ABSTRACT: BACKGROUND: INTRODUCTION: Carcinoma cervix is most common genital carcinoma in India. It accounts for 80% of female genital carcinoma. Invasive carcinoma of cervix is preventable as it is associated with pre-invasive stage which occurs 10-15 years prior to it, thus permitting early detection by screening and leading to effective treatment and thereby reducing mortality rate with greater impact on lives saved. AIM: Cytological and Colposcopic Evaluation of Unhealthy Cervix. OBJECTIVE: To compare the role of conventional Pap smear and Colposcopy (clinical impression) with Colposcopic guided biopsy as the gold standard. MATERIALS & METHODS: It’s a prospective clinical comparative study of 100 women between 20-60 years attending the gynecological outpatient department at Sri Siddartha Medical College with clinically unhealthy cervix between, June 2013 – May 2015. All the women with unhealthy cervix were subjected to pap and Colposcopy and findings noted. Biopsies were taken from Colposcopically abnormal areas and results were analyzed statistically. RESULT: In the present study 100 patient were subjected to Pap smear, Colposcopy and biopsy. Colposcopy sensitivity was 80.37%, specificity 81.06%, PPV 66.89%, NPV 90.52% accuracy 80.50%, respectively. Pap smear sensitivity was 24.3% specificity 98.3%, PPV 93.12%, NPV 74.36% and accuracy of 76%. CONCLUSION: Pap smear had poor sensitivity as compared to Colposcopy. Hence simultaneous use of Colposcopy has shown to increase in the rate of carcinoma cervix detection in women with unhealthy cervix. KEYWORDS: Pap smear, Colposcopy, Unhealthy cervix, Reid’s index.

INTRODUCTION: In Indian women, cervical cancer is the leading malignancy accounting for 26%-43.8% of all the malignancies.¹ Carcinoma cervix is a disease that can be prevented through primary prevention by early detection as it has a long pre-invasive stage and availability of screening tests.² Lack of resources & effective screening program in poorly organized health system have resulted in higher incidence of cervical cancer in developing countries.³ Medical institutes get referrals from peripheral health centers with diagnosis of unhealthy cervix.⁴ The Papanicolaou (pap) smear is simple, safe, non-invasive and effective method for detection of pre-cancerous, cancerous and non-cancerous changes in cervix.⁵ Colposcopy is a worldwide accepted method for detection of early carcinoma cervix, as it gives faster result and guides the site of biopsy which can be done in a single visit proving itself as a better screening modality for premalignant lesion.⁶ No screening test is 100% specific hence our study was intended to evaluate if parallel testing with pap and Colposcopy can maximize the sensitivity and specificity for screening of carcinoma cervix.
MATERIALS AND METHODS: This prospective clinical study was carried out in department of OBG in SSMC, Tumkur, Karnataka for a period of 2 years from (June 2013-May 2015). A total of 200 patient attending the OPD were screened. Among them, 100 patient with unhealthy cervix were included in the study for further evaluation by pap, colposcopy and biopsy. Criteria to select women to study were presence of either one or more of the factors given below.

Inclusion Criteria:
- Age 22-60 years.
- Patient with clinically unhealthy cervix diagnosed by per speculum examination, women with cervical erosion, cervico-vaginitis, cervical polyp, hypertrophied cervix.

Exclusion Criteria:
- Age >60 yrs.
- Patient with bleeding at the time of examination.
- Underwent total hysterectomy.
- Pregnant women.

METHODOLOGY: Informed consent was taken from patient meeting the study criteria. Pap, colposcopy and directed biopsy were done in patient with unhealthy cervix. Reids Modified colposcopic index was used to interpret colposcopic findings. Colposcopic guided biopsy taken from most suspected areas. Pap smear results were correlated with colposcopy and colposcopic guided biopsy. A detailed history of the age, parity and the symptomatology was taken, per speculum examination was done. In patient with clinically unhealthy cervix Pap smear was done and Revised Bethesda system was used to analyze the results. They are classified as ASCUS, LSIL, HSIL & frank carcinoma.

Simple colposcope with magnification of 5x, 10x, 20x with inbuilt green filter was used. The magnification of 7.5x to 10x was preferred, which was excellent for localizing or zooming in the area of interest for examining angio-architecture. The distance between 250 to 350 mm allowed easy working and manipulation of instruments without hampering the vision. Colposcopic examination of unhealthy cervix included primary examination with 3% acetic acid and lugol's iodine test. Findings were recorded and colposcopic diagnosis was made based on modified Reids Colposcopic index.

Reids Colposcopic index/score.⁸,⁹:

| Score | Colposcopic findings          |
|-------|------------------------------|
| 0-2   | Benign inflammation          |
| 3-5   | Low grade lesion             |
| 6-8   | High grade lesion            |
| >8    | Invasive lesion              |
### Colposcopy Sign

| Colposcopy Sign | Score 0                                                                 | Score 1                                                                 | Score 2                                                                 |
|-----------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------|
| Margin          | Condylomatous or micropapillary contour. Flocculated or feathered jagged, angular, satellite lesion, AWA beyond original squamo-columnar junction. | Regular lesion with smooth indistinct borders.                            | Rolled, peeling edges, sharp margins.                                     |
| Colour          | Shiny, snow white, areas of faint (semi-transparent) whitening            | Intermediate shade (shiny but grey white)                                | Dull, oyster grey                                                       |
| Vessels         | Uniform, fine caliber non-dilated capillary loops fine punctuation or mosaic | Absence of surface vessels                                               | Definite, coarse punctuation or mosaic                                    |
| Iodine staining | Any lesion staining Mahagony brown; mustard yellow staining by a minor lesion (by first three criteria) | Partial iodine uptake (mottled pattern)                                  | Mustard yellow staining of a significant lesion (an acetowhite area scoring 3 or more points by first three criteria) |

Biopsy was taken by punch biopsy forceps and specimen sent for histopathological examination. Biopsy results were identified as cervicitis, mild dysplasia, moderate to severe dysplasia, carcinoma in situ & carcinoma.

### RESULTS:

| Age   | Cervix erosion | Hypertrophied cervix | Suspicious looking cervix | Total |
|-------|----------------|-----------------------|----------------------------|-------|
| 21-30 | 9              | 7                     | 0                          | 16    |
| 31-40 | 25             | 24                    | 3                          | 52    |
| 41-50 | 10             | 13                    | 1                          | 24    |
| 51-60 | 6              | 2                     | 0                          | 8     |
| Total | 50             | 46                    | 4                          | 100   |

Table 1: Age distribution and clinical examination

Majority of the patients were in the group of 31-40 years. Cervical erosions were the most common lesions, followed by hypertrophied cervix.
Table 2: Pap smear classification according to Bethesda system 2001.7

Out of 100 patient 83% were negative for intraepithelial lesion or malignancy. 5% had LSIL, 3% HSIL and 1 patient had invasive carcinoma cervix.

Table 3: Colposcopic findings according to Reid’s index8,9

Out of 100 cases 62% of cases were having Reid’s score 0-2 i.e., benign inflammatory lesion. 19% had Reid’s score 3-5 it is low grade lesion and 18% had high grade lesion Reid’s score 6-8 and 1% had invasive carcinoma

Table 4: Histopathology finding

P value=<0.0001 significant.
Table 6: Sensitivity and specificity of Pap smear

| Pap smear | HPE positive | Negative |
|-----------|--------------|----------|
| Positive  | 8            | 1        |
| Negative  | 23           | 68       |
| Total     | 31           | 69       |

Table 5 and 6: In the present study the sensitivity of Pap smear for detecting mild dysplasia is 24.3%, specificity was 98.3%. PPV 93.12%, NPV 74.36% respectively. Accuracy of Pap smear in one study was 76%.

Table 7: Correlation between Colposcopy and histopathology

| Reid’s score | Chronic cervicitis | Mild dysplasia | Moderate dysplasia | Carcinoma |
|--------------|--------------------|----------------|--------------------|-----------|
| 0-2(62)      | 55(55%)            | 6(6%)          | 1(1%)              | 0(0%)     |
| 3-5(19)      | 9(9%)              | 7(7%)          | 2(2%)              | 1(1%)     |
| 6-8(18)      | 4(4%)              | 3(3%)          | 8(8%)              | 3(3%)     |
| >8(1)        | 0(0%)              | 0(0%)          | 0(0%)              | 1(1%)     |
| Total        | 69(69%)            | 16(16%)        | 11(11%)            | 5(5%)     |

P value= <0.001 significant.

Table 8: Sensitivity and specificity of colposcopy

| Colposcopy | HPE positive | Negative |
|------------|--------------|----------|
| Positive   | 25           | 13       |
| Negative   | 6            | 56       |
| Total      | 31           | 69       |

P <0.0001 significant.

Table 7 and 8: in this present study sensitivity of colposcopy was 80.37% with specificity of 81.06% and PPV 66.89% and NPV 90.52% with accuracy of 80.52%.

DISCUSSION: Cervical cancer is most common cause of mortality and morbidity among women. Only 5% women in developing countries are screened for cervical abnormalities.

Pap smear is the most commonly used screening test for cervical cancer. It is not 100% accurate detection technique. Most of the times it may miss small number of cases as cervical cancer has a long latent phase and follow up is required to identify changes in time for treatment. Kavitha Nanda et al concluded after analysis of 12 studies on Pap test that Pap test are mostly biased and is only moderately accurate with sensitivity of 30-87% & specificity of 86-100%. On considering the various studies our results of Pap smear are comparable.
In the present study, sensitivity 24.3%, specificity 98.3%, PPV 93.12%, NPV 74.36% and accuracy 76%. From the data obtained from different studies sensitivity of pap is less and there is increased rate of false negativity.

These studies and the present study show the Pap smear has to be further evaluated (in order to get a correct histological diagnosis) by colposcopy and directed biopsy\textsuperscript{14,15}

The present study sensitivity of colposcopy is 80.37%, specificity was 81.06% and PPV 66.89%, NPV 90.52%. Accuracy of colposcopy in one study is 80.50% which are parallel to the studies by Ashmitha & Shakuntala et al & Mallur et al.\textsuperscript{14,15}

Pap smear had poor sensitivity compared to colposcopy. Simultaneous use of colposcopy has shown to increase the rate of carcinoma cervix detection in women with unhealthy cervix. There is a good correlation between colposcopy and directed biopsy.

An attempt has been made to detect the disease before its onset and prevention by effective screening.

CONCLUSION: Cervix carcinoma is a preventable disease but there is no perfect screening test that has 100% sensitivity and specificity. Therefore in present study an attempt has been made to analyse, pap smear and colposcopy. It is evident that by parallel testing of women with pap and colposcopy we can detect maximum number of cases with accuracy.

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