JGTPS, 2015, Vol. 6(3): 2745 - 2752

ISSN- 2230-7346

Journal of Global Trends in Pharmaceutical Sciences

Journal home page: www.jgtps.com

TRUSCREEN - AN OPTOELECTRONIC DEVICE WITH "REAL -TIME RESULTS – A NEW PARADIGM IN CERVICAL CANCER SCREENING"

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ABSTRACT

TruScreen is a unique electro-optical technology that provides a direct means of tissue differentiation as a primary screening tool in the general population for cervical cancer and precancerous change (CIN). Objectives of the work are evaluation of sensitivity and specificity of the optoelectronic method in the detection of CIN and cervical cancer. The present study shows correlation between the pNOR number and sensitivity/specificity of the optoelectronic method. The study included 293 patients with abnormal cervical cytology result and the following examinations: examination with the use of the optoelectronic method – Truscreen, colposcopic examination, and histopathology biopsy. Specificity of the optoelectronic method for LGSIL was estimated at 65.70%, for HGSIL and squamous cell carcinoma ofcervix amounted to 90.38%. Specificity of the optoelectronic method used to confirm lack of cervical pathology was estimated at 78.89%.The field under the ROC curve for the optoelectronic method was estimated at 0.88 (95% CI, 0.84–0.92) which shows high diagnostic value of the test in the detection of HGSIL and squamous cell carcinoma. The optoelectronic method is characterized by high usefulness in the detection of CIN, present in the squamous epithelium and squamous cell carcinoma of cervix. In conclusion, we suggest that TruScreen holds the potential to detect lesions that might be missed by cytology alone and clarify unsatisfactory or ASCUS cytology results. With regard to patients, they can benefit from more rapid follow-up and early treatment. We also noticed that the women were happy with the real time results, which are now available using TruScreen. TruScreen technology seems to have a high potential to improve and standardize the screening of the cervical carcinoma.

Key words: Truscreen, Optoelectronic Device, Real-Time Results, A New Paradigm & Cervical Cancer.

INTRODUCTION

Cervical cancer is a significant health issue in women worldwide.[1] In terms of number of cases annually registered, cervical cancer is respectively the 2nd after breast cancer most common malignancy in women.[2] Worldwide, there are approximately 5 lacks new cases of cervical cancer diagnosed each year. Globally, cervical cancer mortality accounts for 275000 women each year.[3]

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It is estimated that every minute doctors diagnose cervical cancer, while worldwide every 2 - minutes 1 - woman dies for this reason. Epidemiological rates, describing the presence of this tumour, vary depending on geographic location. Most new cases of cervical cancer concern the population in developing countries. The highest incidence rates may be observed in Africa, Latin America, and parts of Asia. The etiology of this cancer is inextricably linked to chronic infection caused by human papilloma virus, especially highly oncogenic types such as HPV 16& 18.[4] In 1996, the World Health Organization (WHO) has identified infection with oncogenic HPV types 16 and 18 as human carcinogen. Worldwide, co-infection with human papilloma virus can be demonstrated for 99% of diagnosed cases of cervical cancer.[5]Pap smear is a well-known test in screening of epithelial cell abnormalities of the cervix. However, adding other

screening methods to this test may increase the sensitivity and specificity of case finding. In 1968, Richart introduced the concept of cervical intraepithelial neoplasia [Cervical intraepithelial neoplasia (CIN)]. The author also put forward the hypothesis that all dysplasias, henceforth called neoplasias carry a potential risk of developing cancer.[6]There are 3 - degrees of CIN: mild, moderate and severe (CIN 1, CIN 2, CIN 3, respectively). The process of developing of CIN may take many years. On average, it is estimated that it takes 8–10 years, from the infection with human papilloma virus to the development of CIN 3. Development of cervical cancer as a result of progression on the ground of neoplasia takes another 3–5 years. Lowgrade intraepithelial neoplasia – CIN 1 is often a consequence of incidental, transient infection with human papilloma virus. Hence, approximately 80% of these changes regress spontaneously in a few months time. Persistent HPV infection with oncogenic type of virus has a poor prognosis and can lead to the development of intraepithelial Neoplasia of medium or high grade and in consequence of cervical cancer. Despite the development of molecular techniques for detection of DNA HPV HR and mRNA HPV HR there isa constant demand to increase sensitivity and specificity of various diagnostic tools in detecting cervical lesions. Theideal method of detection shall be characterized by a high sensitivity and specificity of the examination, reaching approximately 100%. This diagnostic tool should guarantee the detection of lesions on the ground of cervical intraepithelial neoplasia in sick women. The correct result of thetest, characterized by specificity reaching 100%, would significantly extend the distance between successive screenings without the risk of developing CIN. The test of high values of sensitivity and specificity would result in significant savings resources devoted to the implementation of preventive examinations. These savings would result directly from reducing the number of examinations and the decreased percentage of incorrect diagnostic results. Verification of false−positive cytological diagnoses became a significant proportion of colposcopy and biopsy taken from suspected sites. Population-based diagnostic method for 100%-sensitivity and specificity would lead to a further, significant decrease in morbidity and mortality from cervical cancer, while reducing the current financial expenses incurred by the state budget in the implementation of prevention.

In terms of research on CIN identification, there isa need for cost effective, reproducible and non-invasive methods, which during a single visit approach will allow the doctor for a simultaneous detection of pathologies and extension of the diagnostic process. Such solutions are necessary in all developing countries, where there is a difficult access to a GP, lack of cytodiagnostic laboratories and appropriately qualified medical personnel. In many places around the world there is limited access to a gynecologist. Therefore, there is a need for diagnostic methods, which would allow screening by detection of CIN in a real time **("real time device"),** which in the course of a single visit approach will enable the immediate implementation of further diagnosis or biopsy of suspicious lesions.

Biophysics is becoming an important field in the area of cervical cancer prevention and diagnosis. Biophysical methods have an advantage over cytology in terms of a lower percentage of false positive and negative results, often because of human error. Using biophysical diagnosis for CIN detection allows for the implementation of fully automated examination and its archiving. Technologically advanced methodology allows not only to eliminate human error, but also aims to reduce the need for complicated, costly and time consuming training and continuous upgrading of skills for the use of modern research equipment, endowed with high sensitivity and specificity in detecting CIN. The history of research on the tissue impedance began in1926, when Fricke and Morse examined the flow of electric charge through breast tumours. In 1949, Langman and Burrfound significant differences in electrical potential passing through healthy and pathologically changed cervical tissues. It was only in 1990, when Coppleson applied the optoelectronic method for the detection of pathological lesionsin the area of the cervix. The method uses the following optoelectronic phenomena that occur when the surface of the cervix is exposed to the light beam and the electric potential of specific, well known parameters:

- ✓ direct reflection of the light wave of a specific length,
- ✓ backscattering of the light wave of a specific length,
- ✓ dissipation of electrical charge of a known potential input.

Direct reflection of the light wave of specific length depends on the refractive indices at air and tissue. The nature of reflection informs about the topography and surface structure of the cervix, as well as about the properties of the superficial layers of squamous and a deno carcinoma of the distal cervical canal. Most of the incident beam is subjected to multiple scattering and absorption in the tissue.[7] Repeatable process of light wave scattering provides information on the structure of the analyzed tissues, their vascularisation, as well as on the cells from which they are built. Features such as intensity and spatial distribution of the reemitted, reflected light are different for normal and pathologically modified tissue. The study involving the reflected light wave and its backscattering by applying the same parameters of the wavelength is repetitive and predictable and changes of the

obtained parameters correlate with the degree of cervical pathology.

Characteristics of the electrical parameters of tissuesdepend on the properties of individual cell types which constitute them and intracellular features of the matrix. Assessing the electrical conductivity of a single cell, it is necessary to assess electrical properties of the cytoplasm, cell membrane and other elements of the morphotic elements. The cytoplasm may be treated as a multiphase colloidal system composed of a variety of dissolved molecules. Its how characteristics of the complex electrolyte, in which some of the particles create a dispersed environment, while others constitute a disperse phase. Electrical conductivity also depends on the composition of various ions in the cells structure, as well as on their mobility. The membrane through the lipid layer is an electrical insulator, which in combination with an intra and extracellular substance functions as a capacitor. Other morphotic elements function as semiconductors. Each biological tissue has a definite resistance and reactance, which depends on dielectric properties of the individual components of this tissue or cells.[8] Normal tissues compared to the pathologically changed tissues are characterized by a different impedance value.[9] Stratified squamous epithelium and glandular epithelium are characterized by a completely different effective resistance, compared to the inflamed tissue with metaplastic or neoplasticchanges.[10]

Evaluation of mucous membrane structures using optoelectronic method is possible by using optical sensors recording different wavelengths of visible light and infraredlight as well as biosensors used for electrical stimulation of the epithelium with a frequency of 14 pulses per second. Optoelectronic apparatus measures the returning, reflected, scattered light beam and the electrical response which isa recurring electrical pulse modified by the normal or pathologically changed tissue.The information in the form of reflected scattered light beam and the returning electrical pulse is filtered, prioritized according to the comparison with the model and analyzed by computer. The final element of the analysis is to compare the obtained model, characteristic for a given patient with a pattern. The pattern is a set of key parameters obtainedfrom women of various origin, race, age, parity, etc.[11]Data gathered in the library are the collection of standard optoelectronics experience from studies in women with various types of cervical pathology, particularly with CIN changes and cancers deriving from squamous epithelium and glandular epithelium. Each of these "model" women , obtained a specially developed kind of optoelectronic signature, confirmed by colposcopic, cytological and histologicalanalysis. Optoelectronic evaluation of the cervical epithelium obtained in a real time is objective, through its automation and avoids human error so characteristic for cyto diagnostics.

Confirmation of the usefulness of optoelectronic methods for detecting cervical intraepithelial neoplasia (CIN) in mass preventive examinations can significantly alter the bad situation in the early detection of cervical intraepithelial neoplasia.

Objective of the study was to evaluation of the usefulness of the optoelectronic method in detecting cervical intraepithelial neoplasia and cervical cancer. Evaluation of sensitivity and specificity of the optoelectronic method used to detect cervical intraepithelial neoplasia and cervical cancer. Determination of the relation between the pNOR border number and sensitivity and specificity of the optoelectronic method.

STUDY MATERIAL:

During the period of August 2014 to December 2014,a study was conducted on 293 women with abnormal cytology results at Gynaecology & Obstetrics of RIMS, Kadapa. All patients eligible for the study were adult, not breastfeeding and not pregnant. Patients were at age between 18 and 81. Each patient provided a written consent. Conducted studies were prospective and blinded.

STUDY METHODOLOGY:

In patients directed to the Laboratory of Path physiology of Uterine Cervix in Gynaecology & Obstetrics RIMS Hospital, KADAPA because of abnormal Pap smear evaluation, after collecting the medical history focused on past oncological diseases with particular regard to CIN and cervical cancer, information about the results of previous cytological examinations, including obstetric history, time of first and last menstrual period, type of contraception used and smoking, diagnostic tests were performed in the following order:

- examination with the optoelectronic method,
- Colposcopy,
- guided biopsy of the changed places identified in the result of the above mentioned methods and the performance of diagnostic abrasion of cervical canal,
- Transfer of the collected material to the pathomorphological study.

Departing from the optoelectronic diagnostics tookplace in case of inability to visualize the entire surface of thecervical disc, bleeding changes and in the presence of large Naboth's cysts. Examinations using optoelectronic method were not performed in women who were pregnant, in childbirth, after radio and phototherapy, subjected to cervical surgery within 3 months time (biopsy, conization, etc.).

Optoelectronic method: After previous subjective examination, assessment of thevaginal cervix in the speculum was performed. The study used diagnostic system of the optoelectronicmethod – Truscreen (Polartechnics).

Figure 1: Truscreen optoelectronic device (a) and disposable single use only sheath (b).

Figure 1 (a)

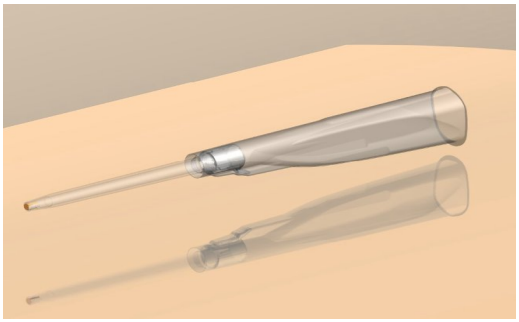

Figure 1 (b)

The device consists of:

i. Computer console,
ii. Head with optoelectronic biosensors,
iii. Disposable single use only sheath and additional equipment.

Used in the study Truscreen diagnostic system is basedon the use of biosensors and optoelectronic computer analysis.[12,13] The device allows for an immediate assessment of the structure of epithelial basement membrane to the boundary, thus differentiating normal epithelium from changes in situ. This identification is possible by comparing the results with the model. The pattern is a set of key parameters obtained from surveyed women with normal and pathological squamous epithelium and cervical adenocarcinoma.

The technique of testing is simple and fast. It consists of a precision tip applicator placed on the uterine cervix in order to perform the scan of the entire surface of the epithelium. The test is painless and takes 1 to 2 minutes. The tip, used by the operator to scan the cervix during the Truscreen examination is covered by disposable single useonly sheath – SUS (single use sensor). The device automatically responds after contact with the cervical surface. The device also automatically informs of the need to move the camera around the cervix in form of a "stop and go" signal. The examination should cover the area of transformation zone. In order to obtain the full diagnostic result, at least 15 full cycles of measurement should be performed. The maximum number of measurement cycles in a single study is 25. 18 -Scans include visible distal endocervical partcoated with glandular epithelium, a transformation zone andthe shield of the vaginal cervix.

ELECTRICAL COMPONENT:

Optoelectronic method uses diagnostic system Truscreen multi function electrodes, which stimulate the cervix withele ctrical impulses at a voltage of 0.8 V and duration of 350μs. Charge flow curve depends on the type of tissue stimulated that is its impedance. 3 -Multifunctional electrodes, which are used in the device, send impulses alternately. When one of them acts as a generator of electric charge, the other two electrodes act as detectors and measure the voltage drop at a time. By using two detectors in a series of alternating load, the system controls the proper adhesion of the tip to the entire surface of the cervix, determining whether the series was diagnostic.

The device performs up to 20 sub cycles per second. After completing the package of diagnostic cycles, the system generates information of the need to change the location of the tip. The red LED indicates too short period of time of the tip application, the yellow one show the duration of the process of cervical surface analysis. The green LED informs of the need to change the adhesion place. Changing the parameters of the component of the electrical charge passed through normal or pathological mucous membrane qualifies the examined tissue to one of 21groups, each of which has different impedance.

OPTICAL COMPONENT:

Optoelectronic method uses a wave of visible light and infrared light. The sources of light are LEDs at power of 7 to130 μW. 4 - LEDs emit light at 3 - different wave lengths. LEDs perform approximately 14 cycles/second. The optoelectronic device uses 3 - different wavelengths of light (infrared light from 780 nm to 1 mm, the red and green light). In contact with the tissue, the light waves are subjected to a direct reflection and multiple backscatter process. The detectors of scattered waves capture the returning light waves of normal or pathological parameters modified by the tissue.

Statistic methods:

Age of the patients was described by the arithmetic mean and standard deviation, as well as by a median, minimum, and maximum value. For comparison of age in the study group and control group, the test of Mann-Whitney was performed. Test results indicated that the age difference between the study group and control group is not statistically significant, namely the two groups are homogeneous in terms of age. Sensitivity, specificity, positive predictive value and negative predictive value of 95% were indicated for the diagnostic methods. In order to assess the ability of the diagnostic parameters of the optoelectronic method, colposcopy and cytodiagnostics, receiver

operating characteristic curve (ROC) was determined. Statistical hypotheses were verified at the level of significance of α= 0.05. Calculations were performed using thestatistical package StatSoft, Inc. (2007), STATISTICA(data analysis software system), v.8.0, Instat 3.00 GraphPadcompany and Analyse−it Software.

RESULTS:

The percentage of histopathological diagnoses associatedwith neoplasia in the study of 293 women was estimated at32.08% (94/293). The results are ranked according to the histopathological diagnosis:

- 38 patients with CIN 1 diagnosis,
- 23 patients with CIN 2 diagnosis,
- 21 patients with CIN 3 diagnosis,
- 8 patients with a squamous cell carcinoma – CA diagnosis,
- 4 patients with adenocarcinoma – ACA diagnosis,
- 199 patients with negative cervical pathology.

The average age of patients in the general populationwas estimated at 37.1 years (minimum 18, maximum 81,median 35).

Results of optoelectronic method –

The percentage of normal and abnormal results for the optoelectronic method at pNOR cut point equal to 0.5 was estimated at 61% and 39%. The analysis of all results obtainedby Truscreen and histopathological diagnoses indicates thatthe biggest percentage included true negative and true positive optoelectronic results, which amounted to 54% and25% respectively of the total. The percentage of false-positive results was amounted to 14% and to 7% for false-negative findings of all studies.

Reduction of the pNOR number below 0.5 value, corresponding to 0.45, 0.4, 0.35, etc. resulted in the increase in thepercentage of false-negative results, decrease in sensitivityand increase in specificity in detecting cervical pathology. Increasing the value of pNOR number, respectively to 0.55,0.6, 0.65, etc., has boosted the percentage of false-positive results, increased sensitivity and decreased specificity of theoptoelectronic method for detecting cervical pathology. Sensitivity of the optoelectronic method (pNOR = 0.5)for histopathological diagnosis of intraepithelial neoplasiaof low grade (CIN 1) was estimated at 65.79% (Table 1).The method allowed for the detection of 25 cases of CIN 1in the group of 38 women with a confirmed diagnosis ofultimate low-grade intraepithelial neoplasia.In case of CIN 2, the optoelectronic method was characterized by higher sensitivity compared to the detection ofCIN 1 which amounted to 86.96% (Table 1). In a populationof 23 women with a confirmed diagnosis of CIN 2, the opto-electroni electronic method was the source of three false-negative results. For CIN 3, the optoelectronic method's sensitivity was determined to be 90.48% (Table 1). The method allowed forthe detection of 19 cases of CIN 3 in 21 women with a confirmed diagnosis of CIN 3. Sensitivity of the optoelectronicmethod for the detection of squamous cell carcinoma wasestimated at 100%. The method allowed for the detection ofonly one type of adenocarcinoma of the four changes of thistype confirmed histologically in the study group of 293women (Table 1). The optoelectronic method sensitivity for the detectionof low− grade lesions in the area of the squamous epitheliumlowgrade – LGSIL (CIN 1) was estimated at 65.79%(95% CI; 0.49–0.80), while for highgrade lesions – HighGrade – HGSIL (CIN 2, CIN 3) and squamous cell carcinoma at 90.38% (95% CI, 0.79–0.97) (Table 2).

Table – 1: Sensitivity of the optoelectronic method (pNOR = 0.5) forthe detection of CIN1, CIN2, CIN3 and squamous cell carcinomaand adenocarcinoma.

Examinationresult by the Optoelectronicmethod	CIN 1	CIN 2	CIN 3	Squamouscellcarcinoma	Adenocarcinoma
Normal	13	3	2	0	3
Abnormal	25	20	19	8	1
Sensitivity	65.79%	86.96%	90.48%	100%	25%

Table – 2: Sensitivity of the optoelectronic method (pNOR = 0.5) forthe detection of low−grade lesions(LGSIL) and high−grade lesions(HGSIL) together with squamous cell carcinoma.

Examination result bythe optoelectronicmethod	LGSIL	LGSIL HGSIL + Squamous cell carcinoma
Number of finalhistopathologicaldiagnoses	38	52
True positive results	25	47
Sensitivity	65.79%	90.38%

The optoelectronic method allowed for the detection ofonly one case of adenocarcinoma. All four cases of adenocarcinoma developed within the epithelium of the cervicalcanal.The specificity of the

optoelectronic method used toconfirm negative cervical pathology was estimated at78.89% (95% CI, 0.73–0.84).

Sensitivity of the optoelectronic method for the detection of all pathologies of squamous epithelium, excludingpathology within the epithelium was estimated at 80% (95%CI, 0.70–0.87). The positive predictive value of this diagnostic test amounted to 63% (95% CI, 0.54–0.72), and negative predictive value was estimated at 90% (95% CI, 0.84–0.94).

DISCUSSION:

The 1st report on the suitability of the method using theoptoelectronic device Polarprobe, Coppleson introduced in1994. This researcher is now widely recognized as one ofthe founders of modern colposcopy. His guidelines on thequalifications and the conditions for the implementation ofthe study, so−called, "Coppleson's conditions" are validtoday as it is. The optoelectronic method applied by Coppleson for the detection of neoplasia on a competitive basistogether with colposcopy and cytology is very significant.Coppleson's study comprised a group of 183 female volunteers aged between 20 and 50 years. Inclusive criterion wasan abnormal result of Pap smear or colposcopy. The sensitivity of the optoelectronic method for identifying CIN 1was estimated at 88%, while for CIN 2 and CIN 3 at 91%and 99% for the invasive cancer. Specificity of the optoelectronic method using the Polarprobe device for the detectionof the normal stratified squamous epithelium, adenocarcinoma, and physiological metaplasia were respectively 94%for CIN 1, 97% for CIN 2, CIN 3 and 86% for invasivecancer.[14]

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. Sensitivity of the optoelectronic method for LGSIL lesions in thepresent work was estimated at 65.79%, while in Coppleson's study at 88%, for HGSIL lesions and squamous cellcarcinoma at 90.38%, while in Coppleson's work at 94%.

In multicenter studies, conducted in Australia and theUK, the sensitivity of the optoelectronic method for thedetection of low−grade lesions within squamous epitheliumwas estimated at 67% (95% CI, 0.63–0.70), and forhigh−grade lesions at 70% (95% CI, 0.67–0.74).[15] Forcomparison, the sensitivity of traditional cytodiagnosticswas estimated at 45% (95% CI, 0.41–0.49) for LGSIL and69% (95% CI, 0.65–0.72) for HGSIL. The sensitivity indicated in the studies conducted for the purpose of this paperfor LGSIL lesions is higher, and it is estimated at 97.37%(95% CI, 0.86–0.99), and for a HGSIL lesions and squamous cell carcinoma it was estimated at 96.15% (95% CI,0.87–0.99). In the cited publication of Singer *et al.*, thespecificity of the optoelectronic method and cytodiagnosticsused to detect cervical intraepithelial neoplasia and cervicalcancer was estimated at 81% (95% CI, 0.78–0.84) and at95% (95% CI, 0.94–0.96), respectively. Sensitivity of thecombined test, that is cytodiagnostics and optoelectronic method for LGSIL lesions was estimated at 87% (95% CI,0.84–0.89), for HGSIL lesions at 93% (95% CI, 0.91–0.95).The specificity of these combined tests was estimated at80% (95% CI, 0.76–0.84).

In the study of Coppleson*et al.* of 1994, a proto type optoelectronic device (Polarprobe) was used. The sensitivity of the optoelectronic method using Polarprobe device for the detection of low-grade cervical intra epithelaial neoplasia was estimated at 85%, for medium-grade andhigh-grade it amounted to 90%, while for invasive cancer itwas estimated at 99%. Used in the study, Truscreen systemis a technological development of Polarprobe device used inCoppleson studies.[14]Acquired in terms of studies conducted by our researchcentre in 2008, the sensitivity of the optoelectronic methodin the detection of intraepithelial neoplasia of low grade(CIN1) was estimated at 53.33%. In case of CIN 2, themethod was characterized by higher sensitivity, which wasestimated at 80%. For CIN 3 and squamous cell carcinoma,the sensitivity of the optoelectronic method was assessed at100%. The specificity of the optoelectronic method foridentifying women with negative cervical pathology wasestimated at 84%.[16]

Sensitivity of the optoelectronic method in the studypopulation for the purpose of this work, for identificationhigh – level intraepithelial lesions – HGSIL (CIN 2, CIN 3)and squamous cell carcinoma was estimated at 90.38%(95% CI, 0.79–0.97). Also noteworthy is the fact that theoptoelectronic method allowed detection of only one of thefour cases of cervical adenocarcinoma. For comparison,a test for the presence of oncogenic types of humanpapilloma virus – HPV DNA HR allowed for the detectionof all four cases of adenocarcinoma and intracervical cancer. The specificity of the optoelectronic method used toconfirm negative cervical pathology was estimated at78.89% (95% CI, 0.73–0.84).The obtained results confirm the usefulness of optoelectronic diagnostics for the detection of precancerous lesionsand invasive cancers within the squamous epithelium of thecervix. The area under the ROC curve for the optoelectronicmethod was estimated at 0.88 (95% CI 0.84–0.92), whichindicates a high diagnostic value of this test in detectinglesions in HGSIL−like and squamous cell carcinoma. Theresulting ROC curve confirmed that the best cutoff point fornormal and abnormal results is the pNOR number whichequals 0.5. Adoption of such a threshold value of pNORallows for optimal

sensitivity and specificity parameters ofthe optoelectronic method for detecting HGSIL−like lesionsand cervical squamous cell carcinoma. Preliminary resultsof the team of Chinese researchers confirmed that the bestcutoff point is the threshold value of pNOR which equals0.5. In the study of Zhang *et al.*, the sensitivity of the optoelectronic method in a study of 392 women for the identification of high−grade intraepithelial changes and squamous cellcarcinoma was estimated at 76.47%. The specificity of theoptoelectronics for identifying women with negative cervical pathology amounted to 77.27%.[17]

New developments in sensor technology and advanceddata processing system allows for automated identificationof abnormal cervical epithelium. Automation benefits underincreased standardization and quality control of screeningand diagnostic examinations. Methods, allowing to obtain the result in a real time, significantly reduce the time of obtaining a definitive diagnosisand clearly minimize the number of required control visits.It is expected that these benefits will accelerate the furtherdevelopment of research on this type of diagnostic technology. Already today it might be said that the real−time typedevices have the chance to become a permanent part of thescreening and diagnosis of cervical intraepithelial neoplasiaand cervical cancer.

The use of automated optoelectronic diagnostics in partsof the world without access to medical care, such as Africaand South America can significantly reduce morbidity andmortality of cervical cancer. Critical to rapid and broadimplementation of this type of diagnosis is the fact that theoperator of the equipment does not have to be a highly qualified doctor. The test can successfully execute a person whois able to download the cytology smear, that is, a nurse ora midwife. The test result is standardized and automated.

During the first visit the test allows for an instant qualification of women for further evaluation and implementation ofcolposcopy and targeted specimens or decides to controlwithin a few years with the proper indication of the examination. The test can significantly shorten the time thatelapses from the abnormal screening test to the final histopathological diagnosis. In many developing countries, dueto the lack of cytological laboratories, trained personnel anda screening system, the optoelectronic method may be thediagnostics of choice, quick and inexpensive to implement.In those European Union countries like the UK andItaly, the optoelectronic method is used interchangeablywith cytodiagnostics. In 2009, the Russian Federationacquired approximately 150 Truscreen systems and helda series of meetings on the prevention of cervical cancer anddiagnostics using optoelectronics. Currently, there are ongoing clinical trials using this method in Turkey.Since approximately three years there has been anexpansion of the optoelectronic diagnostics used to detectthe pathology of the cervix in Asian countries. In many consulting rooms, patients are able to choose between the traditional Pap smear and optoelectronic diagnostics.Both the survey results as well as numerous reports from
world literature argue that the optoelectronic method maybecome a recognized, objective diagnostic tool for thedetection of cervical intraepithelial neoplasia and squamouscell carcinoma of the cervix, as well as the verification ofabnormal Pap smears.
Further cooperation of clinicians and biophysicists maylead to developing more precise diagnostic systems based onoptoelectronic method, which should allow for earlier detection of precancerous lesions and cervical cancer, as well ascancer of other organs. Particularly interesting seems to bethe use of such diagnostic systems in dermatology.

CONCLUSIONS:

Optoelectronic method is highly useful in detecting cervicalintraepithelial neoplasia arising within paraepidermal epithelial and squamous cell carcinoma of the cervix.The sensitivity of the optoelectronic method for LGSILwas estimated at 65.79%, while for a HGSIL and squamouscell carcinoma at 90.38%. The specificity of the optoelectronic method used to confirm the absence of cervical pathology was estimated at 78.89%.The pNOR border number equal to 0.5 allows us toobtain optimal sensitivity and specificity parameters ofoptoelectronic methods for detecting changes HGSIL andcervical squamous cell carcinoma.

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How to cite this article:

U. Agnes Vijaya*, Purushothama Reddy.K, M. Srinivasullu, Mallesh. M, Truscreen - an optoelectronic device with "real -time results – a new paradigm in cervical cancer screening", 6 (3): 2745 – 2752 (2015)