

# *The level of Pap test positivity and the factors associated with it among adult women in Fier, Albania*

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***Eduard KAPAJ, MD***

OBSTETRICS AND GYNECOLOGY SERVICE,  
FIER REGIONAL HOSPITAL, FIER, ALBANIA  
CORRESPONDING AUTHOR  
E-mail: edikapaj@yahoo.com

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***Arben MITRUSHI, MD, Prof. Asoc***

DEPARTMENT OF MORPHOLOGY, FACULTY OF MEDICINE,  
UNIVERSITY OF MEDICINE, TIRANA, ALBANIA

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***Ervin TOÇI, MD, Dr. Sc.***

DEPARTMENT OF PUBLIC HEALTH, FACULTY OF MEDICINE,  
UNIVERSITY OF MEDICINE, TIRANA, ALBANIA

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***Sonila KAPAJ, MD***

OBSTETRICS AND GYNECOLOGY SERVICE,  
FIER REGIONAL HOSPITAL, FIER, ALBANIA

## **Abstract**

*Purpose: Cervical cancer continues to remain a major concern for public health globally. The aim of this study was to determine the positivity level of the Pap test and the prevalence of cervical potentially pre-malignant and malignant lesions in a group of adult women aged 18 years and older in Fier Prefecture in Albania.*

*Material and methods: This cross-sectional study included 1254 women who showed up for a Pap test at the gynecology service at the Fier Regional Hospital during*

2013 and 2014. Basic socio-demographic data (age, place of residence, marital status) as well as data related to women's gynecological history, including information related to menopause status, current pregnancy, menstrual cycle (regular or irregular), data on previous diseases of the genital tract, previous cytological examinations, and previous biopsies was collected. Adequate cervical smears were interpreted, allowing the calculation of the prevalence of various cervical lesions. Binary logistic regression was used to identify factors associated with a positive Pap test result.

*Results:* The average age of women in our study was  $39.8 \pm 10.7$  years. About two-thirds of women resided in urban area, 99.1% were married at the time of the survey and 17.8% were in menopause. Only 1.8% of women had been subjected to a cytological examination in the past. Among the 1134 adequate cervical smears the level of positive Pap test result was 8.7% and the prevalence of LSIL, HSIL and ASC-US was 4.1%, 1.6% and 3%, respectively. No cases of squamous carcinoma were detected. Age was positively, strongly and significantly associated with a positive Pap result: compared to 21-30 years old women, those aged 31-40, 41-50 and >50 years were significantly 1.98, 6.09 and 14.07 times more likely to have a positive Pap test reading. There was a tendency for the Pap test positivity to be higher among urban woman, probably due to earlier initiation of sexual activity and more sexual partners compared to rural women. Only 2% of women had had cytological examinations in the past.

*Conclusions:* The prevalence of abnormal Pap test among adult women in Fier prefecture was relatively high even though comparable to national and international studies. There is need to increase the awareness of women about cervical cancer and their participation in cervical cancer screening programs.

**Keywords:** Albania, ASC-US, cervical cancer, HSIL, LSIL, Pap test.

## Introduction

Cervical cancer continues to remain a major concern for public health in all countries of the world. Cervical cancer is the fourth most common cancer in the world in women: in 2020 there were 640,000 new cases were registered and 342,000 women lost their lives from cervical cancer during; about 90% of new cases and deaths worldwide in 2020 occurred in low- and middle-income countries (Sung et al., 2021). More than 85% of the global burden of cervical cancer occurs in developing countries, where these cancers represent over 12% of all cancers in women. Cervical cancer was the most commonly diagnosed cancer in 23 countries and was the leading cause of death of women in 36 countries of the world in 2020; the vast majority of these countries are found in sub-Saharan Africa, Melanesia, South America, and Southeast Asia (Sung et al., 2021).

Cervical cancer screening programs accelerated the decline in cervical cancer incidence and mortality through the implementation of such interventions in many countries in Europe, Oceania and North America (Sung et al., 2021). These rates have also decreased in Caribbean and Central and South American countries (eg, Argentina, Chile, Costa Rica, Brazil, and Colombia) during the 2000s, although incidence rates remain high (Sung et al., 2021). In the absence of effective screening, as in Eastern Europe and Central Asia, there has been a rapid increase in premature mortality from cervical cancer in recent generations (Sung et al., 2021). Perhaps most concerning are the uniform increases recently reported in 7 out of 8 sub-Saharan African countries, including Gambia, Kenya, Malawi, Seychelles, South Africa, Uganda, and Zimbabwe (Sung et al., 2021).

In 2018, given the significant global burden of cervical cancer and growing inequality, the WHO Director-General issued a call for global action to eliminate cervical cancer (target:  $\leq 4$  cases per 100,000 women worldwide) through the triple intervention strategy of: 1) vaccinating 90% of all girls by age 15, 2) screening 70% of women twice in the 35 to 45 age group, and 3) treatment of at least 90% of all pre-cancerous lesions detected during screening (Sung et al., 2021). A modeling of achieving these targets predicted that over 74 million cases of cervical cancer and more than 62 million deaths from cervical cancer could be avoided over the next century (Sung et al., 2021). This target is projected to be reached between 2055 and 2059 in developed countries, while in developing countries it may be reached by the end of the 21st century, reflecting the apparent gap in baseline incidence rates and the resources needed to achieve the goal (Sung et al., 2021). To achieve these goals, it is important that the population of women is screened according to the guidelines of international health authorities. The application of the Pap test for the screening of cervical cancer has been associated with a spectacular decrease in the incidence of this cancer in all developed countries (Gustafsson et al., 1997). Since the Pap test is essential for the early detection, prevention and control of cervical lesions with a potentially malignant nature, it is important to study the prevalence of lesions diagnosed through the Pap test (the level of Pap test positivity) as well as the factors associated with it. This was exactly the purpose of this study conducted in a population of adult women aged 18 and over in Fier Prefecture.

## **Methodology**

### *Study design*

This is a cross-sectional study. The study population included all women who showed up for a Pap test at the gynecology service at the Fier Regional Hospital during 2013 and 2014.

In total, during this period, 1254 women (aged 18 years or older) presented to our service either on their own initiative to perform the Pap test or recommended by the family doctor for this examination.

### *Data collection*

Basic socio-demographic data (age, place of residence, marital status) as well as data related to women's gynecological history, including information related to menopause status, current pregnancy, menstrual cycle (regular or irregular), data on previous diseases of the genital tract, previous cytological examinations, and previous biopsies was collected.

In addition, data related to the obtaining of cervical smears in women who presented for the Pap test examination was also collected. Cervical smears were read through cytological examination. Interpretation of smears was based on the criteria of the Bethesda System as well. For example, non-neoplastic cellular changes were based on the presence of squamous metaplasia, tubular metaplasia, keratotic changes, atrophy, or pregnancy-related changes (in pregnant women only); reactive cellular changes are generally associated with inflammation or repair, radiation, lymphocytic cervicitis, intrauterine devices, etc. (Pangarkar, 2022). Atypical squamous cells of undetermined significance (ASC-US) are evidenced by nuclear staining on the order of 2.5-3 times the size of intermediate cells, with a slight increase in nuclear/cytoplasmic area ratio, a slight variation in nuclear size or contour, and mild hyperchromasia with evenly distributed chromatin. If cells with surfaces similar to surface and intermediate cells are evident, grouped in small groups or isolated, with transparent cytoplasm, with indistinct borders, large nuclei (up to six times larger than normal), the ratio nucleus/ cytoplasm from 0.33, nuclear membrane smooth or slightly invaginated, with uniform nuclear chromatin, slightly granular, with two or three nuclei (morphological markers of HPV infection including nuclear pleomorphism, hyperchromasia, perinuclear halo with a clearly distinguishable zone around the nuclei and peripheral cytoplasmic thickening), etc., then these are indicative of the presence of LSIL – LSIL, therefore, is a category that describes the changes of infection associated with human papilloma virus. If the elements of dyskaryosis are evident in the cytological examination, such as irregular chromatin, anisocytosis and irregular nuclear membranes, i.e., squamous cells that look very abnormal, then the diagnosis is oriented towards HSIL – HSIL, in this way, shows a real pre- cancerous lesion. However, the above lesions have virtually endless variations and the elements mentioned above are merely indicative. The experience of the cytology professional is a key element to establish the correct diagnosis.

## Statistical analysis

Absolute numbers and corresponding percentages were used to describe categorical data. To describe the numerical data, the mean value and standard deviation were reported. To compare the mean values of a continuous numerical variable across the categories of a categorical variable, the non-parametric Mann-Whitney U-test (for two independent samples) was used in the case when the categorical variable had two categories; if the categorical variable had more than two categories, then the non-parametric Kruskal-Wallis test for k independent samples was used.

Binary Logistic Regression was used to identify factors associated with an abnormal Pap test reading. 2 models were constructed: model 1 that estimated the crude odds ratio (uncontrolled for any confounding effect) and model 2 that estimated the odds ratio adjusting for the confounding effect of age.

An association was considered significant if P value <0.05.

All statistical analyzes were performed through the statistical package Statistical Package for Social Sciences, version 26 (IBM SPSS Statistics for Windows, version 26).

## Results

Table 1 presents basic socio-demographic data as well as other information about the women included in the study.

The average age of women in our study was  $39.8 \pm 10.7$  years. About two-thirds of women resided in urban area, 99.1% were married at the time of the survey and 17.8% were in menopause. Only 1.8% of women had been subjected to a cytological examination in the past. About 90.4% of smears were judged adequate for interpretation.

**TABLE 1.** Distribution of subjects in the study according to age group

| Variable                            | Absolute number | Percentage (%) |
|-------------------------------------|-----------------|----------------|
| Total                               | 1254            | 100.0          |
| Age (mean $\pm$ standard deviation) | $39.8 \pm 10.7$ |                |
| Age-group                           |                 |                |
| ≤20 years                           | 34              | 2.7            |
| 21-30 years                         | 245             | 19.5           |
| 31-40 years                         | 429             | 34.2           |
| 41-50 years                         | 340             | 27.1           |
| >50 years                           | 206             | 16.4           |

|                            |      |      |
|----------------------------|------|------|
| Residence                  |      |      |
| Urban                      | 809  | 66.4 |
| Rural                      | 410  | 33.6 |
| Marital status             |      |      |
| Single                     | 11   | 0.9  |
| Married                    | 1155 | 99.1 |
| Status of menopause        |      |      |
| In menopause               | 221  | 17.8 |
| Not in menopause           | 1021 | 82.2 |
| Previous cytological tests |      |      |
| Yes                        | 22   | 1.8  |
| No                         | 1232 | 98.2 |
| Adequacy of Pap smear      |      |      |
| Yes                        | 1134 | 90.4 |
| No                         | 120  | 9.6  |

\* Any discrepancy with the total number of women (n=1154) is due to missing information.

Table 2 below presents data regarding the presence of LSIL, HSIL, ASC-US, atrophy, inflammation, and squamous cell carcinoma in adequately obtained cervical smears.

It can be noted that in 65.2% of appropriately obtained smears, the Pap test was normal. Meanwhile, the prevalence of LSIL was 4.1%, the prevalence of HSIL was 1.6%, the prevalence of ASC-US was 3%. No case of squamous carcinoma was detected. Atrophy was present in 5.9% of cases (these were considered normal since they were seen in subjects over 45 years of age), whereas inflammation was present in 20.2% of appropriately obtained strips. Globally, the Pap test was positive (abnormal) in 8.7% of appropriately obtained smears.

**TABLE 2.** The presence of cervical lesions in adequately obtained smears

| Variable                      | Absolute number | Percentage (%) |
|-------------------------------|-----------------|----------------|
| Total                         | 1134            | 100.0          |
| Pap test result               |                 |                |
| Negative (normal)             | 739             | 65.2           |
| LSIL                          | 47              | 4.1            |
| HSIL                          | 18              | 1.6            |
| ASC-US                        | 34              | 3.0            |
| Atrophy                       | 67              | 5.9            |
| Inflammation                  | 229             | 20.2           |
| Squamous carcinoma            | 0               | 0.0            |
| Overall Pap test result       |                 |                |
| Negative (normal)             | 1035            | 91.3           |
| Abnormal (LSIL, HSIL, ASC-US) | 99              | 8.7            |

Table 3 presents the distribution of Pap test results according to the age of the women included in the study.

A progressive, statistically significant increase in the percentage of abnormal Pap test results is evident with increasing age of women. For example, in women aged 20 years or younger no Pap test was abnormal, but the percentage of Pap tests with an abnormal result increases to 2.1% in women aged 21-30 years, 4.1% in women aged 31-40 years old, it increases even more reaching 11.7% in women aged 41-50, and peaks in women over 50 where approximately one in four tests (23.5%) were abnormal.

**TABLE 3.** Distribution of Pap test results according to the age of the women in the study

| Variable    | Pap test result |           | P-value   |
|-------------|-----------------|-----------|-----------|
|             | Negative        | Abnormal  |           |
| Age-group   |                 |           | <0.001 ** |
| ≤20 years   | 33 (100.0) *    | 0 (0.0)   |           |
| 21-30 years | 229 (97.9)      | 5 (2.1)   |           |
| 31-40 years | 370 (95.9)      | 16 (4.1)  |           |
| 41-50 years | 263 (88.3)      | 35 (11.7) |           |
| >50 years   | 140 (76.5)      | 43 (23.5) |           |
| Total       | 1035 (91.3)     | 99 (8.7)  |           |

\* Absolute number and row percentage (in parenthesis).

\*\* P-value according to the chi-square test.

Table 4 presents the relationship between selected independent characteristics of women in the study and the abnormal result of the Pap test. It can be noted that increasing age of the woman is a statistically significant risk factor for an abnormal Pap test result. Thus, compared to women aged 21-30, women aged 31-40 are about 2 times more likely to have an abnormal Pap test reading, those aged 41-50 are 6.1 times more likely to have to have an abnormal Pap test reading and women over 50 are 14.1 times more likely to have an abnormal Pap test reading. These differences are highly statistically significant ( $P < 0.001$ ).

On the other hand, when age is treated as a numerical variable, it turns out that for every 1 year increase in women's age, the likelihood of receiving an abnormal Pap test result increases by 1.09 times, and this relationship is also highly significant ( $P < 0.001$ ). Women in urban areas were 1.43 times more likely to have an abnormal Pap test compared to women living in rural areas, but this difference is not statistically significant ( $P > 0.05$ ) [data not shown in Table 4]. After controlling for the confounding effect of age (Model 2 in Table 32), the association was again not statistically significant but weakened further ( $OR = 1.27$ ), implying that the role of place of residence in an abnormal Pap test reading is even smaller.

Regarding menopause, in the univariate analysis menopausal women were 4.72 times more likely to have an abnormal Pap test compared to non-menopausal women, and this difference was highly statistically significant. ( $P < 0.001$ ) [data not shown in Table 4], giving the impression that menopause itself is a risk factor for obtaining an abnormal Pap test reading. However, after controlling for the confounding effect of age (model 2 in Table 4), it is observed that the relationship changes completely, goes in the opposite direction ( $OR = 0.93$ ) and loses statistical significance ( $P > 0.05$ ). This implies that menopause itself is not a risk factor for getting an abnormal Pap test reading but in fact age is the main risk factor.

**TABLE 4.** Association of selected factors with abnormal Pap test result: odds ratio (OR) from binary logistic regression

| Variable         | Odds ratio (OR) * | 95% Confidence Interval (95% CI) ** |             | P-value *** |
|------------------|-------------------|-------------------------------------|-------------|-------------|
|                  |                   | Lower limit                         | Upper limit |             |
| Age-group        |                   |                                     |             |             |
| 21-30 years      | 1.00              | Reference                           | Reference   | <0.001 (2)  |
| 31-40 years      | 1.98              | 0.72                                | 5.48        | Reference   |
| 41-50 years      | 6.09              | 2.35                                | 18.82       | 0.188       |
| >50 years        | 14.07             | 5.44                                | 36.36       | <0.001      |
| Age (in years)   | 1.09              | 1.07                                | 1.12        | <0.001      |
| Residence        |                   |                                     |             |             |
| Rural            | Reference         | Reference                           | Reference   | 0.338       |
| Urban            | 1.27 §            | 0.79                                | 2.07        |             |
| Menopause status |                   |                                     |             |             |
| Not in menopause | Reference         | Reference                           | Reference   | 0.835       |
| In menopause     | 0.93 §            | 0.49                                | 1.76        |             |

\* Odds ratio of an abnormal Pap test result versus a normal result.

\*\* 95% confidence interval (95% CI) for the odds ratio.

\*\*\* Statistical significance value according to Binary Logistic Regression.

§ Age-adjusted OR.

## Discussion

The present study, which included 1254 women who presented to the gynecological service of the Fier Regional Hospital during the period 2013-2014 to perform a Pap test, represents one of the few studies that shed light on the demographic profile of women who undergo a Pap test, data related to previous gynecological diseases, previous pregnancies, and menopause, as well as data related to Pap test results, suitability of smears, and factors associated with an abnormal Pap test result.



To our knowledge, there are no similar studies conducted earlier in Albania that shed light on the above-mentioned aspects of women who presented to have a Pap test at the Fier Regional Hospital at their own request or recommended by their family doctor and/or other health care professionals. We tried to identify other studies conducted earlier regarding the result of the Pap test among women in our country. We were able to find a study conducted at the “Queen Geraldine” Obstetric-Gynecological Hospital (Xhani and Filipi, 2013) and a study conducted among women presented for a Pap test at the American Hospital, in Tirana (Kapllanaj, 2022). Also, a summary report of the Institute of Public Health was identified regarding the results of the National Cervical Cancer Screening Program in Albania, compiled in 2020 (Ylli et al., 2020). It can be affirmed with conviction that the data related to the results of the Pap test among women in our country are insufficient, while the association of these results with various factors is a completely unexplored field in our country. In this context, the present study takes on even greater importance.

The study in Tirana that studied 5146 smears during 200-2012 in the premises of the University Obstetric-Gynecologic Hospital “Queen Geraldine” in Tirana reported a global prevalence of abnormal Pap test of 4.8% (Xhani and Filipi, 2013). In our study, the overall prevalence of abnormal Pap test reading was 8.7%, which is significantly higher than in the study in Tirana. However, the overall abnormal reading rate in our study is lower than the abnormal reading rate among 4,223 smears read at American Hospital (private hospital) during 2019-2020 (1 year), where 25.4% of all smears were abnormal on Pap test (Kapllanaj, 2022). It is clear that the figure in our study is in an intermediate position between the total prevalence of abnormal reading of the Pap test reported by the study in Tirana and the corresponding figure reported in the study at the American Hospital. The reasons for these discrepancies are impossible to be determined from the present study, and therefore further studies are needed to clarify the situation.

On the other hand, data from the evaluation report of the National Cervical Cancer Screening Program in Albania reported that among 12,300 women examined with the HPV test (not the Pap test) until December 2019 (about one year after the start of National Program), the level of positivity for high-risk HPV lesions was 6.1% (Ylli et al., 2020). However, the National Program uses the HPV test, not having direct comparability with our study, where the Pap test was used.

In the international arena, different levels of Pap test positivity are reported, depending on the countries (or more precisely, the level of development of the countries) where the studies are conducted. For example, a study among 1,650 women in India reported an overall prevalence of abnormal Pap test readings (including LSIL, HSIL, and ASC-US) of 8.5% (Sachan et al., 2018), a figure that is entirely similar to the corresponding result in our study. Another study in India

among 550 women reported an overall prevalence of abnormal Pap test reading at 6.7% (Arun, Singh, & Gupta, 2018). A study in Iran among 1000 women reported that the Pap test was positive in 2.6% of them (Pourasad-Shahrak, 2015) while another study in Iran among 440 women aged 20-65 years reported that the Pap test was abnormal in 29.9% of cases (Vahedpoor et al., 2019). In South Korea, a large study that included more than 4 million smears of women aged 30 and over screened with a Pap test reported that the overall rate of Pap test positivity was 6.6% (Han et al., 2012).

The prevalence of LSIL, HSIL and ASC-US in the study in Tirana was 1.6%, 0.18% and 2.76%, respectively (Xhani and Filipi, 2013); in our study, the respective prevalence are 4.1%, 1.6% and 3%, i.e. higher; meanwhile, the study at the American Hospital did not report the specific prevalence of lesions detected through the Pap test, therefore the comparison for specific diagnosis is impossible. A study in India that included 500 women aged 21-65 years reported that the prevalence of LSIL, HSIL and ASC-US was 10.3%, 0.48% and 6.47%, respectively (Sharma and Leekha, 2018).

Studies show that the usual (conventional) Pap test is a procedure that can be performed satisfactorily in low-income countries, including the poorest countries in Africa, Asia and the Americas (Suba and Raab, 2004). However, in low- and middle-income countries there are many challenges or barriers to the implementation of cervical cancer screening programs; the main obstacle is related to the complexity of screening processes, poverty, limited access of the population, lack of knowledge and awareness about cervical cancer, lack of sustainable preventive programs, lack of health care infrastructure that is necessary for these screening programs and lack of trained personnel, etc.; social, religious, and cultural barriers may play an important role as well; finally, government resources can be allocated to other existing programs that have greater visibility and popularity compared to cervical cancer screening programs (Catarino et al., 2015).

In our study we evidenced a strong and statistically significant association between women's age and abnormal Pap test results and specific Pap test diagnoses. This finding is consistent with studies within our country and in the international arena. For example, the study in Tirana reported that the rate of abnormal Pap test results increased from 3.8% among women under 25 years of age to 6.3% among women aged 35-45; likewise, the prevalence of specific diagnoses of cervical lesions increased with increasing age (Xhani and Filipi, 2013). Even the study conducted at the American Hospital reported a statistically significant increase in the prevalence of abnormal Pap test readings with increasing age, from 22.93% in women aged 19-29 years, to 26.65% in women aged 30-39 years, 31.15% among women aged 40-49, 32.18% among women aged 50-59 and 35.78% among women aged 60-69, decreasing (to 26.85%) among women aged 70 and over (Kapllanaj, 2022).

The association of the prevalence of the diagnosis of cervical lesions in the Pap test with the age of the patients is a finding that is also reported in the international literature. Thus, a study among 1650 women reported that the prevalence of LSIL, HSIL, and ASC-US increased with age, but LSIL and HSIL had the highest prevalence at 41-50 years of age and ASC-US at 51-60 years of age (Sachan et al., 2018). However, the large study in South Korea (which examined over 4 million smears of women aged 30 and over) reported the highest Pap test positivity in the 30-39 age group (7.25%), followed by from the 40-49 age group (6.81%), decreasing further in the 50-59 age group (6.46%) and even further in women 60 years and older (6.34%) [Han et al., 2012].

The prevalence of HPV infection was higher among women living in urban areas (6.9%) compared to women living in rural areas (4.7%) [Ylli et al., 2020]. This finding is in accordance with the finding of our study where the positivity of the Pap test was higher in women from urban areas compared to rural ones; this can be explained by the earlier sexual activity and the greater number of sexual partners among women living in urban areas.

Socio-economic factors also play a role in understanding the groups that have less access to cervical cancer screening programs, which include especially people with low incomes, ethnic minorities, etc. Socio-economic factors operate mainly through low education level, which is a risk factor for cervical cancer, through lower access to screening programs, lower access to preventive services due to low information and awareness, etc. (Singini et al., 2021). A possible explanation for the increase in the positivity of the Pap test among women in Fier Prefecture may include precisely the low socio-economic level of older women, who may be in more difficult economic conditions and have difficulties to access the cervical cancer screening service; consequently, they probably present much later to health care services at a time when a large proportion of them are probably already affected by the condition and have developed various pre-cancerous lesions at different stages. However, this remains only an assumption, which must be verified through other studies in our country.

Reports regarding the level of Pap test positivity in different populations are very different. The main factors relate to the reasons mentioned earlier, including the different procedures for obtaining, fixing, storing, preparing the smears, the different training of the cytological professionals who read the smears, the different populations where the screening is applied, the highly variable infrastructure in different countries and areas, application of non-standardized criteria and standards, etc.

## Conclusion

The level of Pap test positivity among adult women in Fier Prefecture is comparable to international reports and it lies between the values reported by previous studies in our country. Given that the Pap test will continue to be used for a long time as a main screening test in our country, then it is necessary for women to be aware of this important examination and to improve the capacities for the correct collection of cervical smears and their correct reading and interpretation. There is need to increase the awareness of women about cervical cancer and their participation in cervical cancer screening programs.

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