

West-Pomeranian program of cervical cancer prevention Results of phase one study

Maria Chosia, Wenancjusz Domagała

Introduction. Although the morbidity and mortality rates in invasive cervical carcinoma have been invariably high in Poland, yet no national program of cervical cancer prevention has ever been introduced. We believe that in order to implement a national program properly one should base on experience acquired in regional centers.

Material and methods. Under the West Pomeranian Program of Cervical Cancer Prevention mass cytological screening (a total of 105,750 women) was performed in the West Pomeranian voivodship. The smears were evaluated in a cytology lab where laboratory and diagnostic procedures are subject to internal quality control.

Results. In total, 735 pathological lesions (0.7%) were detected, including 711 intraepithelial lesions and 24 cases of invasive carcinoma. The analysis of smear quality demonstrated a high percentage of suboptimal smears (59.5%), while 3.2% of samples were unfit for any assessment. The rate of detection of intraepithelial lesions and carcinoma was much higher in good quality smears as compared to suboptimal samples (0.90% vs. 0.65%).

Conclusions. The effectiveness of cytological screening is affected by quality control including also the collection of cytological smears. Therefore, before any nation-wide cervical cancer screening program is implemented the quality of smears taken by gynaecologists has to be improved and both the Bethesda system of assessment of smears and the internal quality control measures introduced in cytology laboratories participating in the program.

Zachodniopomorski program profilaktyki raka szyjki macicy Wyniki I fazy badań

Wstęp. Mimo, że wskaźniki zachorowalności i umieralności na raka inwazyjnego szyjki macicy w Polsce utrzymują się od wielu lat na wysokim poziomie, nie było jak dotąd ogólnopolskiego programu profilaktycznego zwalczania raka szyjki macicy. Uważamy, że dla właściwej implementacji programu ogólnopolskiego mogą mieć znaczenie doświadczenia lokalne.

Materiał i metoda. W ramach Zachodniopomorskiego Programu Profilaktyki Raka Szyjki Macicy przeprowadzono w województwie zachodniopomorskim przesiewowe badania cytologiczne u 105750 kobiet.. Oceny rozmazów dokonano w pracowni cytologicznej, w której procedura laboratoryjna i diagnostyczna objęta jest wewnętrzną kontrolą jakości.

Wyniki. Łącznie wykryto 735 zmian patologicznych (0,7%), w tym 711 zmian śródplaskonabłonkowych (SIL) i 24 przypadki raka inwazyjnego. Analiza jakości rozmazów wykazała wysoki odsetek rozmazów suboptymalnych (59,5%) i 3,2% rozmazów nie nadających się do oceny. Wykrywalność zmian śródplaskonabłonkowych i raka była znacznie wyższa w grupie rozmazów odpowiednich do oceny w stosunku do rozmazów suboptymalnych (0,90% vs 0,65%).

Wnioski. 1. Ważnym elementem wpływającym na skuteczność skryningu cytologicznego jest kontrola jakości, obejmująca także sposób pobrania materiału cytologicznego. 2. Program profilaktyczny powinien być koordynowany regionalnie, gdyż: a) rekrutację kobiet do badań profilaktycznych można powierzyć położnym; b) można uzyskać lepszą jakość rozmazów przez zawarcie w kontrakcie odpowiednich zapisów; c) Regionalne Kasy Chorych posiadają dokładne i aktualne populacyjne bazy danych.

Key words: cervical cancer, cytological screening, quality control

Słowa kluczowe: rak szyjki macicy, skryning cytologiczny, kontrola jakości

For the past 30 years the morbidity and mortality rates of women with invasive cervical cancer in Poland have been alarmingly high [1]. During this time, in numerous countries a significant drop in cervical carcinoma mortality has been achieved due to the introduction of mass cytological screening programs [2, 3]. The number of cytological gynecological tests performed annually in Poland is estimated as approximately 2 million [4]. Nevertheless, no significant decrease in cervical cancer mortality has been achieved, presumably because of the low effectiveness of these tests. The low efficacy may result from several factors, such as targeting inappropriate age groups and lacking implementation of appropriate quality control [5-8]. Nevertheless, it should be emphasized that there are centers in Poland which have been actively performing cytological screening tests for years, e.g. for example in Bialystok [9]. To date, there has been no national program of cervical cancer prevention in Poland. In 2001, the Maria Skłodowska-Curie Memorial Cancer Centre and Institute of Oncology in Warsaw initiated a Program of Model Screening for Breast and Cervical Cancer in Poland (headed by Professor Zbigniew Wronkowski) in which only 45 000 women were screened in the 6 centers which participated in the program.

Below we present the results of Phase One of the West Pomeranian Program of Cervical Cancer Prevention in which a total of 105750 women were screened. We believe that experience gained in the regional center may be of help in future implementation of the nation-wide screening program.

Material and method

The West Pomeranian Program of Cervical Cancer Prevention was initiated in 2001. The program was based on mass preventive cytological screening of women in the 20-59 age group. (In the first year of the program, it was decided to include also women above 59 years of age in order to detect invasive carcinomas in this age group). In the West Pomeranian Province the population of females aged 20-59 years is approximately 496,000. The program has been carried out in the Cytology Lab of the Department of Pathomorphology, Pomeranian Medical University, which employs 9 cytology technicians and 3 specialists in pathomorphology with long-term experience in cytodagnosis. The program was financed by the West Pomeranian Sick Fund (WPSF). The principles of the program are presented in Figure 1. In 2001, a total of 105750 cytological tests were performed in women who visited a gynecologist upon their own initiative following a vigorous regional media campaign. In 2002, the Second Phase was commenced (active screening), where the age range was restricted to 25-59 years. In the Second Phase women from selected counties were invited to participate in cytological testing by community midwives.

The smears were collected by gynecologists and stained according to the Papanicolaou method using an automatic stainer (Shandon). The results of the cytological tests were described according to the Bethesda system. The diagnostic procedures of the Cytology Lab were subject to internal quality control, including re-screening of 10% of randomly selected negative smears and consultations of all positive and suspicious smears by a pathologist. The principles of quality control observed in the Lab are in accordance with the recommendations formulated by European Union experts [7].

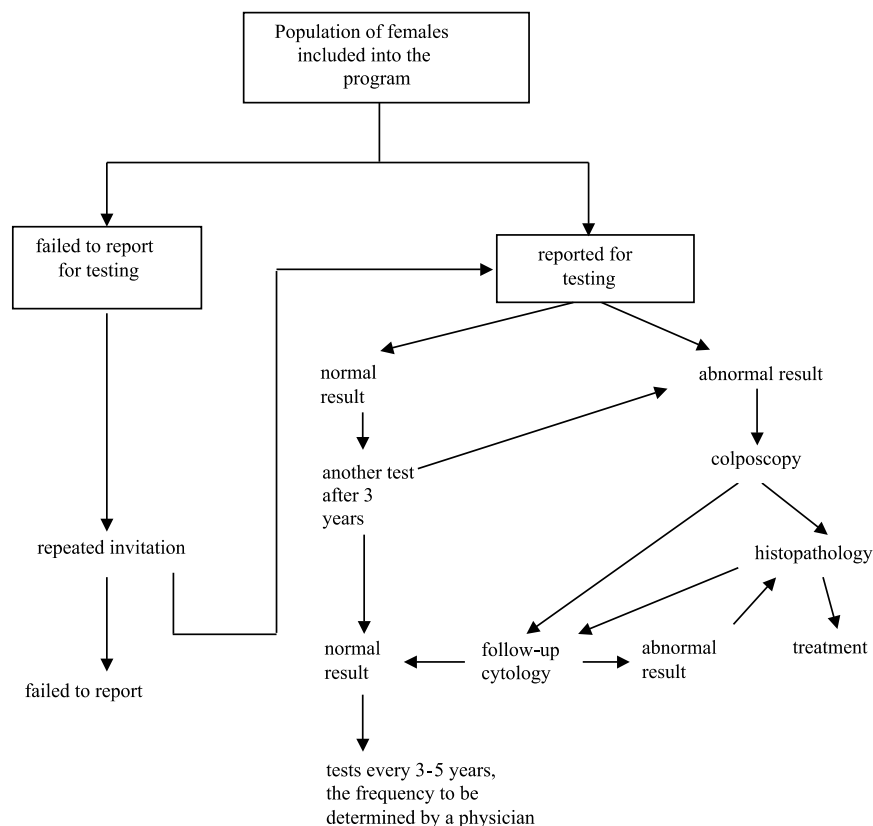


Figure 1. The West Pomeranian Program of Cervical Cancer Prevention

Results

About 37% of all women examined were those below 30 years of age. (Figure 2). However, only 14.9% women in the age group 31-40 showed up. In total, 735 (0.7%) pathological lesions were detected, including 711 intraepithelial lesions and 24 cases of invasive carcinoma. Figure 3 presents detectability rates of pathological lesions depending on age. In women below 30 years of age the high percentage of low grade intraepithelial neoplasia (CIN I and/or HPV/SIL-LG) was found (295/39223 women tested). In the age group below 25

years, CIN I cases were predominant. In the group aged 31-40 years, where the attendance rate was low, 44 cases of high grade intraepithelial lesions (CIN II and CINIII/SIL-HG) and three invasive carcinomas were found. Thus the highest percentage of SIL-LG was noted in young women and it gradually decreased with age. Conversely, with growing age the number of invasive carcinomas increased. Above 61 years of life invasive carcinomas accounted for 23.5% pathologies, while in women aged 31-60 years – for 4.8%.

The analysis of smear quality based on the Bethesda system [10] revealed a very high percentage of smears of

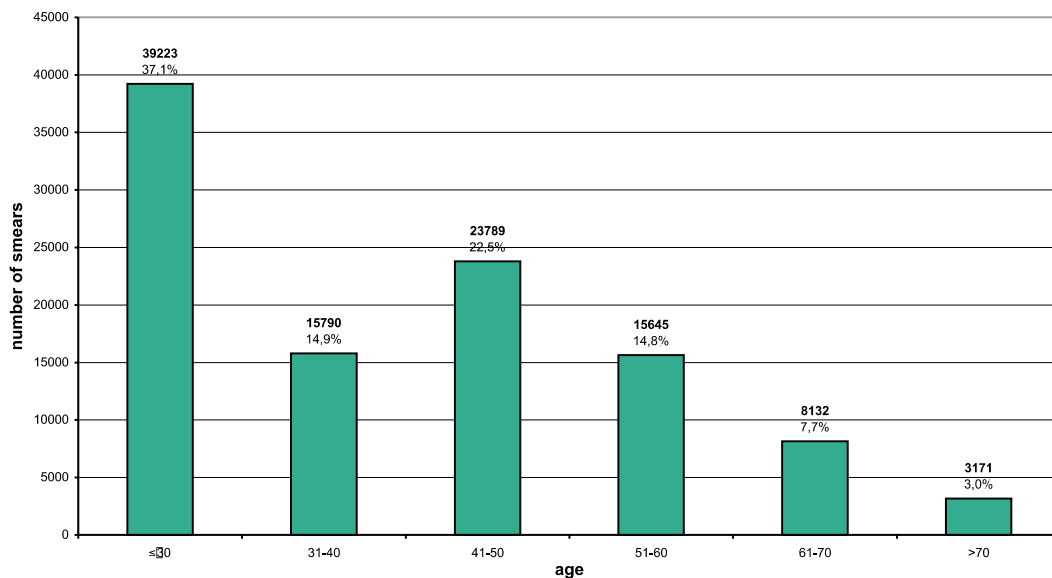


Figure 2. Recruitment of women in relation to age (n=105750)

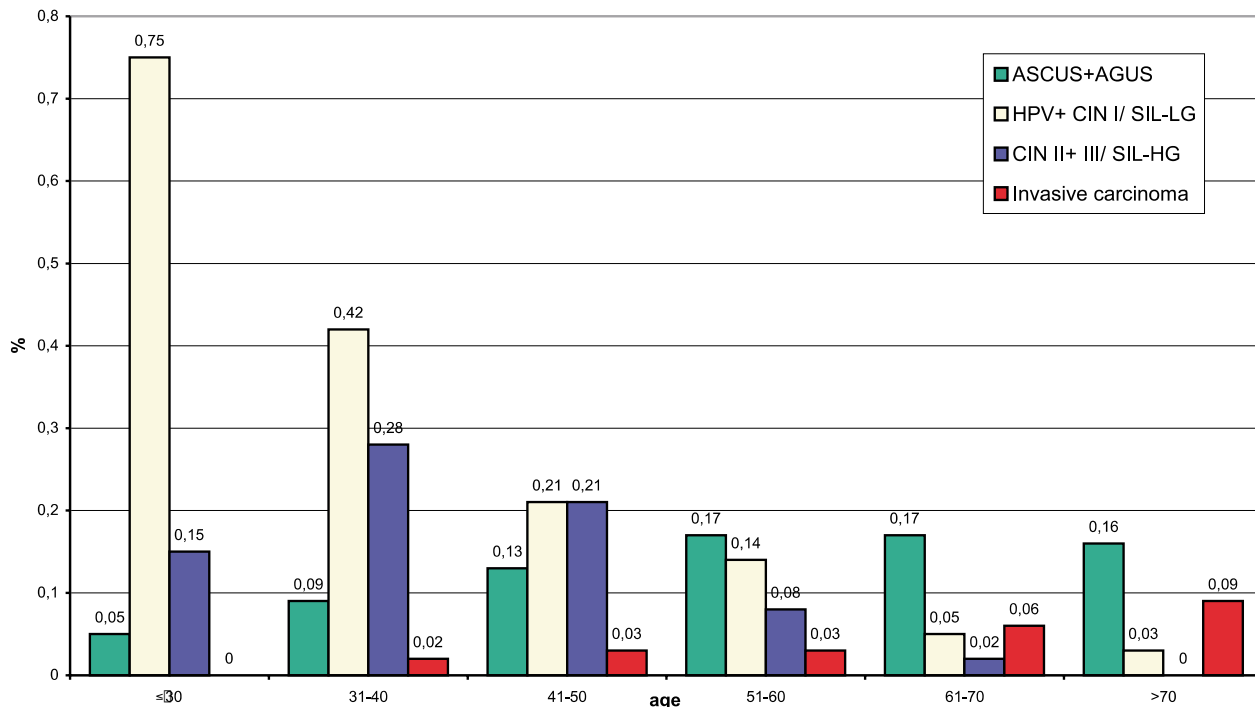


Figure 3. Percentage of epithelial abnormalities in relation to age

suboptimal quality (AII-59.9%) (Figure 4). Here the largest group contained smears devoid of columnar cells of the cervical canal. Smears unacceptable for cytological evaluation (A III) constituted 3.2% of all the samples. We noted a correlation between the quality of the smears and the detectability rate of lesions in cytological tests. In the group of appropriate smears (A I), the detectability rate was 0.90%, while in the group of suboptimal quality smears (A II) – only 0.56% (Figure 5).

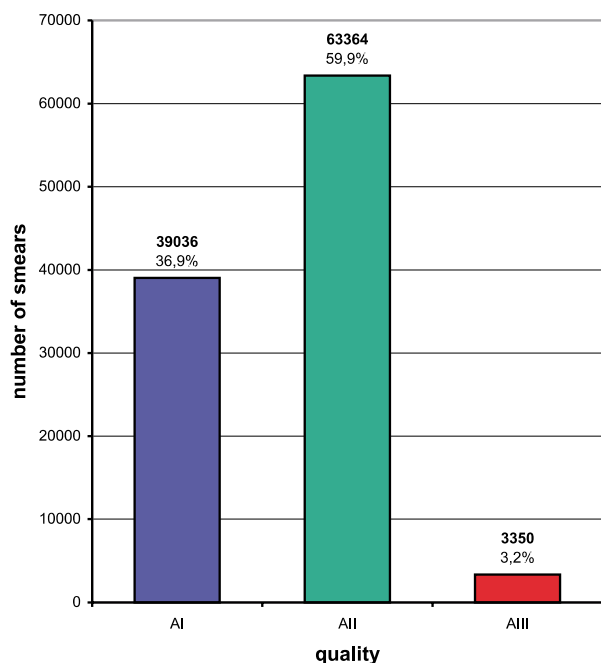


Figure 4. Quality of smears (n=105750)

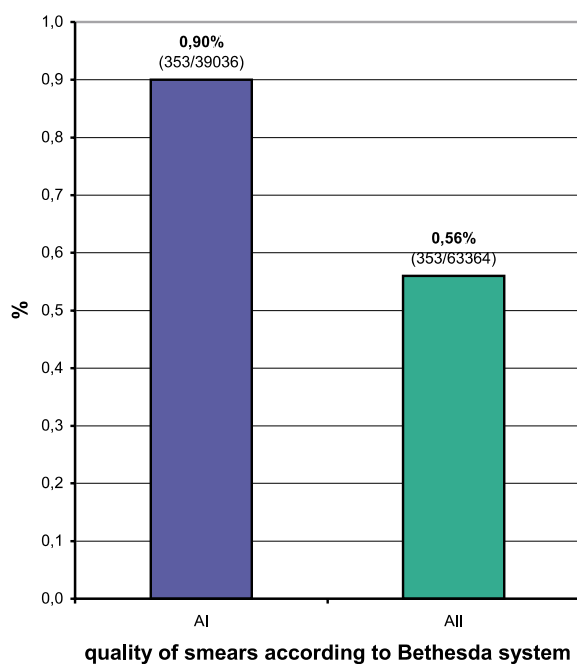


Figure 5. Quality of smears in relation to percentage of detected epithelial abnormalities (number of epithelial abnormalities/number of cytological smears is given in brackets)

Discussion

Experience gained in numerous countries, and especially in Scandinavia, indicates that the introduction of well organized cytological screening programs results in a significant decrease of the mortality rates due to cervical cancer [7]. It has been observed that mass screening programs should be carried out in an administratively defined area (where population registers are available) which is inhabited by at least 250,000 members of the target population. These requirements have been met in our program. The population of women that was ultimately included into the study, was 496,000 and WPSF, the co-organizer of the screening program, has at its disposal the most current population data. In the first phase of the program, the method of passive prevention was employed, i.e. the tests were performed in all women who reported to gynecologists following an intensive campaign in the regional media and among gynecologists whose services had been contracted by WPSF.

A recommended method of increasing the attendance rate is based on an individual system of invitations [7] that may be mailed [9], delivered by trained workers of local administration [11], or by appropriately trained health care personnel. In the second phase of our program this role is to be assigned to community midwives, because in the West Pomeranian province there operates a network of community midwife practices, with one midwife per 10,000 insurance holders. The database maintained by WPSF and the identity PESEL number have been utilized. The experience of other centers indicates that other population databases may be subject to errors involving the current domicile of individuals recruited into a program. For example, during the screening study carried out in the Podlaskie Province in the years 1993-95, as many as 8% of addresses proved to be erroneous [9].

European Union experts recommend cytological gynecological screening tests to be performed in women belonging to the 25-65 year age group [7]. The results of population studies carried out in some countries, e.g. in Iceland [3], point to the necessity of commencing screening in 20-year old females and terminating the program in women aged 60-64 years. Our experience shows that in women below 25 years of age the predominant pathology are low-grade intraepithelial lesions. Since the majority of such lesions progress to higher CIN grades over a several-year period (5-10 years), it seems worthwhile to increase the lower age limit in screening tests to 25 years. However, it should be stressed, that the recommendations commonly advice screening in young women (in the US as early as 18 years old) [12], although it has been known that approximately a half of CIN I and CIN II cases may spontaneously regress [13, 14]. In view of the reported data and our experience in the course of the West Pomeranian Program of Cervical Cancer Prevention, the Second Phase of the Program will include women aged 25-59 years.

According to the UICC report maximum effectiveness of screening may be achieved when the program is carried out in an organized way in women aged 25-60 years with the frequency of testing every 3-5 years [15]. In addition, the European Union experts recommend that screening programs involving healthy women and performed more often than every 3 years should not be financed out of public funds, since their effectiveness is not significantly increased [7]. That is why in our program the 3-year time interval has been accepted and the decision involving more frequent testing has been entrusted to the gynecologists.

A very important, although underestimated, element that affects the effectiveness of screening programs is quality control which includes the method of smear collection, smear preparation and its microscopic assessment. According to Solomon [16] more than 50% of false negative results depends on the way the material was collected and prepared. We have also reported the relationship between the effectiveness in detecting pathological lesions and smear quality [5, 11]. The cytological diagnosis established according to the Bethesda system contains information on the quality of the smear. The analysis of Phase One results of the West Pomeranian Program of Cervical Cancer Prevention indicates that the detectability rate of pathological lesions in smears the quality of which was appropriate for analysis was 0.90%, while in suboptimal smears it was as low as 0.56%. It has been shown on the basis of comparative studies, that cotton swabs should be abandoned in favor of cytobrushes for smear collection [17-19]. To minimize the number of false negative results, numerous countries have initiated quality control procedures based on recommendations formulated by European Union experts [7]. In Poland such principles were developed by a team of pathomorphologists headed by Professor A. Kulig and published in 1999 [20].

The results we present here have been gathered in Phase One of the Program. The Program was coordinated on a regional level and based on financial support of the Sick Fund, for which supporting preventive programs is a statutory obligation. Prevention is also a significant element of the National Health Fund. We have shown that the effectiveness of cytological screening is affected by the quality control. That also includes the method of collection of cytological smears. Therefore, before any nation-wide cervical cancer screening program is implemented the quality of smears taken by gynaecologists has to be improved and the Bethesda system of assessment of smears together with the internal quality control measures introduced in cytology laboratories taking part in the program.

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