in 1900 in London on 143 patients to assess the Risk of malignancy index incorporating CA125, ultrasound and menopausal status for the accurate preoperative diagnosis of ovarian cancer. Serum CA125 level of 30 IU/ml having sensitivity 81% and specificity of 75%. An ultrasound score of >3 had a sensitivity of 96.8% and specificity of 77% for malignant ovarian lesions. Sensitive and Specific methods for pre-operative diagnosis provided a rational basis of referral before diagnostic laparotomy. Combining three criteria serum Ca125 level, ultrasound score and menopausal status gives Risk of malignancy index (RMI) that is more effective in discriminating between malignant and benign lesion as compared to individual methods statistically.[8]

Using a RMI cut off level of 200, the sensitivity was 85% and specificity was 97%. Patients with RMI score greater than 200 had, on average, 42 times the background risk of malignancy and those with lower values had, 0.15 times the background risk.[8]

A prospective study was conducted in 173 women in Norway for evaluation of a risk of malignancy index based on serum CA 125, ultrasound findings and menopausal status in the pre-operative diagnosis of pelvic masses. Using a RMI cut off level 0f 200 to indicate malignancy, it gave a sensitivity of 80% specificity of 92% and PPV of 83%.[9]

Another similar cross sectional study was done on 158 women in Brazil between 1996-1998. The best individual performance was found in CA 125 sensitivity of 78% and specificity of 75%. The performance obtained for RMI at cut off level 150 was sensitivity and specificity of 79%.[64]

A study evaluated the ability of RMI to discriminate benign from malignant pelvic masses in 140 women between January 1998 and June 1999. Using an RMI cut off level of 200 to indicate malignancy, the RMI derived from this data set gave a sensitivity of 87.3% , specificity of 84.4% and a positive predictive value of 82.1%. The study concluded that, RMI is able to correctly discriminate malignant from benign pelvic masses. It can be introduced easily into clinical practice to facilitate the selection of patients for primary surgery.[65]

A study to evaluate the ability of RMI to discriminate between benign and borderline or malignant ovarian tumor enrolled 209 women with pelvic masses admitted for laparotomy between January 2002 and December 2007. Using a cut-off

level of 200 to indicate malignancy, the RMI gave sensitivity of 70.6%, specificity of 83.9%, PPV of 75%, and NPV of 80.6%. The RMI 2 gave sensitivity of 80% specificity of 78.2%, PPV of 71.6%, and NPV of 85.1%. The RMI 2 was significantly better in predicting malignancy than RMI 1. Authors concluded that, the RMI is able to discriminate between benign, borderline and malignant ovarian tumor.[66]

A study aimed to evaluate the use of RMI in primary evaluation of patients with adnexal masses in daily clinical practice, they recruited 151 women with adnexal masses. Using a cut-off level of 238 to indicate malignancy, RMI showed a sensitivity of 89.5%, a specificity of 96.2%, a PPV of 77.3%, a NPV of 98.4% and an accuracy of 95.4%. Study concluded that, RMI is a simple, easily applicable method in the

primary evaluation of patients with adnexal masses of high risk of malignancy, resulting in timely referral to gynecological oncology centres.[67]

Doppler Sonography

The sensitivity of gray scale sonography in the detection of ovarian tumour was superior to that of Doppler sonography (98% vs 67% respectively). Even when Doppler examinations were simplified and limited to the expression of internal color flow, gray scale sonography was a more sensitive indicator of malignancy than Doppler sonography (98% vs 77% respectively).[3,62]

Three dimensional power Doppler sonography

In the evaluation of 71 patients with ovarian masses, Cohen et al similarly found that the three dimensional power Doppler sonography was more accurate than two dimensional Doppler sonography or three dimensional gray scale sonography. The authors reported that three dimensional power Doppler sonography had a sensitivity of 100%, specificity of 75%, positive predictive value of 50%.[62] Several investigators have advocated the use of morphologic scoring systems, which aid in standardizing and quantifying the interpretation of ultrasound images.

Role of CT and MRI in diagnosing ovarian tumour

Magnetic resonance imaging helps to distinguish benign from malignant lesions, with accuracy of diagnosis of malignancy of 93%. The accuracy of MRI in the diagnosis of ovarian tumour is very high. CT is not indicated for the differential diagnosis of adenexal masses because of poor soft tissue resolution.[67]

A study was conducted to know clinicopathological features of epithelial ovarian cancer by Malik I.A. in Pakistan. [53] It was a prospective observational study. 286 patients were accrued in the study. They found that most of the well defined risk factors such as early menarche, late menopause, nulliparity, lack of lactation were uncommonly observed. 20% of patients had a positive family history. At the end, it was concluded that younger age at presentation, higher frequency of positive family history was associated with higher incidence of epithelial ovarian cancer.

To determine clinical and pathological features of ovarian cancer in women with germ line mutations of BRCA1[54] , a study was conducted by Rubin C. Stephen et al. It was found that out of 53 patients with germ line mutation, 43 showed serous adenocarcinoma. Therefore, as compared with sporadic ovarian cancer, cancer associated BRCA1 mutation have a more favourable clinical course.

With the objective to establish relationship between post menopausal hormonal use [55] and ovarian cancer risk, a study was conducted by Danforth K N etal. 389 Ovarian cancer patients were included in health study. It was a prospective observational study. Results showed that use of oestrogen plus progestin was not significantly associated with ovarian cancer risk.

Another study was conducted to compare clinical presentation of benign and malignant ovarian tumours and to identify symptoms leading to early diagnosis of ovarian carcinoma [56] by Wasim Tayyiba et al. It was a consecutive case study. 110 patients which on examination had ovarian cyst or tumours were included in the study. They found that 72% were benign and rest were malignant. Therefore, it was

concluded that ovarian cancer is a silent killer, specially affecting women above 50 years of age group.

With objective to find out frequency of different histological [57] patterns of ovarian tumours a study was conducted by Swamy G et al .120 cases of ovarian tumours were studied at Department of Pathology, Konaseema Institute of medical sciences, India. 71.6% were benign tumours, while 30% were malignant tumours. Commonest benign tumour was found to be serous cyst adenoma and commonest malignant tumour was found to be granulosa cell tumour, endometrial carcinoma.

Another study was conducted to know frequency of various histological patterns of ovarian tumours by Ashraf Ammeena et al. It was a retrospective case series study in which 212 cases of ovarian masses were included. Results showed that 40.09% were non neoplastic, 59.91% were neoplastic lesions. They concluded that Neoplastic lesion were more common than non-neoplastic lesion.[58]

Using an RMI cut-off level of 200, the sensitivity was 85% and the specificity was 97%. [8] Patients with an RMI score of greater than 200 had, on average, 42 times the background risk of cancer and those with a lower value 0.15 times the background risk of ovarian cancer.

To evaluate the ability of a RMI and to discriminate a benign from a malignant pelvic mass and to discriminate early stage (FIGO Stage I) from Stages II, III and IV of ovarian cancer a study was conducted in Norway which included 173 women, consecutively admitted between February 1992 and February 1994 for primary laparotomy of a pelvic mass.[9] Using a RMI cut-off level of 200 to indicate malignancy, the RMI derived from this dataset gave a sensitivity of 80%, specificity of 92% and positive predictive value of 83%. For the Stages II, III and IV of ovarian

cancer the sensitivity increased to approximately 90% without any substantial loss in specificity. It was concluded that RMI is able to correctly discriminate between malignant and benign pelvic masses.

To evaluate the ability of RMI to discriminate benign from malignant pelvic mass a study was conducted wherein 140 women with pelvic masses, between January 1998 and June 1999 were included. Using an RMI cutoff level of 200 to indicate malignancy, the RMI derived from this data set gave a sensitivity of 87.3%, a specificity of 84.4%, and a positive predictive value of 82.1%. Therefore, from this study conclusion was drawn that RMI is able to correctly discriminate malignant from benign pelvic mass. It can be introduced easily into clinical practice to facilitate the selection of patients for primary surgery.[65]

To evaluate the ability of RMI to discriminate between benign and borderline or malignant ovarian tumor a study was conducted on 209 women with pelvic masses admitted for laparotomy between January 2002 and December 2007 were included. Using a cut-off level of 200 to indicate malignancy, the RMI 1 gave sensitivity of 70.6%, specificity of 83.9%, PPV of 75%, and NPV of 80.6%. The RMI 2 gave sensitivity of 80%, specificity of 78.2%, PPV of 71.6%, and NPV of 85.1%. The RMI 2 was significantly better in predicting malignancy than RMI 1. Thus it was concluded that RMI is able to discriminate between benign and borderline or malignant ovarian tumor.[66]

A study was conducted to validate the use of RMI ≥200 as a tool for preoperative identification of ovarian cancer at a tertiary center. 1159 women with pelvic mass. There were 778 women diagnosed with benign pelvic mass, while 251 had ovarian cancer and 74 had borderline ovarian tumor. Fifty-six women were

diagnosed with other forms of cancer. Sensitivity and specificity for ovarian cancer vs. benign pelvic mass for RMI ≥200 were 92% and 82%, respectively. Corresponding positive and negative predictive values were 62% and 97% respectively. It was concluded that RMI ≥200 is a reliable tool for identifying patients with ovarian cancer pelvic masses at a tertiary centre to select patients for further preoperative examinations.[68]

METHODOLOGY

- Information was gathered from patients with ovarian tumours during interview regarding clinicopathological features of ovarian tumours.
- Investigations like USG, tumour markers, CT/ MRI were performed.
- Early menarche is defined as age <11 years at the onset .
- Late menopause is defined as >51 years of age.

New Weighted scoring system-Lerner et al.[69]

Parameter	0	1	2	3
Wall structure	Smooth/ small irregularites <3mm	-	Solid or non applicable	Papillarities ≥ 3mm
Shadowing	Yes	No	-	-
Septa	None or thin < 3mm	Thick ≥ 3mm	-	-
Echogenicity	Sonolucent or low level echo or echogenic core	-	-	Mixed or high

It will include *demographic features* of patients i.e. age in years, family history of malignancy, personal history of any other cancer, history of any Gynaecological problem.

It will also include *menstrual and reproductive history* of patients –age at menarche <11 years at menarche, nulliparity, menopausal status before surgery

(pre and post menopausal status), mean age at natural menopause > 51 years at menopause.

It will also include *clinical features*- abdominal pain, abdominal distension, vague lower abdominal discomfort, nausea and dyspepsia, vaginal bleeding, urinary complaints, clinical signs- pelvic mass, bulky uterus, ascites, pleural effusion, lab abnormalities-high CA125 (IU/ml).

It will also include *pathological features* .

Source of Data: All patients admitted with ovarian tumuor at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum in the Department of Obstetrics and Gynaecology.

Sample size: All patients admitted with ovarian tumour at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from 1st January 2014 to 31st August 2015.

Duration of study: 1st January 2014 to 31st August 2015.

Study design: A Prospective observational study.

Place of study: At KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Department of Obstetrics and Gynaecology, Belgaum.

Data analysis plan: The percentage distribution of clinical features and pathologic features of ovarian tumours was found. Categorical outcomes were summarized as rates and numerical outcomes as mean.

Inclusion criteria:

1. All patients with ovarian tumour attending OPD and admitted with the same at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

2. All patients given neoadjuvant chemotherapy were also included.

Exclusion criteria:

1. Ovarian metastasis from any other malignancy.

2. Recurrence of ovarian tumour.

Ethical clearance:

The ethical clearance was obtained from the Institutional ethics committee, Jawaharlal Nehru Medical College, Belgaum.

Informed consent:

Women fulfilling the selection criteria were explained about the nature of study and a written informed consent was obtained prior to enrolment.

Method of collection of data:

After the enrolment demographic data, reproductive, obstetric history were obtained during a interview with the patient. These findings were recorded on a pre designed proforma**.** Histopathology reports were obtained from the histopathology section of the Department of Pathology, J.N.Medical College, Belgaum.

RESULTS

This study was conducted in the Department of Obstetrics and Gynaecology, KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 119 cases were studied from 1 January 2014 to 31 August 2015. The study period was extended from 1 January 2014- 31 December 2014 to 1 January 2014 – 31 August 2015 due to availability of lesser number of cases. A letter informing this to the Director of Academic Affairs has been directed from the Department of Obstetrics and Gynaecology.

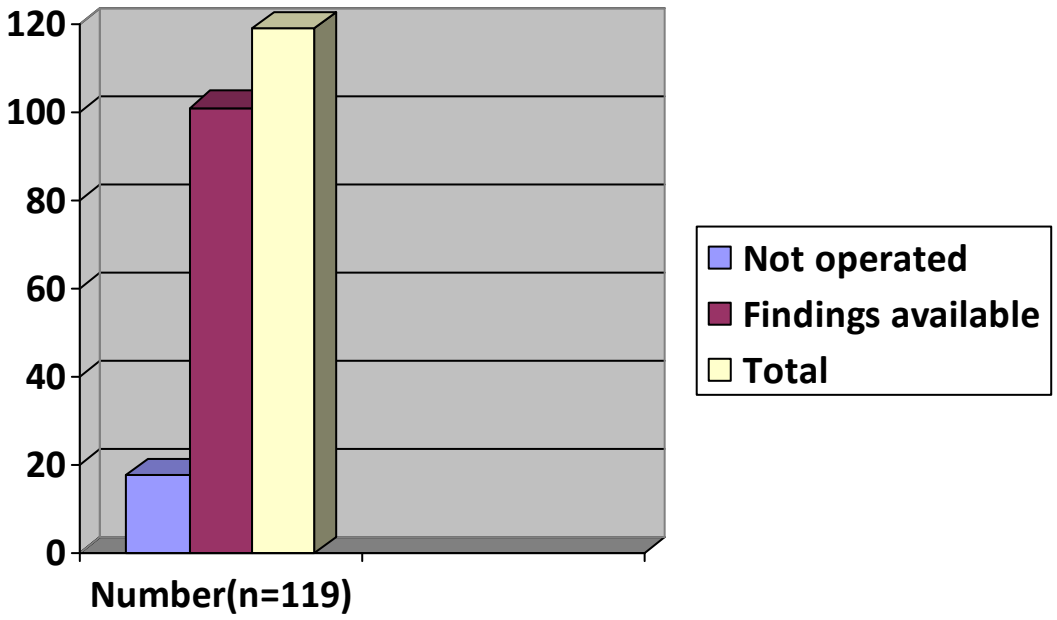
The data obtained was coded and entered into masterchart. The incidence of ovarian tumours was 6.9% of all Gynaecological admissions at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

The data was analysed and final observations were tabulated as below.

Table 1 Total number of cases

Type	Number(n=119)	Percentage(n=119)
Not operated	18	15.12
Findings available	101	84.87
Total	119	100.00

Graph 1 Total number of cases

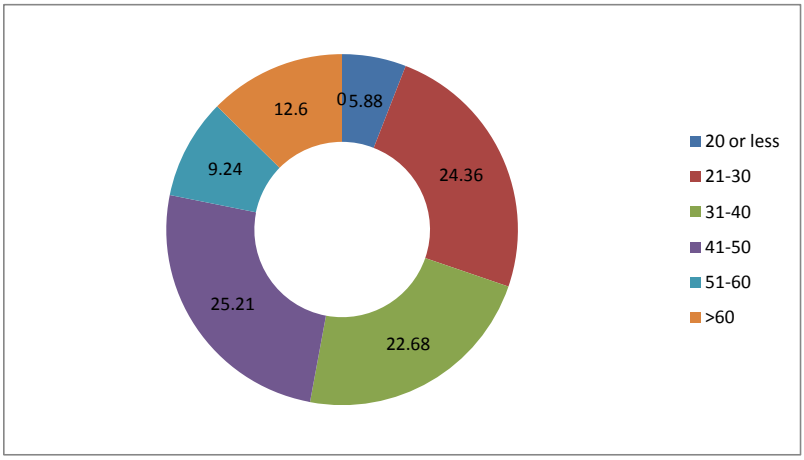


In the present study of 119 women, 18 women were not operated and in the remaining 101 the histopathological reports were available.

Table 2 Age Distribution

Age group(yrs)	Number	Percentage
20 or less	07	05.88
21 to 30	29	24.36
31 to 40	27	22.68
41 to 50	30	25.21
51 to 60	11	09.24
>60	15	12.60
Total	119	100.00

Graph 2 Age distribution

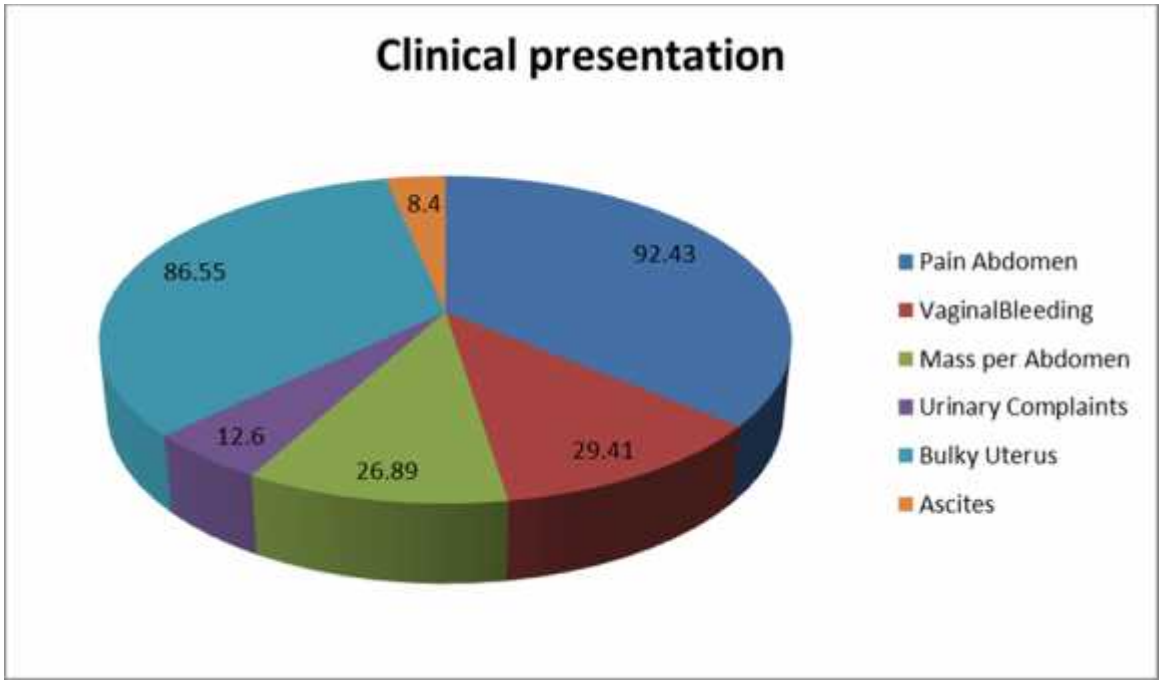


In the present study, 25.21%(30) of the women were in age group of 41 to 50 yrs and 24.36% (29) of the women were in 21 to 30 yrs, 22.68% (27) of women were in 30-40 years, 12.6% (15) women in >60 years age group. The mean age of the study population was 40.60 yrs.

Table 3 Clinical presentation

Characteristics	Number(n=119)	Percentage(n=119)
Pain abdomen	110	92.43
Vaginal bleeding	35	29.41
Mass per abdomen	32	26.89
Urinary complaints	15	12.60
Bulky uterus	103	86.55
Ascites	10	08.40

Graph 3 Clinical presentation

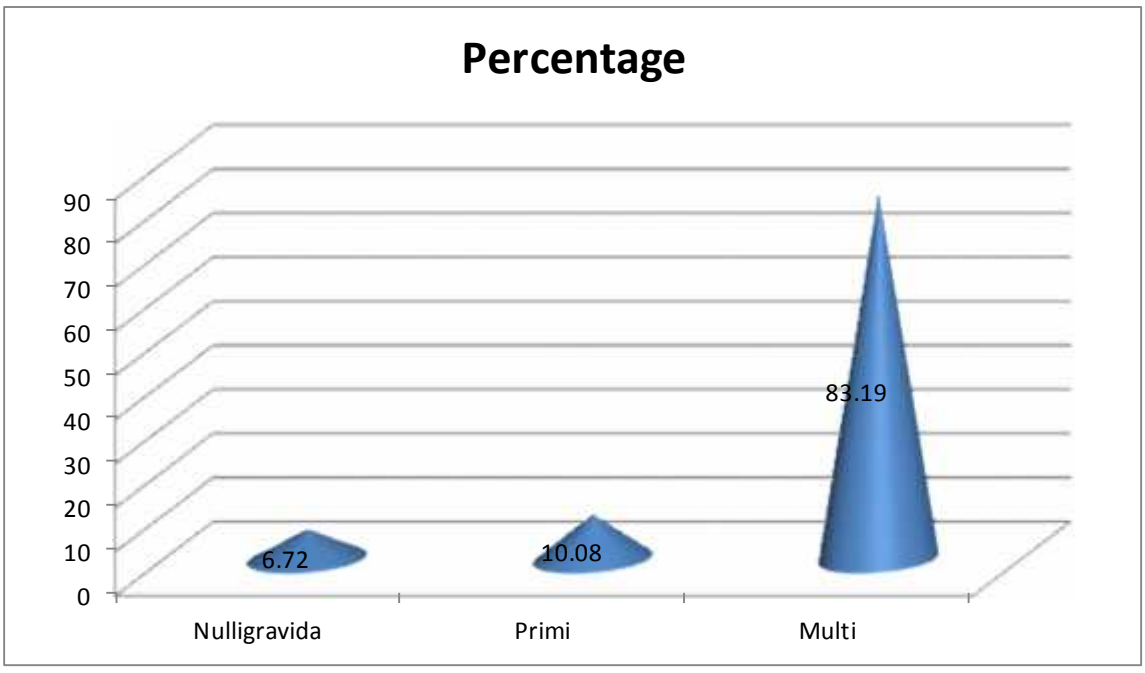


In the study of 119 women, 92.43% (110) of women presented with complaint of pain per abdomen and vaginal bleeding was present in 29.41% (35) of women. Amongst signs 86.55% (103) of women had bulky uterus while ascites was present in 8.40% (10).

Table 4 Parity status

Parity	Number(n=119)	Percentage(n=119)
Nulligravida	08	06.72
Primi	12	10.08
Multi	99	83.19
Total	119	100.00

Graph 4 Parity status

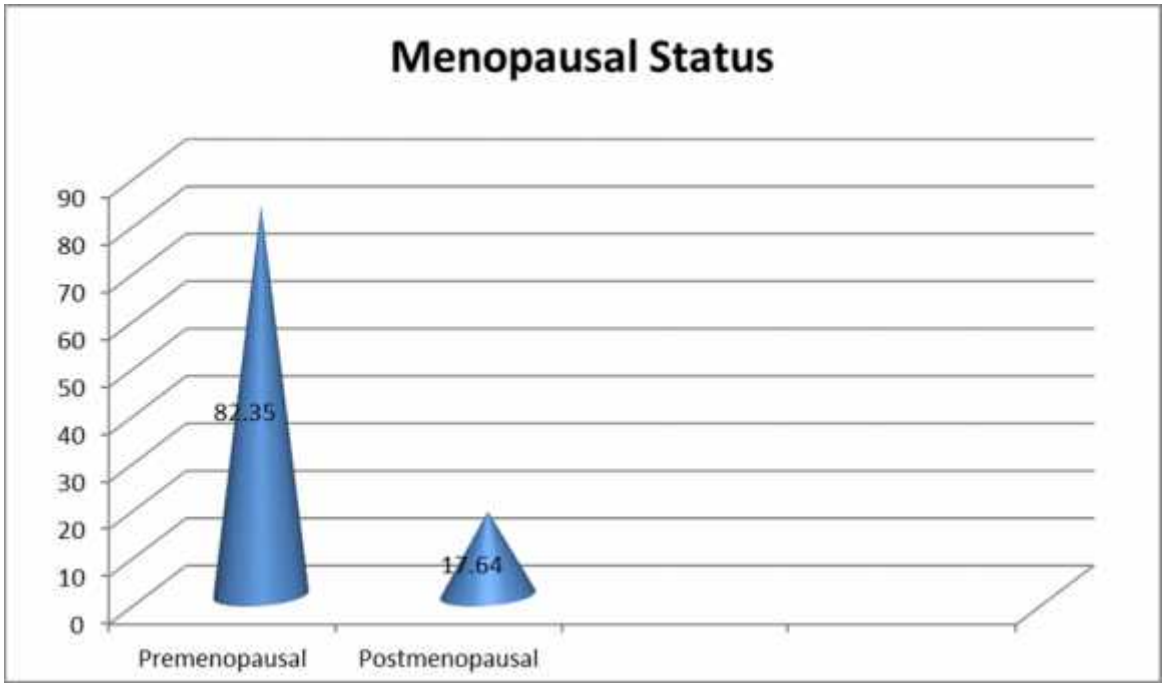


In the present study 83.19% (99) of women were multiparous while 10.08% (12) were primiparous while 6.72% (08) of women were nulligravida.

Table 5 Menopausal status

Menopausal status	Number(n=119)	Percentage(n=119)
Premenopausal	98	82.35
Postmenopausal	21	17.64
Total	119	100.00

Graph 5 Menopausal Status

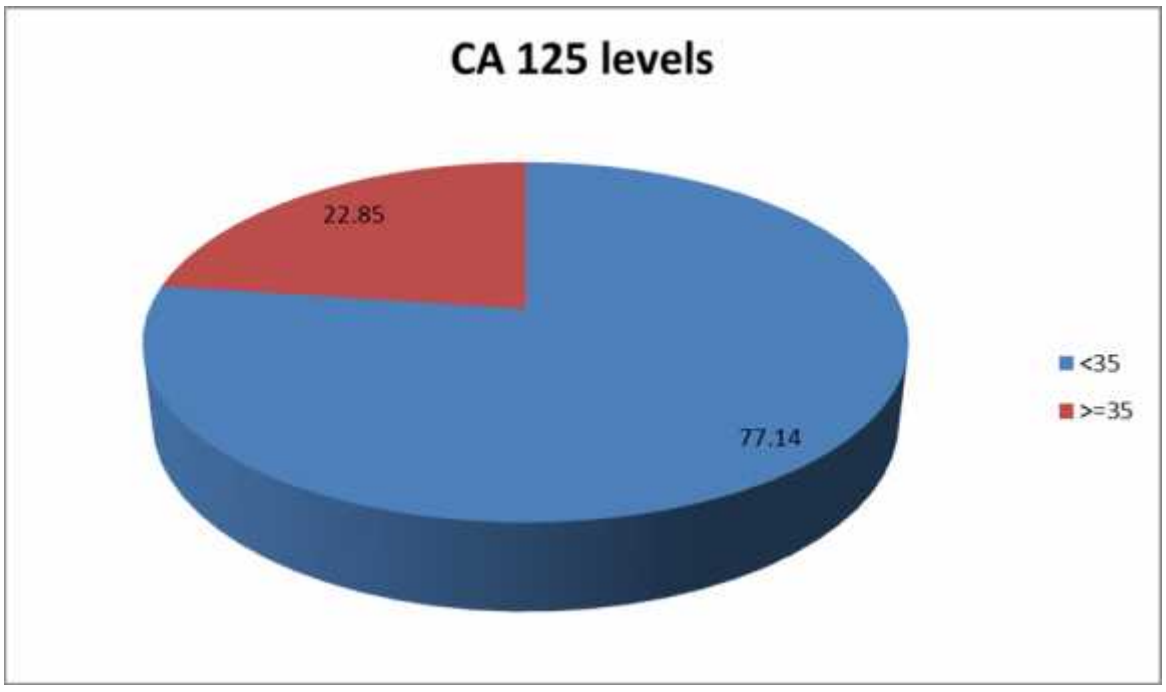


In the present study 82.35 % (98) of women were pre menopausal while only 17.64% (21) of women were post menopausal.

Table 6 CA 125 (IU/ml)

CA125 levels (IU/ml)	Number(n=70)	Percentage(n=70)
<35	54	77.14
>=35	16	22.85
Total	70	100.00

Graph 6 CA 125 (IU/ml)

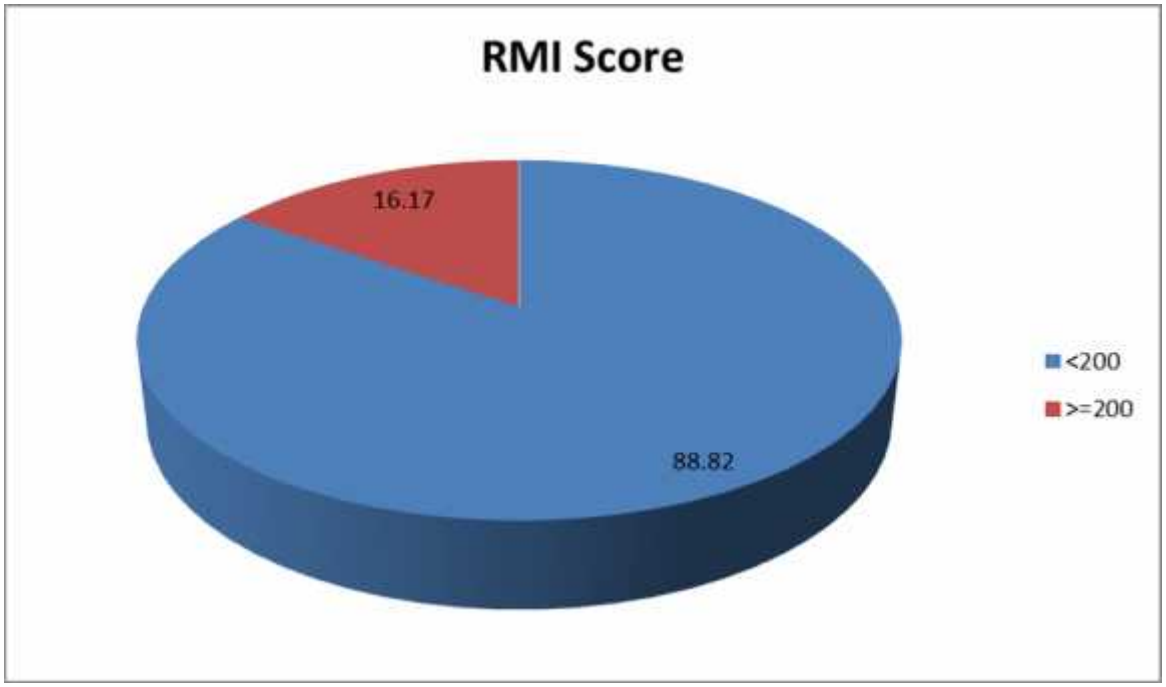


In this study of the total 70 women who had CA 125 value, 77.14% (54) of women had serum CA 125 levels of <35 IU/ml while 22.85% (16) of women had serum CA 125 levels >= 35 IU/ml.

Table 7 RMI Score

RMI Score	Number(n=68)	Percentage(n=68)
<200	57	83.82
>=200	11	16.17
Total	68	100.00

Graph 7 RMI Score

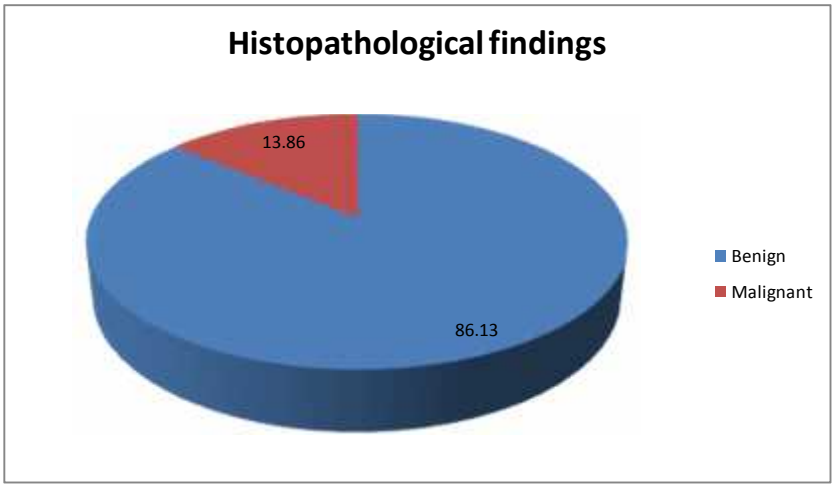


In this study, RMI Score was available in 68 women amongst which RMI Score was found to be < 200 in 83.82% (57) of women and in 16.17 % (11) of women it was>200.

Table 8 Histopathological Findings

Findings	Number(n=101)	Percentage(n=101)
Benign	87	86.13
Malignant	14	13.86
Total	101	100.00

Graph 8 Histopathological Findings



In the present study, out of the total 101 patients whose histopathological reports were available, benign lesions were present in 86.13% (87) of women while in 13.86% (14) of the women malignant lesions were noted.

Table 9 Benign ovarian tumours

Benign	Number	Percentage
Serous cystadenoma	31	35.63
Mucinous cystadenoma	15	17.24
Simple cyst	15	17.24
Haemorrhagic cyst	11	12.64
Benign cystic lesion	04	04.59
Corpus luteal cyst	03	03.44
Benign cystic teratoma	03	03.44
Paraovarian cyst	02	02.29
Follicular cyst	02	02.29
Fibroma	01	01.14
Total	87	100.00

In the present study , the commonest benign lesion was found to be serous cystadenoma 35.63% (31) followed by simple cyst and mucinous cystadenoma 17.24% (15) each out of the total 87 patients who had histopathological report showing benign lesions.

Table 10 Malignant ovarian tumours

Malignant	Number(n=14)	Percentage
Serous papillary adenocarcinoma	07	50.00
Granulosa tumour	02	14.28
Endometrioid carcinoma	02	14.28
Mucinous papillary cystadenocarcinoma	01	07.14
Dysgerminoma	01	07.14
Yolk sac tumour	01	07.14
Total	14	100.00

In the present study, commonest malignant lesion was found to be serous papillary adenocarcinoma 50% (07) followed by endometrioid carcinoma and granulosa tumour 14.28% (02) each.

Table 11 Comparison of menopausal status and HPR

Menopausal status	Malignant		Benign		Total(n=101)
	No.	%	No.	%	
No	14	15.2	66	82.50	80
Yes	02	09.5	19	90.5	21

P=0.64

In the present study amongst the total 21 women who had menopausal status only 2 women had shown malignant lesions on histopathological examination, while 19 of the women had benign lesions on histopathological examination.

Table 12 Accuracy of CA 125 (IU/ml) in comparison to histopathology

HPR	CA 125 >=35	CA 125 <35	Total(n=70)
Malignant	07	03	10
Benign	09	51	60
Total	16	54	70

P<0.001

Sensitivity(%)	Specificity(%)	PPV(%)	NPV(%)
70	85	43.75	94.44

In this study , 70 women who had CA 125 levels were compared with the histopathological reports, amongst10 women who had malignant lesion on histopathological examination 07 women had CA 125 >= 35IU/ml while 03 women had CA 125 < 35IU/ml. Amongst 60 women who had benign lesions on histopathological examination CA 125 >= 35 IU/ml was found in 09 women only while rest 51 women had CA 125 < 35 IU/ml.

The sensitivity and specificity of CA 125 in predicting malignant lesions as compared to histopathology was 70% and 85% respectively.

Table 13 Accuracy of RMI index in comparison to histopathology

RMI index	Malignant	Benign	Total(n=68)
>=200	08	03	11
<200	04	53	57
Total	12	56	68

P<0.001

Sensitivity(%)	Specificity(%)	PPV(%)	NPV(%)
66.6	94.64	72.72	92.98

In the present study 68 women in whom RMI index was calculated were compared with histopathological report, it was found that out of the 12 malignant lesions on histopathology, 8 had RMI Score>=200 while 4 women had RMI <200. Amongst 56 women who had benign lesions on histopathological report, 03 women had RMI >= 200 while 53 women had RMI < 200. The sensitivity and specificity of RMI in predicting malignant lesions as compared to histopathological report was 66.6% and 94.64% respectively.

Table 14 Comparison of ovarian crescent sign with histopathological report

Ovarian crescent sign	Malignant	Benign	Total(n=68)
Present	01	39	40
Absent	08	20	28

P= 0.002

In the study it was found that amongst 68 women, in whom ovarian crescent sign was studied 1 women had presence of ovarian crescent sign was found to have malignant lesion on HPR. Amongst 09 women who had malignant lesion on HPR, ovarian crescent sign was absent in 08 women while it was present in 01 woman only. This is in agreement with the literature which states that ovarian crescent sign is usually absent in malignant lesion. Amongst 59 women who had benign lesion on histopathological report, ovarian crescent sign was present in 39 women and was absent in 20 women.

DISCUSSION

A pelvic mass is one of the most frequent indications for referral to Gynaecologists. Diagnosis of ovarian tumours can be difficult due to variety of pathological conditions that can affect the ovaries and present with similar clinical manifestations. Knowledge of morphology and age specific characteristics can help refine the diagnosis.

The preoperative diagnosis of whether a mass is malignant cannot always be made with current diagnostic modalities. Surgery can be optimally planned if an ovarian neoplasm is known to be benign or malignant in advance. The type of surgical procedure and the experience of the surgeon are important factors for the prognosis of ovarian tumours. An improved method for pre-operative discrimination of a pelvic mass would result in more women receiving first-line therapy from appropriately trained and experienced personnel. For such referrals to be efficient, improved specific and sensitive methods for diagnosing ovarian tumours are needed.

Many investigators have employed a variety of sonographic variables in an attempt to predict a malignancy, including Doppler analysis. A number of articles have discussed ovarian tumours and the panel of different tumour markers. Various combined methods for evaluating the risk of ovarian tumour in women have been proposed.

Our hospital is a tertiary care hospital where patients are referred from the adjoining and far flung areas. As it is a Charitable hospital, a variety of Gynaecological diseases including malignancies are frequently seen. Thus, the present study was aimed to know the incidence and to study the clinicopathological features of ovarian tumours at KLE's Dr. Prabhakar Kore Hospital and Medical Research

centre, Belgaum. The incidence of ovarian tumour at KLE's Dr. Prabhakar Kore Hospital and Medical Research centre was 6.9% of all Gynaecological admissions. The study was conducted on a total of 119 women suspected to have ovarian lesion from 1st January 2014 to 31st August 2015 in the department of Obstetrics and Gynaecology, at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. Of the total 119 women, 18 women were not operated and in the remaining 101 patients histopathological reports were available.

In this study of 119 women, the commonest age group was 41 to 50 years 25.21% (30) followed by 21 to 30 years 24.36% (29). 22.68% (27) of women were in 30-40 years, 12.6% (15) women in > 60 years of age group. The mean age was found to be 40.60 years. These results were in agreement with the findings in literature stating that, the ovarian tumours can occur at any age but their peak incidence is in the reproductive age group. [3,15] Similar studies by other investigators have highlighted that most ovarian tumours (47.2%) are seen between 21 and 40 years, whereas most malignant tumours have been noted (73.1%) above 40 years.[10] In another study from Iran , the median age for malignant lesions was reported to be 49 years.[45] A higher median age of 60-65 years for malignant lesions has been reported from western countries and from southern part of India.[3] However, it was interesting to note very low frequency of early menarche, late menopause, nulliparity and advanced age at first child birth in the present study. Most of the women were multiparous and most of them had lactated in the present study. Repeated stimulation of the ovarian epithelium has been suspected to be a predisposing factor for malignant transformation. Thus increased parity will have a protective effect on the development of ovarian tumours.[64]

In the present study of 119 patients, 92.43% (110) women presented with pain abdomen, 29.41% (35) presented with vaginal bleeding while only 12.60% (15) had urinary complaints. Amongst signs 86.55% (103) of women had bulky uterus while only 8.40% (10) of women had ascites.

With regard to obstetric history, most 83.19% (99) of the women reported were multiparous while only 6.72% (08) were nulligravida.

In the present study 82.35% (98) of women were premenopausal while 17.64% (21) women were postmenopausal. The serum CA 125 levels were <35 IU/ml in 77.14% (54) while in 22.85% (16) of women had serum CA 125 >=35 IU/ml. According to a study it was found that CA 125 cannot adequately be characterized as a screening test due to the presence of overall low incidence of ovarian cancer in general population and the risk of false positive result.[60,63]

In this study RMI Score was calculated to be < 200 in 83.82% (57) cases while 16.17% (11) women had RMI score >=200 IU/ml.

In the present study, out of the total 101 patients in which histopathological reports were available benign lesions were present in 86.13% (87) of women while 13.86% (14) women had malignant lesions on histopathological reports. A similar study to verify the effectiveness of the RMI in the discrimination between benign and malignant adenexal masses in clinical practise reported benign tumour in 62.96% and malignant tumour in 37.04% of the patients.[5] Another prospective study was conducted in Turkey to evaluate the ability of four Risk of malignancy indices (RMI) to detect malignant ovarian tumour in 100 women which reported that 80% had benign disease while 20% had malignant disease.[62]

In the present study, the commonest benign lesion was found to be serous cystadenoma 35.63% (31) followed by simple cyst and mucinous cystadenoma 17.24% (15) out of the total 87 patients who had histopathological report showing benign lesions. The commonest malignant lesion was found to be serous papillary adenocarcinoma 50% (07), followed by endometrioid carcinoma and granulosa tumour 14.28% (02) each. In a similar study, Gupta et al. reported 72.9% benign, 4.1% borderline, 22.9% malignant tumours.[15] Ovarian tumours display heterogenesity. The histological classification of ovarian tumours by the World Health Organization (WHO) is based on the histogenesis of the normal ovary. Histologically, surface epithelial tumours are the commonest.[3]

In our study, 4 patients underwent neo adjuvant chemotherapy. A prospective study from Turkey reported mucinous cystadenocarcinoma as the commonest diagnosis in malignant cases (10 out of 20) and endometriosis in benign cases (27 out of 80 cases).[62]

Overall the pattern of histological types of ovarian tumours is almost the same in our study as in other studies worldwide reporting epithelial tumours being the commonest.

The risk of malignancy index (RMI) is a simple scoring system based on menopausal status, ultrasound and serum concentration of CA 125. The RMI can be applied in less specialized centres. Risk of malignancy index (RMI) is recommended in assessment of patients with adenexal masses. In the present study, RMI was found to be <200 in 83.82% of women and in 16.17% of women it was >200. The sensitivity and specificity of RMI index in detecting malignant lesions was 66.6% and 94.64% respectively.

In the 1990s , Jacobs et al[8] originally developed the RMI , which is now termed RMI 1. Tingulstad et al developed their version of RMI in 1996 and it is known as RMI 2. In 1999, Tingulstad et al modified the RMI , which is termed as RMI 3. Yamamoto et al created their own model of Risk of malignancy index. They added the parameter of tumor size (S) to the RMI and termed it as RMI 4. Jacobs et al originally developed RMI , and subsequently the same group reproduced the results in a second patient group, establishing the superiority of RMI over the individual parameters.

Jacobs et al in his study[8] assessed age, ultrasound score, menopausal status, clinical impression score and serum CA 125 level to see how they could distinguish between patients with benign (n=101) and malignant (n=42) pelvic masses . Each criteria used alone provided statistically significant discrimination. The most useful criteria were serum CA 125 level of 30IU/ml (sensitivity 81% , specificity 75%) and an ultrasound score of 2 (sensitivity 71% , specificity 83%). Three criteria could be combined in a risk of malignancy index (RMI) which is simply calculated using the product of the serum CA 125 levels (IU/ml) , the ultrasound scan result (expressed as a score of 0 , 1 or 3) and the menopausal status (1 if premenopausal and 3 if menopausal). This index was as effective as a discriminant between malignant lesion and benign lesions as more formal methods.

Using RMI index cut-off level of 200, the sensitivity was 85% and the specificity was 97% . Patient with an RMI score greater than 200 had , on average , 42 times the background risk of cancer and those with a lower value 0.15 times the background risk. These findings were comparable with the present study where the

sensitivity of RMI in predicting malignant lesions as compared to histopathology was 93.33% with 87.76% as specificity.[9]

Similar results were reported in recent study where sensitivity of RMI was 83.33%, specificity 94.12 %, positive predictive value 89.29% and negative predictive value 90.57% using RMI cut of 200.[9]

The RMI has been evaluated in 16 studies[51,52,53,54,55] since its description by Jacobs in 1990 he described a cut off level of 200, with sensitivity of 85% and specificity of 97%. However, most studies evaluated a range of cut-off levels varying between 25 and 250. When 200 was used as cut-off level , the pooled estimate for sensitivity was 78% (95% CI 71-85%) for a specificity of 87% (95% CI 83-91%) . At a cut-off level of 50 , the pooled estimate for sensitivity was 91% (95% CI 85-97%) for a specificity of 74% (95% CI 69-80%) . .

A similar study[53] was conducted in National Cancer Institute, Karachi wherein prospective analysis of women with epithelial ovarian cancer was done and suggested that clinicopathological features, stage of disease were similar to the North American or European women with epithelial ovarian cancer.

The data available from this study can help us in recognizing the pattern of ovarian tumours prevalent.

CONCLUSION

It is concluded from the present study that on morphological grounds, tumours originating from surface epithelium are the commonest variant. Majority of them are benign but incidence of malignancy was also significantly observed in our set up. It is therefore suggested that efforts must be made to identify risk factors for malignant lesions of ovary.

Inspite of all advances in the preoperative diagnosis of ovarian tumours, surgical removal followed by histological examination continues to be the final arbiter as to the true nature of the tumour.

SUMMARY

Ovarian tumours are frequent reasons for referral to Gynaecologist.

The present study was planned to know the incidence of ovarian tumour and to study clinicopathological features of ovarian tumours like demographic, reproductive, menstrual factors, clinical features, laboratory findings, pathological features at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

The incidence of ovarian tumours was 6.9% of all Gynaecological admissions at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

In the present study of 119 women, 18 were not operated and in the remaining 101 the histopathological reports were available. The commonest age group was 41 to 50 years 25.21% (30) followed by 21 to 30 years 24.36% (29). 22.68% (27) of women were in 30-40 years, 12.6% (15) women in > 60 years of age group. The mean age was found to be 40.60 years in the present study.

In this study of 119 women, 92.43% (110) of women presents with complaint of pain per abdomen and vaginal bleeding was present in 29.41% (35) of women. Amongst signs 86.55% (103) of women had bulky uterus while ascites was present in 8.40% (10).

In the present study, 83.19% (99) of women were multiparous while 10.08% (12) were primiparous and 6.72% (08) of women were nulligravida.

In this study 77.14% (54) of women had serum CA 125 levels of <35 IU/ml while 22.85% (16) of women had serum CA 125 levels >=35 IU/ml.

In this study RMI Score was found to be < 200 in 83.82% (57) of women and in 16.17 % (11) of women it was>200.

In the present study, out of the total 101 patients in which histopathological reports were available benign lesions were present in 86.13% (87) of women while in 13.86% (14) of the women malignant lesions were present. In the present study, commonest malignant lesion was found to be serous papillary adenocarcinoma 50% (07) followed by granulosa cell tumour and endometrioid carcinoma 14.28% (02) each.

In the present study, the commonest benign lesion was found to be serous cystadenoma 35.63% (31) followed by simple cyst and mucinous cystadenoma 17.24% (15) each out of the total 87 patients who had histopathological report showing benign lesions. In the present study amongst the total 21 women who had menopausal status only 2 women had shown malignant lesions on histopathological examination, while 19 of the women had benign lesions on histopathological examination.

In this study, 70 women who had CA 125 levels were compared with the histopathological reports, amongst10 women who had malignant lesion on histopathological examination 07 women had CA 125 >= 35IU/ml while 03 women had CA 125 < 35IU/ml. Amongst 60 women who had benign lesions on histopathological examination CA 125 >= 35 IU/ml was found in 09 women only while rest 51 women had CA 125 < 35 IU/ml. In the present study 68 women in whom RMI index was calculated were compared with histopathological report, it was found that out of the 12 malignant lesions on histopathology, 8 had RMI Score>=200 while 4 women had RMI <200. Amongst 56 women who had benign lesions on histopathological report, 03 women had RMI >= 200 while 53 women had RMI < 200. The sensitivity and specificity of RMI in predicting malignant lesions as compared to histopathological report was 66.6% and 94.64% respectively.

In the study it was found that amongst 68 women, in whom ovarian crescent sign was studied 1 women had presence of ovarian crescent sign was found to have malignant lesion on HPR. Amongst 09 women who had malignant lesion on HPR, ovarian crescent sign was absent in 08 women while it was present in 01 woman only. This is in agreement with the literature which states that ovarian crescent sign is usually absent in malignant lesion. Amongst 59 women who had benign lesion on histopathological report, ovarian crescent sign was present in 39 women and was absent in 20 women.

Thus, it is concluded that on morphological grounds, tumours originating from surface epithelium are commonest variant and the various diagnostic modalities will help in early recognition of malignant lesions of the ovary, thereby helping us to reduce the mortality rates.

However, inspite of all the advances in the preoperative diagnosis of ovarian tumours, surgical removal followed by histological examination continues to be the final arbiter as to the true nature of the tumour.

BIBLIOGRAPHY

1. Piver MS (1996) Prophylactic oophorectomy: reducing the US death rate from epithelial ovarian cancer. A continuing debate. The oncologist, 1, 326-30.

2. E mal A, Murray T, Ward et al(2005). Cancer statistics, 2005. CA: A Cancer Journal for Clinicians, 55, 10-30.

3. Berek & Novak's Textbook of Gynaecology (14 edition).

4. Seogard R, Knudsen A, Rix P, et al. Risk of malignancy Index in the pre-operative evaluation of patients with adenexal masses.Gynecol Oncol. 2003:90:109-12.

5. Morgante et al . Comparison of two malignancy risk indices based on serum CA 125, ultrasound score and menopausal status iin the diagnosis of ovarian masses. BJOG: An International Journal of Obstetrics and Gynecology 1999;106(6): 524-527.

6. Leelahakorn S, Tangjitgamol S, Manusirivithay et al. .Comparison of ultrasound score, CA 125, menopausal status, and risk of malignancy index in differentiating between benign and borderline or malignant ovarian tumours. J Med Assoc Thai 2005; 88:22-30.

7. Benjapibal M, Neungton C. Pre- operative prediction of serum CA 125 level in women with ovarian masses. J Med Assoc Thai 2007;90:1986-91.

8. Jacob I, Oram D, Fairbanks J et al. A risk of malignancy index incorporating CA125 , ultrasound and menopausal status for the accurate pre- operative diagnosis of ovarian cancer. Br J Ostet Gynecol, 1990;97:922-9.

9. Tingulstad S, Hagen B, Skjelstad FE,et al. Evaluation of a risk of malignancy index based on serum CA125, ultrasound findings and menopausal status in pre-operative diagnosis of pelvic masses. Br J Obstet Gynecol, 1996;103:826-31.

10. K Uma Devi. Current status of gynaecological cancer care in India. J Gynecol Oncol 2009;20(2):77-80.

11. Young RH. A brief history of the pathology of gonads –A review.Mod Pathol 2005; 18: 3-17

12. David J, Ashely B. Evans histopathological appearance of tumours. 4th Ed. New York: Churchill Livingstone Pvt> Ltd; 1990.

13. Parker D, Bradly C, Bogle SM. Serum albumin and CA-125 are powerful predictors of survival in epithelial ovarian cancer Br J Obest Gynecol 1994; 101: 888-93.

14. Hellstorm I, Raycraft J, Hayden Led Better JA, Schummer M, Mc Inthosh M et al. The HE4 (WFDC2) protein is a biomarker for ovarian carcinoma. Cancer Research 2003; 63(13): 3695-700.

15. Jemal A, Murray T, Ward E, et al (2005). Cancer statics, 2005. CA: A Cancer Journal for Clinicians, 55, 10-30.

16. Sharma JB, Gulati N. Gynecological disorders in geriatric age group. J Obstet Gynecol India 1990; 40: 459-63.

17. Maheshwari V. Surface epithelial tumours of ovary. Ind J Pathol Microbiol 1994; 37: 75-85.

18. Ramachandran G, Hiralal K, Chinnamma K, thangavelu. Ovarian neoplasm- A study of 909 cases. J Obstet Gynaec India 1972; 22 309-12.

19. Sikar K, Kumar p, Roy Choedary NN. A study of ovarian malignancy – A review of 149 cases. J Obstet Gynaec India 1981; 31: 478-81.

20. Serov SF, Scully RE, Sabin LH. International Histological classification of tumour. No. (< Histological typing of ovarian tumors. Geneva: World Health Organisation; 1973.

21. Fox H, Wells M. Haines and Taylor obstetrical and gynaecological pathology. Vol 1. 5th Edition, London: Churchill Livingstone Pvt. Ltd; 2003.

22. Gupta SC, Singh PA, Mehrotra TN, Agarwal R. A clinicopathological study of ovarian tumours. Indian J Pathol Microbiol 1986; 29: 354-62.

23. Maheshwari V. surface epithelial tumours. Indian J Pathol Microbiol 1994; 37: 75-85.

24. Aure JC, Hoegk S, Kolsad H. Clinical and histological studies of ovarian carcinoma- A long term follow up of 990 cases. Am J Obstet Gyecol 1973; 37: 109-13.

25. Sampson JA . The endometroid carcinoma of the ovary. Arch surg 1920; 1:10-15.

26. Roth LM, Ovarian Brenner tumours, metaplastic, proliferating and low malignant potential. Cancer 1985; 56: 582-91.

27. Calondex C, Loffer J. Tumors of the female genital tract. diagnostic histopathology of tumours. Vol 1, 2nd Edition, Philadelphia: Churchill Livingstone Pvt. Ltd; 2000.

28. Young RH, Scully RE. Ovarian sex cord stromal tumours- Recent progress. Int J Gynecol Pathol 1982: 1: 101-23.

29. Evans At, Geffey TA. Clinicopathologic review of 118 granulosa and 82 theca cell tumour. Obstet and Gynecol 1980; 55: 231-8.

30. Young RH, Scully RE: Ovarian sertoli-leydig cell tumour. Int J Gynecol Pathol 1984; 2: 349-63.

31. Sexena H, Gupta S. Malignancies of the ovary: J Obset gynecol india 1978; 28: 271-8.

32. Chenot J. Dysgerminoma. J Obstet Gynecol Br Emp 1950; 19: 507-511.

33. Gerbie MV. Primary choriocarcinoma of the ovary. Obstet Gynecol 1975; 46: 720-8.

34. Kumar V, Abbas AK, Fausto N, Robbins< Cartan. Pathologic basis of disease. 17th Edition, Philadelphia: Elsevier Pvt. Ltd. 2004.

35. Bast Rc, Klug TL, St. Johan E, Jension E, Niloff JM, Lazarus H et al. A radioimmunoassay using a monoclonal antibody to monitor the course of apithelial ovarian cancer . N Engl J Med 1983; 309: 883-7.

36. Herbst AL. The epidemiology of ovarian carcinoma and the current status of tumour markers to detect disease (Review). Am J Obstet Gynecol 1994; 170: 107-9.

37. Woolas RP, Xu FJ, Jacobs IJ, Yu YH, Daly L, Berchuck A et al. Elevation of multiple serum markers in patients with stage I ovarian caner. J Nat Cancer Inst 1993; 85: 1748—51.

38. Jacobs I, Davies AP, Bridges J, Stabile I, Fay T, Reynolds C et al. Multimodal approach to screening for ovarian cancer. Lancet 1988; 1: 268-71.

39. Sheiko MC, Hart RW. Dysgerminoma and eleveated serum lactic dehydrogenase- A case report and Review. Cancer 1982; 49: 994-8.

40. Chervnak FA, Issacson GC, Campbell S. Gynecological Malignancy. In: Morley P, Hollman AS (eds). Ultrasound in Obstetrics and gynaecology. 1st Ed. 1993, 1746-59.

41. Sanders RC, Jammes AE. The Principles and Practice of Ultrasonography in Obstetrics and Gynaecology.3rd Ed. 1985 appleton- Century crofts, 473-516.

42. Lawson TL, Alberelli JN. Diagnostic of gynaecologic pelvic masses by gray scale ultrasonography. Analysis of specific and accuracy. Amer J Radiol 1977; 128: 1003-6.

43. Callen PW. Ovarian Sonography. In: Dillmacky MJ, Atri M (eds) Ultrasonography in Obstertics and Gynaecology. 4th Ed. 2000 W B Saunders Company, 857-90.

44. Kurjak A. Adnexal Tumours. In: Kurjak A, Jalud I (eds). An Atlas of Ultrasonography in Obstertics and Gynaecology. 1st Ed 1995 CBS publishers, 171-85.

45. Outwater EK, Siegelman ES, Hunt JL. Ovarian teratomas: tumour types and imaging characteristics. Radiographics 2001; 21: 475-490.

46. Sisler CL, Siegel MJ. Ovarian teratomas: a comparison of the sonographic appearance in prepubertal and postpubertal girls. AJR Am J Roentgenol 1990; 154: 139-141.

47. Quinn SF, Ericson S, Black WC.Cystic ovarian teratomas: the sonographic appearance of the dermoid plug: Radiology 1985;155: 477-478.

48. Patel MD, Feldstein VA. Lipson SD, Chen DC, Filly RA. Cystic teratomas of the ovary: diagnostic value of sonography, AJR Am J Roentgenol 1998;171:1061-1065.

49. Sheth S, Fishman EK. BuckJL, Hamper UM, Sanders RC. The variable sonographic appearances of ovarian terato-mas: correlation with CT. AJR 1998;151:331-334.

50. Patel MD, Feldstein VA, Lipson SD, Chen DC, Filly RA. Cystic teratoma of the ovary: diagnostic value of sonogram-phy. AJR Am Roentgenol 1998;171: 1061-1065.

51. JacobsI, OramD, FairbanksJ, TurnerJ, FrostC, Grudzinskas JG. A risk of malignancy index incorporating CA 125, ultrasound and menopausal status for

the accurate preoperative diagnosis of ovarian cancer. Br J Obstet Gynaecol 1990;97:922-9.

52. Mol BW, Boll D, De kanter M, Heuintz AP, Sijmons EA, Oei SG, et al Distinguishing the benign and malignant adnexal mass: an external validation of prognostic models. Gynecol Oncol 2001;80:162-7.

53. Malik I. A. National cancer institute; Article: A prospective study of clinicopathological features of epithelial ovarian cancer in Pakistan. J. Pak Med Assoc. 2002 Apr, 52(4): 155-8

54. Rubin C. Stephen, Benjamin Ivor, Behbakht Kian, Takahashi Hiroyuki, Norgan A. Mark, Livolsi A. Virginia; Article: Clinical and pathological features of ovarian cancer in women with germ line mutations of BRCA1. The new England journal of medicine 1996; 335: 1413-1416, November 7, 1996

55. Danforth K N, Tworoger S S, Hecht J H, Rosner B A; Article: A prospective study of post menopausal hormone use and ovarian cancer risk Br J Cancer 2007 January 15; 96(1): 151-156.

56. Wasim Tayyiba, Siddiq Saqib department of community medicine Allama Iqbal medical college Lahore; Article: Comparison of clinical presentation of benign and malignant ovarian tumours J Pak Med Assoc. 2009 Jan; 59(1): 18-21

57. Swamy G G, Satyanarayan N, Andhra Pradesh; Article: Clinicopathological analysis of ovarian tumours –a study on five year samples. Nepal Med Coll J. 2010 Dec; 12(4): 221-3

58. Ashraf Ammeena, Shaikh Saeed A., Ishfaq Ayesha, Akrum Abdullah, Kamal Furrakh, Ahmad Nazeefa Fatima medical college; Article: The frequency and histopathological Vol.28 (Jan. –Jun.2012)

59. Dutta Textbook of Gynaecology, 6th edition.

60. Seshadri Laxmi Essentials of Gynaecology, 1st edition

61. Priya C, Sunesh Kumar, Lalit Kumar Borderline ovarian tumours: An update Indian Journal of Medical oncology, Vol. 29 No.2,2008.

62. Jeffcoate's Principles of Gynaecology, 8th edition

63. Kiran Kalghatgi- Kulkarni, Prahlad Kushtagi Ovarian crescent sign and sonomorphological indices in preoperative determination of malignancy in adenexal masses Indian Journal of Medical Sciences, volume 62, December 2008.

64. Irum Sohail, Zartaj Hayat, Sami Saeed A comparative analysis of frequency and patterns of ovarian tumours at a tertiary care hospital between two different study periods (2002-2009), J postgraduate medical institute, 2012

65. Yamamoto Y, Yamada R Oguri H, Maeda N, Fukaya T. Comparison of four malignancy risk indices in the preoperative evaluation of patients with pelvic mass. European journal of Obstetrics, Gynaecology and Reproductive biology 2009;144(2):225-229.

66. Kristen Pepin, Carmen, Dizon CA 125 and Epithelial ovarian cancer: Role in screening, diagnosis and surveillance. Americal Journal of Oncology and Haematology, 2012.

67. Kaori Togashi Ovarian cancer: The clinical role of US, CT and MRI, volume 13, October 2003.

ANNEXURE I – CONSENT FORM

INFORMED CONSENT FOR PARTICIPATION IN THE RESEARCH STUDY

'Clinicopathological features of ovarian tumour – A Prospective Observational study'

Mrs/ Ms. ---------- we are requesting you to enroll yourself in study conducted by Dr. _____, Post Graduate M.S. in the department of Obstetrics and Gynaecology, KLE University under the supervision and guidance of Dr. _____ MD, FICOG, Professor, Department of Obstetrics and Gynaecology, J.N. Medical college, Belgaum. Patients who fulfil the criteria will be included in the study. During the study you will be asked some questions regarding your present complaints and you are supposed to answer to the best of your knowledge.

Your participation in study is voluntary. Your decision whether or not to participate in study will not affect your relationship with the institute or in the standard of care provided to you. If you decide to participate you are free to withdraw at any time.

Purpose of study

The aim of study is to know the incidence of ovarian tumour at Dr. Prabhakar Kore Hospital and MRC, Belgaum and to know the clinicopathological features of ovarian tumours like demographic, reproductive, menstrual factors, clinical features, lab findings, histopathological reports.

Procedure involved

If you agree to enrol yourself in my study, information will be gathered during interview regarding menstrual and reproductive history, clinical features including pain abdomen, mass per abdomen , vaginal bleeding, urinary complaints, clinical signs like pelvic mass, bulky uterus, ascites, pleural effusion, laboratory findings like Ca- 125,liver function tests, radiological findings like CT/MRI, Risk of malignancy indices, ovarian crescent sign and histopathological reports.

Information required will be retrieved from case records itself.

Benefits of study

It will us in knowing incidence of ovarian tumour at Dr. Prabhakar Kore Hospital and MRC, Belgaum and also in knowing clinicopathological features of ovarian tumour.

Voluntary Participation/ Withdrawl

Taking part in study is voluntary. You may choose not to enrol yourself in this study. Your decision will not change present or future health care services offered to you at Dr. Prabhakar Kore Hospital and MRC, Belgaum.

Alternatives

Even if you decline participation in study, you will get routine line of management.

Privacy and Confidentiality

The only people to know that you are a research subject are members of research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except-

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to public results

When the results of the research study are published or disclosed in a conference, no information will be displayed that would disclose your identity. All the information will remain confidential.

Questions

In case you have any questions related to the study, in future or in case of study related complications, you can contact Dr. _____ M.S. Post Graduate in department of Obstetrics and Gynaecology, mobile no. _____ and Dr. _____ MD FICOG , Professor, Department of Obstetrics and Gynaecology, J.N. Medical college mobile no. _____.

In case you have any queries about your rights as a study subject, you may call Dr. Ganga Pilli, Professor, Department of pathology and Chairman, J.N. Medical college Institutional Ethical Committee for Human Subjects Research, Phone no 9448863866 or extension number 4052 at J.N. Medical college, Belgaum.

‘Clinicopathological features of ovarian tumour – A Prospective Observational study’

In KLE’s Dr. Prabhakar Kore Hospital , Belgaum- 590010

Consent for participation in research trial

Myself Mrs/ Ms.---------- voluntarily agree for participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from study anytime. I am signing consent form after having read or been read for me in my own vernacular language, including the risks and benefits and having all my questions answered.

Subject Name----------

Signature of thumb impression of subject----------

Date ----------

Witness Name----------

Signature of Witness ----------

Date ----------

Investigators Name ----------

Signature of investigator ----------

Date ---------- Place ----------

ಸಂಶೋಧನಅಧ್ಯಯನದಲ್ಲಿಭಾಗವಹಿಸುವಿಕಗಾಗಿನತಿಳುವಳಿಕಯುಳ್ಳ ಸಮ್ಮತಿಯ

ಶೀರ್ಷಿಕ:'ಅಂಡಾಶಯದಗಡ್ಡಯನ್ನುClinicopathologicalವೈಶಿಷ್ಟ್ಯಗಳನ್ನು-ಭವಿಷ್ಯದ ವೀಕ್ಷಣೆಯ ಅಧ್ಯಯನವೊಂದು ಶ್ರೀಮತಿ / ಮಿಸ್ ---------- ನಾವು ನಡಸಿದ ಅಧ್ಯಯನದ ನಿಮ್ಮನ್ನು ತೊಡಗಿಸಿಕೊಳ್ಳುವುದು ವಿನಂತಿಸುತ್ತಿದ್ದೇವ ಡಾ_____, ಸ್ನಾತಕೋತ್ತರ ಎಂಎಸ್ಡಾ _____ ಎಮ್ಡಿ, FICOG , ಪ್ರೊಫಸರ್, ಪ್ರಸೂತಿ ಇಲಾಖ ಮತ್ತು ಗೈನಕಾಲಜಿ, ಜ.ಎನ್.ಎಲ್ಚಿಕಾರಣ ಮತ್ತು ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ ಪ್ರಸೂತಿ ಮತ್ತು ಗೈನಕಾಲಜಿ, KLE ವಿಶ್ವವಿದ್ಯಾಲಯ ಇಲಾಖ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಮಾನದಂಡಗಳನ್ನು ಈಡೇರಿಸುವ Belgaum. Patients ಅಧ್ಯಯನ ನಿಮ್ಮ ಪ್ರಸ್ತುತ ದೂರುಗಳಿದ್ದಲ್ಲಿ ಕಲವು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲಾಗುತ್ತದ ಮತ್ತು ನಿಮ್ಮ ಜ್ಞಾನದ ಅತ್ಯುತ್ತಮ ಉತ್ತರಸಲುಸೇರಬೇಕಂದು study. During ಸೇರಿಸಲಾಗುವುದು .

ಅಧ್ಯಯನದಿಂದ ವೈಯಕ್ತಿಕವಾಗಿದ್ದು. ಅಧ್ಯಯನದಲ್ಲಿಭಾಗವಹಿಸಲುಇಲ್ಲವೋ ಎಂಬುದನ್ನು ನಿಮ್ಮ ನಿರ್ಧಾರ ಇನ್ಸ್ಟ್ಯೂಟ್ ಅಥವಾ ನೀವುಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹಿಂಪಡೆಯಲು ಉಚಿತ ಭಾಗವಹಿಸಲುನಿರ್ಧರಿಸಲುyou. If ಒದಗಿಸಿದ ಚಿಕಿತ್ಸೆಯ ಗುಣಮಟ್ಟವನ್ನು ನಿಮ್ಮ ಸಂಬಂಧದಮೇಲ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ.

ಅಧ್ಯಯನದ ಉದ್ದೇಶ ಅಧ್ಯಯನದ ಗುರಿ ಡಾ ಪ್ರಭಾಕರ ಕೋರ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಎಂಆರ್ಸಿ, ಬೆಳಗಾವಿ ಅಂಡಾಶಯದ ಗಡ್ಡ ವ್ಯಾಪ್ತಿಯು ತಿಳಿಯಲು ಮತ್ತು ಜನಸಂಖ್ಯಾ, ಸಂತಾನೋತ್ಪತ್ತಿ, ಮುಟ್ಟಿನ ಅಂಶಗಳು ವೈದ್ಯಕೀಯಗುಣಲಕ್ಷಣಗಳ,ಲ್ಯಾಬ್ಸಂಶೋಧನೆಗಳು, histopathological Lವರದಿಗಳು ರೀತಿಯ ಅಂಡಾಶಯದಗಡ್ಡಗಳ clinicopathologicalಲಕ್ಷಣಗಳನ್ನು ತಿಳಿಯಲು ಆಗದ .

ವಿಧಾನ ಒಳಗೊಂಡಿರುವ ನೀವು ನನ್ನ ಅಧ್ಯಯನದ ನಿಮ್ಮನ್ನು ತೊಡಗಿಸಿಕೊಳ್ಳುವುದುಒಬ್ಬದಲ್ಲಿ ಮಾಹಿತಿ ಮುಟ್ಟಿನ ಮತ್ತು ಸಂತಾನೋತ್ಪತ್ತಿ ಇತಿಹಾಸ ಕುರಿತು ಸಂದರ್ಶನದಲ್ಲಿ ಸಂಗ್ರಹಿಸಿದ ನಡೆಯಲಿದ, ನೋವು ಉದರ, ಉದರ ಪ್ರತಿ ಸಮೂಹ , ಯೋನಿ ಸ್ರಾವ , ಮೂತ್ರ ದೂರು , ಶ್ರೋಣಿಯ ಗಾತ್ರದ ರೀತಿವೈದ್ಯಕೀಯಚಿಹ್ನೆಗಳು ಆಕಾರದ ಗರ್ಭಕೋಶ, ascites , ಎದೆಗೂಡಿನ ಪೂರ ಸೇರಿದಂತ ವೈದ್ಯಕೀಯಗುಣಲಕ್ಷಣಗಳುಮಂಡಿಗಳCa- 125 ರೀತಿಯ ಪ್ರಯೋಗಾಲಯದ ಫಲಿತಾಂಶಗಳು, ಪಿತ್ತಜನಕಾಂಗದ ಕ್ರಿಯಯಪರೀಕ್ಷೆಗಳು, ಸಿಟಿ / ಎಂಆರ್ಐ, ಉಗ್ರತಯಿಂದಸೂಚ್ಯಂಕಗಳುಅಂಡಾಶಯದ ಅರ್ಧ ಸೈನ್ ಮತ್ತು histopathologicalವರದಿಗಳುಅಪಾಯವನ್ನುವಿಕರಣಗಳನಿರ್ಣಯಗಳನ್ನುಅಗತ್ಯ ಮಾಹಿತಿ ಸಂದರ್ಭದಲ್ಲಿ ದಾಖಲಗಳನ್ನು ಸ್ವತಃ ಹಿಂಪಡೆಯಬಹುದಾಗಿದ .ಅಧ್ಯಯನ ಪ್ರಯೋಜನಗಳು

ಇದು ನಮಗ ಡಾ ಪ್ರಭಾಕರ ಕೋರ ಆಸ್ಪತ್ರ ಮತ್ತು ಎಂಆರ್ಸಿ, ಬಳಗಾವಿ ಅಂಡಾಶಯದ ಗಡ್ಡ ವ್ಯಾಪ್ತಿಯುತಿಳಿದುಕೊಳ್ಳುವ ಮತ್ತು ಅಂಡಾಶಯದ ಗಡ್ಡಯನ್ನು clinicopathological ವೈಶಿಷ್ಟ್ಯಗಳನ್ನುತಿಳಿದುಕೊಳ್ಳುವತನ್ನುವ .ವಾಲಂಟರಭಾಗವಹಿಸುವಿಕ/withdrawlಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸದ ವ್ಯಯಕ್ತಿಕವಾಗಿದ್ದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮನ್ನು ತೂಡಗಿಸಿಕೊಳ್ಳುವುದು ಅಲ್ಲ ಆಯ್ಕ ಮಾಡಬಹುದು. ಡಾ ಪ್ರಭಾಕರ ಕೋರ ಆಸ್ಪತ್ರ ಮತ್ತು ಎಂಆರ್ಸಿ, ಬಳಗಾವಿ ನಿಮಗ ಪ್ರಸ್ತುತ ಅಥವಾ ಭವಿಷ್ಯದ ಆರೋಗ್ಯಸೇವಗಳಬದಲಾಗುವುದಿಲ್ಲ ನಿಮ್ಮ ನಿರ್ಧಾರ .ಪರ್ಯಾಯಗಳು ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವಿಕಯನ್ನು ಇಳಿಕ , ನೀವು ನಿರ್ವಹಣಯ ದಿನನಿತ್ಯದ ಲೈನ್ವಡಯುತ್ತಾನ.ಗೌಪ್ಯತ ಮತ್ತು ರಹಸ್ಯವಾದ ಮಾತ್ರ ಜನರು ನೀವುಸಂಶೋಧನಒಳಪಟ್ಟವನೀವು ಅಥವಾ ಸಂಶೋಧನಯ ಸಮಯದಲ್ಲಿ ನೀವುನೀಡದಮಾಹಿತಿಯ ಬಗ್ಗ ಸಂಶೋಧನteam.Noಮಾಹಿತ ಸದಸ್ಯರು ನಿಮ್ಮ ಲಿಖಿತ ಅನುಮತಿ except- ಇಲ್ಲದ ಬಹಿರಂಗಪಡಿಸಲಾಗುತ್ತದ ಎಂದು ತಿಳಿಯಲುತುರ್ತು 1. ನಿಮ್ಮ ಹಕ್ಕುಗಳ ಮತ್ತು ಅಭಿವೃದ್ಧಿಗಾಗಿ ರಕ್ಷಿಸಲು.

2. ಕಾನೂನಿನ ಅಗತ್ಯ ವೇಳೆ.ಸಾರ್ವಜನಿಕ ಫಲಿತಾಂಶಗಳು ಅಧಿಕಾರ ಸಂಶೋಧನ ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳು ಕಾನ್ಫರನ್ಸ್ ಪ್ರಕಟವಾದ ಅಥವಾ ಬಹಿರಂಗ ಮಾಡಿದಾಗ, ಯಾವುದೇ ಮಾಹಿತಿ ನಿಮ್ಮ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸಬಹುದು ಎಂದು ತೋರಿಸಲ್ಪಡುತ್ತದ. ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿಡಲಾಗುವುದು.

ಪ್ರಶ್ನೆಗಳು

ಸಂದರ್ಭದಲ್ಲಿ ನೀವುಭವಿಷ್ಯದಲ್ಲಿ ಅಥವಾ ಅಧ್ಯಯನ ಸಂಬಂಧಿಸದ ತೊಂದರೆಗಳುಉಲ್ಬಣಗೊಂಡು ಸಂದರ್ಭದಲ್ಲಿ ಅಧ್ಯಯನ ಸಂಬಂಧಿಸದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರ, ನೀವುಸಂಪರ್ಕಿಸಬಹುದು ಡಾ_____ಎಂಎಸ್ ಪ್ರಸೂತಿ ಮತ್ತು ಗೈನಕಾಲಜಿ, ಮೊಬೈಲ್ಯಾವುದೇ ವಿಭಾಗದಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರ. _____ ಮತ್ತು ಡಾ_____ ಎಂಡFICOG, ಪ್ರೊಫಸರ್, ಪ್ರಸೂತಿ ಇಲಾಖ ಮತ್ತು ಗೈನಕಾಲಜಿ, ಜ.ಎನ್ವೈದ್ಯಕೀಯಕಾಲೇಜುಮೊಬೈಲ್ಯಾವುದೇ. _____

ಸಂದರ್ಭದಲ್ಲಿ ನೀವು ಒಂದು ಅಧ್ಯಯನದ ವಿಷಯವಾಗಿ ನಿಮ್ಮ ಹಕ್ಕುಗಳ ಬಗ್ಗ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರ, ನೀವುಡಾಗಂಗಾpilli, ಪ್ರೊಫಸರ್, ರೋಗ ಪತ್ತ ಇಲಾಖ ಮತ್ತು ಚೇರ್ಮನ್, ಜ.ಎನ್ ಕರ ಮಾಡಬಹುದು ಮಾನವ ವಿಷಯಗಳಸಂಶೋಧನಾವೈದ್ಯಕೀಯಕಾಲೇಜು ಸಾಂಸ್ಥಿಕ ನೈತಿಕ ಸಮಿತಿ, ಫೋನ್ಯಾವುದೇ 9448863866 ಅಥವಾ ವಿಸ್ತರಣ ಸಂಖ್ಯ 4052 ಜ.ಎನ್ ನಲ್ಲಿ ವೈದ್ಯಕೀಯಕಾಲೇಜು, ಬಳಗಾವಿ.

'ಅಂಡಾಶಯದಗಡ್ಡಯನ್ನುClinicopathologicalವೈಶಿಷ್ಟ್ಯಗಳನ್ನು - ಭವಿಷ್ಯದ ವೀಕ್ಷಣೆಯಅಧ್ಯಯನವೊಂದು' KLE ಡಾ ಪ್ರಭಾಕರ ಕೋರೆ ಆಸ್ಪತ್ರೆಯಲ್ಲಿ, 590010 Belgaum-ಸಂಶೋಧನಪ್ರಯೋಗಭಾಗವಹಿಸಲು ಸಮ್ಮತಿ

ನನ್ನ ಶ್ರೀಮತಿ / MS .---------- ---- ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಅಧ್ಯಯನದ ವಿಷಯವಾಗಿಭಾಗವಹಿಸುವಿಕೆಒಪ್ಪುತ್ತೇನೆ. ಈಗ ನನ್ನ ಹಕ್ಕುಗಳನ್ನುನೀಡುವ ರೂಪ ಈ ಸಮ್ಮತಿ ಸಹಿ ಹಾಕುವ ಮೂಲಕ, Imayಯಾವುದೇಅಧ್ಯಯನದಿಂದಹಿಂಪಡೆಯಬಹುದು. ಒದಿದ ನಂತರ ಅಥವಾ ಅಪಾಯಗಳು ಮತ್ತು ಲಾಭಗಳಸೇರಿದಂತೆ ಮತ್ತು ನನ್ನ ಪ್ರಶ್ನೆಗಳಿಗೆ ಉತ್ತರಿಸಿದ ನಂತರ, ನನ್ನ ನನ್ನ ಸ್ವಂತ ದೇಶೀಯ ಭಾಷೆಯಲ್ಲಿ ನನಗೆ ಒದಲು ಮಾಡಲಾಗಿದ ನಂತರ ಈಗ ಸಹಿ ಒಪ್ಪಿಗೆ ರೂಪ.

ವಿಷಯ ಹೆಸರು ---------- ----------

ವಿಷಯದ ಹೆಬ್ಬೆಟ್ಟಿನ ಗುರುತು ಸಹಿ ----------

ದಿನಾಂಕ ----------

ವಿಟ್ನೆಸ್ ಹೆಸರು ----------

ಸಾಕ್ಷಿಯ ಸಹಿ ----------

ದಿನಾಂಕ ----------

ಇನ್ವೆಸ್ಟಿಗೇಟರ್ಸ್ ಹೆಸರು ----------

ಪರೀಕ್ಷಕರ ಸಹಿ ----------

ದಿನಾಂಕ ---------- ಪ್ಲೇಸ್ ---------- ---

ANNEXURE II - DATA COLLECTION PROFORMA

CLINICOPATHOLOGICAL FEATURES OF OVARIAN TUMOURS-

A PROSPECTIVE OBSERVATIONAL STUDY

Serial Number ☐☐ Date ☐☐☐☐☐☐☐☐

OPD No. ☐☐☐☐☐☐☐ IP No. ☐☐☐☐☐☐☐

Patients Name

_____

Age: ☐☐ years

Address: _____

Contact No._____

Socioeconomic status-

High

Middle

Low

Education status-

Literate

Elementary and high school

Occupation-

Marital status-

Family history-

Smoking a. Yes b.No

OCP use a.Yes b. No

menstrual and reproductive history-

Parity a. Nulli gravida b. Nulli para ☐

c. Primi para d. Multi para

age at menarche

age at first full term pregnancy

lactation mean duration in months

age at menopause

menopausal status before surgery

History of previous pelvic surgery

a. Yes b. No ☐

Symptoms

Pain in abdomen a. Yes b. No ☐

Mass per abdomen a. Yes b. No ☐

Vaginal bleeding a. Yes b. No

Urinary complaints a. Yes b. No

Signs

Pelvic mass a. Yes b. No

Bulky uterus a. Yes b. No

Ascites a. Yes b. No

Pleural effusion a. Yes b. No

Lab findings-

CA 125 level

Liver Function test

Radiological findings-

CT/MRI

Risk of malignancy index scores

Menopausal status a. Pre menopausal (1) b. Post menopausal (3)

CA 125

Variables to be measured in scan TVS/TAS: (Tick the variables which applied out of the 4 major variables)

Inner wall structure

Smooth or irregularities < 3 mm	(0)
……	(1)
Solid or non applicable	(2)
Pappilarities > 3 mm	(3)

Shadowing

Yes	(0)
No	(1)

Septa

No septa or thin < 3 mm	(0)
Thick > 3 mm	(1)

Echogenicity

Sonulucent/Low level echo or echogenic core	(0)
……	(1)
……	(2)

Mixed or high (3)

Total score

USG score for RMI

RMI index

Menopausal status x USG score x CA 125

Ovarian crescent sign a. Yes b. No

Histopathological report –

Benign

Borderline

Malignant

ANNEXURE III – ETHICAL CLEARANCE LETTER

K.L.E SOCIETY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELGAUM-590010 (KARNATAKA-INDIA)
(Affiliated to KLE University, Belgaum)

Website: http/www.jnmc.edu
E-Mail : domejnmc@sancharnet.in
: jnmc@sancharnet.in

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 90.

Date: 07/12/2013

To.

PG student in MS. OBG,
J.N.Medical College,
BELGAUM.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"CLINICO-PATHOLOGICAL FEATURES OF OVARIAN TUMOURS – A PROSPECTIVE OBSERVATIONAL STUDY,"** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr.Hema Dhumale)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belgaum.

(Dr.Ganga Pilli)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belgaum.

ANNEXURE IV – KEY TO MASTER CHART

P/A - Per Abdomen

OCS - Ovarian crescent sign

H/O - History of

FTD - Full term delivery

CA - Carcinoma

CYSTAD - Cystadenoma

NACT - Neo adjuvant chemotherapy

HYST - Hysterectomy

RMI - Risk of Malignancy Index

PI - Primary infertility

IUI - Conceived after Intrauterine Insemination

HPR - Histopathological report

B O M - Billateral Ovarian Mass

AMA - Against Medical Advise