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ABSTRACT

of the dissertation for the degree of Doctor of Philosophy

ONCOEPIDEMIOLOGICAL ASPECTS OF EARLY DETECTION AND PREVENTION OF CERVICAL CANCER ASSOCIATED WITH HUMAN PAPILLOMAVIRUS

Speciality: 3202.01 – Epidemiology

Field of science: Medicine

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URGENCY OF THE PROBLEM AND DEGREE OF DEVELOPMENT

Cervical cancer (CC) is the second most common cause of death from malignant neoplasms among women, second only to breast cancer[1] Every year, 370,000 to 470,000 new cases of cervical cancer are registered worldwide. This accounts for 14.2% of all deaths from malignant neoplasms in women. Cervical cancer ranks first in terms of morbidity and mortality among all malignant neoplasms of the female genital organs. Although in recent years, thanks to the introduction of screening programs in economically developed countries, there has been a general decrease in the incidence of cervical cancer, in a number of countries there has been an increase in the incidence among young women, that is, under 35 years of age. The increase in incidence is especially noticeable among women under 29 years of age, with an annual growth rate of 2.1% [2,3]. Despite the observed downward trend in incidence in many countries around the world, mortality rates from cervical cancer have remained virtually unchanged over the past 20 years. This is due to the fact that the disease is often (46 cases out of 100) detected at a late stage[4,5]. Early diagnosis and timely treatment of patients with dysplasia and preinvasive cancer are of great importance in the prevention of invasive cervical cancer, which is possible thanks

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to cytological screening. Early diagnosis and timely treatment of patients with dysplasia and preinvasive cancer are of great importance in the prevention of invasive cervical cancer, which is possible thanks to cytological screening[6,7,8,9]. The main exogenous factor that plays an important role in the development of intraepithelial dysplasia and acts as the first trigger for neoplastic transformation of the cervical epithelium is considered to be infection with highly oncogenic types of human papillomavirus (HPV). The sharp increase in the number of patients, high heterogeneity of viruses (currently, more than 100 HPV serotypes have been identified, differing in epidemiological significance and clinical symptoms), complexity of diagnostics, multi-organ nature of the pathology caused, as well as the ability to enhance malignant processes, put HPV among the priority medical and social problems. It should also be noted that the frequency of HPV infection is 10 times higher than the frequency of clinical manifestations of the infection. [10, 11].

Thus, the doctor has enough time to detect the initial forms of the lesion, so the problem of timely diagnosis of HPV remains one of the most pressing issues in practical gynecology. The data obtained indicate the relevance and need to improve HPV screening methods, search for new simple, cost-effective and at the same time effective

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methods of prevention and early diagnosis of HPV in order to ensure timely treatment of this severe and dangerous disease.

The object of the study. In 2014-2018, 232 women aged 18 to 44 years (main groups) from various regions and cities of the republic were investigated in the oncological clinics of Azerbaijan. The control group consists 80 women, who was directed to the oncological clinics of the republic, and oncology and viral pathology did not reveal, practical healthy woman. The results of clinical, laboratory, ultrasound and other studies of women in these groups were selected as the subject of research.

The purpose of the work. As a result of clinical-epidemiological examinations, develop and scientifically organize ways to improve measures on the prevention of cervical cancer.

Duties of the study:

1. Estimate the dynamics of the HPV-associary cervical pathology in Azerbaijan and the level of illness;
2. To discover the spread of high-onkogenic types of HPV and evaluate the virus load, and assess the Persistence of HPV highly-oncogenic types;
3. To discover the leading risk factors of infection with HPV with high onkogenous risk in women;
4. To determine the prognostic significance of Routine cythological method, liquid cythology, extensive colposcopy and HPV testing in women.
5. Developed the system of organizational measures in the patients with diagnosed cervical cancer and its high-rise risk groups.

Research methods. The examinations were carried out on the prospective method, including the case-control method. During the examination of women in all groups, anamnez data analysis was carried out and was used by clinical, laboratory, ultrasound and statistical methods.

The main provisions of the defense:

1. Analyze the effectiveness of diagnostic measures in the timely detection of the risk factors of cervical cancer which associated with HPV and analyzing oncoepidemiological condition in Republic.

2. Correlation of cervical correlation with the quantitative indicators of HPV with high onkogenic risk of the gravity of pathological changes in the mucous membrane.

3. The main directions of improving medical care to women with a cervical canceria, associating with a human papillomavirus.

Scientific novelities:

1. For the first time, the frequency of various genotypes of HR-HPV in Azerbaijan was studied. It has been determined that women often infect HR-HPV-16, 33 and 32 and 52nd genotypes and mentioned infection was detected in this time.

2. For the first time in various groups of women, various examination methods was used for the discovery of LSIL, HSIL and CC: HPV-testing, cytological method, liquid cythology and the prognostic significance of the colposcopyia.

3. The mono- and Micst-infection of the Papilloma virus with a person with high onkogenic risk has been determined to interact with the characteristics of their quantitative amount and the clinical course of the Papillomavirus infection;

4. The main risk factors of high onkogenous HPV was determined among women;

5. On the basis of the results of the examinations, criteriaes of prognostigation of the development risk of the pathological processes of the cervical, which are associating with HPV had prepared. At the same time, their clinical forms, the process of the infectious, the genotypes and quantitative indicators of the genotypes and the amount of HPV were taken into account.

Practical significance of the study. Analysis of the cervical cancer's epidemiology in Azerbaijan allows health organizers to understand the clear view of the frequency and illness of the disease. This also allows the adoption of scientifically-founding organizational-methodical measures in the early detection and prevention of Cervical Cancer, as well as adoption of measures to weaken some risk factors. Thanks to the study of the study, the women's HR-HPV was a high (26.0%). It was found that HR-HPV belongs to the risk of infection: Low education, smoking, marital status-not pregnancy, age $\leq$ 29, oligomenory, wet $\leq$ 29, oligomenory, and trichomoniaz, sexual life start $\leq$ 17 years old.

Approbation and application of the dissertation.

Dissertation materials were reported:

- "Modern achievements of Azerbaijani medicine" at the scientific-practical conference (Baku, 2017).

-“Actual problems of epidemiology of infectious and non-infectious diseases” Materials of an international scientific and practical conference with the participation of international party universities (Uzbekistan, 2022)

- At the inter-department meeting of the Profile Department of AMU (Baku, 2025);

- At the scientific seminar under the ATU (Baku, 2025)

The dissertation materials are used in the teaching process of the Department of Epidemiology and Biostatics and Department of Oncology of the AMU, and the proposed recommendations are applied to practice.

The organization where the dissertation was completed. The dissertation was carried out on the bases of the epidemiology and biostatology department of the Azerbaijan Medical University, the oncology clinic at the Azerbaijan Medical University.

Printing works. The basis results of the dissertation were published in 8 article (3 of them in foreign journals - in Moscow, Belarus, Amsterdam, on the list of AAK) and 8 theses.

Structure and volume of the dissertation. The dissertation consists of 160 pages printed on a computer (209450 marks), "Contents", "Introduction" (8 pages, volume: 9200 marks), "Results" (2 pages, volume: 2700 marks), "Practical recommendations" (1 page, volume: 950 marks) and "Referenced literature list" (21 pages).

The main content of the dissertation is divided into 6 chapters. Chapter I "Literature Review" (27 pages, volume: 53850 marks), Chapter II "Material and Methods" (12 pages, volume: 19600 marks), Chapter III "Research Results" (19 pages, volume: 17400 marks), Chapter IV (18 pages, volume: 16400 marks), Chapter V (35 pages, volume: 62750 marks), Chapter VI (15 pages, volume: 26600 marks).

When writing the dissertation, 204 literary sources were used, of which 10 are works of Azerbaijani, 63 are Russian and 130 are

foreign scientists. The dissertation is illustrated with 52 tables and 21 figures.

RESEARCH MATERIALS AND METHODS

The study was conducted within the framework of scientific programs of the Oncology Clinic of the Azerbaijan Medical University in 2014-2018. The examinations were conducted prospectively at the laboratory of the Oncology Clinic of the Azerbaijan Medical University. The study involved 232 women who applied to various oncological clinics in Azerbaijan with a pathological process of the cervix (CC) (main group). The control group consisted of 80 healthy women without oncological and viral pathology.

Retrospectively, all patients of the main group were divided into 5 groups depending on the morphological type of the pathological process of the cervix uteri (CU). The first group consisted of patients with benign pathological processes of CU associated with PVI (n=55), the second - women with CIN I (n=44), the third - with CIN II (n=48), the fourth - with CIN III (n=38), the fifth – patients with invasive squamous cell CU (stage I; n=47). In our study, there were no patients with adenocarcinoma of CU.

The patients of the main group were divided into the following groups: Group 1 – 45 women with manifest forms of PVI (anogenital (venereal) warts); Group 2 – 187 women with subclinical or latent forms of PVI. The study of risk factors and the identification of the most significant among them—specifically, oncological risk factors contributing to the development of cervical cancer—was conducted using the "case-control" method. During the examination of women in all groups, an analysis of anamnesis data was carried out, using clinical, laboratory, ultrasound, and statistical examination methods. The obtained data were entered into individual patient records. The indications for women to seek outpatient-polyclinic services included: complaints related to pathological discharge from the genital tract; contact bleeding during sexual intercourse; and preventive screening.The indications for hospitalization include: a morphologically verified diagnosis of uterine pathology; abnormal

colposcopic and cytological findings; menometrorrhagia or hypermenorrhea; hyperplastic processes in the endometrium according to ultrasound data; uterine fibroids or adenomyosis; primary or secondary infertility; and pain syndrome.

The inclusion criteria for the study were reproductive age (from 18 to 45 years), morphologically verified cases of pathological processes of the cervix associated with HPV, a positive test result for HPV, the presence of paraffin blocks in women who had previously undergone biopsy or excision of the cervix, consent to participate in the study and compliance with the examination protocol.

The exclusion criteria from the study were pregnancy and lactation, administration of the HPV vaccine, severe somatic pathology of patients (renal, liver, cardiovascular failure), morphologically verified malignant neoplasms (except squamous cell carcinoma).

The examined patients had clinical, anamnestic and diagnostic features of the pathological process of CU, both at the outpatient and inpatient stages of examination and treatment. The influence of social and hygienic factors on the activation of the HPV infection mechanism was determined by grouping 232 examined women depending on their financial status, level of sanitary and hygienic culture and housing and communal conditions. Testing of various HPV prevention methods and their epidemiological assessment were carried out as follows. The above 232 women with HPV were divided into 3 groups: married - 80 patients (34.5±3.0%), unmarried young people - 38 patients (16.4±2.2%), unmarried adults, often divorced - 114 patients (49.1±3.2%).

During the objective examination, the patient's height, body structure, and the condition of the mammary glands were assessed. The uterine cavity and cervix were examined using a disposable Cusco speculum, and the nature, consistency, and color of vaginal discharge were assessed. During the examination of the cervix, attention was paid to its volume, shape, and the presence of pathological changes in the ectocervix. After taking material for laboratory tests and conducting an extended colposcopy, a bimanual examination of the cervix was performed, during which the shape,

volume, condition, mobility, pain upon palpation, and pathological changes in the uterine appendages were assessed.

As part of the study, samples were collected from the cervical canal for both conventional and liquid-based cytology examinations.

For the preparation of a conventional smear, after the insertion of a gynecological speculum, excess mucus from the vaginal portion of the cervix was gently removed using a gauze swab. An Ayre spatula was then carefully inserted into the external os of the cervix, and a 360-degree rotational movement was performed.

This method allows for the collection of an adequate amount of material for examination. The spatula was then carefully removed, and the obtained material was evenly spread in a thin layer onto a labeled glass slide using a single linear motion (covering approximately two-thirds of the slide's surface). The smear was fixed by air-drying. Staining was performed using the Romanowsky-Giemsa method. For liquid-based cytology, the material was collected using a "DiaSkrin" cytobrush.

In order to determine the prognostic significance of various research methods in detecting LSIL, HSIL and cervical cancer, women underwent traditional and liquid cytological studies, extended colposcopy, HPV testing of material taken by a doctor and using the Gvintip device. In case of abnormal results, all women were offered a targeted cervical biopsy. Detection and differentiation of 12 YR-HPV genotypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59) was carried out on a CFX-96 plate amplifier manufactured by Bio-RaD (USA) using the PCR screening and genotyping method of HPV VKR DNA (set No. 1) manufactured by VECTOR-BEST - RealBest CJSC. The principle of the study is based on recording the amplification process of the selected DNA fragment, consisting of repeating cycles: temperature denaturation, annealing of primers with a complementary sequence, alignment of these primers with the polynucleotide sequence of Taq DNA polymerase. Statistical processing of the obtained data was performed using the BioStat 2009 program and the STATISTICA 6.0 software package (USA). Differences between groups in qualitative features were assessed using the $\chi 2$ criterion. Differences were considered significant at a

reliability level of $p<0.05$. The relationship between the studied parameters was assessed using correlation analysis and determining the Spearman correlation coefficient (r), which was considered significant at $p<0.05$.

RESULTS OF PERSONAL OBSERVATIONS AND THEIR DISCUSSION

A total of 1366 people were included in the examination, of which 232 patients (16.9±2.5%) had HPV (Fig 1).

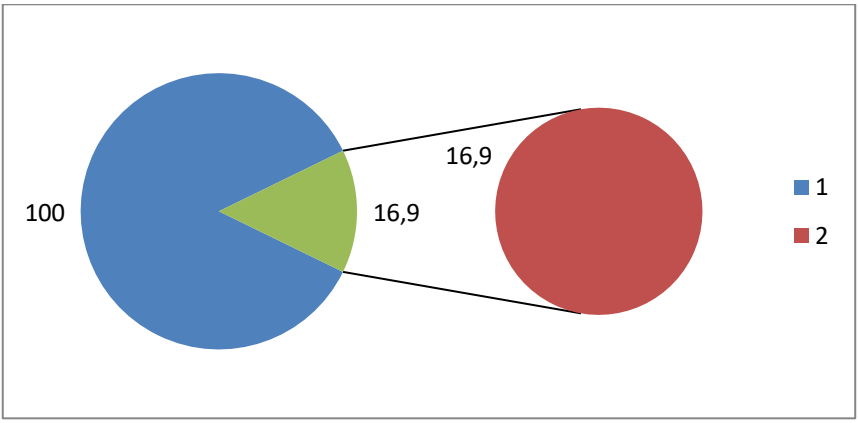

Fig. 1. Incidence of HPV in women examined.
1- Total number of examined; 2- Women with HPV

According to the clinical course of PVI, the patients of the main group were divided into the following groups: in the 1st group - 45 women (18.7%) with the manifest form of the virus; in the 2nd group - 187 people (80.6%) with a subclinical or latent form of the virus. The lowest indicator - 16 people (6.9%) was in the age group of 18-24 years. The maximum values were noted in the age group of 25-29 years - 111 people (47.8 ± 3.3%), in other age groups there was a decrease in the incidence rate from 17.8 ± 2.5% to 11.6 ± 2.1%. Thus, the majority of patients with PVI were of working, reproductive age, which is of great social importance. According to

the anamnesis data, out of 232 women with HPV, 139 (59.9±3.2%) patients could not accurately indicate the duration of HPV infection, 27 (11.6±2.1%) patients considered themselves infected for 2 months, 24 (10.3±1.9%) patients – from 2 months to 1 year, 16 (6.9%) patients – from 1 to 3 years, and 26 (11.3%) patients – more than 3 years. Thus, more than half of the patients (139; 59.9±3.2%) did not know about their HPV infection (Fig 2).

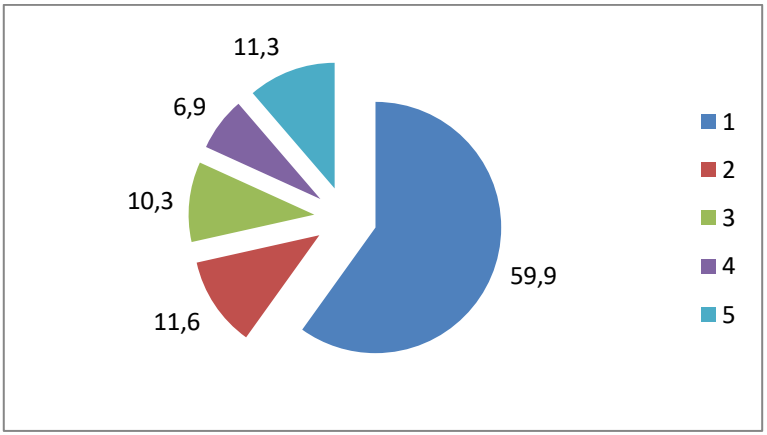

Fig. 2. Disease duration in patients with PVI (n=232; 100%, 1-not possible to determine; 2- 0-2 months; 3- up to 1 year; 4- from 1 to 3 years; 5- more than 3 years).

Analysis of the hereditary burden of patients revealed an increased tendency to malignant tumor processes in 130 (56.0±3.3% 42.7%) patients of group I and in 48.7±5.6 (39 cases; $\chi 2=0.36$; $p=0.551$) patients of group II. It was found that cancer of the reproductive system organs was quite common in close relatives of the examined patients of the main group - 88 patients (37.9±3.2%). Other oncological diseases were registered in close relatives of 42 patients (18.1±2.5%). The most common were breast cancer (14.6±2.3%) and cervical cancer (11.6±2.1%). When analyzing somatic diseases, it was found that the examined women more often suffered from gastrointestinal tract pathology, which was registered in 114 patients (49.1±3.3%).

Among infectious diseases in the main group of examined patients, rubella was most frequently recorded - in 190 patients (81.9±2.5%), acute respiratory viral infections 2 times a year or more - in 152 patients (64.6±3.0%), influenza - in 128 patients (55.2±3.3%), chickenpox - in 111 patients (47.8±3.3%). Other infectious diseases are somewhat less common - from 6.0% to 23.7±2.8%. When analyzing somatic diseases, it was found that the examined women more often suffered from gastrointestinal tract pathology, which was recorded in 114 patients (49.1±3.3%). Data on STIs suffered by the examined patients show that 80 (35.4±3.0%) women have mixed infections (a combination of 3 or more infections). In the main group of examined patients, after the STIs were performed, the following were registered: STIs - in 57 patients (24.6±2.8%), chlamydia - in 55 patients (23.7±2.8%), recurrent bacterial vaginosis - in 41 patients (17.8±2.5%), trichomoniasis - in 32 patients (13.8±2.3%), influenza - in 128 patients (55.2±3.3%).

When analyzing the clinical signs, the following complaints were most often encountered: pain in the lower abdomen, not related to the menstrual cycle - in 130 patients (56.0±3.3%), menorrhagia - in 119 patients (51.3±3.2%), and copious discharge from the genital tract (in 97 patients, 41.8±3.2%). A detailed analysis of the frequency and structure of gynecological diseases in the examined patients revealed the prevalence of chronic cervicitis in 106 (45.7±3.3%) patients. In addition, the presence of mixed uterine pathology (adenomyosis, uterine myoma, endometrial hyperplasia) in 55 (23.7±2.8%) women is noteworthy. When analyzing the characteristics of sexual life and contraception, the number of sexual partners ≥3 in 87 (37.5±3.2%) patients (since the beginning of sexual life) and the age at the beginning of sexual life of 17 years (without the use of barrier contraception) in 162 (69.8±3.0%) women drew attention. Analysis of HPV infection showed that persistence of HR-HPV was registered in 170 women (73.3±2.9%), in 106 patients (45.7±3.3%) the viral load (HR-HPV) was more than 105 genomic equivalents, and in 126 (54.3±3.3%) associations of 2 or more types of HR-HPV were simultaneously detected (table 1).

Table 1

Characteristics of HPV infection in examined patients

Type of HPV	Number of the patients (n=232)	
	abs.	%
HR- Persistence of HPV	170	73,3 ±2,9
Genome equivalents more than 10^5 HR-HPV	106	45,7 ±3,3
Genome equivalents less than 10^5 HR-HPV	126	54,3 ±3,3
Simultaneous association of 2 or more HR-HPV types	121	52,2 ±3,3

When analyzing the reasons for seeking medical help from women infected with HPV (n=232), it was found that 85 (36.6±3.2%) patients had no complaints from the genitourinary system, of which 27 (11.6±2.1%) patients sought help for preventive purposes. The remaining 147 (63.4±3.2%) patients had subjective signs of urogenital infections: discharge from the genital tract (97; 41.8±3.2%), rashes in the genital area (41; 17.8±2.5%), 123 (12.9%) women subsequently developed clinical signs of HPV, lower abdominal pain (130; 56.0±3.3%) and other symptoms (menstrual irregularities, pain during intercourse, itching and burning in the genital area - 27; 11.6±2.1%). The above complaints were observed in 32 (13.8±2.3%) patients.

According to the anamnesis data, out of 232 women with HPV, 139 (59.9±3.2%) patients could not accurately indicate the duration of HPV infection, 27 (11.6±2.1%) patients considered themselves infected for less than 2 months, 24 (10.3±1.9%) patients – from 2 months to 1 year, 16 (6.9%) patients – from 1 to 3 years, and 26 (11.3%) patients – more than 3 years. Thus, more than half of the patients (139; 59.9±3.2%) did not know about their HPV infection.

Physical examination of women revealed that out of 48 women with manifest forms of HPV, 32 (66.7%) women had papillomatous lesions localized in the vulva, 10 (20.8%) had lesions on the vaginal

mucosa, 5(10.4%) had lesions in the anal area, and 1(2.1%) woman had lesions in the external urethral opening. The data obtained indicate that the persistence of the virus during infection was 73.3±2.9%,and during transient viral infection–26.7±2.9% (p=0.003).

When assessing the gynecological status of patients with HPV-associated cervical lesions, significant differences were found in the visual assessment of the os and vaginal discharge during examination of the cervix. The most common findings in Group 1 were cicatricial deformation of the cervix and ectropion. According to extensive videocolposcopy, after 12 months of observation, the only colposcopic signs found in the control group were ectopia of the columnar epithelium, the frequency of which did not differ significantly from similar indicators in Group 1. In general, HPV-positive patients were compared in the frequency of detection of acetowhite epithelium, puncturation, mosaic, exophytic condylomas of the cervix, and keratosis. In all patients, no abnormal colposcopic picture was detected at the time of the first examination, which already corresponded to a low-differentiated lesion determined by cytological examination after 1 year. The study of vaginal biotope acidity showed that in patients of the 1st group, slightly alkaline and alkaline reaction of vaginal secretion was more common than in the 2nd group ($p<0.05$). In the control group, neutral reaction of vaginal secretion was recorded in 75% of cases, and slightly alkaline reaction was expressed less often than in the 1st group - 2.7 times ($p<0.05$). Deviations in vaginal tract health indicators (arising against the background of dysbiosis) were detected in every 4th woman with an unsatisfactory course of HPV-associated lesions of the cervix. In patients of the 1st group, slightly acidic reaction of vaginal secretion was determined 3.7 times more often than in the control group ($p<0.05$). Acidic reaction of the cervix also prevailed in patients of the 1st group and was not detected in any woman in the control group. According to the ultrasound examination of the cervix, the length and thickness of the cervix, the thickness of the endocervix, and the visualization of individual endocervical cysts of the cervix were compared. At the same time, in patients of the 1st group, compared with the control group, there was a significantly greater (by 3.29 times, respectively) elongation and

thickening of the cervix ($p<0.05$), thickening of the endocervix (by 4.4 times), detection of retention cysts of the cervix (by 6.3 times, respectively). Comparative analysis of the clinical and anamnestic characteristics of patients in the main and control groups showed that they differed in a number of parameters. Thus, the assessment of complaints (discharge from the genital tract), anamnesis (past STIs, menstrual and reproductive dysfunction, hereditary oncological predisposition), gynecological and somatic status at the time of the examination made it possible to identify a number of universal signs that reliably distinguish patients with HPV-associated lesions from healthy women. Among them: a high burden of previous inflammatory diseases of the genital organs; a high frequency of dysbiotic conditions of the vaginal microecology and vaginal biotope; weak interest in the barrier method of contraception against unwanted pregnancy, childbirth and surgical abortions; high extragenital predisposition and, as a consequence, a low somatic health index (diseases of the gastrointestinal tract, respiratory organs); the presence of bad habits (smoking for more than 3 years). The data of a comparative analysis of biochemical parameters of the contents of the uterine cavity (assessment of the pH level), the state of the ectocervix during extended videocolposcopy, as well as ultrasound examination of the uterine cavity showed significant differences compared to a cohort of practically healthy women.

There were no significant differences in the quantitative indicators of the amount of oncogenic risk virus in patients of groups 1 and 2 infected with HPV genotype 1: the average value of the quantitative indicators of the amount of HPV in patients of group 1 ranged from 0.78 to 7.5 lg copies of HPV DNA per 100 thousand cells, the average value was 3.73±1.54 (median 3.86), and in patients of group 2 – from 0.82 to 7.6 lg copies of HPV DNA per 100 thousand cells, the average value was 3.19±2.07 (median 3.04) ($p=0.06$). However, when infected with 2 or more HPV genotypes, patients in group 2 had significantly higher HPV levels (HPV DNA from 0.81 to 6.84 lg copies, mean 5.45±1.52 (median 6.06)) compared to patients in group 1 (from 0.89 to 7.32 lg copies per 100,000 cells, mean 4.58±1.26 (median 4.63)) ($p=0.01$).

During physical examination, clinical signs of vulvovaginitis (hyperemia, swelling of the mucous membrane of the vulva or vagina, pathological vaginal discharge) were detected in 56 patients (24.1±2.8%) with PVI in the 1st group (in 8 (16.7±5.4%) and 48 (26.1±3.2%) patients in the 2nd group and in 4 (5.0%) patients in the control group). Clinical signs of cervicitis (hyperemia, edema, friability of the ecto- or endocervical mucosa, pathological discharge from the cervical canal) were detected in 163 patients (70.3±3.0%) with PVI in the 1st group (40 (83.3±5.4%) and 123 (68.5±3.4) patients in the 2nd group and 9 (11.3±3.6%) patients in the control group). Pseudo-erosion of the cervical mucosa in childhood was detected in 157 (67.7±3.1%) patients with PVI (33 (68.7±2.6%) patients in the 1st group and 124 (67.4±3.4%) patients in the 2nd group and 3 (3.75%) patients in the control group). In 206 (88.8±2.1%) women with PVI, PVI was associated with pathogens of STIs and urogenital infections, while in patients of groups 1 and 2 it occurred with the same frequency - 41; 85.4±6.9% and 165; 89.7±2.2%, respectively. In 26 (11.2±2.1%) patients with PVI, the causative agent of infection was not detected, while in patients of group 1 - 7 (14.6±5.2%), and the same frequency - in patients of group 2 - 19 (10.3±2.3%). In the comparison group of 80 women, 65 (85.0±3.9%) patients had no infectious factor during the observation period. The most frequently recorded background microbial associations in patients with PVI and in patients of the control group were OM, which were detected in 64.6±6.9% of patients with manifest manifestations of PVI, in 61.9±3.6% - in patients with latent and subclinical forms of PVI. Compared with patients of the 2nd group infected with 1 HPV genotype (73; 55.3±4.3%), the prevalence of OM in this group of patients infected with 2 or more HPV genotypes was higher (37; 71.2±6.2%). Despite the fact that the general structure of PVI is characterized by the presence of obligate pathogenic associations in various variants of the clinical course of PVI (99; 75.8%), the features of OM detection in various variants of the course of PVI have not been determined. Also, no similar features of detection of obligate-pathogenic associations were revealed in different variants of the course of PVI, while in patients of the 2nd group infected with

2 or more HPV genotypes, compared with patients infected with 1 HPV genotype with a high oncogenic risk (13; 3.8%), the disease was detected more often (27; 14.7±2.6%). Viral associations were observed in patients of the 1st group (12; 25.0±6.2%) and the 2nd group (13; 23.4±3.1%) compared with patients infected with 2 or more HPV genotypes (14; 16.3±4.1%). In the case of transient (15; 24.2±5.5%) and persistent (33; 19.5±3.1%) PVI, HPV genotype 1 infection was detected significantly more often (46; 31.6±3.8%), and also more often (15; 24.2±5.5%) in the case of transient PVI compared to the detection of obligate pathogenic associations (8; 12.2±4.1%).

The influence of socio-hygienic factors on the activation of the HPV infection mechanism was determined by grouping 232 examined women depending on their financial status, level of hygiene culture and housing and communal conditions. 232 women with HPV were divided into 3 groups: married - 80 patients (34.5±3.0%), unmarried young people - 38 patients (16.4±2.2%), unmarried adults (mostly divorced) - 114 patients (49.1±3.2%).

The awareness of their sexual partners about the disease was also determined, namely: the degree of awareness, cessation of sexual activity, diagnostic examination and specific treatment. Of course, there are quite a lot of socio-hygienic factors, but we selected those that have the greatest epidemiological significance in the spread of HPV. It is no coincidence that they have the lowest level of HPV infection - 4.8±1.4%. As the level of infection decreases, it gradually increases to 7.2 ± 1.8% ($t = 2.36$; $p < 0.01$), then to 16.5 ± 1.8% ($t = 6.14$; $p < 0.001$) and reaches the highest value among women with an extremely low financial situation, who irregularly and rarely observe hygiene rules, living in primitive housing and communal conditions - 28.6 ± 1.5% ($t = 4.75$; $p < 0.001$). This fact is most likely explained by the fact that the above-mentioned socio-hygienic factors are usually characteristic of socially less adapted segments of the population - these include fragile family ties, single-parent families, late and unsuccessful marriages, extramarital sex, irregular sex when it is impossible to start a family, etc. That is,

favorable conditions are created for the spread of infections in these population groups.

When identifying the listed social and hygienic factors, we noticed a rather interesting pattern. Thus, as these factors worsen, the number of families increases. First of all, we note that among the 232 women we examined, the proportion of women from families consisting of 1-2 people is quite high - 22.4±2.7% (52 women), but the largest proportion of families of 3-5 people is 43.7±3.2% (100 women, t=8.54; p<0.001). As the number of families increases, their proportion decreases. Thus, the proportion of families consisting of 6-8 people is 19.5±2.6% (45 women, t=9.76; p<0.001), the proportion of families consisting of 9-11 people is even lower - 13.0±2.5% (31 women, t=11.98; p<0.001), the proportion of families consisting of 12 people is the lowest - 2.0% (4 women, t=13.09; p<0.001), that is, the more family members, the lower their frequency of occurrence (Г=-0.68±0.21; p<0.05).

To assess the risk factors, a retrospective case-control study was conducted among 312 examined women aged 18-44 years. In this case, 2 groups were formed: group I - 232 women with YR-IPV (genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59), group II - 80 women with negative IPV test results. Risk factors were assessed based on questionnaire data. When analyzing socio-demographic indicators, it was found that women with IPV infection did not have higher education, but more often had secondary education (OR = 1.60; p = 0.013), and were not married (OR = 1.13; p < 0.001). Of the bad habits, only alcohol consumption was not associated with a higher risk of IPV infection (OR=1.03; p=0.813). Smoking was more common in women of group I (OR=2.71; p=0.001, p<0.001, respectively). The effect of smoking cessation on reducing the risk of HR-HPV infection was analyzed separately. Then, the obstetric and gynecological history was assessed in the examined groups. The duration of menstruation did not differ statistically significantly: in women of group I it was 4.7±1.2 days, in group II - 4.5±1.1 days (p=0.176). Patients of group I more often complained of postcoital bloody discharge (p=0.036), while patients of both groups noted lower abdominal pain and profuse vaginal

discharge with the same frequency (p=0.888 and p=0.281, respectively). The nature of sexual activity is also a risk factor for HPV infection. In patients of group III, the first sexual experience occurred at 17.8±2.1 years, and in women of group IV – 1 year later – at 18.6±2.3 years (p<0.001). In the group of HPV-infected women, the onset of sexual activity in 2/3 cases (71.2%) occurred before the age of 18, and in HPV-negative women – at 18 years and older (88.6%).

The groups are basically comparable in terms of the incidence of various gynecological diseases. It is noteworthy that some diseases, such as uterine myoma and endometriosis, are quite common in women with negative HPV test results (p=0.084 and p=0.052, respectively). Some authors note the presence of various surgical manipulations on the cervix in the anamnesis among risk factors. In this study, such a dependence was not revealed (p>0.05). The presence of various somatic diseases in the respondents and oncological diseases in close relatives did not affect the incidence of HR-HPV infection (p>0.05). Oncology of any localization was detected in 56.0±3.3% (130 cases) of the relatives of patients in group I, group II - in 48.7±5.6 (39 cases; $\chi 2$=0.36; p=0.551). The probability of this event (HPV infection) occurring is 90%.

Timely detection of HPV patients and their effective treatment are considered the most effective preventive measure, since they lead to the neutralization of the source of infection and the prevention of its further spread. Therefore, mandatory treatment of sexual partners is considered an effective preventive measure. It is noteworthy that among the patients there were more divorced people (114 people (49.1±3.3%)), who are already adults, sometimes leading an independent lifestyle with different sexual partners and, therefore, are more susceptible to the risk of HPV infection. The number of married patients was less - 80 people (34.5±3.1%; t=10.51; p<0.001), among whom there were also people from risk groups. Unmarried women were registered less often - 38 people (16.4±2.4%; t=4.92; p<0.001). A total of 84 (36.2±3.2%) women informed their partners about their disease, 101 women (43.5±3.3%) stopped having sex, 47 sexual partners (20.3±2.6%) considered it necessary to undergo diagnostic examination, and 18.5±2.5% of them were involved in specific

treatment when HPV was detected. With such a high risk of infection of sexual partners, only 18.5±1.2% (43 people) received specific treatment, which, of course, could have allowed for HPV prevention. However, the noted indicators in different groups of patients differed significantly. Thus, among married women, the indicator of informing sexual partners about their disease is the highest - 61.2±5.4%, and the reason for this is quite understandable, since it is impossible to hide the disease in the family for a long time, and from a moral and ethical point of view this is incorrect, and especially in such cases there is a need to preserve the family. This indicator is slightly lower among unmarried women – 23.6±6.8% ($t=6.44$; $p<0.001$) and the lowest in the group of divorced patients – 14.9±3.3% ($t=2.38$; $p<0.05$), since they have no particular need to inform their partners about the disease. Interestingly, among patients who got married for the above-mentioned reasons, the frequency of diagnostic examination by their sexual partners is the highest – 36.2±3.2%, among unmarried patients this indicator decreases to 25.0±3.2% ($t=3.28$; $p<0.001$), and among divorced patients it reaches the lowest values – 11.4±5.4% ($t=3.42$; $p<0.001$). As a result, the frequency of specific treatment of sexual partners when HPV is detected in these groups of patients decreases in the same sequence - to 26.8 ± 3.2%, 15.6 ± 3.% ($t = 3.56$; $p < 0.001$) and 5.5 ± 1.4% ($t = 3.36$; $p < 0.01$), respectively.

The implementation of organizational and methodological measures aimed at early detection of CC is considered a priority task, since even with the help of surgical treatment of most "localized" In the treatment of oncological diseases, 90-95% of cancer patients can achieve a stable long-term cure. The incidence rate for each cancer localization depends on a complex of numerous factors to which the patient was exposed before the disease, and the body's response to these multifactorial effects. This complex includes the duration of the disease, the age of puberty, the nature of the menstrual function, the reproductive function, sexual function, endocrine and metabolic disorders, previous diseases, genetic factors, psycho-emotional factors, socio-economic factors, ethnicity and other parameters. Currently, socio-economic factors are considered by researchers as important in terms of their impact on public health.

At the stage of providing medical care, primary and secondary prevention of cervical cancer is carried out. Primary prevention includes:

1) identification of risk factors for the development of cervical cancer and their elimination, including promotion of a healthy lifestyle, health education, counseling of women and men, increasing the literacy of the population in the area of sexual behavior, intimate hygiene;

2) organization of preventive vaccination against HPV. Secondary prevention is cervical screening, that is, examination of women in order to identify benign and precancerous pathologies of the cervix and their timely treatment.

In our opinion, the main measures enabled by cervical cancer to improve oncological care for patients include: the proper and high-quality operation of examination rooms, and their establishment in all outpatient and polyclinic facilities; the mandatory collection of smears for cytological examination during all types of medical screenings; a more advanced system for increasing the professionalism of primary-level oncology physicians; the organization of thematic seminars for general healthcare network doctors on the early diagnosis and treatment of female genital cancers; and the obligatory study of regional characteristics of the spread of malignant tumors of the cervix.

Based on the data obtained, an algorithm for screening cervical cancer was developed, presented in Figure 3.

When infection with 2 or more genotypes of high oncogenic risk HPV or 16 genotypes of HPV is detected, quantitative indicators of high oncogenic risk HPV are more than 5 lg copies of HPV DNA per 100 thousand cells, subclinical forms of HPV, persistent course of the infectious process, a high risk of developing a pathological process of the cervix associated with high oncogenic risk human papillomavirus is predicted. At the same time, the detection of a combination of these indicators increases the risk of developing pathological processes (especially with epithelial changes in the mucous membrane of the cervix).

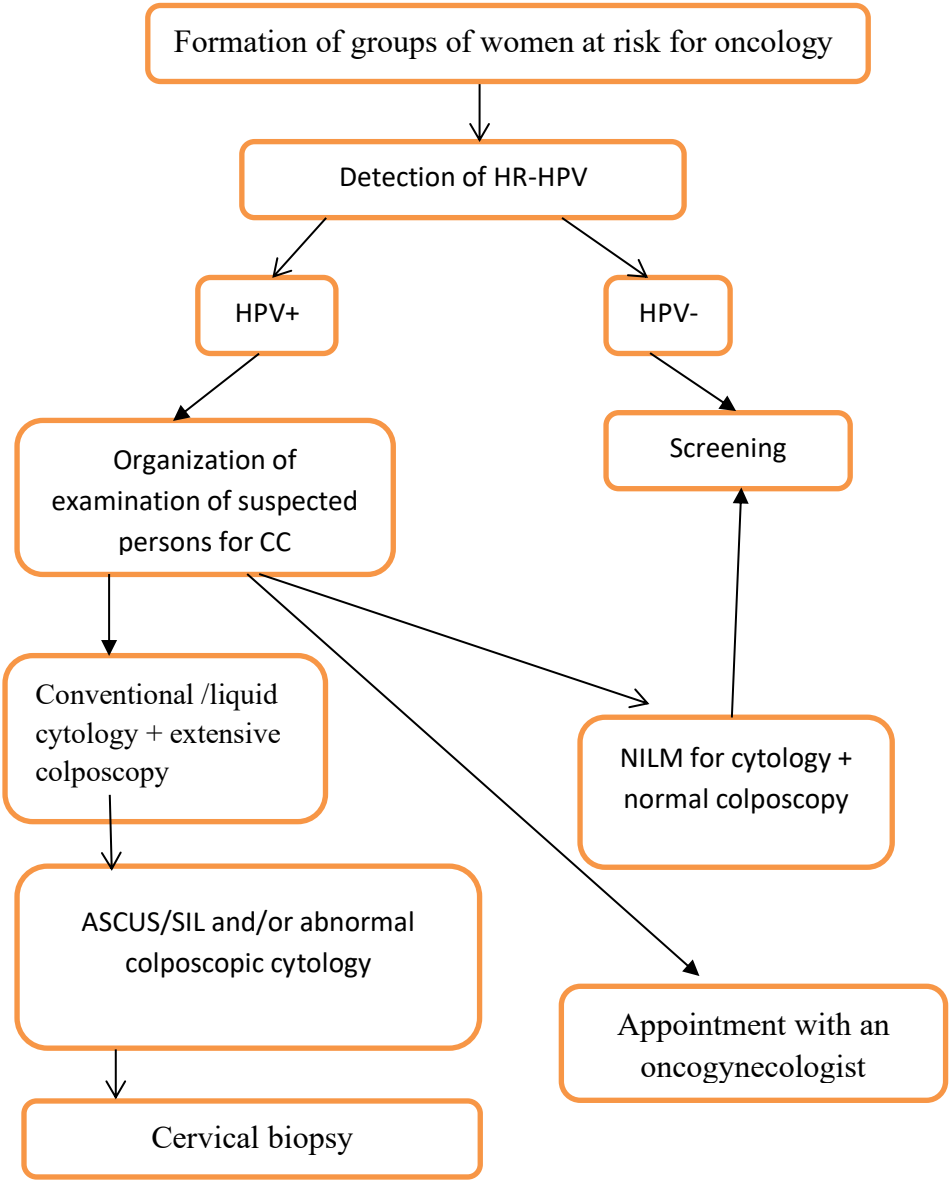

Fig. 3. Algorithm for screening of CC

Patients are recommended:

- gynecologist consultation;
- colposcopic examination and cytological examination of smears from the mucous membrane of the cervix;
- repeat examination after 6 months with determination of the genotype and quantitative content of high-oncogenic risk HPV.

New opportunities for specialized treatment methods can yield high results only under conditions of improved organizational forms of medical services, and above all, through the enhancement of the dispensary method, which has proven effective in the past. Strengthening the organizational-methodological work of oncology institutions - especially oncology dispensaries - and ensuring their close cooperation with all bodies of the regional healthcare system and the treatment network is considered a key condition for improving the quality of oncological care.

Clinical and anamnestic data and diagnostic characteristics obtained in the groups of patients allowed us to identify statistically significant risk factors for the development of malignant pathology of the cervix. In order to further improve approaches to the formation of high-oncogenic risk groups, we conducted the next stage of research aimed at identifying pathogenetic risk factors for the development of cervical cancer by precise assessment of risk factors in pathological processes of the cervix associated with PVI.

RESULTS

1.According to the results of the epidemiological analysis, 3031 cases of cervical cancer were registered in Azerbaijan during the period 2014-2018. In 2018, this figure increased significantly compared to 2014, reaching 682 cases, which is 22.8% more. During the period under review, the incidence rates of cervical cancer varied from 11.5% to 15.1%, showing only minor fluctuations. During the exami-nation of women, HR-HPV was detected in 16.9±2.5% of them [1, 3, 4, 5].

2.Criteria have been developed for predicting the development of pathological processes of the cervix associated with high onco-

genic risk human papillomavirus, according to which the risk group includes women infected with more than two genotypes of oncogenic risk viruses or with a quantitative indicator of the amount of HPV DNA of the 16th genotype of more than 5 lg copies of HPV DNA per 100 thousand cells, with subclinical or latent forms of HPV, persistent and infected with HPV for more than 6 months [2, 6, 7].

3. The most significant clinical and statistical risk factors for exacerbation of the pathological process of HPV-associated cervix and the development of malignant transformation (with the highest OR>1 and the lower limit of 95% CI>1) are: viral load equal to more than 105 genomic equivalents of HPV-HPV; persistence of HPV-HPV; previous morphologically verified CIN in the anamnesis; Mixed sexually transmitted infections (3 or more); recurrent bacterial vaginosis; traumatic injury to the bladder (postpartum, after abortion); early onset of regular sexual activity (before 17 years) - without the use of barrier methods of contraception; more than 3 sexual partners (since the onset of sexual activity); simultaneous presence of 2 or more types of HR-HPV; chronic cervicitis; hereditary predisposition to cancer of the reproductive system; hereditary predisposition to other oncological diseases; concomitant presence of uterine fibroids with adenomyosis and / or endometrial hyperplasia; smoking [8, 9, 10, 11, 13].

4. Liquid cytology has the highest specificity (specificity - 100%) and DN+ in detecting both LSIL and HSIL. The efficiency of HSIL detection using HPV testing was high regardless of the method of material collection (when material was collected by a doctor - 86.8%, when collected by Gvintip -91.1%). The most efficient prognostic model for HSIL detection is the use of colposcopy in combination with HPV (sensitivity - 73.5%; specificity - 72.1%). Adding liquid cytology to the HPV test increases the specificity to 100% [12, 14, 15].

5. Prevention of cervical cancer depends on the organizational forms of referral to more professional specialists (gynecological oncologists), the availability of highly informative examination methods, the mandatory use of methods for individual prediction of its occurrence in this group of women and ensuring timely treatment

of precancerous pathology of the cervix in the conditions of modern healthcare [14, 16, 17, 18].

PRACTICAL RECOMMENDATIONS

1. For an individual approach to HPV-associated cervical diseases, it is advisable to conduct comprehensive clinical examinations with an assessment of clinical and amnestic parameters, as well as the determination of epigenetic characteristics, and on this basis to identify high or low oncological risk groups.

2. Laboratory studies should be aimed at identifying HPV pathogens, including oncogenic risk viruses. It is recommended to conduct studies using the PCR method in real time to identify the genotypes of oncogenic risk viruses and determine quantitative indicators of the virus amount.

3. Indications for testing for high oncogenic risk HPV are: anogenital warts, other sexually transmitted infections, in women - vaginal pathology and / or changes in colposcopic or cytological examination, sexual contacts with partners who have positive PCR results for HPV and / or anogenital warts.

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ABBREVIATIONS

AMU	–	Azerbaijan medical university
CC	–	Cervical cancer
CI	–	Confidence interval
CIN	–	Cervical intraepithelial neoplasia
COC	–	Combined oral contraceptives
CIS	–	Carcinoma in situ
CU	–	Cervix uteri
DNA	–	Deoxyribonucleic acid
GIN	–	Genital intraepithelial neoplasia
HİV	–	Human immunodeficiency virus
HPV	–	Human papilloma virus
HSIL	–	High-grade squamous intraepitelial lesions
HR - HPV	–	Human papilloma virus with high oncogenic risk
LSIL	–	Low-grade squamous intraepitelial lesions
NPV	–	Negative predictive value
NiLM	–	Normal, corresponds to class 1 smear, no intraepithlial lesion
OM	–	Opportunistic microbes
OR	–	Odds ratio
PVİ	–	Papillomavirus infection
STIs	–	Sexually transmitted infections

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