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RESEARCH ARTICLE

TRUSCREEN - AN OPTOELECTRONIC DEVICE WITH REAL - TIME RESULTS A NEW TECHNOLOGY FOR CERVICAL CANCER SCREENING

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ABSTRACT

Background: Truscreen is a portable system used to directly identify cancer or pre-cancerous cells in cervical tissue. Truscreen uses low levels of electric signals and light to examine the cervix by gently touching the surface of the cervix with a hand-held wand. The system comprises a hand piece, console and single use sensor (SUS). The hand piece uses advanced electro-optical biosensors to measure the response of cervical tissue to light together with tissue capacitance. Unlike cytology, Truscreen does not only examine surface epithelial cells. With the aim of to screen the Cervix with truscreen for detection of Pre - cancerous and cancerous lesions of the cervix to minimize morbidity, mortality, to advance the health and to improve the quality of life of women. An ongoing pilot study was conducted at Govt. Maternity Hospital; Osmania Medical College, Hyderabad, Andhra Pradesh, with duration of 3 months (August to October 2008) by including 50 porous women were screened and within the Age group between 25-55 yrs. Both the truscreen and pap-smear cases are totally 100. But here now we are tabulated only truscreen positive cases (10). On comparison of truscreen and pap screen study we found 12 % pickup rate is more with truscreen and 71.4 % sensitivity observed with truscreen. Truscreen device is a simple, easy, non-invasive, primary screening tool with immediate results. Time saving and high sensitivity is observed with truscreen in the present study. Even though the truscreen is having high pickup rate and immediate results it is expensive and suitable only for certain affordable groups. In 3rd world countries like India because of non-affordability of all groups of women we are unable to advice for mass screening.

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INTRODUCTION

Cervix is the commonest site for gynecological cancers. It is the 4th most common cancer in women. GLOBOCAN data revealed 5,28,000 new cases in 2012. (Ferlay *et al.*, 2015) Cervical cancers is considered as a preventable malignancy because of its close relation with the causative agent human papillomavirus (HPV) and the long period of precancerous lesions. HPV DNA was detected in 95%-100% cervical cancer patients.² Moreover; it takes 58 months for the development of Cervical Intraepithelial Neoplasia (CIN - 1) to carcinoma in situ and 38 and 12 months for CIN 2 and CIN 3, respectively.³ The incidence of cervical cancer has decreased in developed countries with the aid of cervical cancer screening policies. However, in developing and under-developed countries, cervical cancer is still considered as an important public health problem. Inadequate screening programs, absence of experienced pathologists and financial difficulties in organizing

community-based screening programs seem to be the main reasons for the high incidence of cervical cancer in developing and under-developed countries. Therefore, screening programs are crucial for decreasing morbidity/mortality and for increasing the cure rate of the cervical cancer treatment. (Thomas *et al.*, 2001)

Concepts of screening

Active search for disease among apparently healthy individuals. Screening is a challenge to modern techniques by means of rapidly applied tests, examinations and other procedures. Screening is a preventive care function or a logical extension of health care. Moreover, adjunctive complementary test methods can be helpful for the improvement of detection rates of CINs and cervical cancer.

Principles of a screening test

Screening should be done on apparently healthy individuals, so apply cable only for those groups.

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It was less expensive, widely acceptable and repeatable. Must be highly sensitive (TP+FN) even at the expense of low specificity (TN+FP).

Problem statement of cervical cancer

Cancer in all forms causing 12% of deaths worldwide. Carcinoma of breast is the most common cancer in women globally. Cervical Cancer is the most common cancer in women of developing countries (India). Cancer Cervix is the commonest cancer of female genital organs. Orthodox Jews are almost immune to Cancer Cervix. Practically unknown in virgins. Age adjusted Incidence of Cancer cervix in India is 20.6 – 29.8/1 lakh. (Ferlay *et al.*, 2015; Thomas *et al.*, 2001)

Recommendations for cancer cervix screening: (Stoy *et al.*, 1982)

- ◆ All women – one screen at the beginning of sexual activity/at least at the age of 25.
- ◆ Screen at antenatal booking by inspection and smear.
- ◆ One screen after first delivery.
- ◆ Later every 2 to 3 yrs up to 65 yrs.
- ◆ Annual screening in high risk women.
- ◆ If 2 consecutive annual smears are negative those can be subjected to once in 3 yrs up to 65 yrs.
- ◆ Women with sub-total hysterectomy should be screened.
- ◆ Exclusion in hysterectomised women and after > 65 yrs who have been screened adequately.
- ◆ Frequency of screening should be cost effective.
- ◆ Informed consent to be taken.
- ◆ Legal issues to be considered.

Etiological factors of cervical cancer (Dutta, 2008)

Presence of HPV 16 and 18 is the chiefly susceptible cause, Early marriage, Age 25 – 45 yrs (the most common), Low socio economic, Poor genital hygiene, Repeated child births, HSV – Type II infection, Polygamy– multiple sex partners, CSW (commercial sex workers), High-risk male partner-transmit STD's, Uncircumcised male partner, Husband-who's previous wife had Cancer cervix, Males with high protamine content in their sperms, Oral Contraceptive pills with high estrogen content, Repeated cervical irritation and infections, Immuno-suppression status with HIV, Infections like CMV, Chlamydia and habits of smoking, diets with low B-carotene, Vit.-C and E etc.

Natural history of cervical cancer

Normal cells ↔ Inflammation ↔ Mild Dysplasia ↔ Moderate Dysplasia → Severe dysplasia (pre cancer) (15 – 20 yrs ?) → Carcinoma in - situ (pre invasive) (CIS/CIN - I, II, III/SIL/LSIL - HSIL) (CIN-III – stage-0) (8 – 10 yrs) → Micro invasive and invasive cancer (stages I - IV).

Prevention of cancer cervix

Sl. No.	Primary prevention	Secondary prevention
1.	Risk factors control	Early detection by screening and treatment.
2.	HPV-vaccine (Polyvalent)	Education for early diagnosis by warning symptoms and signs.

Down staging (Barrow and Wu, 2007)

This is proposed for India and other developing countries. Detection by a nurse and other non-medical health workers using a simple speculum for visual inspection of cervix in an earlier stage when still curable.

Screening tests for cancer cervix (Dutta, 2008; Barrow and Wu, 2007; Coppleson *et al.*, 1994)

Various methods are available to screen them are, Conventional cytology (pap-smear), Liquid-based thin layer cytology (LCT), Automated cytologic screening, human-papilloma viral testing (HPV), Colposcopy, Speculoscopy, Cervicography, Color doppler, Laser-induced fluorescence. Tru screen (polar probe) and Pap-smear have stood the test of time (from 1928 till date).

Now-a-days, many methods are available for evaluating the various physical properties of human tissue. Radiation, magnetic and electrical fields, sound waves and light can be used for the evaluation of human tissue. Optical and di-electrical impedance of human tissue is one of the potentially promising methods for the evaluation of human tissue. Because of the optical and di-electrical properties of different tissue components, human tissue has a specific intrinsic resistance and capacitance. (Stoy *et al.*, 1982) Because normal or HPV infected tissues have differences in fundamental structure, it can also be assumed that optical and di-electrical impedance differences can exist between these tissues. Tru-Screen (Polarprobe; Polartechnics, Sydney, Australia) is a new real-time optoelectric screening method for cervical cancer. (Dutta, 2008)

The working mechanism of this method is based on the frequency-dependent impedance spectrum. The system injects a current in different frequencies into the tissue and measures the voltage response of the tissue. There is no specification of the degree of abnormality as in a Papanicolaou (Pap) smear in the design of Tru-Screen. The test detects an abnormality of the cervical tissue if present and gives results as normal or abnormal. This real-time optoelectronic device offers the advantage of instant diagnosis, decreases the need for pathologists and allows clinicians to counsel and manage the patient with abnormal test results in the 1st screening visit. These advantages can be a solution for difficulties in appropriate cervical screening programs in developing countries.

TRU Screen Device: (Barrow and Wu, 2007)

It works on biophysical principles. It is having soft-ware implemented tissue classifier. It is an in vivo system uses electrical and optical properties of cervical tissue.



Figure 1. TruScreen Device

The hand piece

It contains tissues stimulation and sensor elements with indicator lights which are connected to the console by a cable. It is 170 mm long (17cms length) and Pen shaped.



Figure 2. The hand PIECE

Hand piece with TIP

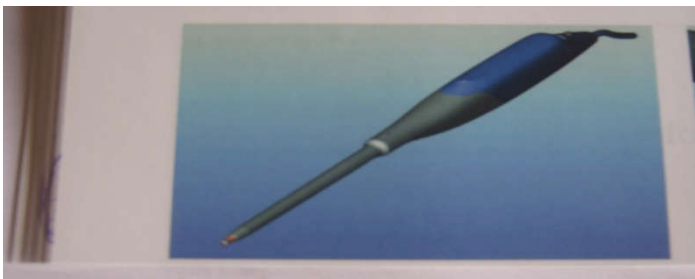


Figure 3. Hand piece with TIP

Hand piece with indicator lights



Figure 4. Hand piece with indicator lights

Probe tip with sensor elements



Figure 5. Probe TIP with sensor elements

Probe TIP

Probe Tip should have 5 mm diameter, Gold electrodes at periphery. Electrodes surrounds 4 light emitting diodes. Diodes separated by optical fiber spacers.

Probe tip with optical fibers

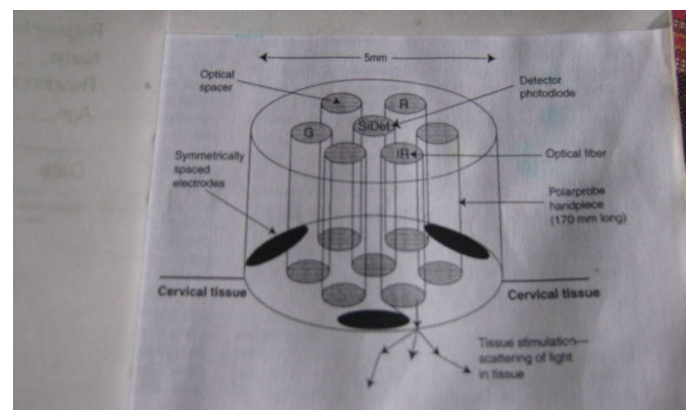


Figure 6. Probe TIP with optical fibers

Console with hand piece

The Console contains micro processor module and digital signal processor. The console allows patient information to be entered and stored. And incorporates a printer for the screening results. The measured response (or tissue-signature) is compared with data-bank of previously determined tissue types of tissue-matching algorithm. Results are classified into Normal and Abnormal.

Electrical Signal discriminators: (Abdul *et al.*, 2006)

When an electrical voltage (0.8 V of 260 μ s) is applied to tissue and then turned off abruptly, the tissue behaves like a decaying battery - lasting for a fraction of second. Decay time and wave form will differ among different tissue types. The voltage decay wave form can provide a dynamic signature of tissue that assists in its classification.

Low voltage pulses applied to the cervix via a combination of three electrodes. The resultant electrical decay curve is measured and analyzed.



Figure 7. Console with hand piece

Truscreen signal processing

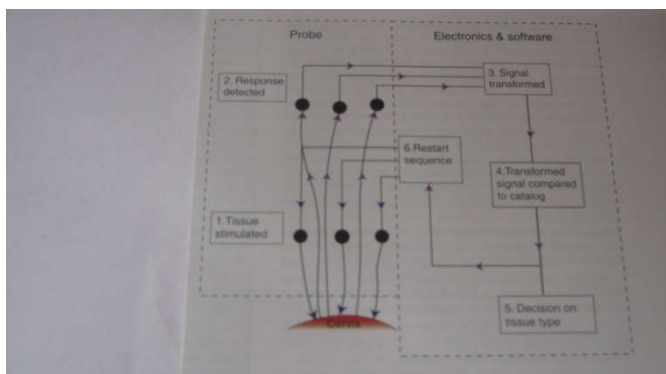


Figure 8. Truscreen signal processing

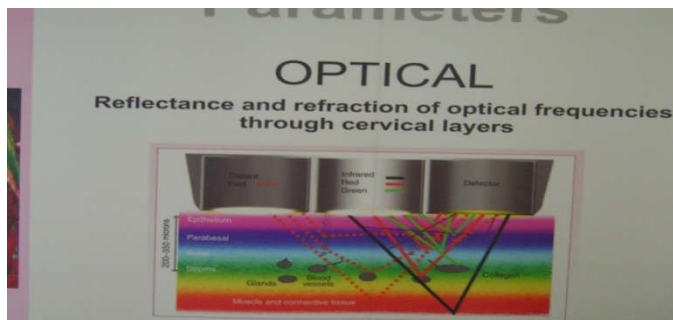


Figure 9. Reflectance and refraction of optical discriminator

Optical signal discriminators

Optical fibers convey light of different wave lengths to the probe tip. Cervical tissue is stimulated. The response is detected. A total of 17 tissue types have been incorporated into the system. These further divided into normal and abnormal.

Advantages of Truscreen: (Nygard et al., 2005)

It is highly sensitive. It gives immediate results. It is an in vivo test. It has minimal discomfort. Acceptable but cost effective. It is portable instrument, suitable for mass screening. No laboratory assistance is needed. Expert opinion is not required for reporting. It is really a time saving procedure. Logistical issues are present.

Procedure

Truscreen screening should be done by keeping woman in Lithotomy position, to visualize the cervix with Cusco's Speculum. Move the tip of the probe from 9°clock – 9 ° clock positions in a zig-zag direction over the cervix to cover the entire ectocervix and visualized part of endocervix. Proper touch spot is indicated by emitting green light signal at hand piece.

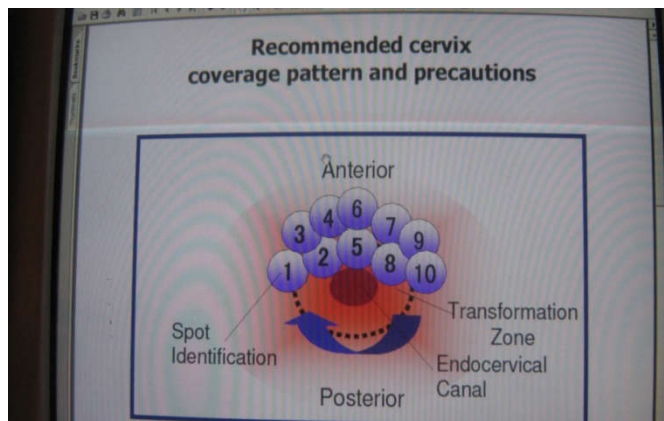


Figure 10 ZIG - ZAG Pattern of Touch Spots

Zig - Zag pattern of touch spots

A minimum of 20-25 spots to be touched in a zig-zag direction from ecto to endocervix to ensure the entire transformation zone (TZ) is covered. The optical and electrical waves will go up to stroma. Entire procedure will take 2-3 mins. At the end the overall result is obtained on print out from console.



Figure 11. Truscreen set up at OPD

Aim of the study

To screen the Cervix with Truscreen for detection of Pre - cancerous and cancerous lesions of the cervix to minimize morbidity, mortality, to advance the health and to improve the quality of life of women.

Study design

An ongoing pilot study was conducted at Govt. Maternity Hospital; Osmania Medical College, Hyderabad, Andhra Pradesh, with duration of 3 months (August to October 2008)

by including 50 parous women were screened and within the Age group between 25-55yrs. Selection of cases were done by excluding the cases which comes under exclusion criteria.



Figure 12. Probe tip-touching the cervix

Exclusion Criteria

Who are known to be pregnant, < 4 months post-partum, During menstruation, Pap-smear within 6 weeks, Biopsy and surgical treatment < 6mths, Previous H/o radio therapy to pelvis, H/o chemotherapy within 5 weeks, Hysterectomised women, Acute infections of vagina and cervix, H/o photosensitivity. All 50 cases were screened by both truscreen and also pap-smear, but only tru screen positives were subjected to colposcopic directed biopsy for HPE.

MATERIALS AND METHODS

Polartechnics' Tru- Screen device was used to perform Tru-Screen screening for the patients who were chosen according to the exclusion criteria. The operator placed the tip of the probe (TruScreen) with its single-use sensor. The probe tip targeted at different points of the cervix using a

<p>TruScreen® cervical screening system</p> <p>Patient's Name: Akhila 35 yrs.</p> <p>Operator's Name: Dr. Vijaya U.A.</p> <p>Date of Exam: 6/10/08</p> <p>Exam Centre: CMH SSKH, Hyd.</p> <p>SUS Batch Code: pap smear no: 750-</p> <p>Console Serial No. C8003</p> <p>Handpiece Serial No. H6095</p> <p>Algorithm Version: 02.036</p> <p>Firmware Version: F5.74</p> <p>Exam Result: <input type="checkbox"/> Normal</p> <p>No. of Spots: 26</p> <p>Exam Type: Screening</p> <p>Exam Reference: 1</p> <p>Comments:</p> <p>Operator's Signature:</p> <p><small>Screening test only. Interpretation of the results of the screening tests is the sole responsibility of the physician.</small></p>	<p>TruScreen® cervical screening system</p> <p>Patient's Name: Abiya W/o Mahadev 45 yrs.</p> <p>Operator's Name: Dr. Vijaya U.A.</p> <p>Date of Exam: 6/10/08</p> <p>Exam Centre: CMH SSKH, Hyd.</p> <p>SUS Batch Code: pap smear no: 752.</p> <p>Console Serial No. C8003</p> <p>Handpiece Serial No. H6095</p> <p>Algorithm Version: 02.036</p> <p>Firmware Version: F5.74</p> <p>Exam Result: <input type="checkbox"/> Abnormal</p> <p>No. of Spots: 21</p> <p>Exam Type: Screening</p> <p>Exam Reference: 4</p> <p>Comments: Biopsy no: 661/08</p> <p>Operator's Signature:</p> <p><small>Screening test only. Interpretation of the results of the screening tests is the sole responsibility of the physician.</small></p>
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Figure 133. True screen - real time results

pre-determined protocol and topographical scanning path, which is defined in the manual of the device. After the completion of the examination, the result was calculated by the device and printed out from the console. The results are defined as “normal” for normal squamous epithelium, columnar epithelium, physiological metaplasia or latent HPV-related changes or “abnormal” for CIN 1, 2 and 3 and invasive cervical carcinoma. (Barrow and Wu, 2007)

RESULTS

Both the truscreen and pap-smear cases are totally 100. But here now we are tabulated only tru screen positive cases 10.

Age group wise screening

Out of 10 Positive truscreen 4 cases were in the age group of 36 – 40, 3 cases were 31 – 35 and remaining 3 cases were in 41 – 45 respectively.

Duration of Marital life: Out of 10 Positive truscreen 4 cases were have marital life of 15 – 19 and more than 20 years and only 2 case were on 10 – 14 years of marital life respectively.

Socio economic background

Majority of the cases were found to be as Low socio economic group i.e., 8, the remaining 2 were Middle income group and none were found from High income group.

Table 1. Age group wise Screening

Sl. No.	Age groups in years	No. of cases	Percentage (%)
1.	31 to 35	3	30 %
2.	36 to 40	4	40 %
3.	41 to 45	3	30 %
	Total	10	100

Majority – between 36 – 40yrs

Table 2. Duration of marital life

Sl. No.	Marital life in years	No. of cases	Percentage (%)
1.	10 to 14	2	20 %
2.	15 to 19	4	40 %
3.	>20yrs	4	40 %
	Total	10	100

Majority - 15yrs marital life

Table 3. Socio economic wise distribution of cases

Sl. No.	Socioeconomic status	No. of cases	Percentage (%)
1.	Low socio economic group	8	80 %
2.	Middle income group	2	20 %
3.	High income group	0	0

Table 4. Based on Parity

Sl. No.	Parity	No. of cases	Percentage (%)
1.	Para 2	3	30 %
2.	Para 3	4	40 %
3.	Para 4	3	30 %
	Total	10	100

Majority – Para 3cases

Table 5. Cases distribution based on underwent to screening procedures

Type of Screening	Normal study	Percentage (%)	Abnormal	Percentage (%)	Total (%)
Truscreen	40cases	46.5 %	10 cases	71.4 %	50 (100 %)
Pap screen	46 cases	53.5 %	04 cases	28.6 %	50 (100 %)
Total	86 cases	100 %	14 cases	100 %	100 (100%)

Table 6. Comparison of Truscreen and pap-smear results

Parameter	Normal study	Percentage (%)	Abnormal Or Dysplasia	Percentage (%)	Total(%)
Truscreen	40cases	46.5 %	10 cases	71.4 %	50 (100 %)
Pap screen	46 cases	53.5 %	04 cases	28.6 %	50 (100 %)
Pickup rate		20 %		8 %	28 %
Sensitivity		71.4 %		28.5 %	99.9 %
Total	86	100%	14	100%	100 (100%)

Based on Parity

Majority of the cases 4 were para 3, the remaining 6 were found to be para 2 and 4 equally.

Cases distribution based on underwent to screening procedures

A total of 100 cases were screened for the both truscreen and pap screen in equal quantity. Out of 100 cases 86 cases were got normal study pattern among that 40 cases were truscreen and 46 cases were pap screen. Totally 14 cases were got abnormal study pattern among that 10 cases were truscreen and only 4 cases were pap screen.

Comparison of Truscreen and pap-smear results

On comparison of truscreen and pap screen study we found 12 % pickup rate is more with truscreen and 71.4 % sensitivity observed with truscreen.

Colposcopic biopsy and Histopathological Examination [HPE (gold standard)]

Abnormal truscreen cases are subjected for colposcopic biopsy and HPE - 10cases among that 7cases were Dysplasiaand3cases were No dysplasia.

Reasons for false positive results

It may be due to as a newer technology so Errors in operational skills, Errors in sampling, Lab handling and Interpretation of results etc.

DISCUSSION

Pap smear is the standard screening test for cervical cancer and premalignant cervical lesions. It was determined that approximately 50% of women who have cervical cancer have no history of regular cervical screening.¹⁰ According to the report from Agency for Health Care Policy and Research, the conventional Pap smear has a sensitivity of 51% and a negative predictive value of 47%.¹¹ On the other hand, according to a study in 2000, 47% of women who develop cervical cancer may report an adequate screening history. (Singer *et al.*, 2003) They indicated that the complementary tests can improve detection rates for high grade CINs and can also increase the overall sensitivity for cervical cancer screening. These data reveal that new screening methods should be developed for patients who cannot be determined by conventional screening methods. (Li *et al.*, 2011)

Including our country, most countries have difficulties in cervical cancer screening that covers the entire population. Despite the presence of a large number of people to be screened, a lack of experienced cytopathologists makes a proper population-based screening program challenging. Moreover, subjectivity in the interpretation of Pap smear tests and need for consecutive doctor visits in case of abnormal results reveal an urgent need for additional, cost-effective methods for better results in the early diagnosis of cervical carcinoma. (Long *et al.*, 2013)

Majority of recent studies also describe TruScreen as a good and objective method for cervical screening with high sensitivity results. (Luu *et al.*, 2013) In our study, the sensitivity of TruScreen was 71.4 %which is similar to Singer *et al.* (Sung *et al.*, 2000) results. An increase in the effectiveness of a cervical cancer prevention program is related to women's participation, test's acceptability, affordability, accuracy, and rapidity. (Morin *et al.*, 2001) Conventional cytology needs not only special equipment and supplies but also trained specialists for interpretation.

The obligation of second doctor visit for results can be defined as another factor that decreases the acceptability and increases the affordability of the screening program with the Pap smear. In contrast, TruScreen would minimize training requirements and assist in the standardization of results. (Sellors *et al.*, 2003) The results obtained in the course of the study are consistent especially in the range of sensitivity with the Coppleson's report and confirm the advantage of the optoelectronic method – Truscreen over the traditional cytodiagnostics in the process of detecting cervical pathology. (Coppleson *et al.*, 1994)

Conclusion

Truscreen device is a simple, easy, non-invasive, primary screening tool with immediate results. Time saving and high sensitivity is observed with truscreen in the present study. Even though the truscreen is having high pickup rate and immediate results it is expensive and suitable only for certain affordable groups. In 3rd world countries like India because of non-affordability of all groups of women we are unable to advice for mass screening. But definitely useful and advisable for affordable women for immediate results. Women with Positive results should be confirmed by different cytological examinations like, conventional cytology (pap-smear), liquid-based thin layer cytology (LCT), Automated cytologic screening, human-papilloma viral testing (HPV), colposcopy, speculscopy, cervicography, color doppler, laser-induced fluorescence, but finally they should be subjected for colposcopic directed biopsy histopathological examination that is gold standard for cervical cancer. In case of woman with negative results should be followed up as per the recommendations.

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