

**SCREENING FOR CARCINOMA CERVIX BY CORRELATING  
RESULTS OF CYTOLOGY, HISTOPATHOLOGY WITH  
COLPOSCOPY IN UNHEALTHY CERVIX**

**By**

**Dr. CHAITHANYA.C**



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OBSTETRICS AND GYNAECOLOGY**

**Under the Guidance of**

**Dr. SHEELA. S. R. Professor and HOD**

**And**

**Co- Guidance of**

**Dr.KALYANIR**

**Professor of PATHOLOGY**



**DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY  
SRI DEVARAJ URS MEDICAL COLLEGE, TAMAKA, KOLAR-563101**

**MAY- 2021**

ALMA MATER

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Date:

Place: Kolar

**SIGNATURE OF THE GUIDE**

**Dr. SHEELA. S. R**  
Professor and HOD

Department of Obstetrics and Gynecology,  
Sri Devaraj Urs Medical College, Tamaka, Kolar

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Date:

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**SIGNATURE OF THE CO GUIDE**

**Dr. KALYANI.R**

Professor and HOD

Department Of Pathology

Sri Devaraj Urs Medical College,

Tamaka, Kolar.

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**Dr. SHEELA. S.R**

Professor & HOD

Department Of OBG

Sri Devaraj Urs Medical College,

**Dr. SREERAMULU. P. N**

Principal,

Sri Devaraj Urs Medical College

Tamaka, Kolar Tamaka, Kolar

## **ETHICS COMMITTEE CERTIFICATE**

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<b>Name of Major Supervisor</b>	DR.SHEELA.S.R
<b>Department</b>	OBSTETRICS AND GYNAECOLOGY
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**Dr. CHAITHANYA.C**

## **LIST OF ABBREVIATIONS USED**

<b>ASCUS</b>	<b>- Atypical Squamous cells of undetermined significance</b>
<b>CIN</b>	<b>- Cervical intraepithelial lesion</b>
<b>CIS</b>	<b>- Carcinoma in situ</b>
<b>HSIL</b>	<b>- High grade squamous intraepithelial lesion</b>
<b>HPV</b>	<b>- Human papilloma virus</b>
<b>LBC</b>	<b>- Liquid based cytology</b>
<b>LSIL</b>	<b>- Low grade squamous intraepithelial lesion</b>
<b>RCI</b>	<b>- Reid Colposcopy Index</b>
<b>WHO</b>	<b>– World Health Organisation</b>
<b>VIA</b>	<b>-Visual inspection with acetic acid</b>
<b>VILI</b>	<b>-Visual inspection with lugol's iodine</b>

## **ABSTRACT**

### **INTRODUCTION: -**

Cervical cancer is one of the most frequent genital tract cancers and accounts for 80% of all female cancers worldwide. Annually the incidence is about 5 lakh and 2,80,000 people die due to carcinoma cervix yearly. In India 1,26,000 new cases are detected and 71,000 deaths occur annually. Cervical cancer is a preventable condition, since it is associated with prolonged pre invasive stage, so that early screening and appropriate treatment can be undertaken to prevent the progression into invasive stage.

### **OBJECTIVES: -**

1. To perform cytology, histopathology & colposcopy in patients with unhealthy cervix.
2. To correlate these tests to make a early diagnosis of cervical cancer.

### **METHODS: -**

All the study subjects enrolled in our study were subjected to Pap smear, colposcopy & colposcopy directed biopsy. The data was statistically analysed for sensitivity, specificity, PPV, NPV and accuracy of Pap smear & colposcopy, with considering colposcopy directed biopsy as the gold standard for diagnosis.

### **RESULTS: -**

Pap smear had a sensitivity and specificity of 69.2 percent and 88.2 percent respectively. The colposcopy had sensitivity of 97.4% % specificity of 88.5%. The colposcopy had higher

sensitivity but similar specificity & positive predictive value as Pap smear. According to our studies, the accuracy of colposcopy was higher than that of Pap smear.

#### **CONCLUSION: -**

Prompt identification of CIN in females is an appealing objective. CIN lesions and aggressive malignant growths are to be identified in a pre-invasive stage for initiating effective treatment. Carcinomatous growth of cervix is viewed as preventable since it is associated with a prolonged pre-invasive stage, which is ideal for screening and treatment.

According to our study, the colposcopy was unquestionably more reliable than that of cervical smear because of its better sensitivity and accuracy. By combining Pap smear with colposcopy, we can make cervical screening programme an effective programme by reducing the mortality rate.

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# INTRODUCTION

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## INTRODUCTION

Our Indian women have unhealthy cervix due to poor genital hygiene and many belong to low socio-economic status<sup>1</sup>. The visual evaluation of unhealthy cervix is unreliable and many pre-malignant lesions will be missed and considered as straightforward cases of erosion of cervix because of inflammation.

Uterine & cervical cancer is a stern health issue in India<sup>2</sup>. Indian sub-continent accounts for one fifth of the world's burden of cervical cancer. The annual incidence of cervical cancer in our country is 1.3 lakh and accounts for twenty percent of all female mortality in our country. India has an average cervical cancer age of 30.7 years, which is youngest in Asia and is associated with high mortality rate of 17.4 per 1,00,000, which is also highest in South Asia.<sup>3</sup>

Invasive cancer of cervix is preventable malignancy as it has a long pre-invasive stage, so that prompt cervical cytology screening and treatment can be undertaken to prevent the progression into malignancy.<sup>4</sup> The direct visualization of the cervix with simple sampling technique has reduced the requirement of extensive investigations on cervical lesions. The present evidence shows that malignancy of cervix develops from dysplasia. Hence cervical screening by cytology and colposcopy can considerably reduce the rate of malignancy.

Downstaging of cervical cancer is identifying the disease at a premalignant stage, so that prompt treatment can be undertaken to cure the disease. Detection of the pre-malignant lesion can be done by any healthcare worker with knowledge about the appearance of the unhealthy cervix. Down-staging screening is effective in areas where there is no proper availability of usual screening facilities, to achieve a reduction in the mortality rate.<sup>5</sup>

Pap smear is most common method used for screening of cervical cancer. Its merits include simplicity of the procedure, low cost, less time consuming, early diagnosis and good specificity it is the common screening procedure done all over the world.<sup>6</sup> However there are certain demerits like a low sensitivity rate of 51 percent and a false negative rate of 49 percent.

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Colposcope is binocular microscope used for visualisation of surface epithelium and connective tissue stroma with vascular pattern.<sup>7</sup> it is an ocular method of visualising the female reproductive and genital tract under bright radiance using stereoscopic vision, hence colposcopy is considered to be superior to cytology. Colposcopy is a simple and non-invasive out-patient procedure. It helps in making accurate indications for cervical biopsy, by pinpointing sites for biopsy. It helps in avoiding unnecessary diagnostic procedure for simple lesions caused due to inflammation and also helps us in making accurate diagnosis.

Biopsy of the cervical lesions is considered to be the gold standard method to arrive at the ultimate diagnosis. Colposcopy aids in identifying the exact lesions so that the biopsy can be taken to provide the ultimate diagnosis which is considered as the gold standard in diagnosis of malignant lesions.



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# OBJECTIVES

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## **OBJECTIVES**

1. To perform cytology, histopathology & colposcopy in women with unhealthy cervix.
2. To correlate these tests to make a early diagnosis .

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# REVIEW OF LITERATURE

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## REVIEW OF LITERATURE

Cervical cancer is one among all the malignancies which is preventable. The direct visualisation of the cervix and long pre-invasive stage during which majority of initial stage can be treated conservatively, makes carcinoma cervix an ideal target for the medical professionals so that screening can be undertaken in women with high risk factors and to prevent it going to invasive stage.

Cervical cancer is one among the common cancers in Indian population with incidence of 1,26,000 cases yearly and 70,000 deaths per annum. Incidence is more when compared to the western countries<sup>8</sup>. Cervical cancer is responsible for 7 percent of all the female neoplasia in western countries which is very less when compared to 24 percent in third world countries like India. This difference is because of less awareness of the population towards early precancerous screening & treatment of precancerous lesions in developing countries.<sup>9</sup>

The idea of screening is to screen women with high risk factors and to treat those with 'apparently abnormal' PAP smear under medical supervision. Screening is conducted with a anticipation that early diagnosis and treatment brings a good outcome in patients' health and improves the survival rate.

An ideal screening method should be very simple, non-invasive or minimally invasive, cost-effective and mainly acceptable by the patient. The disease screened should also have a good treatment option. The screening test should also be easy to perform so that it can be applied even to healthy population to identify the hidden disease. Participation in the various screening programs at regular interval brings a radical reduction in the death rates caused by the carcinoma cervix. The success rate of any screening test is directly related to screening method undertaken, and the availability of the financial resources. The cultural and educational background of the screening population also plays an important role in the overall success rate of the screening programme.

In 1986, concerning five hundredth of ladies in affluent countries were screened for cervical cancer compared with five-hitter of ladies in non-affluent countries. Maybe the best experimental studies demonstrating the good thing about of cervical cancer screening studies are those reportage cervical cancer death rates within the

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Scandinavian countries before and when the establishment of cervical cancer screening studies. The introduction of regular screening has reduced the cervical cancer death rates between eight percent and 73 percent. The greatest drop was in Iceland which also had the best rate of participation, while in Norway, which had the least participation rates, had the fatality rate which was nearly unchanged.<sup>10</sup>

## **MORPHOLOGY OF UTERINE CERVIX**

Cervix is located in the caudal part of the female internal reproductive organ which is narrowed when compared to the other female internal reproductive organs. It is shaped conically with a truncated apex directed downwardly and posteriorly. The cervix measures 2.5 cm and extends continuously up to the top with the uterus body & below it projects into the vaginal canal forming fornices. There are 4 fornices, namely anterior, posterior and two laterals. The posterior fornix is deeper than the anterior one. Isthmus is the junction between cervix and corpus. The cervix is split into 2 parts, namely the Portio-vaginalis which protrudes into the vagina & the Portio-supravaginalis part, which lies overhead the vagina and underneath the corpus. Portio-vaginalis is roofed by non-keratinizing squamous epithelial tissue. However, the canal is lined by a columnar mucus-secreting epithelial tissue that is projected into a series of V-shaped pleats that looks like the shrubberies of the palm and are thus referred to **as plicae palmitae**. The higher edge of the canalis cervicis uteri is marked by the internal os, where the slender cervical os broadens out into the endometrial cavity. The lower edge of the canal, marked by the external os, comprises the transition from squamous epithelial tissue of the portio vaginalis to the columnar epithelial tissue of the endocervical canal. This occurs at a inconstant level in relation to the os and fluctuates with hormonal variations that happens during a lady's life. This is the dynamic area of cellular transition in which the uterine cervix is most vulnerable to neoplastic transformation.<sup>11</sup>

### **Transformation zone:**

The cervix consists of columnar epithelial tissue, that lines the endocervical canal, and squamous epithelial tissue, that covers the ectocervix. The area at which they meet is

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named as the squamous-columnar junction (SCJ). The SCJ is a dynamic area that varies in response to adolescence, gravidity, climacteric and hormonal stimulus. In new-borns, the SCJ is found at ectocervix. At the beginning of reproductive life, the secretion of oestrogen causes the vaginal epithelial tissue to fill with glycogen polysaccharide. Lactobacilli act on the glycogen polysaccharide making the pH more acidic, which stimulates the sub-columnar reserve cells to undergo metaplasia. Metaplasia advances from the primary SCJ inward, to the external os and above the columnar villi. This process establishes a site recognized as the transformation zone. This area spreads from the primary SCJ to the physiologically dynamic SCJ. When the metaplastic epithelial tissue in the transformation zone matures, it commences to yield glycogen polysaccharide and ultimately resembles the original squamous epithelial tissue, colposcopically and histologically.<sup>12</sup> The squamous epithelial tissue of the vaginal canal and ecto-cervix has 4 layers<sup>12</sup>

1. **Basal layer (Stratum Germinatum):** This layer rests on the basement membrane and consists of one row of cube-shaped or columniform cells with minimal basophilic cytoplasm and spherical to oval big nucleus which is placed centrally.
2. **Parabasal or Prickle cell layer:** The layer is located higher the basal coat, 4-10 cells in thickness consisting of huge polyhedral cells consisting basophilic staining cytoplasm and centrally placed nucleus, organised in an asymmetrical mosaic form.
3. **Intermediate cell layer:** It forms the major part of the epithelial tissue. It is also named as clear cell layer. These cells are huge, elliptical to polygonal with asymmetrical vesicular nuclei and appearances like a basket weave pattern. The cytoplasm is abundant in glycogen polysaccharide.
4. **Superficial layer or Stratum corneum:** It consists of flattened, elongated or polygonal cells with acidophilic cytoplasm and tiny pyknotic nuclei.

#### **AETIOPATHOGENESIS:**

- 1) **Age** – The common age of presentation is about 50-55 years of age. CIN occurs comparatively at an earlier age, with one-third of cases found to be in less than 30 years.

- 
- 2) **Sexual activity, marital and motherhood** –Sexually active woman is two to fourfold more prone to develop malignancy than in sexually inactive woman. Young age at preliminary intercourse, several sexual partners and multiparity are implicated since they are considered as hazardous features for CIN and carcinoma cervix.<sup>13</sup>
  - 3) **Race** – The females from a particular ethnicity, notably Jews are considered resistant to cervical malignancy. Carcinoma cervix is also unusually common in African ladies.
  - 4) **Social and economic factors** – The ailment is more widespread in low socioeconomic status women.
  - 5) **Coitus** – The practice of sex activity is currently established as being a chief cause of cervical neoplasia. It is rarely seen in groups such as nuns and virgins. Young age at initial intercourse and numerous partners are linked with more risk of evolving into cervical malignancy.
  - 6) **HPV (Human Papilloma Virus)**– HPV contagion is associated with almost 99% of women with cervical cancer. HPV types considered to be associated with cervical cancer includes types 6,11,42,44 ,16,18,31,33,35,39,45,51,52,56,58. HPV subtypes sixteen and eighteen are associated with most of cervical carcinomas. The pathogenesis HPV affects cellular growth and differentiation is by the collaboration of viral E6 & E7 proteins with cancer suppressor genes p53 and Rb, respectively. Suppression of p53 gene stops cell cycle arrest and cellular apoptosis, which happens when damaged genetic material is present, while inhibition of Rb interrupts transcription factor E2F, ensuing in unmonitored cellular proliferation.<sup>13</sup>

#### **CERVICAL CANCER SCREENING METHODS:**

1. Conventional exfoliative cytology method
2. Liquid based cytology method
3. Automated cervical screening techniques
4. Visual inspection with acetic acid (VIA)

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5. Visual inspection with Lugol's iodine (VILI)

6. Speculoscopy

7. Cervicography

8. HPV DNA testing

9. Colposcopy

10. Fluorescence spectroscopy

11. Polar probe

### **Cytology Methods:**

#### **History:**

Traut & Papanicolaou were the first scientists who suggested the application of exfoliative cervical cytology for the screening of carcinoma cervix and its precancerous conditions utilising the material obtained from the cervix. Ayre was the first to report the utilization of a wooden spatula to scrape the cytological material directly from the cervical transformation zone. The Papanicolaou screening method has been documented extensively as a best malignancy screening investigation in the history of medicine. It was introduced by George Papanicolaou in 1940. In 1945, the cervical smear was acknowledged by the American Cancer Society as an effective technique for the prevention of cervical cancer. Centre of Cytology in Vancouver, British Columbia confirmed that cytologic screening lead to a decrease in the degree of aggressive cancer of the uterine cervix<sup>14</sup>. This ingenious method of collection of exfoliated cytology from the cervix uteri and examining under a microscope has remained basically untouched for quite 50 years.<sup>15</sup>

### **The normal Cytology**

Two types of epithelial tissues usually line the uterine cervix. They are as follows,

1. Non keratinising squamous epithelial tissue lining the ectocervix.

- 
2. Columnar epithelial tissue lining endocervix.

Both these epithelial tissues are under hormonal control.

The Cervical epithelial tissues comprise of following cells:

1. The superficial squamous cells: They are well developed, usually polygonal squamous epithelial cells. The cell cytoplasm is cyanophilic /eosinophilic & the nucleus is pyknotic.
2. The Intermediate squamous cells: These are also well developed, polygonal squamous epithelial cells. The cells are of same size as superficial cells and their cytoplasm is also cyanophilic and nuclei vesicular.
3. The Parabasal cells: These are ovoid or rounded immature squamous epithelial cells and their cytoplasm is basophilic with even cytoplasmic borders.
4. Basal cells: These are not normally present in the smear. If they are visualised, it suggests that a pathologic process has injured the superior layers of squamous epithelial tissues. The cells scanty basophilic cytoplasm and the nuclei are of the same size as parabasal cells.<sup>16,17</sup>

The cytology studies have various merits. They are as follows,

- ideal for mass screening,
- high specificity,
- easy to perform,
- less time consuming
- low cost study

However, the study also has various demerits, which are as follows<sup>18</sup>,

- low sensitivity,
- need for personals with expertise to take proper smear
- false negative rate

### **The limitations of PAP Smear<sup>19</sup>**

1. Inadequate samples constitute about 8 percent of the specimens processed.

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2. High false negative rate of about 20-30% are described, which is primarily due to clumping of cells if they are not homogenously spread on the glass slide.
  3. Sometimes contamination of the sample by blood, bacteria, yeast prevent the detection of abnormal cells and if it is unprotected & exposed to air for longer duration before being fixed on the slide, the cervical cells will become distorted.
  4. The first threat to accurate interpretation, examiner error. On average cervical smear consists of at least 50,000-300,000 cells that must be examined. If the smear contains only a couple abnormal cells within a populated background of normal cells, the abnormal cells could easily be neglected.

### **Liquid Based Cytological Studies (LBC):**

A conservative Pap smear is 47-62 percent sensitive & 60-90 percent specific and has high false negative rates. So as to scale back the false-negative results, the liquid-based cytology is well linked technique of sample collection where a cervical brush is employed to collect the sample which provides almost twice as many epithelial cells. The specimens are collected directly and with preservative solution, the slides are prepared meticulously avoiding any bumpy physical spreading of the cells & thus plummeting the examiner errors while interpreting the slides. LBC is more sensitive & specific than that of Pap smear because the cells are fixed immediately which leads to best preservation of the cellular structure.<sup>19</sup> In a study undertaken to evaluate LBC & to compare the sensitivity of LBC with conventional Pap smear, cytologic abnormality was found in 26.2% of cases by LCB method, whereas conventional cytology detected abnormality in just 15%. Sensitivity of LBC was 97.6% which was far better than that conventional Pap smear which had sensitivity of only 53.7 percent. However both studies had a specificity 50 percent only. LBC was strongly advocated to be better than cervical smear studies, since it improves the specimen quality & diminishes the likelihood of false negative results.<sup>14</sup> The Thin Prep study was established to improve sensitivity by examining a monolayer of cells by the cytologist for analysis and interpretation. A prospective study of 8636 study subjects concluded that the Thin Prep was associated with significantly higher sensitivity than the cervical smears, at identifying severe dysplasia and cancer, with sensitivity rates of 92.9 percent & 100 percent vs 77.8 percent & 90.9 percent, respectively. This supports the fact that Thin Prep was comparatively better to that of PAP smear at detecting carcinoma cervix.<sup>20</sup>

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### **HPV-DNA Testing:**

The association between high risk oncogenic sorts of HPV and the development of cervical cancer and its precursor lesions is well established.<sup>21</sup> The Hybrid capture II assay is that the most helpful technique for HPV-DNA check. This technique utilizes multiple non-radioactive Ribonucleic acid (RNA) probes in a modified Enzyme Linked Immunosorbent Assay (ELISA) procedure to identify the presence or absence of 13 strains of high-risk HPV-DNA. Canadian researchers randomly screened more than 10,000 ladies for HPV testing and Pap smear. The ladies with abnormal results underwent further testing, and a random sample of women with normal results also underwent further testing. This large study showed the sensitivity of HPV DNA testing was about 95 percent and the sensitivity of Pap smear was only a mere 55 percent. This study also showed the specificity of the HPV-DNA testing being 94% and that of Pap smear being 97 percent. According to this study, HPV testing compared to Pap testing had a greater sensitivity for the detection of cervical intraepithelial neoplasms.<sup>22</sup>

The ASCUS/ Low grade Squamous Intraepithelial Lesion (LSIL) Triage Study- The ALTS trial, which is a large multi-centric study, followed up 3488 study subjects & stated that HPV-DNA analysis established a sensitivity of about 96 percent for severe CIN lesions, referring about 54 percent women for further colposcopic studies. The HPV-DNA testing for ladies with ASCUS abnormalities had better sensitivity, was cost-effective & also resulted in significantly lesser colposcopy referrals. The study concluded that HPV-DNA testing appeared to be most useful investigation in defining the suitable women with ASCUS abnormalities for further evaluation and analysis<sup>23</sup>.

### **Visual Inspection with Acetic acid study (VIA):**

The cervix is examined with application of 3-5 percent acetate and then the cervix is inspected after one minute. The area of cervix staining acetowhite is considered to be positive for VIA study. In a large prospective study four hundred women were screened with cervical smear, VIA and colposcopy. This study disclosed that the sensitivity of VIA 96.7 percent, which was higher than that of cervical smear (50%) & was nearly close to that of colposcopy (100%). However, the specificity for VIA was

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only 36.4 percent which was much lower than that of cervical smear (92.4 percent) and colposcopy (96.9 percent) resulting in a higher false positive rate for VIA. The merits of VIA test are its lower cost, easy to perform, higher sensitivity and immediate results. But its main demerit was a higher rate of false positive results which can lead to over evaluation & treatment, if see & treat policy is applied<sup>24</sup>. In another analytical cross-sectional study, VIA & cytological smears were done on non-pregnant women aged 30-60 years. Ladies with positive VIA, positive cytology & one in ten negative women (controls) were biopsied. A total of the 5010 ladies were enrolled for the study. About 4813 women (96.1%) from the study population were screened & only 574 (11.9%) of them underwent colposcopy. A total of 1743 biopsies were obtained out of which 528 were taken as controls. The VIA, had a sensitivity of 70.4 percent which was comparatively much better than cytology, which had sensitivity of only 47.7 percent. However, the VIA had specificity of only 77.6 percent which was comparatively lower than that of cytology with specificity of 94.2 percent. They determined that VIA has suitable test qualities & can be used in lesser income countries as an outsized scale screening test<sup>25</sup>. In another study, 1921 asymptomatic ladies underwent a complete clinical evaluation including cervical smear and VIA. Participants who had abnormal findings in either of these tests were subjected to colposcopy and biopsy. On statical analysis, the VIA had better sensitivity than the of Pap smear. However, the VIA study had positive predictive value of only 8.5 percent for detection of CIN II, which was slightly higher than that of Pap smear (6.3 percent). It was observed that only 2.3 percent of VIA positive patients failed to come back for follow up studies, as compared to 26.3 percent of cervical smear positive patients, which was statistically very significant. This showed that VIA was very much useful for identifying of precursor lesions of cervical carcinoma not only in settings with lesser resources, but also in well-equipped health and cancer centres.<sup>26</sup>

#### **VILI -Visual Inspection with Lugol's iodine**

This is also referred to as Schiller's Iodine test. In this procedure, the cervix uteri is coated with aqueous iodine solution. The typical squamous epithelial tissue which is rich in glycogen polysaccharide takes up a dusky brown pigment with iodine staining.

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Quickly multiplying cells use all the glycogen and are deficient in glycogen. Hence, these cells persist unstained. Accordingly, the iodine negative areas are considered abnormal<sup>27</sup>. In a huge prospective study, 11,834 healthy ladies underwent VIA, VILI, conventional cervical smear & Hybrid Capture II (HCII). Participants who had an abnormal result among any of these tests were further evaluated with colposcopy and biopsies. This study showed VIA positivity in 61.8 percent of the ladies who had CIN 1, 57.0 percent of those who had CIN 2, 35.0 percent of ladies who had CIN 3 & in 75 percent of women with invasive cervical cancer. About 10 percent of women with no disease had an abnormal VIA study. VILI, was positive in 83.3 percent of ladies who had CIN 1 & 62.5 percent of ladies who had CIN 3 had an abnormal test. VILI was unsuccessful in detecting three cases of invasive cancer. This study concluded that, the sensitivity, specificity & PPV of both VIA & VILI in diagnosing CIN 2 or CIN 3 could be significantly improved when combined with Pap smear or HCII.<sup>28</sup>

### **Cervicography Study:**

Cervicography is an imaging study of cervix, in which the photographs of cervix are taken using a special camera known as cervicoscope, after painting the cervix with 5 percent acetic acid. And then the images are processed digitally, projected & examined by an expert colposcopist.<sup>29</sup> In a prospective study undertaken in Nairobi, Kenya, 653 study subjects attending a family planning clinic undertook 4 screening methods: pap smear, VIA, PCR for high risk HPV & cervicography. The Pap smear showed highest specificity of 94.6 percent, HPV testing being highly sensitive for cervical cancer detection (94.4%). However, the visual methods like VIA & cervicography, showed similar sensitivity & specificity and were more accurate in detecting abnormal lesions when compared to the former two tests.<sup>30</sup>

In another prospective study, 809 patients underwent screening of cervix with VIA, HPV testing using hybrid capture II (HCII) & the conventional Pap smear. The study subjects also underwent colposcopy after pelvic examination and biopsies were taken from suspicious areas. This study concluded that the HCII had the highest sensitivity of 73 percent & Pap smear was the most specific investigation (93 percent) for detecting CIN 2 or worse. Together, Pap smear & HCII showed the highest sensitivity of 82 percent for detection of CIN 2 or worse. However, a combination of VIA and

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Pap smear had highest specificity of 83 percent.<sup>31</sup> In another study, 100 ladies were subjected to screening for cervical intraepithelial neoplasia & invasive cancer by cervical smears & colposcopy. This study concluded that colposcopy being more sensitive (95%) than the cervical smear (20%), & cervical smear being more specific (91.25%) than colposcopy (63.75%). However, the predictive value of both these tests were comparable, that is 36 % for Pap smear & 39.58 % for colposcopy. The false positive rate of colposcopy was 63.64 percent comparable to Pap smear (60.42%). The false negative rate was lowest for colposcopy (1.92%) as compared to that of Pap smear (17.98%).<sup>32</sup>

### **Speculoscopy Study:**

Speculoscopy is a study in which the inspection of the cervix is undertaken following application of 5 percent acetic acid with chemiluminescent & a 4X-6X power magnification microscope. In a prospective study undertaken in Rajavithi Hospital, Thailand the study subjects underwent a Pap smear, speculoscopy and colposcopy. Biopsies were obtained from women who had a abnormal colposcopy result. Pap smear combined with speculoscopy had a sensitivity of 33.33 percent, once compared to sensitivity of 6.67 percent with Pap smear alone. The addition of speculoscopy, to the pap smear study reduced the false negativity from 93.33% to 66.67 percent. The combination of two tests, decreased the specificity from 97.52% to 77.68% and false positive rate increased from 2.48% to 22.31 % respectively. Addition of speculoscopy significantly increased the sensitivity of cervical screening & also there was noteworthy reduction of the false negative result. However, the drawback was slight decrease in specificity, due to high false positive rate of speculoscopy itself.<sup>33</sup> In another prospective study, 1000 women were subjected to cytology and speculoscopy examinations. Among the study subjects, only ten had significant cervical smear findings whereas, 144 of them had an altered speculoscopy pattern. This study concluded that combining speculoscopy with a Pap study, significantly increased the identification of cervical lesions.<sup>34</sup>

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## Classification of Pap Smear<sup>35,36,37</sup>:

Description	CIN Grading	Bethesda System
Normal	Normal	Normal
Atypia, Reactive or Neoplastic	Atypia	ASCUS
HPV	HPV	Low-grade SIL
Atypia with HPV	Atypia,"condylatomatous", atypia and "koilocytic" atypia	Low-grade SIL
Mild Dysplasia	CIN I	Low-grade SIL
Moderate Dysplasia	CIN II	High grade –SIL
Severe dysplasia	CIN III	High grade –SIL
Carcinoma in situ	CIS	High grade –SIL
Invasive cancer	Invasive cancer	Invasive cancer

## Colposcopy Study:

### History:

Hans Hinselmann, a German gynaecologist, pioneered the use of colposcopy for cervical lesions. He hypothesized that cervical malignant growth must begin as a little 'spot' undetectable to the unaided eye. He formulated a progression of amplifying focal points which would make the speck obvious and this started the clinical examination known as colposcopy. The 2<sup>nd</sup> World War was a extraordinary difficulty to its turn of events. At the point when cytology screening was undertaken everywhere on the world in 1950s & 1960s, numerous cases of irregular cytology were identified and every one of these cases underwent further evaluation with colposcopy. Subsequently,1970s saw the 'Renaissance' of colposcopy and its notoriety expanded<sup>38</sup>. Colposcopy is an optical technique for imaging the uterine cervix with splendid light utilizing stereoscopic vision, at an amplification somewhere in the range of 4 and 40 crease.

It has numerous favourable circumstances over cytology. It allows the geographical investigation of sores during clinical assessments. It is a significant device which praises cytology and histopathology in timely detection of different cervical lesion.In this way colposcopy is the customary strategy for valuation of odd Pap smears and today, colposcopy has a focal function in the cervical smear screening programs. At first, colposcopy was utilized to distinguish asymptomatic early invasive stage,

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consequently improving patient endurance. Consequently, it helped in identifying pre-invasive lesions, with subsequent decrease in the incidence of cervical malignancy & a huge drop in the amount of symptomatic conization.

### **Basics of Colposcopy:**

Colposcopy is a clinical technique which assesses variations in the vascular organization of terminal cervix that reflects the metabolic & biochemical changes in the tissues. It comprises of assessment of the cervical connective tissue, over the mucosa utilizing stereoscopic vision.

The factors which are assessed .<sup>39</sup>

1. Colour & tone the mucosa
2. Surface contours & opacity of mucosa
3. The transformation zone should be clearly visible since most cancers originate there.
4. Should look for any abnormal vessels on the surface.
5. 5 % Acetic acid application and staining pattern

The appearance on colposcope depends on various factors like, structural & vascular pattern variation of the connective tissue and also due to changes in the mucosa due to application of acetic acid.

### **Various changes noted in cervix after application of acetic acid (3-5%) are as follows**

1. It coagulates the proteins present the cells. The irregular epithelium has an expanded nuclear: cytoplasmic proportion prompting an expanded measure of cellular proteins, which are coagulated and consequently interferes transmission of light and the lesions seem white.
2. Dissolution of mucous.
3. Osmotic changes leading to intracellular dehydration.

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4. Acetic acid causes swelling of individual villi of the columnar epithelium.
  5. The severity of the abnormality determines the intensity of whiteness, speed of appearance, duration of stay and speed of disappearance.

On examination, the contour, colour & border of each lesion should be noted. Various causes of acetowhite epithelium are CIN, HPV infection, immature squamous metaplasia, healing / regenerating epithelium, congenital transformation zone & invasive squamous cell carcinoma.

### **Normal Colposcopic Finding.<sup>27</sup>**

1. Original squamous epithelium
2. Columnar epithelium
3. Transformation zone

### **Abnormal Findings on Colposcopy:**

- a. Mosaic pattern: Terminal capillaries surrounding roughly circular or polygonal-shaped blocks of acetowhite epithelium crowded together giving the appearance similar to mosaic tile.<sup>39</sup>
- b. Punctuation: This pattern is seen due to dilated capillaries on the surface appearing a collection of dots and thus are referred to as punctuation<sup>39</sup>.
- c. Acetowhite epithelium: It is a focal transient lesion usually visible after application of acetic acid. The contour of the surface maybe flat or can have papillary projections & brain like convolutions.<sup>40</sup>
- d. Leukoplakia: It is whitish epithelial plaque seen before application of acetic acid. Its seen due to hyperkeratosis & parakeratosis leading to deposition of keratin on the surface & overlies the normal as well as abnormal epithelial tissue. It is only significant if it is thick with irregular surface which is usually seen in pronounced atypical lesions.<sup>40</sup>
- e. Atypical vascular pattern: It is a characteristic lesion of cervical carcinoma which includes looped branching vessels & reticular vessels.<sup>39</sup>

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**Cervical Intraepithelial Neoplasia (CIN):** It states to a potentially precancerous transformation of cells in cervical tissue, later leading to Invasive cervical Cancer.

**Glandular Intraepithelial neoplasia:** it presents as a loss of villous pattern with a vague presence of villi. Its colposcopy features are more subtle than CIN & are not well recognized<sup>41</sup>

**Suspect overt carcinoma:** It is marked by congestion of the connective tissue with irregular surface contour. On staining, it appears as acetowhite lesion, with irregular surface & raised edges known as mountain range appearance. Atypical vessels with punctations & mosaicism is usually seen.

**Invasive Carcinoma:** The lesion appears oyster white after application of acetic acid, due to presence of high amount of protein in neoplastic cells. These cells are immature, undifferentiated & also lack glycogen which stain negative with iodine.

**Exophytic lesions:** The lesions appear intense acetowhite, with rough surface, granular appearance with atypical vessels. These vessels are irregular in size, shape, calibre, course & mutual arrangement. Few bizarre vessels in the form of spaghetti, corkscrew or comma shapes are also seen.<sup>42</sup> These lesions stain iodine negative.

**Endophytic lesions:** These lesions are hard with retracted cervix. On acetic acid painting, they appear dense acetowhite. It may or may not be associated with any vascular abnormality.<sup>42</sup>

Marana et al. (2000) assessed the utilization of colposcopy scoring for biopsy choices. They proposed that the colposcopy scoring framework is a viable device for colposcopy guided punch biopsy choice & noticing high-grade cervical injuries in various patient groups.<sup>43</sup> A forthcoming report was completed utilizing Reid colposcopy record (RCI) scoring framework and coordinated biopsy was done on 344 ladies. Results were reflectively contrasted and a past report completed on 353 ladies by similar doctors. In this past investigation, the colposcopy discoveries didn't utilize RCI list. The quality of the relationship between colposcopy impression & biopsy histology in RCI colposcopy bunch was high than the regular colposcopy gathering (0.74 versus 0.45). The positive predictive estimate of any colposcopy variation from the normal for any histologic anomalies in the RCI group was as high as 92 percent. However, the negative predictive estimate of a benign colposcopy impression was

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only 70.5 percent. The sensitivity was 74% & the specificity was about 90.7 percent. They inferred that, the great relationship between colposcopic impression and histologic finding by utilizing Reid index in colposcopy would provide good quality. Accordingly, the Reid index can be utilized as a reproducible procedure, which can be easily in colposcopic clinic.<sup>44</sup>

Pete et al. (1998) contrasted cytology & colposcopy discoveries and the histological outcomes in patients associated with having carcinoma cervix. Sensitivity & specificity of cytology were 47 percent & 77 percent respectively. The sensitivity & specificity for colposcopy were 87 percent & 15 percent. When cytology & colposcopy were combined together, the sensitivity was 96 percent & the specificity was 14 percent. The authors concluded that despite the fact that colposcopy had a higher sensitivity, yet it was hindrance because of lower specificity when compared to cytology in evaluating for cervical neoplasm.<sup>45</sup>

Gerber et al (2001) assessed the clinical status & the forecast of neoplasia among the patients with relentless discoveries of ASCUS in a recurrent Pap smear through a colposcopic assessment. Out of 186 colposcopic assessments, colposcopy showed an abnormal result in 95 patients (51%). Histology showed 38 patients (21%) with low grade squamous intraepithelial injuries (LSIL) & 17 (9%) of them had high-grade squamous intraepithelial injuries (HSIL). They presumed that colposcopy can be considered as a modality of choice for assessment in a patient with Pap smear suggestive of ASCUS.<sup>46</sup>

Benedet et al (2004) assessed the diagnostic relationship between reference cytology, biopsies & colposcopy impression in patients surveyed in a common place cytology screening program. The colposcopy impression was associated within one degree in over 90 percent of cases. Cytological to Histological correlation within one degree happened to be 82 percent. They presumed that both cytology and colposcopy have higher sensitivity however lower specificity. Colposcopy is more precise in recognizing high-grade lesions. Colposcopic impression associates intently with the cytology analysis and consolidating the two produces ideal results.<sup>47</sup>

Tamiolakis et al (2005) assessed the usefulness of an amplified chemoluminescent screening assessment (Colposcopy) combined with the cervical smear in recognizing cervical irregularities. They examined a companion of 58 participants who were

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referred for colposcopy assessment because of reference cytology showing features of persistent inflammation, and pre invasive lesions. They believed that an incorporated cytology-colposcopy program allows for better assessment and diagnosis of cervical lesion.<sup>48</sup>

Irene et al. (2005) looked at MIS colposcopy, traditional colposcopy & PAP test. The study suggested that MIS colposcopy had 1.7 percent faulty diagnostic rate in contrast with PAP test & regular colposcopy which had false identification rate of 24.4 percent & 22 percent respectively.<sup>49</sup>

Alvarez and Wright (2007) assessed utilization of a novel optical recognition framework (ODS) as an adjuvant to colposcopy in expanding the identification of CIN II/III. They concluded that the true positivity rates were 14.4 percent versus 11.4 percent for the joined colposcopy and ODS contrasted with colposcopy alone, respectively in participants with either an ASC or low grade LSIL on cytology. They thought that consolidating ODS with colposcopy gives a clinically significant expansion in the identification of CIN II/III in ladies referred for the assessment of irregular cytology results.<sup>50</sup>

Cantor et al (2008) selected 1,850 study participants into an indicative and a screening group contingent upon their abnormal discoveries on Papanicolaou tests. Colposcopy assessments were performed and biopsy sample taken from irregular and ordinary colposcopy location for all patients. They found that colposcopy had better sensitivity & specificity in identifying LSIL & HSIL in symptomatic group than in the patients of screening group. They finally concluded that colposcopy performed well in the indicative setting & was ineffective in the screening setting.<sup>51</sup>

### **Problems seen during colposcopy may be due to**

1. **Lack of expertise:** An inexperienced colposcopist will have problem in identification & interpretation of various lesions. Identification of squamocolumnar junction is crucial to identify the higher limit of the lesion. An inexperienced colposcopist gives extra status to mosaic pattern or punctations than to major grades of acetowhite epithelium, which leads to biopsy from a wrong area & resulting in more false negative rates.

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2. **Interpretive problems and limitations:** There are various situations which confuse in differentiation of colposcopic findings. Early lesion of immature CIN will be difficult to discriminate from active metaplastic epithelial tissue, due to abnormal vascular network may lead to a perplexing picture. Sometimes Colposcopy may be unsatisfactory.
  3. **Failure to follow standard diagnostic protocol:** Deviation from a well established increases the chances of inaccurate diagnosis. As a result in inappropriate treatment.<sup>52</sup>

### **Colposcopic Directed Biopsy:**

Biopsy has to be taken under colposcopy direction from an area inside the most abnormal zone. Histopathology gives the last affirmation of determination in most circumstances, despite the fact that specific conditions can't be pinpointed, for example, inflammatory conditions. It is of central significance in choosing the methodology of treatment and type of medical procedure. In this way it is basic to have dynamic communication among the colposcopist, cytologist and histopathologist to relate their discoveries for accomplishing ideal results so it leads to appropriate management strategy.<sup>53</sup>



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# MATERIALS & METHODS

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## METHODOLOGY

**1.Source of Data:** The study was conducted on patient who attend the gynaecological outpatient department at RLJH hospital, women with unhealthy cervix on inspection will be evaluated by cytology, colposcopy and colposcopically guided biopsy and the results will be compared.

A. Study Design: observational study

B. Study Period: OCTOBER 2018 TO JUNE 2020

C. Sample Size: 90 cases who fulfilled selection criteria.

### 2. Data Collection Methods:

Sample size-Estimated based on carcinoma cervix screening with cytology & colposcopy a prospective clinical study conducted on 200 women with sensitivity of 94.7%, precision of 2% with confidence interval of 95%, the sample size estimated is 90.

#### Formula

$$n = \frac{z_{1-\alpha/2}^2 p(1-p)}{d^2}$$

Where,

p : Sensitivity of the new test

d : precision

$Z_{1-\alpha/2}$  : Desired Confidence level

#### Inclusion criteria:

1. All sexually active females age >18years to 55 years
2. Patients with unhealthy cervix such as cervical erosion, cervical polyp, cervicovaginitis
3. Women with presenting complaints such as leucorrhea (white discharge per vagina), inter-menstrual & post coital bleeding.

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## **Exclusion criteria:**

1. Pregnant women.
2. Active bleeding.

## **Procedure:**

Participants were told about the procedure in brief and written and informed consent was taken.

## **Presenting complaints:**

Presenting complaint, obstetric history, menstrual history, any significant past history, family history was taken

## **Examination:**

The patient was examined in dorsal position, retracting the anterior & posterior vaginal wall using the Cusco's speculum and the cervix was examined for any unhealthy features.

## **Pap smear:**

After inspection of the uterine cervix, Pap smear was taken with Ayre's spatula from the SCJ by rotating 360 degree. The obtained specimen was spread on a glass slide & fixed with 95% of ethyl alcohol & smears were analysed by the pathologist.

## **Colposcopy:**

Colposcopy was done in women with unhealthy cervix irrespective of PAP results. Using normal saline, green filter & acetic acid colposcopy was performed. Colposcopy diagnosis was made based on the findings recorded using Modified Reid Colposcopic Index (RCI).<sup>55</sup>

The three objective categories given by Reid et al were based on four colposcopic signs which are colour, margin (including surface contour), vascular pattern and

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iodine response. Each category was offered scores of 0 to 2 and sum of all the categories was taken for final grading of CIN. The grading is as follows

0-2: CIN1 / HPV

3-5: CIN1 – II

6-8: CIN II – III

**Colposcopy guided biopsy:** Under colposcopy guidance, biopsy was taken from the abnormal area using cervical punch biopsy forceps and the biopsy results were categorized as

1. Cervicitis/ metaplasia
2. CIN-1 (mild dysplasia/ correlating with LSIL)
3. CIN-2/3 (moderate to severe dysplasia/ correlating with HSIL)
4. Squamous cell carcinoma

### **Statistical analysis:**

Data were entered in MS-Excel and analyzed in SPSS V21. Descriptive statistics were represented with frequencies and percentages, Kappa statistics was applied to measure agreement between two methods. Sensitivity and specificity were calculated.

P<0.05 was considered as statistically significant.

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**Table 1 : THE COMBINED COLPOSCOPIC INDEX<sup>56</sup>**

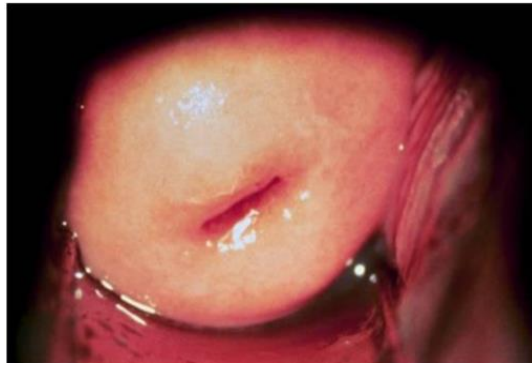
<b>COLPOSCOPY SIGN</b>	<b>0(ZERO)</b>	<b>1(ONE)</b>	<b>2(TWO)</b>
MARGIN	Condylomatous or micropapillary contour, indistinct acetowhitening ,flocculated or feathered margins. Angular jagged lesions. Satellite lesions and acetowhitening beyond the transformation zone	Regular lesions with  Straight outlines	Rolled peeling, internal demarcation between areas of differing appearance
Colour	Shiny, snow-white color, indistinct acetowhitening	Intermediate shade (shiny gray)	Dull, oyster white
Vessels	Fine-caliber vessels, poorly formed patterns	No abnormal vessels	Definite punctations and mosaicism
Iodine	Positive iodine uptake	Partial iodine uptake	Negative staining of significant lesion.



**Figure 1 COLPOSCOPE**



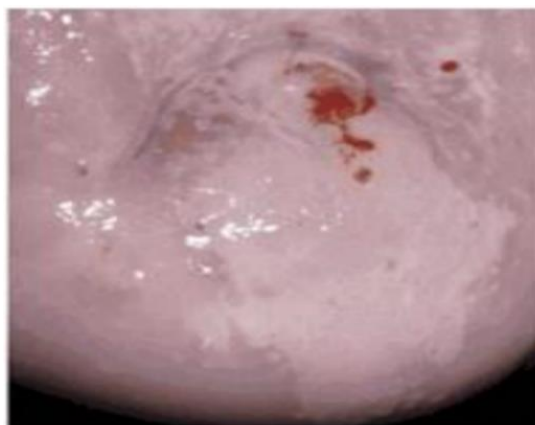
**Figure 2 AYRE'S SPATULA**



**Figure 3 NORMAL CERVIX**



**Figure 4: Sharp distinct well defined acetowhite area with raised margins abutting SCJ (HSIL)**



**Figure 5 :Strikingly dense acetowhite area (LSIL)**



**Figure 6 Striking dense acetowhite area in columnar epithelium**



**Figure 7 Strikingly dense acetowhite area with vascular pattern (HSIL)**



# RESULTS

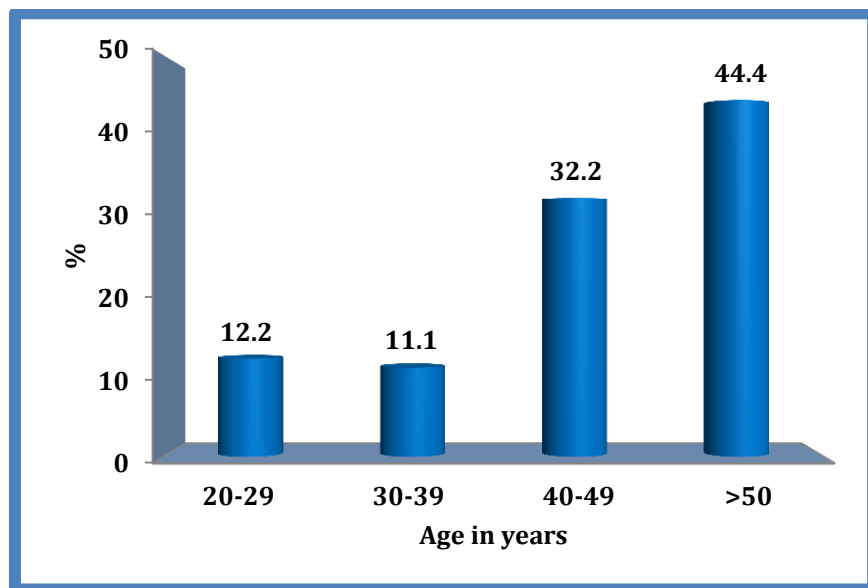


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## RESULTS

**Table-2: - Distribution of women according to age.**

Age	Frequency	Percent
20-29	11	12.2
30-39	10	11.1
40-49	29	32.2
>50	40	44.4
Total	90	100.0



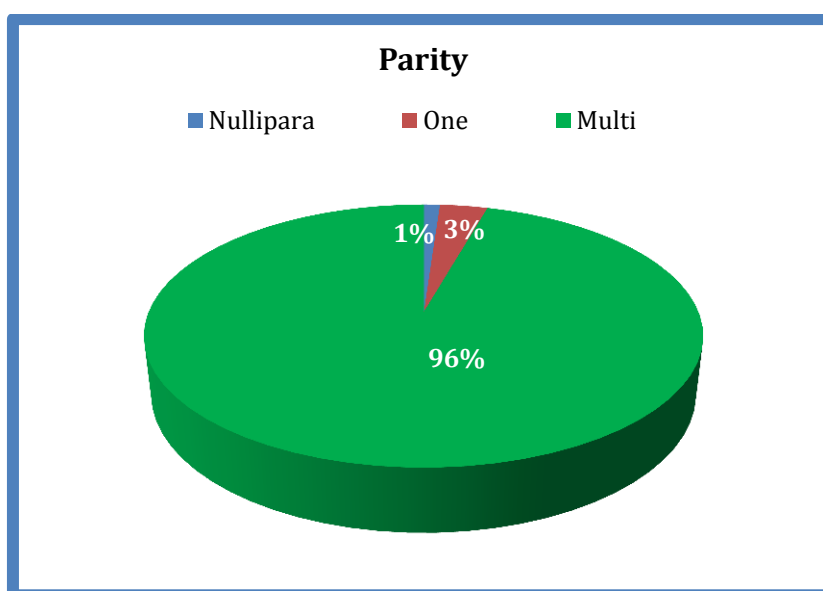
**Graph-1: - Distribution of women according to age.**

Maximum number of women were found to be in the age group of more than 50years (44.4%)

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**Table -3: - Distribution of women based on parity**

Parity	Frequency	Percent
Nullipara	1	1.1
One	3	3.3
Multi	86	95.6
Total	90	100.0

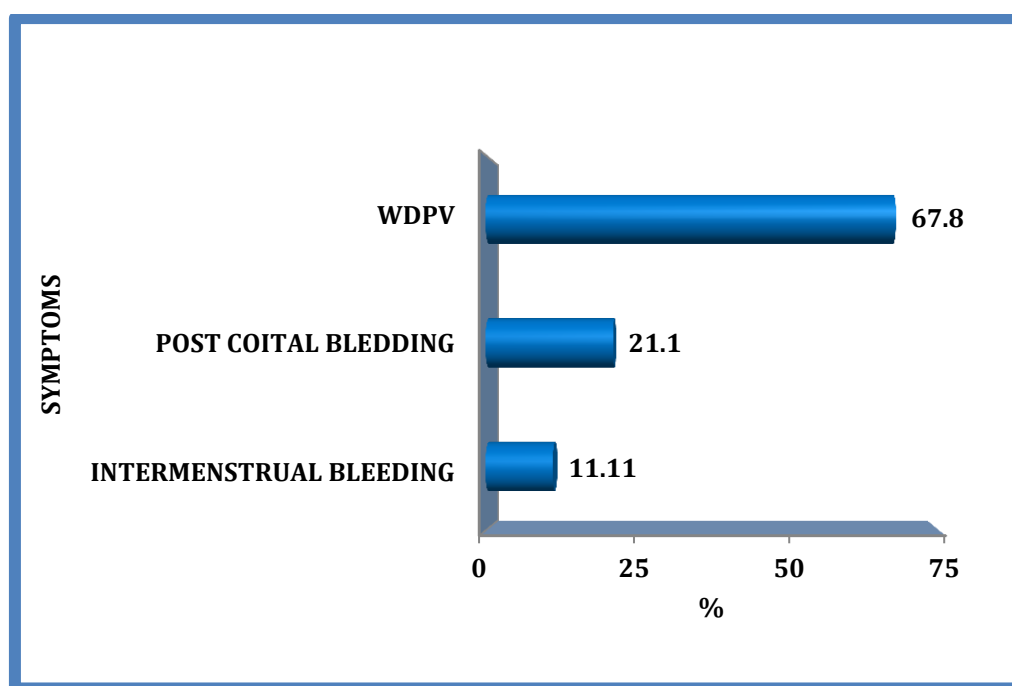


**Graph-2: - Distribution of women based on parity**

Majority of the women were multipara accounting for 95.6%

**Table 4: - Distribution of women based on symptoms**

SYMPTOMS	Frequency	Percent
INTERMENSTRUAL BLEEDING	10	11.11
POST COITAL BLEDDING	19	21.1
WDPV	61	67.8
Total	90	100.0

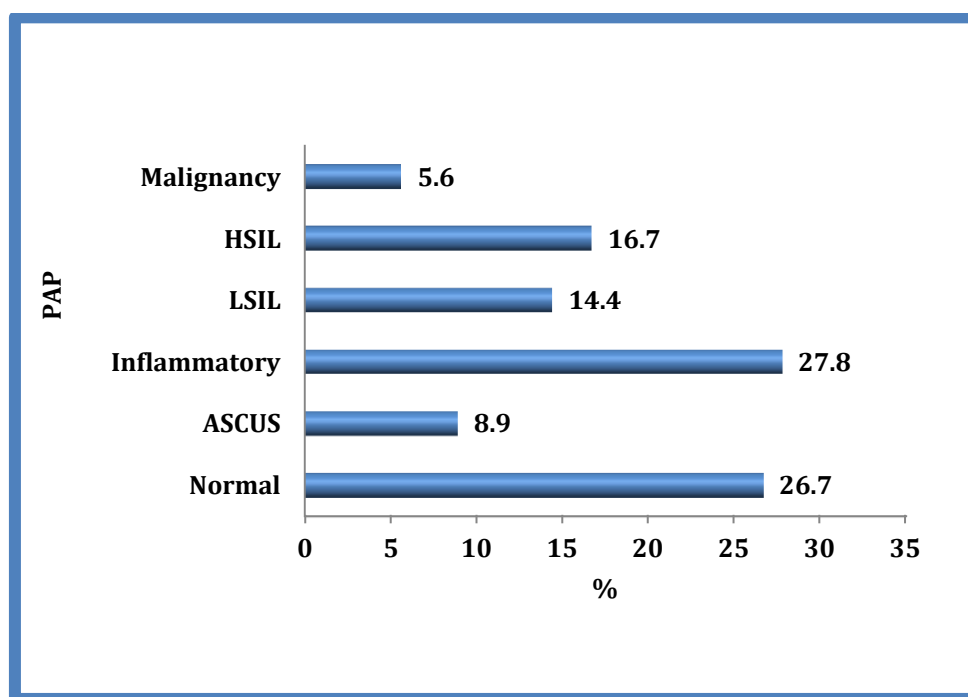


**Graph 3: - Distribution of women based on symptoms**

The commonest symptom in the study participants was white discharge per vagina (67.8%)

**Table 5: - Pap smear findings**

<b>PAP</b>	<b>Frequency</b>	<b>Percent</b>
Normal	24	26.7
ASCUS	8	8.9
Inflammatory	25	27.8
LSIL	13	14.4
HSIL	15	16.7
Malignancy	5	5.6
Total	90	100.0



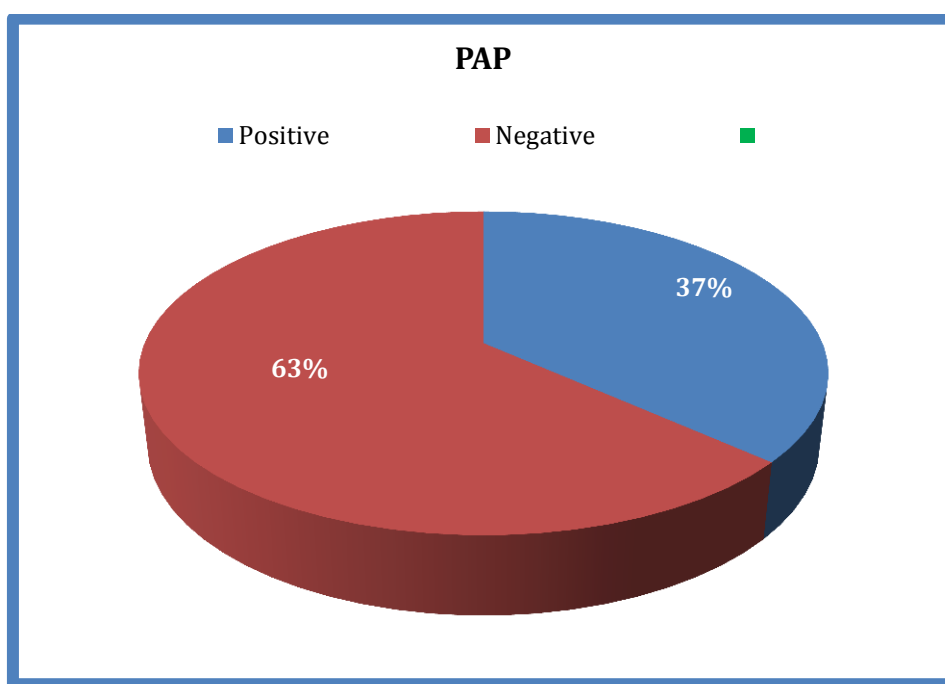
**Graph 4: - Pap smear findings**

Most common finding on Pap smear was, inflammatory smear (27.8%) and 26.7% of the study subjects had normal Pap Smear.

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**Table 6: - Pap smear results**

PAP	Frequency	Percent
Positive	33	36.6
Negative	57	63.3
Total	90	100.0



**Graph 5: -Pap smear results**

Pap smear revealed that 35% was positive which included LSIL, HSIL and Malignancy and 63% were negative which included NILM and inflammatory smear (ASCUS).

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**Table 7: -Colposcopy findings**

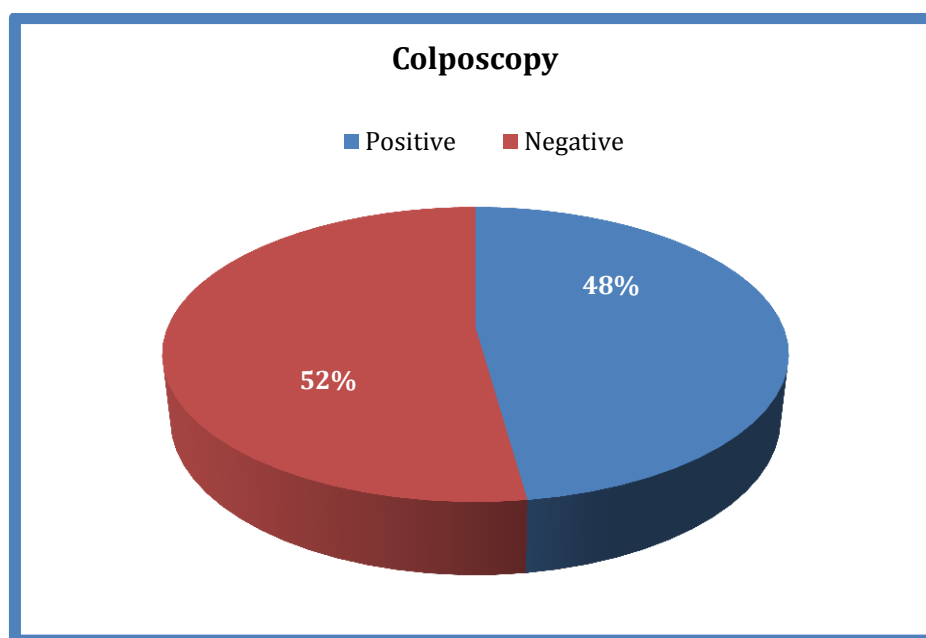
Colposcopy	Frequency	Percent
NORMAL	5	5.6
INFLAMMATION/SQUAMOUS METAPLASIA/EROSION/TZ SEEN/HYPERAEMIA	36	40.0
HAZY/FINE ACETOWHITE AREA/FINE PUNCTATION OR MOSAICISM(LSIL)	21	23.3
DENSE ACETOWHITE AREA/COARSE PUNCTATION OR MOSAICISIM(HSIL)	11	12.2
UNSATISFACTORY	6	6.7
MALIGNANCY(INTENSE ACETOWHITE AREA, COARSE IRREGULAR PUNCTATION	11	12.2
Total	90	100.0

Most common finding on colposcopy was squamous metaplasia/erosions (40%) and only 5 subjects had a normal colposcopy ,rest had abnormal colposcopic findings.

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**Table 8: - Colposcopy results**

Colposcopy	Frequency	Percent
Positive	43	48
Negative	47	52.2
Total	90	100.0



**Graph 6: - Colposcopy results**

On colposcopy 43 women were found to have positive result which accounted for 48%.Colposcopy was considered positive if the lesions were suggestive of LSIL/HSIL/MALIGNANCY. Among the 48% abnormal colposcopies LSIL accounted for 21 cases(23.3%),HSIL for 11 cases(12.2%),malignancy in about 11cases(12.2%).And colposcopy was negative in 47cases (52%) which included colposcopy with normal findings 5cases(5.6%),inflammatory findings 36cases (36%) and unsatisfactory findings in 6 cases(6.7%).

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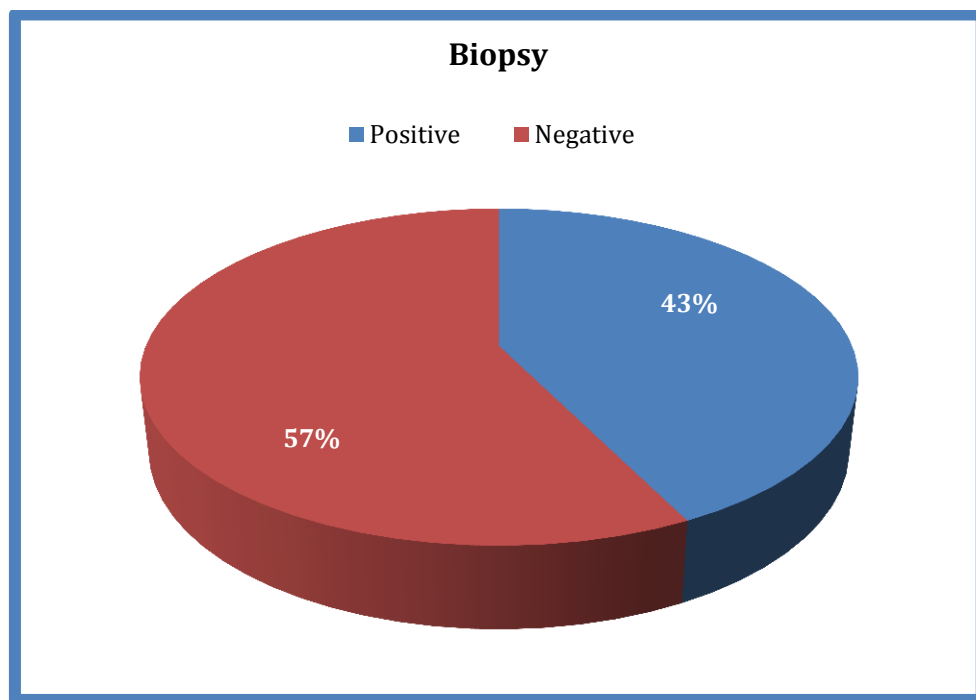
**Table 9: - Biopsy findings**

Biopsy	Frequency	Percent
Cervicitis / Metaplasia	51	56.7
Mild Dysplasia(LSIL)	15	16.7
Moderate Dysplasia/Severe Dysplasia(HSIL)	12	13.3
Malignancy	12	13.3
Total	90	100.0

Most common biopsy finding was metaplasia which accounted for 56.7 percent and 13.3 percent had malignancy.

**Table 10: - Biopsy results**

Biopsy	Frequency	Percent
Positive	39	43.3
Negative	51	56.7
Total	90	100.0



**Graph 7: - Biopsy results**

The positive biopsy includes 39 cases (43.2%) out of 90. Biopsy was considered to be positive if it revealed LSIL/HSIL/MALIGNANCY. It includes mild dysplasia (LSIL) 15cases (16.7%), moderate to severe dysplasia (HSIL) 12cases (13.3%) and malignancy 12 cases (13.3%). The negative biopsy accounted for 51cases (56.7%) which included cervicitis changes.

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**Table 11: -Correlation between Pap smear and biopsy**

PAP	BIOPSY				Total
	Cervicitis/ Metaplasia	Mild Dysplasia/LSIL	Moderate Dysplasia/Severe Dysplasia/HSIL	Malignancy	
Normal	24	0	0	0	24
ASCUS	5	2	1	0	8
Inflammatory	16	8	0	1	25
LSIL	4	4	2	3	13
HSIL	2	1	9	3	15
Malignancy	0	0	0	5	5
Total	51	15	12	12	90

33 cases out of 90 study participants were positive on Pap smear. 39 out of 90 women were positive on biopsy. Pap smear was positive in 27 out of 39 biopsy proven positive cases. 8 cases of LSIL and 1 case of malignancy was underreported as inflammatory on Pap smear. 6 cases of cervicitis was overreported as LSIL/HSIL on Pap smear.

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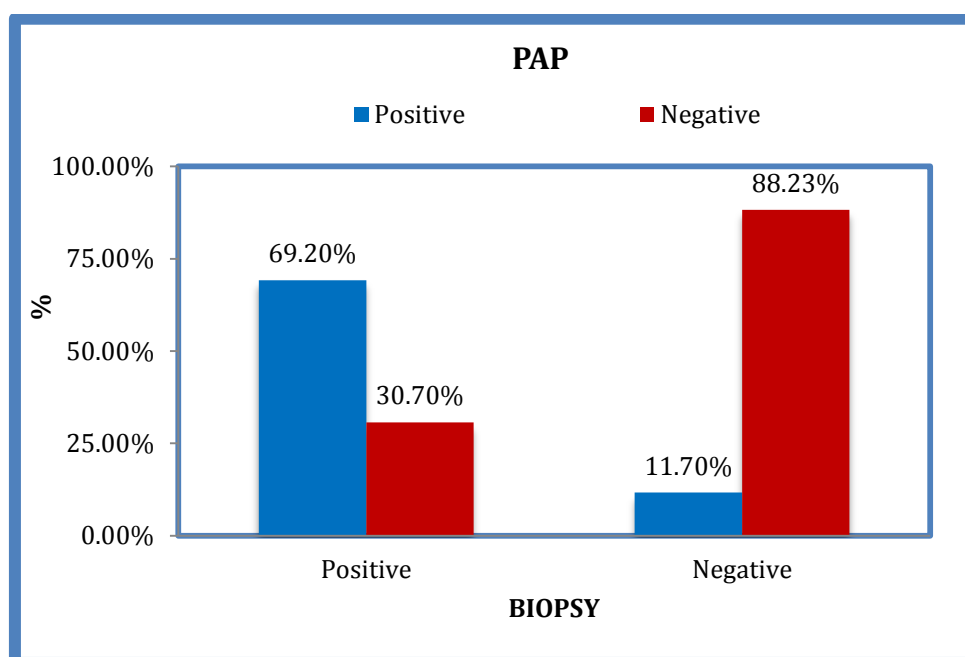
**Table 12:- Correlation between colposcopy and biopsy**

Colposcopy	Biopsy				Total
	Cervicitis/ Metaplasia	Mild Dysplasia	Moderate Dysplasia/ Severe Dysplasia	Malignancy	
NORMAL	5	0	0	0	5
INFLAMMATION/SQUAMOUS METAPLASIA/EROSION/TZ SEEN/HYPERAEMIA	35	0	1	0	36
HAZY/FINE ACETOWHITE AREA/FINE PUNCTATION OR MOSAICISM(LSIL)	4	13	4	0	21
DENSE ACETOWHITE AREA/COARSE PUNCTATION OR MOSAICISIM(HSIL)	1	2	7	1	11
UNSATISFACTORY	6	0	0	0	6
MALIGNANCY( INTENSE ACETOWHITE AREA, COARSE IRREGULAR PUNCTATION	0	0	0	11	11
TOTAL	51	15	12	12	90

43 out of 90 women were positive on colposcopy .39 out of 90 were positive on biopsy.colposcopy was positive in 38 out of 39 biopsy proven positive cases, colposcopy was unsatisfactory in 6 cases,1 case of moderate dysplasia was underreported as metaplasia on colposcopy .5 cases of cervicitis was overreported as LSIL/HSIL on colposcopy.

**TABLE 13: -DIAGNOSTIC EFFICACY OF PAP SMEAR**

PAP	BIOPSY				Total	
	Positive		Negative			
	Count	%	Count	%	Count	%
Positive	27	69.2%	6	11.7%	33	35.0%
Negative	12	30.7%	45	88.23%	57	55.5%
Total	39	100.0%	51	100.0%	90	100.0%
Kappa value = 0.62; P < 0.001						



**GRAPH 8: - DIAGNOSTIC EFFICACY OF PAP SMEAR**

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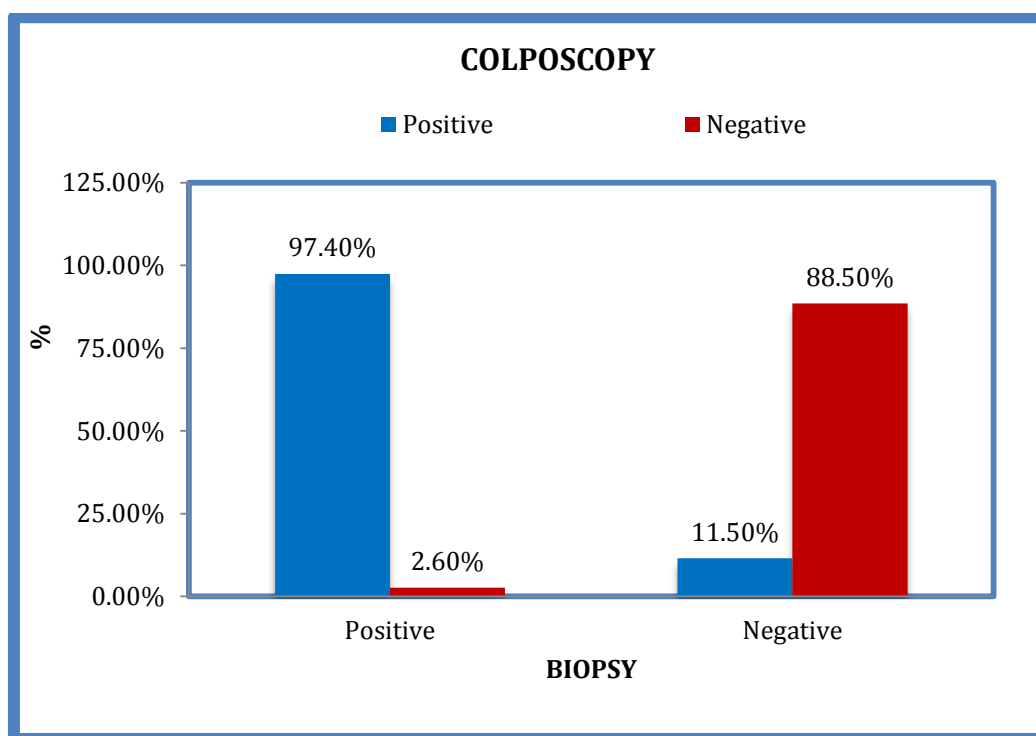
**TABLE 14: - SENSITIVITY AND SPECIFICITY OF PAP SMEAR.**

Statistic	Value	95% CI
Sensitivity	69.2%	56.74% to 87.51%
Specificity	88.23%	74.26% to 95.17%
Positive Predictive Value	81.25%	66.69% to 90.37%
Negative Predictive Value	82.00%	71.96% to 88.99%
Accuracy	81.71%	71.63% to 89.38%

Sensitivity of Pap smear is 69.2%, specificity is 88.23% and accuracy is 81.71%.

**TABLE 15: - DIAGNOSTIC EFFICACY OF COLPOSCOPY**

COLPOSCOPY	BIOPSY				Total	
	Positive		Negative			
	Count	%	Count	%	Count	%
Positive	38	97.4%	6	11.5%	44	47.8%
Negative	1	2.6%	45	88.5%	46	52.2%
Total	39	100.0%	51	100.0%	90	100.0%
Kappa value = 0.84; P < 0.001						

**GRAPH 9: -DIAGNOSTIC EFFICACY OF COLPOSCOPY**

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**TABLE 16: - SENSITIVITY AND SPECIFICITY OF COLPOSCOPY.**

Statistic	Value	95% CI
Sensitivity	97.37%	86.19% to 99.93%
Specificity	88.46%	76.56% to 95.65%
Positive Predictive Value	82.05%	74.36% to 92.91%
Negative Predictive Value	97.87%	86.90% to 99.69%
Accuracy	92.22%	84.63% to 96.82%

Sensitivity of colposcopy is 97.37%, specificity is 88.46% and accuracy is 92.22%.

So from the above results it indicates that colposcopy is more sensitive than Pap smear, but specificity of both the test is comparable and colposcopy is more accurate than Pap smear.

**Table 17:- DIAGNOSTIC EFFICACY OF PAP AND COLPOSCOPY IN CORREALTION WITH BIOPSY**

Predicted PAP+COL	BIOPSY			
	Positive		Negative	
	Count	%	Count	%
Positive	37	97.4%	6	11.5%
Negative	1	2.6%	46	88.5%
Total	38	100.0%	52	100.0%

**TABLE 18:- SENSITIVITY AND SPECIFICITY OF PAP AND COLPOSCOPY IN CORRELATION WITH BIOPSY**

Statistic	Value	95% CI
Sensitivity	97.37%	86.19% to 99.93%
Specificity	88.46%	76.56% to 95.65%
Positive Predictive Value	86.05%	74.36% to 92.91%
Negative Predictive Value	97.87%	86.90% to 99.69%
Accuracy	92.22%	84.63% to 96.82%

The combined sensitivity of PAP smear and Colposcopy is 97.4% & specificity is 88.4% and accuracy is 92.22% which is more when compared to PAP smear, when used alone as a screening test.

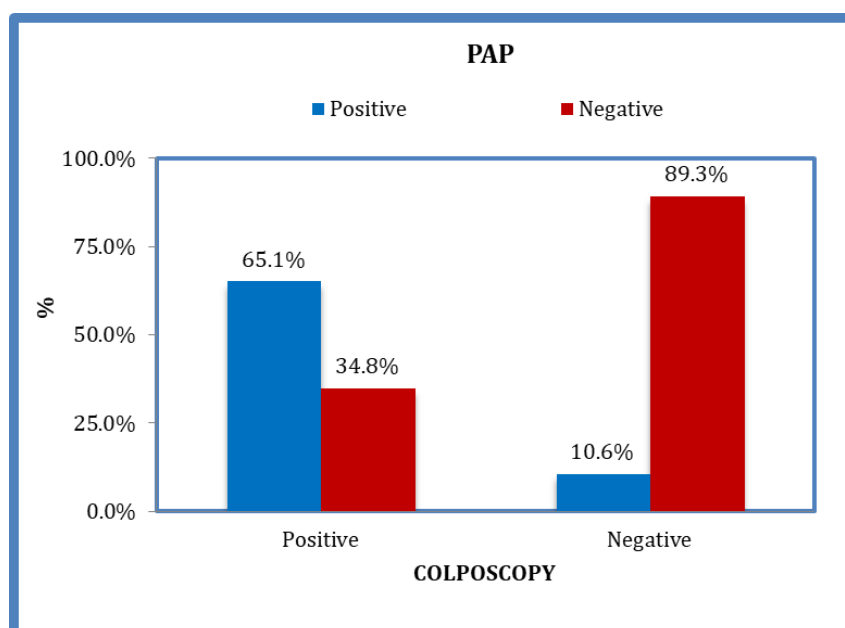
**TABLE 19: - COORELATION BETWEEN COLPOSCOPY AND PAP SMEAR.**

COLPOSCOPY	PAP						Total
	NORMAL	ASCUS	Inflammatory	LSIL	HSIL	MALIGNANCY	
NORMAL	4	0	0	1	0	0	5
INFLAMMATION / SQUAMOUS METAPLASIA / EROSION / TZ SEEN / HYPERAEMIA	16	5	12	2	1	0	36
HAZY / FINE ACETOWHITE AREA / FINE PUNCTATION OR MOSAICISM	1	2	8	6	4	0	21
DENSE ACETOWHITE AREA / COARSE PUNCTATION OR MOSAICISIM	0	1	2	1	7	0	11
UNSATISFACTORY	3	0	2	0	1	0	6
MALIGNANCY ( INTENSE ACETOWHITE AREA, COARSE IRREGULAR PUNCTATION	0	0	1	3	2	5	11
Total	24	8	25	13	15	5	90

43 out of 90 study participants were positive on colposcopy & 33 out of 90 were positive on PAP smear. PAP smear was positive in 28 out of 43 positive colposcopy. 15 study participants were under reported negative which was positive on colposcopy, 5 cases were over reported as positive which was negative on colposcopy.

**TABLE 20: -DIAGNOSTIC EFFICACY OF PAP WITH CORRELATION TO COLPOSCOPY**

PAP	COLPOSCOPY				Total	
	Positive		Negative			
	Count	%	Count	%	Count	%
Positive	28	65.11%	5	10.6%	33	36.6%
Negative	15	34.8%	42	89.3%	57	63.3%
Total	43	100.0%	47	100.0%	90	100.0%



**GRAPH: -10 PAP SMEAR IN CORRELATION WITH COLPOSCOPY**

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**TABLE 21: - SENSITIVITY AND SPECIFICITY OF PAP WITH  
CORRELATION TO COLPOSCOPY.**

Statistic	Value	95% CI
Sensitivity	65.50%	50.87% to 81.43%
Specificity	89.10%	74.37% to 96.02%
Positive Predictive Value	83.38%	69.76% to 92.67%
Negative Predictive Value	73.00%	64.24% to 81.85%
Accuracy	78.05%	67.54% to 86.44%

The sensitivity of Pap smear in relation to Colposcopy was only 65.50% and specificity was 89.10%. The positive predictive value was 83.38% and the negative predictive value was 73.0% with a accuracy rate of 78.5%.

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**Statistical analysis:**

Data were entered in MS-Excel and analysed in SPSS V21. Descriptive statistics were represented with frequencies and percentages, Kappa statistics was applied to measure agreement between two methods. Sensitivity and specificity were calculated. P value of 0.05 was considered as statistically significant.



# DISCUSSION

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## DISCUSSION

The rate of cervical malignancy can be decreased up to 80 percent if the quality, inclusion & development of screening strategies are of elite standards.<sup>57</sup> Often times frequent cytology screening programs have prompted an enormous decrease in cervical malignancy occurrence & mortality in western countries. Cytology based screening programs have made restricted progress in agricultural nations like India because of absence of prepared staff, lab offices, types of gear, significant expense of administrations and poor development. Hence it is important to discover methodology which is highly sensitive and specific which can complement cytology for elective screening.<sup>57</sup>

The current examination was completed in R L Jalappa medical college & reasearch centre, Tamaka, kolar. 90 cases were incorporated who satisfied the determination rules were enlisted for the examination, Greatest number of cases was discovered in the age group of more than 50years (44.4%). Mean age was 52 years. Most of the women were multipara (95.6%) The commonest clinical symptom was white vaginal discharge. (67.8%).

### **AGE:-**

Regarding age distribution, in the present study most cases of CIN was found among the age group of above 50years (44.4%) with mean age of 52 years. Kushtagi and Fernandes<sup>58</sup>, showed the overall prevalence of CIN was more in women over 30 years. Similarly, Vaidya<sup>60</sup> in his study showed that prevalence of CIN was more in the age group of more than 35 years. All these studies indicate that premalignant and malignant lesion of the cervix are most commonly seen in elderly age group.

### **PARITY: -**

In the present study, increased incidence of CIN was noted in multiparous women (95.6%). A study which was similar to our study done by Shalini et al<sup>59</sup> showed the mean parity was 4 in patients with invasive carcinoma cervix. Kushtagi & Fernandez<sup>58</sup> in their study concluded that the prevalence of CIN was higher in multiparous women. In a study done by Vaidya<sup>60</sup> showed more positive cases of CIN were found in women with parity more than four. This might be attributed to the

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nutritional & hormonal changes that occur in pregnancy, immune-suppression during pregnancy, & cervical trauma during vaginal delivery.

**SYMPTOMS: -**

Majority of women (67.8%) complained of excessive white vaginal discharge. Vaidya et al<sup>60</sup> concluded that white discharge accounted for 24% percent of cases. He postulated that excessive vaginal discharge played a significant role for the development of CIN. In the present study post coital bleeding was found in 21 % of cases. Shalini et al in their study showed the relationship of post coital bleeding and CIN.

**PAP SMEAR: -**

In all cases pap smear was taken. Mild dysplasia was found in 14.4% (13/90), moderate dysplasia / severe dysplasia 16.7% (15/200), malignancy in 5.6% (5/90). Pap smear correctly estimated positive cases in 69% and underestimated in 30.7% (12/90) and overestimated in 11.7% (6/90) (false positivity). Sensitivity of pap smear was found to be 69.2% compared to its specificity which was 88.23%. This was attributed to the false negative smears. Correlation between cytology and biopsy was poor and the P value was <0.001 which was statistically significant.

**SENSITIVITY AND SPECIFICITY OF PAP SMEAR.**

S.NO	AUTHORS	SENSITIVITY	SPECIFICITY
1	Londhe M, George S, Seshadri I. <sup>63</sup>	13.2%	96.3%
2	Shalini R, Amita S, Neera M.A. <sup>59</sup>	56%	90%
3	Pete I, Toth V, Bosze P. <sup>62</sup>	47%	77%
4	Present study	69.2%	88.23%

This above data suggests that by using colposcopy as a screening method, the rate of false negative cytology can be significantly decreased.

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## **COLPOSCOPY: -**

In the present study, there was a good correlation between colposcopy findings and biopsy results. Out of 39 biopsy proven cases colposcopy was positive in 38 case which increased the sensitivity of colposcopy to 97.37% and specificity was found to be 88.46%, false negative results was seen only in 1 case and false positivity in 6 cases( 11.5%) When compared with PAP smear ,colposcopy had high sensitivity and specificity of colposcopy was comparable with that of PAP smear was due to the high incidence of unsuspected AW epithelium which might be due to inflammation, immature metaplasia, erosion and latent HPV infections.

## **SENSITIVITY AND SPECIFICITY OF COLPOSCOPY BY VARIOUS AUTHORS**

SL.NO	AUTHORS	SENSITIVITY	SPECIFICITY
1	Olaniyan B. Meta analysis. <sup>61</sup>	87-99%	26-87%
2	Sukhpreet L. Singh et al. <sup>64</sup>	95%	63.5%
3	Present study	97.37%	88.46%

Colposcopy was positive in 38 out of 39 (97.37%) biopsy proven cases, but pap smear was positive in 27 out of 39 (69%) biopsy proven cases. This indicated the usefulness of colposcopy in diagnosing lesions missed by pap smear. So, colposcopy is very useful in identifying premalignant & malignant lesions of the uterine cervix. Colposcopy & cytology used together in patients with cervical lesions have a higher probability of detecting cervical intraepithelial lesions/malignancy as compared to either procedure when performed alone.

Olaniyan et al,<sup>61</sup> did a meta-analysis of eight longitudinal studies and compared the correlation of Colposcopy impression with biopsy results. Colposcopy accuracy was

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found to be 89% which agreed exactly with histology in 61% of cases. In the present study, the accuracy of Colposcopy impression was found to be 92.2%.

Joshi et al<sup>64</sup>, in her study, showed that the CIN I was 28 percent, CIN II 11 percent, CIN III 4 percent. She emphasizes the use of all 3 methods PAP cytology (conventional method), colposcopy, and histology is complementary to each other and helps to reduce false negative cases.

Gupta P et al<sup>65</sup>, concluded in his study that the accuracy of cytology when compared to colposcopy was 81.82 percent. The accuracy of colpo-histopathology was 83.6 percent. The combined accuracy was 76.36 percent. The results were comparable to our study also.



# SUMMARY



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## SUMMARY

The study was conducted on 90 women attending gynaecology outpatient at R L JALAPPA HOSPITAL AND REASEARCH CENTRE. The study objectives were to correlate the cytology, colposcopy and colposcopy directed biopsies in an unhealthy cervix and also to assess the accuracy of colposcopy in detecting the premalignant & malignant lesions of the cervix. Colposcopy directed biopsy is considered as gold standard for diagnosis of cervical cancer. The study results of Pap smear and colposcopy was compared to it.

- Majority of the women in the study group were more than 50 years of age (44.4 %) and most of them were multipara (95.6%). The commonest symptom was white vaginal discharge (67.8%).
- On Pap smear studies, 31.1 % cases of CIN. Inflammatory smears was seen in 27.8%. only 5.6 % of them showed malignancy. In 26.7 percent of cases smears were within normal limits. In Our study, the Pap smear had a sensitivity & specificity of 69.2% and 88.2% respectively.
- In majority of the women (40%), colposcopy was suggestive of inflammatory/metaplastic lesions and in 35.5% patients the findings were suggestive of CIN. Colposcopy was normal in 5.6% cases. 11cases (12.2%) were suggestive malignancy. The sensitivity and specificity of colposcopy was 97.37% and 88.46% respectively.
- Our study showed that colposcopy had a higher sensitivity of 97.37% as compared to that of cytology which was 69.2%. However, colposcopy & cytology were comparable in specificity and positive predictive value.
- Colposcopy had a better accuracy (92.87%) than cytology (81.71%) for screening of cervical carcinoma. Thus, colposcopy is useful in detecting pre-invasive & invasive lesions of the cervix. Colposcopy & Pap smear used together in women with unhealthy cervix have a relatively better chances of detecting CIN/malignancy as compared to either procedure when used alone.



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# CONCLUSION

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## CONCLUSION

Carcinoma cervix being the most common gynaecological malignancy in developing country like India accounting for Majority of mortality among women, hence it is to be viewed that Malignant growth of cervix is a preventable condition since it is preceded by a long pre-invasive stage (CIN), making it an ideal cancer for screening & treatment. Hence, early identification of CIN in women is considered to an alluring objective, since early diagnosis and prompt treatment can reduce the overall morbidity and mortality.

Our study results, clearly indicate that colposcopy is unquestionably more reliable than Pap smear because of its sensitivity and accuracy. Our study, also demonstrates that Colposcopy aids in identifying the exact site for taking biopsy. Best result in early detection of pre-invasive carcinomas could be obtained by combined use of cytology and colposcopy directed biopsy. By combining pap smear with colposcopy, we can make cervical screening programme an effective programme by increasing the sensitivity and reducing the morbidity and mortality rate.

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## **LIMITATION OF THIS STUDY**

The only limitation of this study was with respect to less sample size.



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# ANNEXURES

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## PROFORMA

CASE NO-

HOSPITAL NO-

NAME-

AGE-

SEX-

OCCUPATION –

ADDRESS-

SES-

PH NO-

INFORMED CONSENT-

CHIEF COMPLAINTS-

MENTRUAL HISTORY:-

OBSTETRIC HISTORY:-    PARITY-

AGE    OF MARRIGE-

PAST HISTORY-

YES

NO

TB

SEXUALLY

TRANSMITTED INFECTION

OCP USE

DIABETES MELLITUS

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## MALIGNANCY

PERSONAL HISTORY:-

DIET-

BOWEL/BLADDER-

SLEEP-

HABITS-

FAMILY HISTORY :-

General physical examination:-pallor-

icterus-

clubbing-

cynosis-

lymphadenopathy

edema-

Systemic examination:-CVS-

RS-

PA-

CNS-

PER SPECULUM EXAMINATION:-

PER VAGINAL EXAMINATION:-

**INVESTIGATION:-**

PAP FINDINGS-

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COLPOSCOPY FINDINGS:-

BIOPSY FINDINGS:-

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## PATIENT INFORMATION SHEET

**Study title-** SCREENING FOR CARCINOMA CERVIX BY CORRELATING RESULTS OF CYTOLOGY, HISTOPATHOLOGY WITH COLPOSCOPY IN UNHEALTHY CERVIX

**Study location:** R.. L .Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

Please read the following information and discuss with your family members.

- Patients who are visiting OBG department OPD of R L Jalappa hospital attached to Sri Devaraj Urs medical college are recruited in the study after obtaining patient information consent.
- All patients with unhealthy cervix are recruited and subjected to PAP, colposcopy and colposcopic guided biopsy and the results will be correlated.
- You can ask any question regarding the study. If you agree to participate in the study, we will collect information (as per proforma) from you or from a person responsible for you or both.
- Relevant history will be taken. This information collected will be used only for dissertation and publication.
- All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. This study has been reviewed by the Institutional
- Ethics Committee and you are free to contact the member of the Institutional Ethics Committee. There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

For further information contact

**Dr. CHAITHANYA.C** Post graduate, Department of obstetrics and Gynaecology, R .L. Jalappa Hospital, Kolar. Phone NO:9901388592.

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## CONSENT FORM

I **Dr. Chaithanya C.**, post graduate, Department of obstetrics and gynaecology, conducted a research work for award of MS degree in obstetrics and gynaecology.

**STUDY TOPIC:-“SCREENING FOR CARCINOMA CERVIX BY CORRELATING RESULTS OF CYTOLOGY, HISTOPATHOLOGY WITH COLPOSCOPY IN UNHEALTHY CERVIX”**

This is an observational study on women who are sexually active with unhealthy cervix, who come to gynaecology out patient department and those admitted to gynaecology ward. It will be carried out in Sri Devraj Urs Medical College, Tamaka, Kolar.

### **OBJECTIVES:**

- To perform cytology, histopathology and colposcopy in patients with unhealthy cervix.
- To correlate these tests to make early a diagnosis.

I here by state that the study procedure in details ere explained and all the questions where fully and clearly answered to the participant/his/her relative.

Investigators signature:

Date:

Place:

Contact Address- Dr. Chaithanya. C

Post graduate.

Department of obstetrics and gynaecology

Sri Devraj Urs Medical College, Tamaka, Kolar

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I ----- have been told in a language that I understand about the study .I have been told that this is for a research procedure, that my participation in voluntary and I/he/she reserve the full right to withdraw from the study at my own initiative at any time, without having to give any reason and that right to participate or withdraw from the study at any stage will not prejudice my/his/her, rights and welfare. Confidentiality will be maintained and only be shared for academic purposes.

I hereby give consent to participate in the above study. I am also aware that I can withdraw this consent at any later date if I wish so. This consent form being signed voluntarily indicating my agreement to participate in the study until I decide otherwise. I understood that I will receive a signed and dated copy if this form.

I have signed this consent form before my participation in this study.

Signature of the research subject:

Date:

Place:

Signature of the witness:

Date-

Place-

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## KEY TO MASTER CHART

**P-PARA**

**L-LIVING**

**WDPV-WHITE DISCHARGE PER VAGINA/LEUCORRHEA**

### **PAP SMEAR CATEGORY**

<b>CODING</b>	<b>DECODING</b>
1	NORMAL
2	ASCUS
3	INFLAMMATORY
4	LSIL
5	HSIL
6	MALIGNANCY

### **PAP SMEAR RESULTS**

**1-POSITIVE (CATEGORY 4,5,6)**

**2-NEGATIVE ( CATEGORY 1,2,3)**

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## COLPOSCOPY

CODING	DECODING
1	NORMAL
2	INFLAMMATION/SQUAMOUS METAPLASIA/EROSION/TZ SEEN/HYPERAEMIA
3	HAZY/FINE ACETOWHITE AREA/FINE PUNCTATION OR MOSAICISM
4	DENSE ACETOWHITE AREA/COARSE PUNCTATION OR MOSAICISM
5	UNSATISFACTORY
6	MALIGNANCY ( INTENSE ACETOWHITE AREA, COARSE IRREGULAR PUNCTATION

## COLPOSCOPY RESULTS

**1-POSITIVE (CATEGORY:-3,4,5,6)**

**2-NEGATIVE( CATEGORY:-1,2)**

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### **BIOPSY**

<b>CODING</b>	<b>DECODING</b>
1	NORMAL
2	CERVICITIS/METAPLASIA
3	MILD DYSPLASIA
4	MODERATE DYSPLASIA/SEVERE DYSPLASIA
5	MALGNANCY

### **BIOPSY RESULTS:-**

- 1- POSITIVE ( CATEGORY 3,4,5 )
- 2- NEGATIVE ( CATEGORY 1,2 )

SL NO	OP/IP NO	NAME	AGE(YEARS)	PARITY	INCLUSION CRITERIA	PAP	PAP Category	PAP (Positive-1, Negative-2)	COLPOSCOPY	COLPOSCOPY Category	COLPOSCOPY (Positive-1, Negative-2)	BIOPSY	BIOPSY category	BIOPSY (Positive-1, Negative-2)
1	730798	LAKSHMI DEVI	45	P2L2	WDPV/LEUCORRHEA	NORMAL	1	2	TZ SEEN	2	2	CERVICITIS	2	2
2	732826	RATNAMMA	48	P3L3A1	WDPV	LSIL	4	1	HAZY A-W AREA.	3	1	MILD DYSPLASIA	3	1
3	725651	LAKSHMIDEVAMMA	40	P2L2	WDPV	LSIL	4	1	TZ SEEN	2	2	MODERATE DYSPLASIA	4	1
4	738278	RATHNAMMA	45	P2L2	WDPV	HSIL	5	1	HAZY A-W AREA WITH FINE PUNCTATION	3	1	MILD DYSPLASIA	3	1
5	725026	LAKKSHMI	54	P3L3	WDPV	LSIL	4	1	INTENSE ACTOWHITE AREA WITH IRREGULAR PUNCTATION	6	1	MALIGNANCY	5	1
6	691117	RAMAKKA	54	P3L3	INTERMENSTURAL BLEEDING	ASCUS	2	2	SQUAMOUS METAAPLASIA	2	2	CERVICITIS	2	2
7	736054	VENKATALAKSHMAMMA	45	P2L1	WDPV	HSIL	5	1	INTENSE ACETO WHITE AREA	6	1	MALIGNANCY	5	1
8	682188	GOWRAMMA	55	P3L3	POST COITAL BLEEDING	HSIL	5	1	DENSE ACETOWHITE AREA	4	1	SEVERE DYSPLASIA	4	1
9	691134	RATHNAMMA	56	P3L3	WDPV	LSIL	4	1	DENSE ACETOWHITE AREA	4	1	MODERATE DYSPLASIA	4	1
10	666015	MANJULA	45	P2L2	WDPV	ASCUS	2	1	COARSE PUNCTATION	4	1	MILD DYSPLASIA	3	1
11	708035	SUMITRA	48	P3L3	WDPV	INFLAMMATORY	3	2	FAINT ACETOWHITE AREA	3	1	CERVICITIS	2	2
12	655156	SUNITHA	45	P1L1	POST COITAL BLEEDING	INFLAMMATORY	3	2	EROSION	2	2	CERVICITIS	2	2
13	845481	SOUBHAGYA	52	P2L2	WDPV	INFLAMMATORY	3	2	HYPERAEMIA	2	2	CERVICITIS	2	2
14	702381	SHARDHAMMA	55	P2L2	WDPV	HSIL	5	1	COARSE PUNCTATION WITH DENSE ACETOWHITE AREA	4	1	MALIGNANCY	5	1
15	765922	NARAYANMMA	45	P6L5D1	INTERMENSTURAL BLEEDING	ASCUS	2	2	FINE ACETO WHITE AREA,FINE MOSAICISM	3	1	MODERATE DYSPLASIA	4	1
16	765016	GANGAMMA	55	P4L4	WDPV	INFLAMMATORY	3	2	UNSATISFACTORY	5	2	CERVICITIS	2	2
17	866649	CHANGAMMA	54	P3L3	POST COITAL BLEEDING	NORMAL	1	2	TZ SEEN	2	2	CERVICITIS	2	2
18	773431	RADHA	30	P2L2	WDPV	NORMAL	1	2	TZ SEEN	2	2	CERVICITIS	2	2
19	866610	ROOPA	35	P2L2	WDPV	INFLAMMATORY	3	2	FINE PUNCTATION,HAZY A-W AREAS	3	1	MILD DYSPLASIA	3	2
20	866639	KRISHNAKUNARI	53	P2L2	WDPV	HSIL	5	1	COARSE PUNCTATION WITH DENSE ACETO WHITE AREA	4	1	MODERATE DYSPLASIA	4	1
21	774522	JYOTHI	30	P2L2	WDPV	LSIL	4	1	FAINT ACETOWHITE AREA	3	1	CERVICITIS	2	2
22	783491	PREMMAMMA	53	P3L3	POST COITAL BLEEDINDG	ASCUS	2	2	TZ SEEN	2	2	CERVICITIS	2	2

SL NO	OP/IP NO	NAME	AGE(YEARS)	PARITY	INCLUSION CRITERIA	PAP	PAP Category	PAP (Positive-1, Negative-2)	COLPOSCOPY	COLPOSCOPY Category	COLPOSCOPY (Positive-1, Negative-2)	BIOPSY	BIOPSY category	BIOPSY (Positive-1, Negative-2)
23	825353	VENKATALAKSHMAMMA	55	P3L3	WDPV	ASCUS	2	2	HAZY A-W AREA.	3	1	MILD DYSPLASIA	3	1
24	825675	RAMADEVI	45	P2L2	WDPV	INFLAMMATORY	3	2	COARSE PUNCTATION,	4	1	CERVICITIS	2	2
25	822814	VARALAKSHMI	37	P2L2	INTERMENSTRUAL BLEEDING	LSIL	4	1	SQUAMOUS METAPLASIA	2	2	CERVICITIS	2	2
26	819659	LAKSHMAMMA	54	P3L3	WDPV	MALIGNANCY	6	1	INTENSE ACETOWHITE AREA WITH IRREGULAR PUNCTATION	6	1	MALIGNANCY	5	1
27	809363	VIJAYALAKSHMI	32	P2L2	WDPV	ASCUS	2	2	TZ AREA SEEN	2	2	CERVICITIS	2	2
28	816913	VANI	27	P3L3	INTERMENSTRUAL BLEEDING	NORMAL	1	2	TZ SEEN	2	2	CERVICITIS	2	2
29	643031	ASHA	28	NULLIPARA	POST COITAL BLEEDING	INFLAMMATION	3	2	TZ SEEN	2	2	CERVICITIS WITH METAPLASIA	2	2
30	805320	PILLAMMA	55	P4L4	WDPV	HSIL	5	1	COARSE PUNCTATION,DENSE ACETOWHITE AREA	4	1	MODERATE DYSPLASIA	4	1
31	786316	MUSTANI	55	P5L5	WDPV	NORMAL	1	2	NORMAL	1	2	CERVICITIS	2	2
32	790325	GUNAVATHY	50	P4L4	WDPV	LSIL	4	1	NORMAL	1	2	CERVICITIS	2	2
33	790744	SHANTHAMMA	32	P2L2	POST COITAL BLEEDING	HSIL	5	1	DENSE ACETOWHITE AREA	4	1	MODERATE/SEVERE DYSPLASIA	4	1
34	788888	SHARADHAMMA	48	P3L3	POST COITAL BLEEDING	NORMAL	1	2	METAPLASIA	2	2	CERVICITIS	2	2
35	773962	SAJIDA BEGUM	42	P2L2	WDPV	NORMAL	1	2	NORMAL	1	2	CERVICITIS	2	2
36	775086	BHUVESHWARI	30	P2L2	POST COITAL BLEEDING	NORMAL	1	2	HYPERAEMIA	2	2	CERVICITIS	2	2
37	729928	CHANGAMMA	32	P3L3	WDPV	NORMAL	1	2	SQUAMOUS METAPLASIA	2	2	CERVICITIS	2	2
38	778146	SARALADEVI	53	P3L3	WDPV	NORMAL	1	2	INFLAMMATION	2	2	CERVICITIS	2	2
39	779428	RAMAKKA	55	P4L4	WDPV	LSIL	4	1	FAINT ACETOWHITE AREA	3	1	MILD DYSPLASIA	3	1
40	777292	AISHWARYA	27	P2L2	WDPV	NORMAL	1	2	INFLAMMATION	2	2	CERVICITIS	2	2
41	779169	SUVARNA	42	P1L1	WDPV	NORMAL	1	2	SQUAMOUS METAPLASIA WITH NABOTHIAN CYST	2	2	CERVICITIS	2	2
42	669717	SUPRIYA	28	P1L1	WDPV	NORMAL	1	2	NORMAL	1	2	CERVICITIS	2	2
43	674663	BHARATHI	46	P2L2	POST COITAL BLEEDING	INFLAMMATION	3	2	FAINT ACETO WHITE AREA	3	1	MILD DYSPLASIA	3	1
44	745937	KEMPAMA	45	P2L2	POST COITAL BLEEDING	ASCUS	2	2	SQUAMOUS METAPLASIA	2	2	CERVICITIS	2	2

SL NO	OP/IP NO	NAME	AGE(YEARS)	PARITY	INCLUSION CRITERIA	PAP	PAP Category	PAP (Positive-1, Negative-2)	COLPOSCOPY	COLPOSCOPY Category	COLPOSCOPY (Positive-1, Negative-2)	BIOPSY	BIOPSY category	BIOPSY (Positive-1, Negative-2)
45	664287	MUNIYAMMA	55	P3L3	WDPV	LSIL	4	1	INTENSE ACETO WHITE AREA	6	1	MALIGNANCY	5	1
46	732138	ABIDHA	40	P2L2	WDPV	INLAMMATORY	3	2	INFLAMMATION -HYPERAEMIA	2	2	CERVICITIS	2	2
47	721889	CHALLAMMA	54	P5L5	WDPV	HSIL	5	1	DENSE ACETOWHITE AREA	4	1	MODERATE DYSPLASIA	4	1
48	719257	BHAGYAMMA	30	P2L2	WDPV	LSIL	4	1	FAINT ACETOWHITE AREA	3	1	CERVICITIS	2	2
49	723017	JAYARATNA	55	P2L2	POST COITAL BLEEDING	LSIL	4	1	FAINT ACETOWHITE AREA	3	1	MILD DYSPLASIA	3	1
50	728116	SEETHAMMA	55	P3L3	WDPV	HSIL	5	1	INTENSE ACETOWHITE AREA	6	1	MALIGNANCY	5	1
51	702381	SHARADHAMMA	55	P4L4	WDPV	HSIL	5	1	FAINT ACETOWHITE AREA,FINE PUNCATATION	3	1	SEVERE DYSPLASIA	4	1
52	684111	NAGARATHNAMMA	55	P2L2	WDPV	NORMAL	1	2	UNSATISFACTORY	5	2	CERVICITIS	2	2
53	712759	JAYAMMA	52	P2L2	POSTCOITAL BLEEDING	ASCUS	2	2	SQUAAMOUS METAPLASIA	2	2	CERVICITIS	2	2
54	697637	VENKATALAKSHMI	45	P2L2	WDPV	NORMAL	1	2	FINEACETOWHITE AREA	3	1	CERVICITIS	2	2
55	699108	KANTHAMMA	38	P2L2	WDPV	INFLAMMATORY	3	2	HYPERAEMIC	2	2	CERVICITIS	2	2
56	691117	RAAMAKKA	56	P2L2	POST COITAL BLEEDING	INFLAMMATORY	3	2	FINE ACETOWHITE AREA	3	1	MILD DYSPLASIA	3	1
57	722251	PUSHPAMMA	39	P2L2	WDPV	MALIGNANCY	6	1	INTENSE ACETHITE AREA	6	1	MALIGNANCY	5	1
58	714551	PUNYAVATHMMMA	54	P2L2	WDPV	NORMAL	1	2	INFLAMMATION	2	2	CERVICITIS	2	2
59	703515	YASHODHAMMA	54	P2L2	INTERMENSTRUAL BLEEDING	HSIL	5	1	DENSE ACETOWHITE AREA	4	1	SEVERE DYSPLASIA	4	1
60	716470	LAKSHMIDEVAMMA	55	P5L5	WDPV	INFLAMMATORY	3	2	DENSE ACETOWHITE AREA	4	1	MILD DYSPLASIA	3	1
61	719647	MUNIYAMMA	45	P6L6	WDPV	MALIGNANCY	6	1	INTENSE ACETOWHITE AREA	6	1	MALIGNANCY	5	1
62	837554	SUSHEELA	26	P2L2	POSTCOITAL BLEEDING	INLAMMATORY	3	2	TZ SEEN	2	2	CERVICITIS	2	2
63	850319	SAROJAMMA	30	P2L2	WDPV	LSIL	4	1	INTENSE ACETOWHITE AREA	6	1	MALIGNANCY	5	1
64	864826	LAKSMAMMA	54	P2L2	WDPV	HSIL	5	1	FAINTACETOWHITE AREA,WIT FINE PUNCTATION	3	1	MODERATE DYSPLASIA	4	1
65	844618	LALITHA	30	P2L2	WDPV	MALIGNANCY	6	2	INTENSE ACETOWHITE AREA	6	1	MALIGNANCY	5	1
66	852332	MUNIVENKATTAMMA	38	P3L3	WDPV	INFLAMMATORY	3	2	INFLAMMATION	2	2	CERVICTIS	2	2

SL NO	OP/IP NO	NAME	AGE(YEARS)	PARITY	INCLUSION CRITERIA	PAP	PAP Category	PAP (Positive-1, Negative-2)	COLPOSCOPY	COLPOSCOPY Category	COLPOSCOPY (Positive-1, Negative-2)	BIOPSY	BIOPSY category	BIOPSY (Positive-1, Negative-2)
67	866788	SUBBAMMA	53	P2L2	WDPV	NORMAL	1	2	NORMAL	1	2	CERVICTIS	2	2
68	866781	NAARAYANAMMA	56	P2L2	POST COITAL BLEEDING	INFLAMMATORY	3	2	TZ SEEN	2	2	CERVICITIS	2	2
69	866807	LNGAMMA	46	P2L2	WDPV	NORMAL	1	2	UNSATISFACTORY-POLY	5	2	CERVICTIS	2	2
70	866813	VENKATAMMA	52	P3L3	WDPV	NORMAL	1	2	INFLAMMATION	2	2	CERVICITIS	2	2
71	866799	NAGAMANI	54	P2L2	POST COITAL BLEEDING	INFLAMMATORY	3	2	FINEACETOWHITE AREA	3	1	MILD DYSPLASIA	3	1
72	866768	NANJAMMA	55	P4L4	WDPV	NORMAL	1	2	UNSATISFACTORY	5	2	CERVICITS	2	2
73	866622	VARSHA	56	P2L2	WDPV	INFLAMMATORY	3	2	SQUMUS METAPLASIA	2	2	CERVICITIS	2	2
74	866658	LAKSHMAMMA	50	P3L3	WDPV	INFLAMMATORY	3	2	INFLAMMATION	2	2	CERVICITIS	2	2
75	866631	NARASIMHAMMA	53	P2L2	WDPV	INFLAMMATORY	3	2	HYPEREMIC	2	2	CERVICITIS	2	2
76	855519	INDRAMMA	53	P2L2	WDPV	INFLAMMATORY	3	2	INTENSE WWITE AREA	6	1	MALIGNANCY	5	1
77	822814	VARALAKSMI	50	P3L3	WDPV	NFLAMMATORY	3	2	FINEACETOWHITE AREA	3	1	MILD DYSPLASIA	3	1
78	819659	LAKSHMAMMA	54	P3L3	POST COITAL BLEEDING	MALIGNANCY	6	1	INTENSE ACETOWHITE AREA	6	1	MALIGNANCY	5	1
79	855519	LAKSHMAMMA	50	P2L2	WDPV	HSIL	5	1	FINEACETWHITE AREA	3	1	SEVERE DYSPLASIA	4	1
80	883351	RENUKAMMA	48	P2L2	WDPV	INFLAMMATORY	3	2	UNSATISFACTORY	5	2	CERVICITIS	2	2
81	736246	VASANTHAMMA	52	P3L3	WDPV	NORMAL	1	2	HYPEREAMIC	2	2	CERVICITIS	2	2
82	738278	RATHNAMMA	45	P2L2	WDPV	NORMAL	1	2	EROSION	2	2	CERVICITIS	2	2
83	867423	MANJULAMMA	46	P2L2	POSTCOITAL BLEEDING	INFLAMMATORY	3	2	FINEACETOWHITE AREA	3	1	LSIL	3	1
84	867434	NEELAMMA	50	P3L3	WDPV	NORMAL	1	2	SQUAMOUS METAAPLASIA	2	2	CERVICITIS	2	2
85	867433	SIRISHA	48	P2L2	WDPV	NORMAL	1	2	HYPEREAMIC	2	2	CERVICTIS	2	2
86	867360	VIJAYALAKSHMI	50	P3L2	POSTCOITAL BLEEDING	INFLAMMTORY	3	2	FINEACTOWHITE AREA	3	1	LSIL	3	1
87	867380	GOWRAMMA	45	P2L2	WDPV	INFLAMMATORY	3	2	HYPEREAMIC	2	2	CERVICITIS	2	2
88	867404	VENKATAMMA	52	P2L2	WDPV	HSIL	5	1	UNSATISFACTORY	5	2	CERVICITIS	2	2

SL NO	OP/IP NO	NAME	AGE(YEARS)	PARITY	INCLUSION CRITERIA	PAP	PAP Category	PAP (Positive-1, Negative-2)	COLPOSCOPY	COLPOSCOPY Category	COLPOSCOPY (Positive-1, Negative-2)	BIOPSY	BIOPSY category	BIOPSY (Positive-1, Negative-2)
89	867507	DHANALAKSHMI	55	P3L3	WDPV	HSIL	5	1	SQUAMAOUAS METAPLASIA	2	2	CERVICITIS	2	2
90	867455	GOWRAMMA	50	P2L2	WDPV	LSIL	4	1	FINEACETOWHITE AREA	3	1	LSIL	3	1