

ORIGINAL ARTICLE

Psychological effects of concurrent cytology and colposcopy testing in women referred to cancer counseling outpatient clinic in Belgrade

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Summary

Purpose: To investigate the psychological effects of PAP smear and colposcopy performed simultaneously and receipt of abnormal tests' results on women's well-being and quality of life (QoL) using different relative questionnaires.

Methods: A prospective cohort study included 324 women with abnormal PAP smear result obtained at the primary care centers, requiring repeat smear test and colposcopy in our hospital. Questionnaires regarding the patient demographic characteristics, 7-point Likert scales which indicate concern about the smear and colposcopy results and risk of developing cervical cancer, Bek Anxiety Inventory (BAI), European QoL questionnaire - Euro QoL (EQ-5D) and visual analogue scale (EQ VAS) were used. Women filled in the questionnaires at the pre-procedural assessment, and again, 7-10 days after testing, just after the reception of results.

Results: According to BAI scale, almost one-quarter of women (23.5%) showed mild to severe anxiety; higher level

of anxiety had women with abnormal test results ($p=0.008$). After adjustment for age, the difference reached statistical significance in the follow up period, too ($p<0.05$). At the pre-procedural assessment, there was no significant difference in the concern about test results (4.09 vs 4.22) and the perceived risk of developing cervical cancer (3.99 vs 4.14) using self-assessment by the Likert scales. However, women with abnormal test results had lower quality of life compared to women with normal PAP smear and colposcopy (mean EQ-VAS score 77.35 ± 15.63 vs 81.14 ± 16.07 ; $p=0.020$).

Conclusions: We conclude that referral for evaluation after a first abnormal PAP test leads to anxiety. Close and clear communication about test meaning and its consequences is needed in the organized screening test.

Key words: anxiety, cervical carcinoma, colposcopy, Pap smear, quality of life, screening

Introduction

Cervical cancer is still one of the four most frequent localizations of malignancies in women in Serbia, after breast, colorectal and lung cancer. According to the latest data from the Serbian Cancer Register in 2012 and 2013, crude incidence rates of cervical cancer were 36.4 and 32.0 and age-standardized rates were 28.3 and 20.3 per 100,000 inhabitants, respectively [1]. The

age-standardized incidence rates are much higher than the EU average (13.4), and they run second just after Bulgaria (28.5) [2]. In the same years, age-standardized mortality rates were 6.4 and 6.8 per 100,000 inhabitants [1]. Mortality rates showed continuous and significantly increased trend during the period 1991-2011, with an average rate of 7.03 [3]. This information indicates

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that cervical cancer represents a major public health issue in Serbia.

The first National Organized Screening program for early detection of cervical cancer in Serbia was approved by the Serbian Government in 2008. Due to a number of different constraints, it has officially been developed and established in 2013, in accordance with the last Regulation [4]. According to this program, women aged 25-65 should be invited to undergo initial screening which involves two cervical smear (PAP) tests in 6-month interval and if both are negative women could continue to participate in regular gynecologic check-ups in 3-year intervals. Women with cytology showing atypical and dyscaryotic squamous cells (PAP test III-V) are referred to colposcopy, and further management depends on its result [4]. However, systematic organized screening has not yet been well implemented in practice. The opportunistic type of screening is still present. Women of all ages are simply encouraged to undergo preventative gynecological examinations which usually involve free of charge cytology provided by gynecology specialist in the primary health care centers. The particulars of the health care system in Serbia is such that women can go directly to a specialist gynecologist, so they do not require a referral from general practitioners.

If borderline or suspicion of atypical cervical changes have been found on the primary level, women are referred to secondary level hospital (in the province) or to tertiary level-university hospital clinics (in big cities), where cervical smear test is performed again, and concurrent colposcopy and/or human papillomavirus (HPV) test. A consequence of this type of screening is still high incidence of cervical cancer mostly diagnosed in advanced stage [3].

It is well known that cancer diagnosis evokes anxiety and panic [5]. Abnormal cytology and referral for colposcopy are also associated with anxiety and slightly impaired psychosocial components of health related QoL (HRQoL), regardless of the type of screening management used [6]. At the time of awaiting national screening plan to be completely implemented in practice, we investigated the psychological effects of simultaneously undertaken cytology test and colposcopy and reception of abnormal test results on women's well-being and QoL.

Methods

Study design and participants

This prospective cohort study was conducted in

the University Clinic of Obstetrics and Gynecology "Narodni Front" in Belgrade during January-June 2013. Women with abnormal PAP smear result obtained at the primary care centers requiring colposcopy in our hospital were invited to participate in the study. According to the practice in our country, all women with abnormal PAP test are referred to the Hospital where repeat cytology and concurrent colposcopy are performed.

Inclusion criteria were age 18-65 and absence of genital warts during the past 2 years. Of 347 women who accepted to participate in the study, 4 became pregnant during the study period and were excluded. One woman with invasive cervical carcinoma and one with status post-hysterectomy were also excluded as well as 17 women who did not fulfill the questionnaire, which left 324 women eligible for analysis (Figure 1). None of them had received HPV vaccine in the past.

On admission each eligible woman was asked to complete the general questionnaire which consisted of questions regarding demographic data (age, education, marital status, having children or not), gynecological data (age at first menstruation, age at first sexual intercourse, present life situation, sexual history, and number of pregnancies and deliveries), and concern about tests results and perceived risk of developing cancer in the next 10 years. At the same time they also filled in a questionnaire assessing general and psychological health and QoL. Part of these women participated in a second psychological assessment 7-10 days after testing, just after receiving the result. The women were given privacy to complete these questionnaires while one trained examiner could be reached any time. After cytology and colposcopy testing women with either atypical cytology or colposcopy were referred for a consequent HPV testing. Detailed flowchart of cervical cancer screening process is shown in Figure 2.

Psychological outcomes assessment

Concern about the smear and colposcopy results and perceived risk of developing cervical cancer in the next 10 years were assessed using the 7-point Likert scale where higher scores indicate higher concern and higher risk perceived, respectively.

Clinical anxiety was assessed using the BAI, the self-reporting scale inventory which consists of 21 questions and measures anxiety symptoms during the past week. Each question inquires a common symptom of anxiety. Items are scored in a 0 (not at all) to 3 (severely). A sum between 0-9 indicates minimal anxiety, 10-16 mild anxiety, 17-29 moderate anxiety and a sum exceeding 30 is considered as a severe anxiety. The inventory has been used in gynecological studies. Serbian version of this questionnaire is commonly used in psychological investigations and in our sample showed high internal consistency (Cronbach's $\alpha = 0.96$, $N = 314$) [7].

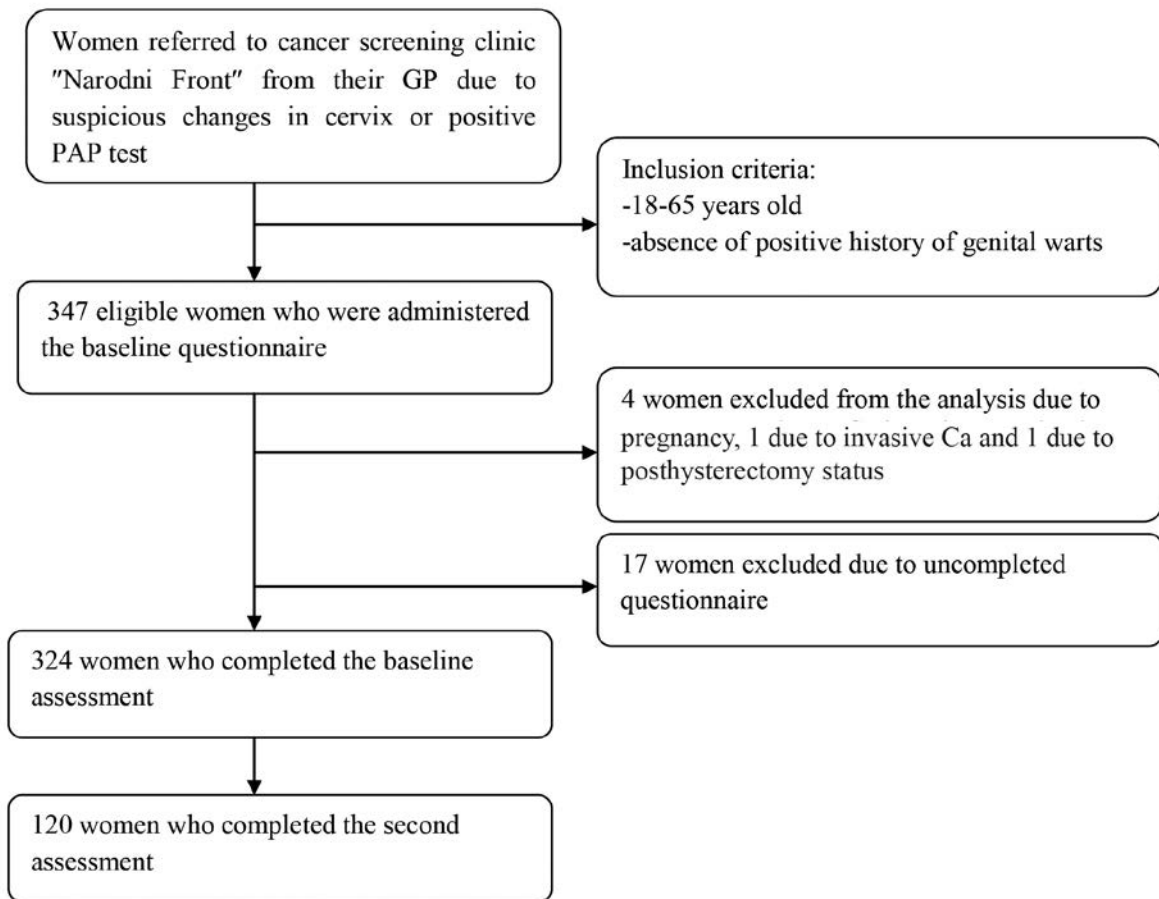


Figure 1. Flowchart of study population.

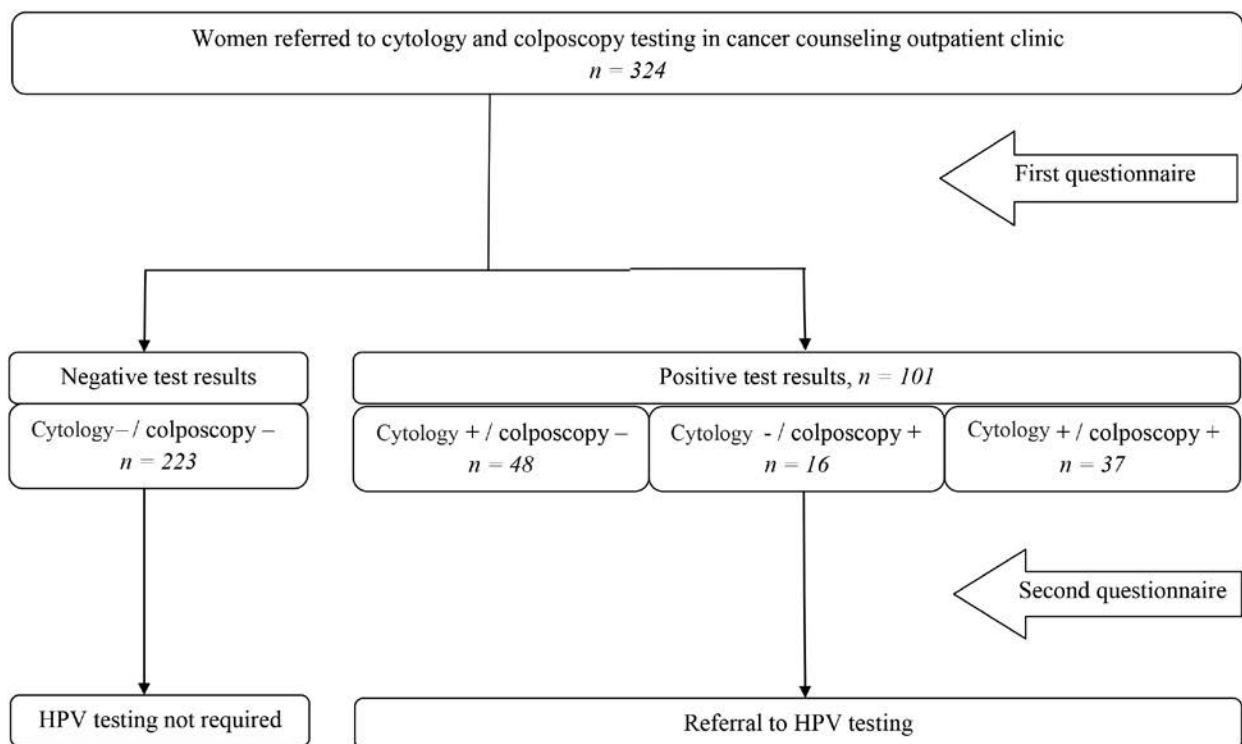


Figure 2. Flowchart of the process of cervical cancer screening of the study participants.

Table 1. Participant demographic characteristics (n=324)

<i>Demographic characteristics*</i>	
Age (years) [†]	36.2 ± 10.6
Level of education	
Without formal education (0-3 yrs in school)	15 (4.9)
Elementary school (4-8 yrs in school)	12 (3.9)
Secondary school (9-12 yrs in school)	166 (53.7)
Faculty (> 12 yrs in school)	116 (37.6)
Marital status	
Married/ Cohabiting	185 (61.6)
Single	108 (36.0)
Divorced/separated/widowed	7 (2.3)
Birthplace	
Rural	10 (3.1)
Urban	309 (96.9)
Residence	
Rural	19 (6.0)
Urban	299 (94.0)
Employment	
Housewife/unpaid job/students	23 (8.2)
Merchant	16 (5.7)
Work women	124 (44.3)
Nature-related occupation	44 (15.7)
Community and social service occupation	73 (26.1)
<i>Gynecological data</i>	
Age at menarche (years) [†]	13.4 ± 1.6
Age at first sexual intercourse (years) [†]	19.1 ± 2.4
Number of deliveries [‡]	
0	138 (42.6)
1	67 (20.7)
≥ 2	106 (32.8)
Number of abortions [‡]	
0	218 (67.3)
1	53 (16.4)
2	29 (9.0)
≥ 3	11 (3.4)
Number of children [‡]	
0	136 (42.0)
1	69 (21.3)
2	85 (26.2)
≥ 3	19 (5.9)

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Number of sexual partners (total)*	2 (2)
0	13 (4.0)
1	84 (25.9)
2-5	96 (29.6)
≥ 6	14 (4.3)
Number of sexual partners (in 3 last months)*	1 (0)
0	38 (11.7)
1	238 (73.5)
2-5	4 (1.2)
≥ 6	1 (0.3)
<i>Psychological state at admission</i>	
Concern about test results [†]	4.1 ± 1.8
Perceived risk of developing cervical cancer [†]	4.04 ± 1.9
<i>Anxiety (as assessed by BAI)</i>	
Minimal	245 (75.6)
Mild	50 (15.4)
Moderate	20 (6.2)
Severe	5 (1.5)
<i>HRQoL components analysis</i>	
EQ-5D index [†]	0.92 ± 0.10
EQ-5D VAS Score [‡]	79.9 ± 16.0

*Data are numbers (%) unless otherwise stated.

[†]Data are presented as mean ± SD.

[‡]Data presented as median (IQR).

Health related quality of life was assessed using the EuroQol EQ-5D, a generic instrument which comprises two parts: EQ-5D descriptive system measuring unique health status by combining 5 health state dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) into single utility index, where 0 indicates 'death' and 1 'full health'; and EQ VAS which presents the patients' own view of their overall health and can range from 0 (worst possible health) and 100 (best possible health) on a 20cm vertical VAS.

All women provided written informed consent to participate in the study. The Ethics Committee of the Medical Faculty, University of Belgrade, approved the study.

Statistics

Descriptive statistical methods were used to analyze baseline characteristics of the respondents. The distribution of the continuous variables was evaluated by Kolmogorov-Smirnov test. Baseline differences in continuous characteristics such as psychological outcomes and concern level between two groups were assessed using Student's independent T-test or Mann-Whitney U test. Categorical data were presented as numbers and percentages and compared between groups using

Pearson's chi-square test or Fisher's exact test. Skewed variables were normalized by using logarithm transformation before parametric statistical analysis. ANCOVA analysis with adjustment for baseline values was used to test for differences in psychological outcome variables between normal and abnormal test result groups at follow up assessment. Internal consistency and reliability of each questionnaire was assessed by determining its Cronbach α coefficient. All statistical tests were two-sided and were performed at 5% significance level. The statistical analysis was performed using SPSS20.0 software (SPSS Inc., Chicago, ILL, USA).

Results

Characteristics of the study participants

The mean age of the women who participated in this study (N=324) was 36.2 ± 10.6 years (range 18-66). Study participants characteristics are presented in Table 1. About 9% of women were without formal education or finished elementary school; 62% were married or lived in cohabiting, but 42% had not children. One-quarter of women showed mild to severe anxiety level.

Table 2. Response rates by test results

Test result	Study population (n=324)	Number of respondents n	Response rate %	p value
Normal cytology and colposcopy	223	64	28.7	< 0.001
Abnormal cytology and/or colposcopy	101	56	55.4	
Cytology+ / colposcopy-	48	22	45.8	< 0.001
Cytology- / colposcopy+	16	8	50	
Cytology + / colposcopy+	37	26	70.3	

Seven to 10 days after the examination, 101 women (31.2%) received positive results either of cytology or colposcopy and were classified as atypical result group. The majority of them (N=48;47.5%) had positive cytology and negative colposcopy results. One third of the atypical results (N=37;36.6%) were confirmed by both cytology and colposcopy. Women with abnormal test results were younger at first sexual intercourse (18.6 ± 2.1 vs 19.4 ± 2.5 years, $p=0.020$), had more than 6 sexual partners (6.9 vs 3.1%, $p=0.052$) and were younger (34.3 ± 9.8 vs 37.0 ± 10.8 years, $p=0.063$) than women with normal test results. Other variables did not yield statistically significant differences.

Response rates

Of 324 women who completed, the first pre-procedural questionnaires, 120 (37.0%) responded to the second assessment, immediately when they received the cytology and colposcopy results. The response rate was significantly higher in the group who received atypical test results compared to group who received normal test results (N=56; 55.4 vs 64;28.7%, $p<0.001$) (Table 2). Interestingly, the highest response rate was observed in the group of women whose results of cytology and colposcopy were both positive (70.3%).

Sensitivity analysis

Respondents and non-respondents were similar in terms of marital status, birthplace, residence and employment status, as well as in gynecological data (Table 3). In the group of women with normal cytology and colposcopy, respondents were older and better educated than non-respondents. However, there were no significant differences in the demographic characteristics between respondents and non-respondents in the group with abnormal test results.

Comparing baseline, pre-procedural psychological outcomes, respondents with normal test results were more anxious (mean 6.3 ± 9.5 vs 2.8 ± 7.15 , $p=0.001$), and had lower QoL (EQ-5D index) score (mean 0.8 ± 0.6 vs 1.0 ± 0.1 , $p<0.001$)

than non-respondents (Table 3). Respondents and non-respondents in both groups were not significantly different in their concern about test results, perceived risk of developing cervical cancer and EQ-5D VAS score.

Psychological outcomes at baseline at follow up

At the pre-procedural assessment, there was no significant difference in the concern about test results (4.09 vs 4.22) and the perceived risk of developing cervical cancer (3.99 vs 4.14) using self-assessment by Likert scales. However, women who received abnormal test results differed from women who received normal test results in anxiety measured by BAI questionnaire (mean 6.13 ± 9.00 vs 3.83 ± 7.45 , $p=0.008$). After adjustment for age, the difference reached statistical significance in the follow up period, too. At the VAS, during pre-procedural assessment, women who received abnormal test results indicated their health as worse than women with normal results (EQ-5DVAS score, mean 77.35 ± 15.63 vs 81.14 ± 16.07 , $p=0.020$). After reception of the test results these differences declined reaching insignificant level (Table 4).

Discussion

This study assessed the anxiety, HRQoL and concern about colposcopy results in a cohort of women with abnormal PAP test results obtained in the primary health center and followed for repeat PAP test and colposcopy in hospital.

In our study, pre-procedural concern about test results, as well as perceived risk of developing cancer in the next 10 years, did not differ among women with normal and abnormal test results. However, the level of concern in women with normal results was higher than those observed in women with normal screening test in other studies [8,9]. This could be explained by the fact that our participants had already received borderline or abnormal cytology results in the primary health care centers, and all, regardless of whether they received normal or abnormal results, showed a high level of anxiety.

Table 3. Baseline characteristics of respondents and non-respondents according to test results

	<i>Normal cytology and colposcopy</i>			<i>Abnormal cytology and/or colposcopy</i>		
	<i>Respondents</i> (n = 64)	<i>Non-respondents</i> (n = 159)	<i>p value</i>	<i>Respondents</i> (n = 56)	<i>Non-respondents</i> (n = 45)	<i>p value</i>
<i>Socio-demographic characteristics*</i>						
Age (years) [†]	39.5 ± 11.1	36.4 ± 10.7	0.048	33.9 ± 9.7	36.0 ± 11.0	0.310
Education						
Without formal education	1 (1.6)	10 (6.6)	0.007	0 (0.0)	4 (9.5)	0.065
Elementary school	1 (1.6)	8 (5.3)		3 (5.7)	0 (0.0)	
Secondary school	34 (54.0)	74 (49.0)		32 (60.4)	26 (61.9)	
Faculty	27 (42.8)	59 (39.0)		18 (33.9)	12 (28.6)	
Marital status						
Married	37 (60.7)	79 (53.4)	0.361	29 (55.8)	21 (53.8)	0.163
Single (living alone)	15 (24.6)	40 (27.0)		14 (26.9)	10 (25.6)	
Single (living with parents)	5 (8.2)	16 (10.8)		5 (9.6)	3 (7.7)	
Cohabiting	2 (3.3)	12 (8.1)		4 (7.7)	1 (2.6)	
Divorced/separated/ widowed	2 (3.3)	1 (0.7)		0 (0.0)	4 (10.3)	
Birthplace						
Rural	1 (1.6)	5 (3.2)	0.678	3 (5.6)	1 (2.3)	0.625
Urban	63 (98.4)	151 (96.8)		51 (94.4)	43 (97.7)	
Residence						
Rural	6 (9.4)	8 (5.1)	0.235	3 (5.7)	2 (4.7)	0.825
Urban	58 (90.6)	150 (94.9)		50 (95.3)	41 (95.3)	
Employment						
Housewife	1 (1.7)	10 (7.6)	0.291	2 (4.1)	2 (5.4)	0.634
Merchant	3 (5.1)	6 (4.4)		5 (10.2)	2 (5.4)	
Artist	0 (0.0)	2 (1.5)		0 (0.0)	0 (0.0)	
Employee	25 (42.4)	59 (43.7)		19 (38.8)	21 (56.8)	
Community and social service occupation	22 (37.3)	32 (23.7)		12 (24.5)	7 (18.9)	
Nature-related occupation	8 (13.6)	24 (17.8)		8 (16.3)	4 (10.8)	
Student	0 (0.0)	2 (1.5)		3 (6.1)	1 (2.7)	
<i>Psychological state on admission</i>						
Concern about test results [†]	4.3 ± 2.2	4.0 ± 1.8	0.233	4.2 ± 1.8	4.2 ± 1.8	0.734
Perceived risk of developing cervical cancer [†]	4.2 ± 2.3	3.9 ± 1.8	0.447	4.0 ± 1.7	4.3 ± 1.9	0.502
Anxiety (BAI) [‡]	6.3 (9.5)	2.8 (6.2)	< 0.001	5.9 (8.7)	6.4 (9.4)	0.641
HRQoL components analyse						
EQ-5D index [‡]	0.8 (0.6)	1.0 (0.15)	< 0.001	1.0 (0.2)	1 (0.1)	0.485
EQ-5D VAS Score [†]	81.0 ± 14.2	81.2 ± 16.8	0.612	76.4 ± 15.6	78.5 ± 15.8	0.475

*Data are numbers (%) unless otherwise stated.

[†]Data are presented as mean ± SD.[‡]Data are presented as median (IQR).

Table 4. Psychological outcomes at enrollment and after receipt of results of cervical smear and colposcopy

	<i>Normal cytology and colposcopy</i>	<i>Atypical cytology and/or colposcopy</i>	<i>p value</i>	<i>p value*</i>
Concern about test results	4.09 ± 1.94	4.22 ± 1.80	0.628	0.516
Perceived risk of developing cervical cancer	3.99 ± 1.95	4.14 ± 1.80	0.571	0.421
Anxiety (BAI)				
Pre-procedural	3.83 (7.45)	6.13 (9.00)	0.008	0.006
Follow-up [†]	5.17 (8.73)	5.77 (9.03)	0.770	0.053
HRQoL (EQ-5D) components				
Index				
Pre-procedural	0.84 ± 0.27	0.86 ± 0.22	0.631	0.814
Follow-up [†]	0.81 ± 0.25	0.89 ± 0.20	0.089	0.999
EQ VAS				
Pre-procedural	81.14 ± 16.07	77.35 ± 15.63	0.020	0.011
Follow-up [†]	81.09 ± 14.32	76.70 ± 15.26	0.121	0.358

HRQoL: Health-related quality of life, EQ-5D: EuroQol 5-dimension, 3-level health state utility instrument.

Values are mean ± SD or median (IQR).

[†]Adjusted for baseline differences.

*Adjusted for age.

Using BAI as a brief measure of anxiety with a focus on somatic symptoms of anxiety, we found that women with abnormal test results had higher level of anxiety than women with normal test results before performing repeat PAP test and colposcopy. After age adjustment, significantly higher level of anxiety was found at the moment when women received their results of PAP smear and colposcopy. These results suggest that BAI does reflect general anxiety more precisely than it is revealed by Likert scale. A large number of previous studies reported on anxiety in women before and after medical procedures such as colposcopy [10-12], others revealed that women had high anxiety at the first time-point after colposcopy [13]. High levels of anxiety before and during colposcopy can have adverse consequences such as pain and discomfort during the procedure [14].

Several studies have found BAI to be an accurate measure of anxiety symptoms associated with the diagnosis of many cancers, including cervical cancer [15,16]. Women referred for colposcopy for further diagnostic evaluation of pre-cancerous cell changes have experienced significant emotional distress [10,13]. They worry not only because of the procedure itself, but also because of the prospect of having cancer and its consequences on further life, sexual and reproductive function. Our findings are consistent with results obtained in these studies. In a recent systematic review of studies published between 1986 and 2014, the authors revealed that the adverse psychological outcomes associated with colposcopy can be anxiety, depression, distress and worries/fears about cancer and future fertility [17]. It was

reported that anxiety at the first post-colposcopy assessment was lower than pre-colposcopy [8]. Referral for colposcopy after an abnormal cervical smear does not result in long-lasting anxiety. Although 2-year state anxiety levels were lower than pre-colposcopy levels, one in three women still had a fear of cancer. We found lower anxiety level 7-10 days after colposcopy than before, but only in women with abnormal results. Smaller percent of response rate was found in the group of women with normal cytology and colposcopy, probably caused the higher anxiety after colposcopy than before colposcopy in these women.

As one of the methods for reducing anxiety and pain due to colposcopy, the authors of a study investigated the positive effect of music during colposcopy, pre-colposcopy education and counseling [14], and conveying the PAP smear test results by the trained screener.

Although gynecological results can be sent by letter or e-mail [18], most women prefer to receive results information through face to face communication with their doctor. In our county, women are given PAP test and colposcopy results in personal communication with their gynecologist.

There were no significant differences in HRQoL between two groups measured by EQ-5D. Perhaps this test is not sensitive enough to reveal any changes in the QoL as has been the case in other studies [19] or simply the time span has been too short for the changes to be detected. Women with atypical test results marked their health as worse on VAS only in the pre-procedural assessment in our study.

In this study, we also found a few significant

differences between groups regarding socio-demographic characteristics. High prevalence of abnormal smears in younger women, was already observed in other countries. Young age at first intercourse and more than 4 sexual partners were found as important risk factors in both our study and other studies [20,21].

The limitation of this study is the unavailability of clinical data from primary health centers which precludes the comparison with repeat cytology results. However, the strengths of this prospective study is availability of results of repeat cytology performed by gynecologists trained to perform screening tests. Opportunistic screening has been performed in Serbia for decades. In primary health centers, PAP smears were read by gynecologists with additional education in cytology, but without quality control of training and quality control of work. In new, mass cervical cancer screening in our country, gynecologists in primary health centers will be the screeners, while educated for screening according to the European guideline. Reading a cervical smear will be organized only in accredited laboratories. This will ensure that screenings take place in health institutions that women are familiar and comfort-

able with, even though they might not be examined by their personal gynecologist at a screening test. Moreover, handing the test results in person along with providing explanations to their meaning and additional clarification of the importance of early discovery of potential pre-cancer lesions, would lead to a reduction in anxiety and improvement in the QoL.

Conclusion

We conclude that referral for evaluation after the first abnormal PAP test leads to anxiety. Close and clear communication about test meaning and its consequences is needed in the organized screening test.

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Conflict of interests

The authors declare no conflict of interests.

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