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Organized colorectal cancer screening in Serbia – The first round within 2013–2014

Organizovano ispitivanje kolorektalnog karcinoma – prvi ciklus tokom 2013–2014.

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Abstract

Background/Aim. The National Organized Colorectal Cancer Screening Program was conducted in the Republic of Serbia during 2013–2014 covering the population of both genders, aged 50 to 74 years, in 28 municipalities out of 180, with the target population of 651,445 people. This organized colorectal cancer screening aim is to reduce mortality from colorectal cancer in the target population. The aim of this study was to show the results of organized screening for colorectal cancer during the first biannual round in Serbia. Methods. General practitioners from the primary health centers, invited target population by mail and by phone to perform immunochemical fecal occult blood test. Persons with a positive test results were referred to the colonoscopy. The database of health insurance and other citizens of the target population was used for invitation for screening in primary health centers. Descriptive statistical analysis of the results in organized colorectal cancer screening in the first round was performed for the key screening indicators. Results. In the first round a total of 99,592 persons were invited. The participation rate was 62.5%. Colonoscopy was

performed in 1,554 persons. Adenomas were found in 586 persons (0.9% of all the tested), e.g. 37.7 % of all colonoscopied. In 129 persons colorectal cancer was diagnosed (0.2% of all the tested), e.g. 8.3% of all the colonoscopied. In the left half of the colon (rectum, sigmoid and descending colon) there were 70.4% diagnosed polyps and 77.3%carcinomas, while 29.6% of polyps and 22.7% carcinomas were found in the proximal parts of the colon. Conclusion. In the first round of the organized colorectal cancer screening in Serbia the participation rate of the targeted population was high and gave encouraging result. It was expected that in the forthcoming rounds even higher coverage of the target population would be accomplished. A positive predictive value of the completed colonoscopies showed that further observing the stages of diagnosed adenomas and carcinomas would reach the goals of the expected improvement in early detection of colorectal cancer in Serbia.

Key words:

colorectal neoplasms; serbia; mass screening; diagnosis; occult blood; predictive value of tests; colonoscopy; adenoma.

Apstrakt

Uvod/Cilj. Nacionalni program organizovanog ispitivanja kolorektalnog karcinoma sproveden je u Republici Srbiji tokom 2013. i 2014. godine, obuhvatajući stanovništvo oba pola, starosti 50–74 godine, u 28 od 180 opština, sa ciljnom populacijom od 651 445 ljudi. Program ima za cilj sniženje mortaliteta od kolorektalnog karcinoma u ciljnoj populaciji. Cilj rada bio je da se prikažu rezultati organizovanog ispitivanja kolorektalnog karcinoma tokom dvogodišnjeg perioda u Srbiji. Metode. Izabrani lekari iz domova zdravlja pozivali su pismom i telefonom ciljnu populaciju da urade imunohemijski FOB test za otkrivanje okultnog krvarenja u stolici. Osobe sa pozitivnim nalazom testa upućivane su na kolonoskopiju. Korišćena je baza

podataka osiguranika i ostalih građana ciljne populacije u pozivanju na snimanje u domovima zdravlja. Rađena je deskriptivna statistička analiza rezultata u organizovanom ispitivanju kolorektalnog karcinoma dvogodišnjem ciklusu, za ključne indikatore ispitivanja. **Rezultati.** U prvom ciklusu bile su pozvane ukupno 99 592 osobe. Odziv na testiranje bio je 62,5%. Kolonoskopija je urađena kod 1 554 osobe. Adenomi su otkriveni kod 586 osoba (0,9% svih testiranih), tj. 37,7% svih kolonoskopiranih. Kod 129 osoba otkriven je kolorektalni karcinom (0,2% svih testiranih), tj. kod 8,3% svih kolonoskopiranih. U levoj polovini kolona (rektumu, sigmoidnom i descedentnom kolonu) bilo je 70,4% dijagnostikovanih polipa i 77,3% karcinoma, dok je 29,6% polipa i 22,7% karcinoma bilo u proksimalnim delovima kolona. **Zaključak.** U prvom ciklusu organizovanog ispitivanja kolorektalnog karcinoma u Srbiji odziv ciljne populacije na testiranje bio je visok i predstavljao je ohrabrujući rezultat. Očekuje se da će u narednim ciklusima biti postignuta čak i veća pokrivenost ciljne populacije. Pozitivna vrednost predviđanja urađenih kolonoskopija pokazuje da će se daljim radom na praćenju stadijuma otkrivenih adenoma i karcinoma dostići ciljevi

očekivanog napretka u ranoj dijagnozi kolorektalnog karcinoma u Srbiji.

Ključne reči:

kolorektalne neoplazme; srbija; masovno isitivanje; dijagnoza; okultna krv; testovi, prognostička vrednost; kolonoskopija; adenom.

Introduction

Epidemiology

In Serbia, as in developed countries, colorectal cancer represents a very significant public health problem because of the high frequency and high mortality. Organized screening showed to be a powerful weapon against this disease ¹.

According to the data of Globocan from 2012, colorectal cancer in Serbia is the second most frequent malignant tumor in men, after lung cancer, since the number of newly discovered cases is around 3,400, and the standardized incidence rate is 43.4 per 100,000 males. In females, colorectal cancer is the fourth most frequent malignant tumor, after the breast, lung and cervical cancer. The number of the newly discovered cases is around 21,00 and the standardized incidence rate is 22.3 per 100 000 females. According to the same source, regarding mortality from malignant diseases in Serbia, colorectal cancer stands in the second place after lung cancer, with the standardized mortality rate of 22.8 per 100 000 males, with around 1,900 deaths per year, while in females it is the third most frequent cause of death from malignant diseases, after the breast and lung cancer, with a standardized mortality rate of 11.5 per 100 000 and 1,200 death cases *per* year ².

The data of the Register for Cancer of the Institute for Public Health of Serbia "Dr Milan Jovanović Batut" for the year 2012 are almost similar, showing that colorectal cancer in Serbia is the second most frequent cancer in males for both incidence and mortality. In females it is also the second leading cause of mortality due to malignancy. According to this data, in 2012 there were 4,080 newly diagnosed colorectal cancers in Serbia (2,495 males and 1,585 females) while 2,652 patients died (1,579 males and 1,073 females) ³.

According to the data of the International Agency for Research on Cancer (IARC) from the year of 2012, Serbia is in the 13th place among the European countries regarding the incidence of colorectal cancer, while it is in the 6th place in Europe, after Hungary, Croatia, Slovakia, Slovenia and the Czech Republic regarding mortality from colorectal cancer. This information shows that colorectal cancer in Serbia is frequently detected in advanced stage when chances for cure are significantly reduced.

Organized Colorectal Cancer Screening Program in Serbia

In order to reduce the incidence and the mortality from colorectal cancer, experts of the Ministry of Health of the Republic of Serbia, in cooperation with the most eminent experts in this area, led by Academician Prof. Dr. Zoran Krivokapić, in a decade long work, created and improved Organized Colorectal Cancer Screening Program in Serbia, and coordinated it with the European Guidelines for Quality Assurance of Colorectal Cancer of Screening (year 2010.) 4, which utilize programs of screening of most of the European countries. This program was realized in coordination with National program for early detection of colorectal cancer (Official Gazette of the Republic of Serbia 73/2013) 5.

The goal of the organized colorectal cancer screening program is to reduce the incidence and the mortality of colorectal cancer by early detection, in precancerous stadium, the stadium of benign polyps (whose removal prevents transformation into colorectal cancer), or detection of colorectal cancer in an early phase when it is localized and a complete cure is possible in almost 90% of cases.

Due to its slow progression (adenoma-carcinoma sequence), colorectal cancer is an ideal target for early discovery and prevention thorough organized screening ⁶.

In developed countries, in which screening programs have been successfully utilized for several decades, a significant decrease in the mortality from colorectal cancer has been recorded ^{2,4}.

The aim of this study was to show the results of organized screening for colorectal cancer during the first biannual round in Serbia.

Methods

The database of those with health insurance and other citizens of the targeted population was used for invitations to screening, planning to include 75% of the target population.

The selected process indicators of the results of screening were analyzed from the screening reports from 20 municipalities in Serbia in the year 2013, as well as additional 8 municipalities included in 2014, with a total of 28 municipalities in the course of the first biannual round of the organized colorectal cancer screening.

A model of the Organized Colorectal Screening Program in the Republic of Serbia

A National Program of the Organized Colorectal Cancer Screening is conducted by the Ministry of Health in association with the Institute for Public Health of Serbia and the Republican Fund for Health Insurance.

Screening for colorectal cancer is conducted on the territory of the Republic of Serbia as an organized decentralized program. The target population were men and women from 50 to 74 years of age in a round of screening for two calendar years. Screening test was immunochemical fecal occult blood (iFOB) test. In all cases of positive iFOB test colonoscopy was performed.

The end of the process of screening was defined as: cases with negative iFOB test; in case of positive iFOB test colonoscopy was performed (with endoscopic polypectomy or biopsy depending on findings and histopathological report) ⁵.

The participants in organized colorectal cancer screening were: Ministry of Health, Republican Expert Commission for Implementation of the Program for Early Detection of Malignant Diseases in the Republic of Serbia, Republican Fund for Health Insurance, Cancer Screening Office and local health institutions such as primary health centers as basic carriers of screening, as well as general hospitals, health centers, clinical hospital centers, clinical centers and the Institute for Public Health in Serbia "Dr Milan Jovanović Batut" with a network of 24 institutes of public health in each of the districts.

Invitations to the target population by letters and by phone were conducted by the primary health care centers in cooperation with district institutions of public health. The tests were delivered by the general practitioners (GPs) in the primary health care centers, while analysis of the results of iFOB tests was done in the laboratories of the primary health care centers. Colonoscopies for all the participants in the screening with positive iFOB test were performed in the closest district hospitals and colonoscopy units ⁵.

In 2013 and 2014, 27 primary health care centers, in cooperation with secondary and tertiary health care institutions, conducted the organized colorectal cancer screening with their available capacities and scope which did not affect their primary occupation.

As above mentioned the year 2013, the target population from 20 municipalities from the territory of the Republic

of Serbia was invited and tested under the organized screening for colorectal cancer in 19 primary health care centers. During 2014, the scope of invitations and testing of the target population was expanded with 8 additional municipalities, which included a total of 28 municipalities in the first biannual round out of 180 municipalities in Serbia.

Statistics

Descriptive statistical analysis of the basic epidemiological indicators was performed. The process indicators, coverage by invitations, participation rate, coverage by iFOB test, percentage of positive iFOB tests, colonoscopy compliance rate, adenoma and cancer detection rate, as well as positive predictive value for detection of adenoma and colorectal cancer were calculated.

Results

Participation rate

In the first round during 2013 and 2014 there were 99,592 invited persons of the target population, i.e. 19% of the total target population in the municipalities in which organized colorectal cancer screening was conducted (Table 1). A total of 62,252 persons performed and returned the test, so the participation rate was 62.5% of all the invited persons. The number of positive iFOB test was 3,690 representing 5.9% of all the tested persons. Colonoscopy was performed in 42.1% of those with positive iFOB test.

Adenomas were found in 586 (37.7%) of all the colonoscopied, while in 129 (8.3%) colorectal cancer was found.

The coverage by invitations and the participation rate of the target population was higher in the year 2014, as shown in the Figures 1 and 2.

Results of colorectal cancer (CRC) screing programme performed during two-years period according to the different municipalities are shown in Table 2.

Table 1

Basic indicators of organized colorectal cancer (CRC) screening							
Indicator		Relative to issue					
mulcator	2013	2014	Total	— Relative to issue			
Invited	38,290 (15.3)	61,302 (20.5)	99,592 (19)	Eligable			
Tested iFOBT	23,761 (62.1)	38,491 (62.8)	62,252 (62.5)	Invited			
Positive iFOBT	887 (3.7)	2,803 (7.3)	3,690 (5.9)	Tested			
Colonoscopied	463 (52.2)	1,091 (38.9)	1,554 (42.1)	Positive iFOBT			
Adenom detected	145 (31.3)	441 (40.4)	586 (37.7)	Colonoscopy			
CRC diagnosed	41 (8.9)	88 (8.1)	129 (8.3)	Colonoscopy			

iFOBT - immunochemical fecal occult blood test.

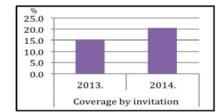


Fig. 1 – Proportion of persons of the target population invited to participate in the program according to years.

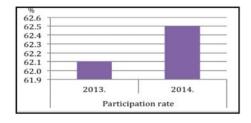


Fig. 2 – Participation rate by year.

Table 2
Distribution of invited persons, participation rate, positive immunochemical fecal occult blood (iFOB) test, screening colonoscopies and the persons with detected adenomas and colorectal cancer (CRC) in municipalities in

Serbia, 2013–2014

	Invited	Participa-	Positive		013-2014				
	persons	tion rate	test		Colonosocopy	Adenoma		CRC	
Municipality	n	%	n	%	n	n	% of colonoscopy	n	% of colonoscopy
Zemun	2,580	41.6	76	7.1	45	17	37.8	2	4.4
Voždovac	6,774	92.1	298	4.8	96	42	43.8	15	15.6
Čukarica	9,939	70.3	615	8.8	465	212	45.6	37	8
Barajevo	751	73.8	114	20.6	17	2	11.8	0	0
Sopot	2,808	67.7	122	6.4	34	10	29.4	5	14.7
Novi Bečej	1,460	59.2	110	12.7	41	20	48.8	1	2.4
Sečanj	2,110	75	72	4.6	49	28	57.1	5	10.2
Pančevo	12,461	61.4	337	4.4	176	47	26.7	7	4
Kragujevac	4,637	51.4	200	8.4	52	21	40.4	3	5.8
Topola	887	71.5	39	6.2	15	2	13.3	4	26.7
Knić	15,96	60.2	24	2.5	7	2	28.6	0	0
Niš	22,162	43.7	597	6.2	127	44	34.6	5	3.9
Doljevac	1,478	89	45	3.4	15	5	33.3	5	33.3
Kosjerić	1,803	64.4	14	1.2	12	3	25	1	8.3
Požega	3,954	54.5	25	1.2	17	1	5.9	1	5.9
Leskovac	3,793	83.4	140	4.4	43	9	20.9	9	20.9
Vlasotince	1,589	65.8	57	5.5	31	11	35.5	8	25.8
Lebane	1,795	53.4	14	1.5	7	2	28.6	2	28.6
Medveđa	1,236	67.9	15	1.8	8	5	62.5	1	12.5
Mali Iđoš	1,083	57.7	30	4.8	15	7	46.7	0	0
Sr. Mitrovica	2,730	47.7	89	6.8	28	2	7.1	3	10.7
Lučani	1,238	70.4	16	1.8	2	0	0	0	0
Ivanjica	854	46.7	9	2.3	3	1	33.3	0	0
Ćuprija	1,017	79.1	178	22.1	50	21	42	1	2
Valjevo	3,045	93.1	230	8.1	77	19	24.7	10	13
Sombor	4,052	66.8	76	2.8	30	19	63.3	2	6.7
Kraljevo	1,760	88.5	148	9.5	92	34	37	2	2.2
Total	99,592	62.5	3,690	5.9	1554	586	37.7	129	8.3

Participation rate

In the first biannual round of the organized colorectal cancer screening, participation rate was high (62.5%) and there was no statistically significant difference in participation rate of the target population between municipalities in Serbia (Figure 3).

Positive iFOB test rate

A total number of persons with positive iFOB test was 3,690 which makes 5.9% of the tested. The highest percentage of positive iFOB tests was recorded in the town Cuprija (22.1%) and Barajevo (20.6%), and the lowest in the town of Kosjerić and Požega (1.2%). A large difference in the per-

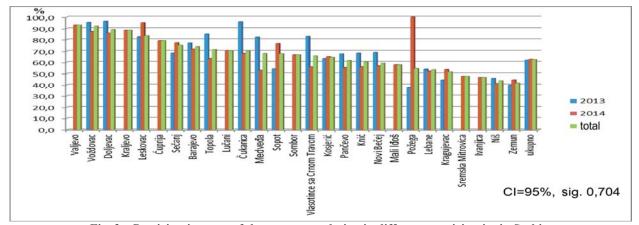


Fig. 3 – Participation rate of the target population in different municipaties in Serbia.

centage of positive iFOB test findings between municipalities urged further investigation, considering that primary health care centers until then did not use the same iFOB test. There was no statistically significant difference in positive iFOB test rate in different municipalities in Serbia (Figure 4).

Colonoscopy compliance rate

Colonoscopy was performed in 1,554 out of 3,690 persons with positive iFOB test, so colonoscopy compliance rate was 42.1%.

In the group of 1,554 persons in whom during the first round of organized colorectal cancer screening colonoscopy was performed, 586 (37.7%) persons of all colonoscopied, i.e. 0.9% of all the tested, adenomas were diagnosed and treated with endoscopic polypectomy, while in 129 (8.3%) of all colonoscopied, i.e. 0.2 of those tested, colorectal cancer was found.

Adenoma detection rate

Adenoma detection rate was 9‰. It represents proportion of persons with at least one detected adenoma in relation

to complete number of tested persons in the observation period, calculated *per* 1,000 participants. There was no statistically significant difference in adenoma detection rate in different municipalities in Serbia (Figure 5).

Positive predictive value (PPV) for detection of adenoma (percentage of persons with at least one detected adenoma in relationship with persons with positive FOB test who undertook colonoscopy within the period of observation) measured 37.7%. There was no statistically significant difference in PPV for detection of adenoma in different municipalities in Serbia (Figure 6).

Cancer detection rate

The cancer detection rate was 2‰. In different municipalities in Serbia there was no statistically significant difference in the cancer detection rate (Figure 7).

PPV for detection of cancer

PPV for detection of cancer was 8.3%. There was no statistically significant difference in PPV for detection of cancer in different municipalities in Serbia (Figure 8).

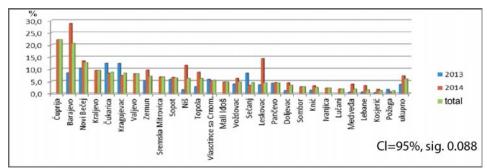


Fig. 4 – Positive immunochemical fecal occult blood test administered to persons in different municipalities in Serbia.

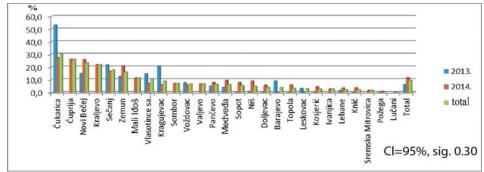


Fig. 5 – Adenoma detection rate in different municipalities in Serbia.

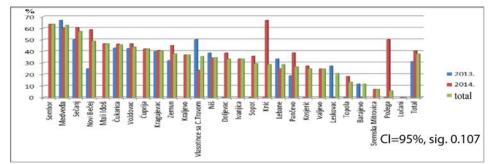


Fig. 6 - Positive predictive value for detection of adenoma in different municipalities in Serbia.

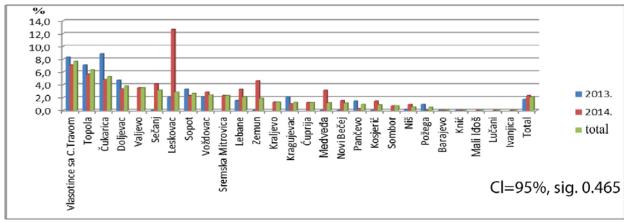


Fig. 7 – Positive predictive value for detection of cancer in different municipalities in Serbia.

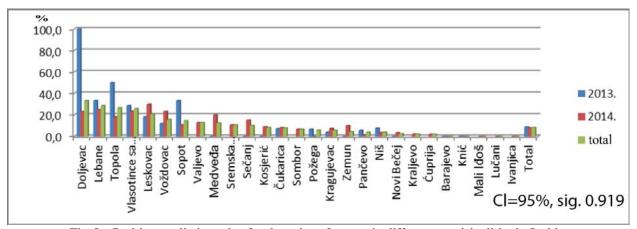


Fig. 8 – Positive predictive value for detection of cancer in different municipalities in Serbia.

Localization of adenomas and colorectal carcinoma

Totally 70.4% of diagnosed polyps and 77.3% of carcinomas were in the left half of the colon (in rectum, sigmoidal and descending colon), while 29.6% of polyps and 22.7% of the carcinomas were in the proximal parts of the colon (in cecum, ascending and transversal colon). This was observed on a sample of 40% of persons with the positive diagnosis on colonoscopy (Table 3).

Discussion

Participation rate

This study, conducted after the first round indicated high participation rate of the target population, which showed an increase in the second year of screening round, like in studies conducted in Canada, New York and in Sweden ⁷⁻⁹. Implementation of the National program in which GPs administered

Table 3

Localization of detected polyps and colorectal carcinoma (CRC)							
Part of colon		CRC (%)					
Part of colon	localization	≤ 10 mm	≥ 10 mm	localization			
Left							
rectum	11.2	12.9	10.9	27.3			
sigmo-rectum	5.9	5.7	6.7	12.1			
sigmoid	43.1	38.1	53.8	30.3			
descending	10.1	11.1	6.7	7.6			
total	70.4	67.8	78.1	77.3			
Right							
transverse	15.9	16.8	14.3	4.5			
ascending	7.2	9.2	4.2	16.7			
cecum	6.6	6.2	3.4	1.5			
total	29.6	32.2	21.9	22.7			

iFOB tests after issuing letters of invitation was 62%, confirming such recommendations as sucsesful ¹⁰. In the first round of colorectal cancer screening with FOB tests in Finland, it was 62–68% in males and 77–80% in females ⁶.

In Ontario, Canada, where guaiac FOB test was used in 2005 and 2006 when the program of organized screening of colorectal carcinoma was introduced, participation rate was 26%, and in the period of 2010–2012 increased to 63% ^{9, 11, 12}. Such uptake was accomplished in the first round in Serbia, as well.

The participation rate in such a program in Ireland was 51% ¹³. In this program of the organized colorectal cancer screening in the second year there was an increase in uptake. These results are in concordance with the results of the organized screening presented in this study.

Although with a far wider scope, organized colorectal cancer screening in France in the first biannual round with a primary guaiac FOB test achieved uptake of 34%. Compared to the uptake in Serbia, which was almost two times higher (although on a smaller sample of target population), it is shown that the delivery of the test from a general physician after a written or telephone invitation is far more effective than the mailing of the test with an invitation and instructions ¹⁴.

Faivre and Hamza ¹⁵ has pointed out the paramount importance of the response higher than 50% for the success of the screening and effectiveness in lowering of mortality of the colorectal cancer. That is the reason for the results of the first cycle of screening in Serbia with the response rate of 62% of the target population to be very encouraging.

In the course of the four-year cycle of testing in Korea, the uptake of the target population rose from 10% at the beginning to 20% at the end of the organized colorectal cancer screening round with the use of iFOB test ¹⁶.

The coverage of the population with invitations and testing continues to be low despite all the European and American Cancer Society recommendations. Coverage of target population in various European countries varies from 7.2 to 90% when the initial FOB test was used and between 7% and 55% when colonoscopy was used ^{2,4}.

Positive iFOB test

Results from different municipalities in Serbia showed that in the first cycle, there were on the average 5.9% of persons with positive findings. In 2013, the percentage of persons with positive findings of FOB test was 4.3%, while in the year 2014, it was 7.3%. In the first round of the organized colorectal cancer screening, a high percentage of persons with positive findings of iFOBT, particularly in some municipalities, according to other authors could have been connected with invitations to persons who did not belong to the group of average risk ¹⁷. In the research of Benson International Colorectal Cancer Screening Network from the year 2012, which included 26 programs of organized screening for colorectal cancer and 9 pilot programs in 24 countries, it is shown that the results from Serbia are in concord with programs in Europe, America and the countries of the West Pacific, which had used iFOB test. The percentage of positive iFOBT was 6.1% ¹⁸. Compared to the iFOB test, guaiac test has less percentage of positive findings, which on the average is 4.6% ^{17, 18}.

In the first round of the organized screening in Serbia, the percentage of positive iFOB test was 4.4–11.1%. The results achieved in Serbia are within the established and recommended values of the European recommendation ⁴.

Adenoma detection rate and PPV for the detection of adenoma

We recorded a somewhat lower rate of adenoma detection (9‰) which was slightly less compared to previous Euro-plan programs (13.3–22.3‰) ⁴. On the other hand, the PPV for the detection of adenoma in all the colonoscopied was 37.7% in the first round of organized colorectal cancer screening. It was found that PPV for detection of adenoma in our study is in concordance with the European recommendations (19.6–40.3%) ⁴.

It was shown that colonoscopy had high potential for detecting adenomas. These data are comparable with the results of organized screening program in Hungary, which also has a high incidence of and mortality from colorectal cancer, and used iFOB test, as well as in Italy ¹⁹. Although the PPV for detection of adenomas was in line with previous results of the European population based screening program, adenoma detection rate was lower, caused by low colonoscopy compliance rate. The results from the first round of colorectal cancer screening for five provincial programs in Canada have shown that a high colonoscopy compliance rate (80.5%) produced the increased adenoma detection rate which was 16.9‰ ²⁰.

Cancer detection rate and PPV for the detection of cancer

The PPV for the detection of cancer in Serbia was 8.3%, slightly higher compared to the results after the first two-year round in France (7.5%) and Canada (4.4%). Despite low a colonoscopy compliance rate, the cancer detection rate in Serbia was 2%, similar to that in France (1.9%) and Canada (1.8%), where colonoscopy compliance rate was as almost two times higher, 80.5% in Canada, and 88.5% in France ^{14, 20}. Cancer detection rate in our study is in concordance with European programs conducted (1.8–9.5‰) ⁴, as well as PPV for detection of cancer in our study is in the concordance with the European recommenoations (4.5–8.6%) ⁴.

These results indicate that Serbia needs to continue with education of the target population regarding the importance of colonoscopy for the detection of the cause of fecal bleeding in patients with a positive iFOB test, in order to increase colonoscopy compliance rate and the number of persons with detected adenomas and colorectal cancer.

Localization of polyps and carcinoma

A total of 70.4% of detected polyps were located in the left colon, which is slightly more than proportion of detected polyps in the left colon in Croatia $(64\%)^{17}$.

A total of 77.3% of detected carcinomas at colonoscopy were left-sided, which is identical to the results of organized screening for colorectal cancer in England ²¹.

Conclusion

According to the data from the first biannual round of organized colorectal cancer screening in Serbia, the participation

rate of the target population to testing was high, that is encouraging. We believe that in the forthcoming rounds, we could increase the coverage of the target population through organized screening for colorectal cancer. The established positive predictive value of completed colonoscopies shows that in further observing the stages of the diagnosed adenomas and carcinomas, we could reach the expected improvement regarding earlier detection of colorectal cancer in Serbia.

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