

Research Article

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 histopathologic biopsy. Specificity of the optoelectronic method for LGSIL was estimated at 65.70%, for HGSIL and squamous cell carcinoma of cervix 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.

Keywords: 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]. 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 are 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. Low grade 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 is a constant demand to increase sensitivity and specificity of various diagnostic tools in detecting cervical lesions. The ideal 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 the test, 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 is a 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 cytodagnostic 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 in 1926, when Fricke and Morse examined the flow of electric charge through breast tumours. In 1949, Langman and Burr found 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 lesions in 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 adenocarcinoma 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 tissues depend 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. It shows 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 cell 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 neoplastic changes [10].

Evaluation of mucous membrane structures using optoelectronic method is possible by using optical sensors recording different wavelengths of visible light and infrared light 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 is a 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 obtained from 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 histological analysis. Optoelectronic evaluation of the cervical epithelium obtained in a real time is objective, through its automation and avoids human error so characteristic for cytodiagnosics.

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 breast feeding 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 Pathophysiology 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 took place in case of inability to visualize the entire surface of the cervical 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 the vaginal cervix in the speculum was performed. The study used diagnostic system of the optoelectronic method – Truscreen (Polartechnics).



Fig-1 (a): Truscreen optoelectronic device

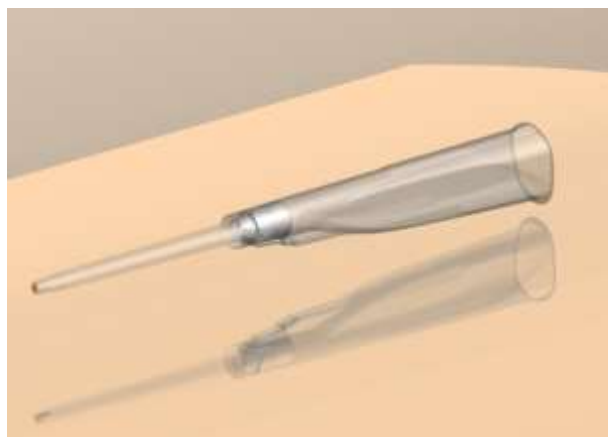


Fig-1 (b): Disposable single use only sheath

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 based on 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 use only 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 part coated with glandular epithelium, a transformation zone and the shield of the vaginal cervix.

ELECTRICAL COMPONENT

Optoelectronic method uses diagnostic system Truscreen multifunction electrodes, which stimulate the cervix with electrical impulses at a voltage of 0.8 V and duration of 350 μ s. 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 subcycles 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 21 groups, 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 to 130 μ W. 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 cytodiagnosics, receiver operating characteristic curve (ROC) was determined.

Statistical hypotheses were verified at the level of significance of $\alpha = 0.05$. Calculations were performed using the statistical package StatSoft, Inc. (2007), Statistica (data analysis software system), v.8.0, InStat 3.00 Graph Pad company and Analyze-it Software.

RESULTS

The percentage of histopathological diagnoses associated with neoplasia in the study of 293 women was estimated at 32.08% (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 population was 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 obtained by Truscreen and histopathological diagnoses indicates that the biggest percentage included true negative and true positive optoelectronic results,

which amounted to 54% and 25% 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 values, corresponding to 0.45, 0.4, 0.35, etc. resulted in the increase in the percentage of false-negative results, decrease in sensitivity and 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 the optoelectronic method for detecting cervical pathology.

Sensitivity of the optoelectronic method (pNOR = 0.5) for histopathological diagnosis of intraepithelial neoplasia of low grade (CIN 1) was estimated at 65.79% (Table 1). The method allowed for the detection of 25 cases of CIN 1 in the group of 38 women with a confirmed diagnosis of ultimate low-grade intraepithelial neoplasia. In case of CIN 2, the optoelectronic method was characterized by higher sensitivity compared to the detection of CIN 1 which amounted to 86.96% (Table 1). In a population of 23 women with a confirmed diagnosis of CIN 2, the optoelectronic 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 for the detection of 19 cases of CIN 3 in 21 women with a confirmed diagnosis of CIN 3. Sensitivity of the optoelectronic method for the detection of squamous cell carcinoma was estimated at 100%. The method allowed for the detection of only one type of adenocarcinoma of the four changes of this type confirmed histologically in the study group of 293 women (Table 1).

Table-1: Sensitivity of the optoelectronic method (pNOR = 0.5) for the detection of CIN1, CIN2, CIN3 and squamous cell carcinoma and adenocarcinoma.

Examination result by the Optoelectronic method	CIN 1	CIN 2	CIN 3	Squamous cell carcinoma	Adenocarcinoma
Normal	13	3	2	0	3
Abnormal	25	20	19	8	1
Sensitivity	65.79%	86.96%	90.48%	100%	25%

The optoelectronic method sensitivity for the detection of low-grade lesions in the area of the squamous epithelium low grade – LGSIL (CIN 1) was estimated at 65.79% (95% CI; 0.49–0.80), while for

high grade lesions – High Grade – HGSIL (CIN 2, CIN 3) and squamous cell carcinoma at 90.38% (95% CI, 0.79–0.97) (Table 2).

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

Examination result by the optoelectronic method	LGSIL	LGSIL HGSIL + Squamous cell carcinoma
Number of final histopathological diagnoses	38	52
True positive results	25	47
Sensitivity	65.79%	90.38%

The optoelectronic method allowed for the detection of only one case of adenocarcinoma. All four cases of adenocarcinoma developed within the epithelium of the cervical canal. The specificity of the optoelectronic method used to confirm negative cervical pathology was estimated at 78.89% (95% CI, 0.73–0.84).

Sensitivity of the optoelectronic method for the detection of all pathologies of squamous epithelium, excluding pathology 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 the optoelectronic device Polarprobe, Coppleson introduced in 1994. This researcher is now widely recognized as one of the founders of modern colposcopy. His guidelines on the qualifications and the conditions for the implementation of the study, so-called, “Coppleson’s conditions” are valid today as it is. The optoelectronic method applied by Coppleson for the detection of neoplasia on a competitive basis together 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 was an abnormal result of Pap smear or colposcopy. The sensitivity of the optoelectronic method for identifying CIN 1 was 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 detection of the normal stratified squamous epithelium, adenocarcinoma, and physiological metaplasia were respectively 94% for CIN 1, 97% for CIN 2, CIN 3 and 86% for invasive cancer [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 cytodiagnosics in the process of detecting cervical pathology. Sensitivity of the optoelectronic method for LGSIL lesions in the present work was estimated at 65.79%, while in Coppleson’s study at 88%, for HGSIL lesions and squamous cell carcinoma at 90.38%, while in Coppleson’s work at 94%.

In multicenter studies, conducted in Australia and the UK, the sensitivity of the optoelectronic method for the detection of low-grade lesions within squamous epithelium was estimated at 67% (95% CI, 0.63–0.70), and for high-grade lesions at 70% (95% CI, 0.67–0.74) [15]. For comparison, the sensitivity of traditional cytodiagnosics was estimated at 45% (95% CI, 0.41–0.49) for LGSIL and 69% (95% CI, 0.65–0.72) for HGSIL. The sensitivity indicated in the studies conducted for the purpose of this paper for 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.*, the specificity of the optoelectronic method and cytodiagnosics used to detect cervical intraepithelial neoplasia and cervical cancer was estimated at 81% (95% CI, 0.78–0.84) and at 95% (95% CI, 0.94–0.96), respectively. Sensitivity of the combined test, that is cytodiagnosics 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 at 80% (95% CI, 0.76–0.84).

In the study of Coppleson *et al.* of 1994, a prototype optoelectronic device (Polarprobe) was used. The sensitivity of the optoelectronic method using Polarprobe device for the detection of low-grade cervical intraepithelial neoplasia was estimated at 85%, for medium-grade and high-grade it amounted to 90%, while for invasive cancer it was estimated at 99%. Used in the study, Truscreen system is a technological development of Polarprobe device used in Coppleson studies [14]. Acquired in terms of studies conducted by our research centre in 2008, the sensitivity of the optoelectronic method in the detection of intraepithelial neoplasia of low grade (CIN1) was estimated at 53.33%. In case of CIN 2, the method was characterized by higher sensitivity, which was estimated at 80%. For CIN 3 and squamous cell carcinoma, the sensitivity of the optoelectronic method was assessed at 100%. The specificity of the optoelectronic method for identifying women with negative cervical pathology was estimated at 84% [16].

Sensitivity of the optoelectronic method in the study population for the purpose of this work, for identification high – 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 the optoelectronic method allowed detection of only one of the four cases of cervical adenocarcinoma. For comparison, a test for the presence of oncogenic types of human papilloma virus – HPV DNA HR allowed for the detection of all four cases of adenocarcinoma and intracervical cancer. The specificity of the optoelectronic method used to confirm negative cervical pathology was estimated at 78.89% (95% CI, 0.73–0.84). The obtained results confirm the usefulness of optoelectronic diagnostics for the detection of precancerous lesions and invasive cancers within the squamous epithelium of the cervix. The area under the ROC curve for the optoelectronic method was estimated at 0.88 (95% CI 0.84–0.92), which indicates a high diagnostic value of this test in detecting lesions in HGSIL-like and squamous cell carcinoma. The resulting ROC curve confirmed that the best cutoff point for normal and abnormal results is the pNOR number which equals 0.5. Adoption of such a threshold value of pNOR allows for optimal sensitivity and specificity parameters of the optoelectronic method for detecting HGSIL-like lesions and cervical squamous cell carcinoma. Preliminary results of the team of Chinese researchers confirmed that the best cut off point is the threshold value of pNOR which equals 0.5. 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 cell carcinoma was estimated at 76.47%. The specificity of the optoelectronics for identifying women with negative cervical pathology amounted to 77.27% [17].

New developments in sensor technology and advanced data processing system allows for automated identification of abnormal cervical epithelium. Automation benefits under increased standardization and quality control of screening and diagnostic examinations.

Methods, allowing to obtain the result in a real time, significantly reduce the time of obtaining a definitive diagnosis and clearly minimize the number of required control visits. It is expected that these benefits will accelerate the further development of research on this type of diagnostic technology. Already today it might be said that the real-time type devices have the chance to become a permanent part of the screening and diagnosis of cervical intraepithelial neoplasia and cervical cancer.

The use of automated optoelectronic diagnostics in parts of the world without access to medical care, such as Africa and South America can significantly reduce morbidity and mortality of cervical cancer. Critical to rapid and broad implementation of this type of diagnosis is the fact that the operator of the equipment does not have to be a highly qualified doctor.

The test can successfully execute a person who is able to download the cytology smear, that is, a nurse or a 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 of colposcopy and targeted specimens or decides to control within a few years with the proper indication of the examination. The test can significantly shorten the time that elapses from the abnormal screening test to the final histopathological diagnosis. In many developing countries, due to the lack of cytological laboratories, trained personnel and a screening system, the optoelectronic method may be the diagnostics of choice, quick and inexpensive to implement. In those European Union countries like the UK and Italy, the optoelectronic method is used interchangeably with cytodiagnostics. In 2009, the Russian Federation acquired approximately 150 Truscreen systems and held a series of meetings on the prevention of cervical cancer and diagnostics using optoelectronics. Currently, there are ongoing clinical trials using this method in Turkey. Since approximately three years there has been an expansion of the optoelectronic diagnostics used to detect the 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 may become a recognized, objective diagnostic tool for the detection of cervical intraepithelial neoplasia and squamous cell carcinoma of the cervix, as well as the verification of abnormal Pap smears.

Further cooperation of clinicians and biophysicists may lead to developing more precise diagnostic systems based on optoelectronic method, which should allow for earlier detection of precancerous lesions and cervical cancer, as well as cancer of other organs. Particularly interesting seems to be the use of such diagnostic systems in dermatology.

CONCLUSION

Optoelectronic method is highly useful in detecting cervical intraepithelial neoplasia arising within paraepidermal epithelial and squamous cell carcinoma of the cervix. The sensitivity of the optoelectronic method for LGSIL was estimated at 65.79%, while for a HGSIL and squamous cell 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 to obtain optimal sensitivity and specificity parameters of optoelectronic methods for detecting changes HGSIL and cervical squamous cell carcinoma.

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