

## Evaluation of screening devices and methods for pre-malignant and malignant cervical cancer disorders in order to prevent this pathology in Albania

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### Abstract:

*The objective of this paper is to evaluate the screen device and methods for early diagnosis of CeCa in Albania. In order to prevent this pathology some methods are used such as evaluation of Colposcopy and Pap smear test. In this research participated 106 patients, which were under control during one year.*

*From the tests resulted that the sensitivity of Pap smear test was 22% and the specificity was 93%. Regarding to Colposcopy test resulted that sensitivity was 95% and specificity was 52%.*

*In this research was conclude that the screening methods used and follow-up helps to prevent CeCa with the identification and treatment of preliminary lesions.*

**Key words:** Pap smear, Colposcopy, HPV, screening method.

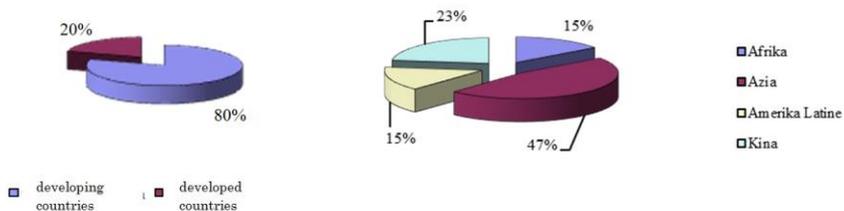
### Introduction

In the world each year, approximately 250,000 women die from cervical cancer. Over the past 57 years, wealthy countries have experienced a widespread decline in the burden of cervical due to a frequent screening with cervical cytology/ Pap smear test throughout a women's life (1) (2) (3).

In different countries, which are able to afford and support organized cervical cancer prevention programs, screening with cytology has reduced mortality from invasive cervical cancer by <80% (4). They have established different guidelines with respect to screening intervals, ages and diagnostic algorithms in response to positive screening test results, and have achieved different levels of coverage (5) (6) (7).

However, it is important to note that cancer screening programs will only produce these reductions in incidence and/or mortality if they are delivered through well organized programs with high coverage of the target population and strict quality control at all levels. Without these elements, the incidence and mortality reductions will be much lower or completely absent, but the program will increase morbidity through the unnecessary follow-up of false positives and consume an enormous amount of money.

As it is shown in the Figure 1, the number of CeCa cases is higher in the developing countries compared with developed countries. The factors which affect in developing the mortality and incidence are: the collection of cases, the lack of access into limited services, the lack of problem's awareness and the lack of massive screening programs.



**Figure 1. Incidence of cases with CeCa in the world**

The available evidence also indicates that cancer rates are increasing in Albania, following global trends that result from population aging. However, the mean age of the Albanian population is the youngest in Europe (31 years) so the

magnitude of increases here will be larger. Cervical cancer rates are also affected by lifestyle factors which will exert their influence in Albania as European integration continues and the standard of living improves. As a result of these factors, cervical cancers will place a steadily increasing burden on the Albanian population and the health system over the coming years unless effective prevention measures are implemented. Davies *et. al* (8) states that the current situation in Albania cannot support mass screening programs for cervix and the most cancers were detected at advanced stages (III/IV).

Regarding to INSTAT, tumorous diseases are in the second place of reasons which lead to death in Albania (9). Was observed that the awareness toward Pap smear is very low, 20% and only 3.4 % have undergone Pap smear (10). Mortality of CeCa from 0.5 in 1999 reaches 1.1 in 2010.

This paper presents a research done in Albania, in order to establish a national strategy for the prevention of CeCa. There was no national program for women's screening and there was no register for cancer in national level. The screening devices were possible to be found only in the capital of Albania, Tirana and not all over the country. Furthermore, there was no study on HPV types spread in Albania.

## **Materials and methods**

In order to prevent this pathology in Albania this study induces the evaluation of screening devices /methods for early diagnosis of CeCa. This was done with a quality evaluation of Colposcopy and Pap smear test.

The target group selected for this study were patients, which were sexually active, not pregnant; they do not have anamnesis for cancerous diseases and agreed to be under control for one year.

There were two groups of cases: the first was "*disease absent*" – which results of biopsy appear as "normal" or

«atypical» and they were grouped as disease absent. The second group was "disease present" –were all cases with HPV and CIN were grouped as abnormal cases. The evaluation of the characteristics of the test is shown in Figure 2.

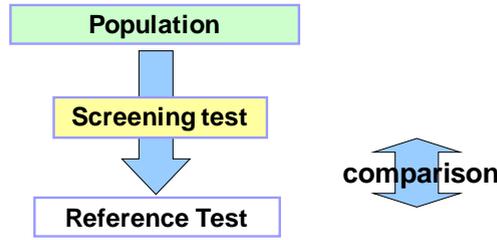


Figure 2. Evaluation of test’s characteristics

### Results and discussions

The figure 3 shows the Colposcopy and Pap smear ratio toward biopsy.

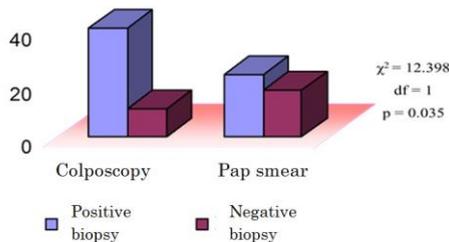


Figure 3. Colposcopy and Pap smear ratio toward biopsy

False positive cases by PAP smear are much more than by colposcopy.

Table 1. Results of positive Pap smear and positive Colposcopy and Biopsy

| Histological Diagnosis | Pap smear (+); Colposcopy (+) | Pap smear (-); Colposcopy (+) | Pap smear (+); Colposcopy (-) | Total      |
|------------------------|-------------------------------|-------------------------------|-------------------------------|------------|
| (CIN I CIN II CIN III) | 7                             | 40                            | 3                             | 50         |
| No dysplasia           | 13                            | 37                            | 6                             | 56         |
| <b>Total</b>           | <b>20</b>                     | <b>77</b>                     | <b>9</b>                      | <b>106</b> |

48 cases are negative for neoplasia by all test evaluation

The table 2 shows the test evaluation for accuracy & clinical use.

**Table 2.** Test evaluation

|      |   | Early disease |             |          |
|------|---|---------------|-------------|----------|
|      |   | Ill (+)       | Not ill (-) |          |
| Test | + | A (47)        | B (50)      | a+b (97) |
|      | - | C (3)         | D (54)      | c+d (57) |
|      |   | a+c (50)      | b+d (104)   |          |

**Accuracy**

$$Se = a/a+c$$

$$Sp = d/b+d$$

**Clinical use**

$$PPV = a/a+b$$

$$NPV = c/c+d$$

In the table 3 are given the efficiency ranges of Colposcopy from different researchers in this field.

**Table 3.** Efficiency ranges of Colposcopy

| Studies           | No. of patients | TV        | FP        | FN       | TN        | Prevalence % | Se        | Sc        | Pv        | Pn        |
|-------------------|-----------------|-----------|-----------|----------|-----------|--------------|-----------|-----------|-----------|-----------|
| Staff & Mattingly | 659             | 493       | 118       | 6        | 42        | 74.8         | 98.8      | 26.3      | 80.7      | 87.5      |
| Benedet &         | 549             | 434       | 53        | 2        | 60        | 79.1         | 99.5      | 53.1      | 89.1      | 96.8      |
| Javaheri &        | 903             | 680       | 28        | 1        | 194       | 75.1         | 99.8      | 87.4      | 96.1      | 99.5      |
| Edebiri &         | 222             | 113       | 30        | 17       | 62        | 50.9         | 86.9      | 67.4      | 79.0      | 78.5      |
| Seshadri &        | 152             | 61        | 54        | 9        | 28        | 40.1         | 87.1      | 34.2      | 53.0      | 75.7      |
| Benedet&          | 3252            | 2284      | 467       | 13       | 370       | 70.2         | 94.6      | 44.2      | 84.1      | 73.9      |
| Kierkegaard &     | 783             | 697       | 27        | 29       | 30        | 89.0         | 96.0      | 52.6      | 96.3      | 50.9      |
| Christoforoni &   | 188             | 127       | 38        | 20       | 3         | 67.6         | 97.7      | 34.5      | 77.0      | 87.0      |
| <b>Bajo</b>       | <b>154</b>      | <b>47</b> | <b>50</b> | <b>3</b> | <b>54</b> | <b>30.5</b>  | <b>95</b> | <b>52</b> | <b>48</b> | <b>94</b> |

The Colposcopy was used in order to identify the intraepithelial atypical areas for biopsy in patients. This is a managing strategy for patient's follow-up and plays a key role in early

diagnosis of CeCa and in establishing the diagnosis, its confirmation with biopsy.

As one of the techniques of a particular importance, it offers the possibility for building capacities in certain regions of the world where there is a lack of technical expertise and which are less developed. The transferring of computer imagery is a valuable method which is worth to be incited for diagnosis, “on site “trainings and continuous evaluation, certification and further support or collaboration.

In the table 4 are given the efficiency ranges of Pap smear from different researchers in this field. The test performance was of high level of accuracy and high sensitivity toward specifics. We may say that the identification of lesions is more worthy than periodic check-up.

Table 4. Efficiency ranges of Pap smear

| Authors     | Sensitivity       | Specifics   |
|-------------|-------------------|-------------|
| Duggan      | 63.7 %            | (*)         |
| Bishop      | 63.6 %            | 99.7 %      |
| Matsuura    | 51.0 %            | 95.0 %      |
| Mayeux      | 45.0 %            | 80.0 %      |
| Reid        | 52.0 %            | 92.0 %      |
| Schneider   | 29.0 %            | 96.0        |
| Soost       | 80.0 % (78.1)**   | 94.4 %      |
| Tabbara     | 79.0 % (66.0 %)** | 82.0 %      |
| <b>Bajo</b> | <b>22 %</b>       | <b>83 %</b> |

There are some factors which influence in false-negative cases such as the technique of material's extraction influences on the quality of utensil's preparation and sample's interpretation. Another problem is the samples' transportation. Furthermore the traditional Pap smear presents the results of the sub-sample received, chosen occasionally and does not represent the

whole lesion. Moreover, the epidemiologic, biochemical factors, cytologic and social-economical factors as well are part of cytology efficiency in a screening test.

The main purpose of Pap smear as a screening method and follow-up is to prevent Cervical Cancer with the identification and treatment of preliminary lesions.

But in order to do this there are some challenges such as: the test's improvement with highly cost-effective methods and the effective selection of cases with ASCUS for evaluation with colposcopy

## Conclusions

The study showed that all types of mistakes which generate as a consequence of patient selection and the methodology used, may be eliminated with performing a colposcopy/biopsy. The value of colposcopy, remains significant and an integral part of devices/methods for the diagnostification of neoplasia in early stages.

A massive awareness campaign for devices and services offered in Albania, regarding Pap smear, CeCa, etc., as the level of problems' awareness and practical application is still very low.

Very important is the mapping of the strategy to fight CeCa based on information development, education and communication in and outside clinical sphere is necessary and as well the drafting of a national program for screening of women for CeCa. Significant is as well the drafting of protocols for management of cases, based on trainings, algorithm system and needs that women with CeCa have.

Another important thing to be done is the introduction of additional techniques such as HPV test so as to increase catchment sensitivity of CIN lesions and the application of new methods for an effective cytology in massive screening programs.

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