**EVALUATION OF FECAL IMMUNOCHEMICAL TESTS FOR COLORECTAL CANCER DETECTION.**

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**ABSTRACT.** Colorectal cancer is the second leading cause of cancer-related death in the Western industrialized world. Early detection by screening programmes has the power to improve control of the disease. Between 1 November 2011 and 31 December 2014, 2204 patients performed fecal immunochemical tests. In 198 (8.98%) patients with a mean age of 64.8 years the result of the fecal immunochemical tests was positive. In our group we had a rather low adherence to the follow-up colonoscopy, only 97 performed colonoscopy. In 26 patients (26.8%) cancer was found and in 30 (30.92%) polyps were found. Patients with cancer and polyps tend to be older than the other patients. In our group no cancer or polyp was detected in patients younger than 50 years. Hence we consider that the age of 50 for beginning the colorectal cancer screening is suitable for our area. Fecal immunochemical test can be an important tool in detection of colorectal carcinoma and preneoplastic lesions and efforts had to be made in order to run a screening programme.

**KEY WORDS:** screening, colorectal carcinoma, adenoma, colonoscopy, fecal immunochemical test

**INTRODUCTION**

Colorectal cancer is the second leading cause of cancer-related death in the Western industrialized world with an estimated 330 000 new cases and 149 000 deaths in 2008 in Europe. Increasing incidence rate are due to an aging population and ”westernised” life style in many regions of the world. (FerlayJ et al., 2008)

Fortunately the systematic early detection by screening programmes has the power to improve control of the disease. In 1990 Fearon and Vogelstein formulated a genetic model for colorectal tumorigenesis, the so-called adenoma-carcinoma sequence, that nowadays still represents the paradigm and the basis of our understanding of the disease (Fearon ER et al., 1990)

Approximately 70%–80% of the colorectal carcinoma arise within previously benign adenomatous polyps. The long preclinical phase from the development of adenomas to colorectal cancer allows for opportunities to successfully screen, eliminate early neoplastic lesions and save lives. (Miutescu B et al., 2013; Miutescu B et al., 2013; U.S. Preventive Services Task 2008)

U.S. Preventive Services Task Force recommends routine colorectal cancer screening in adults beginning at age 50 and continuing only until age 75. The following screening modalities are recommended: high-sensitivity fecal occult blood tests, sigmoidoscopy with interval fecal occult blood tests, or colonoscopy (U.S. Preventive Services Task 2008).

Fecal immunochemical tests are currently the test of choice for population screening. (Segnan N et al., 2009)

**AIM**

The aim of this study is to assess the results of fecal immunochemical tests detecting colorectal carcinoma and early neoplastic lesions is the Arad County.

**MATERIALS AND METHODS**

The patients referred to the laboratory that performed immunochimical test, between 1 November 2011 and 31 December 2014, were assessed. Patients were recruited by general practitioners, gastroenterologists and internal medicine physicians. We choose to evaluate not only patients aged between 50 and 75 years but also patients aged between 40 and 79 years in order to compare the local situation with the U.S. Preventive Services Task Force recommendations. We enrolled in the study asymptomatic persons.
The exclusion criteria were colonoscopy, sigmoidoscopy, CT colonography performed in the last 5 years, patients known with colon cancer, adenomas and inflammatory bowel diseases, and those with a familial history of colorectal cancer or adenomas.

Fecal immunochemical tests are widely used nowadays as a valuable screening tool because they are more sensitive and specific compared with conventional guaiac-based tests (Kahl CJ et al., 2009; Levi Z et al., 2011; Morikawa T et al., 2005). They are a non-invasive, relatively cheap method. Colorectal carcinoma and adenomas bleed intermittently and fecal immunochemical tests are designed to detect only human globin. Because the test use specific antibodies raised against globin which is species specific, the fecal immunochemical tests do not interfere with dietary blood. Hence no dietary restrictions are needed. Also globin is gradually degraded by the proteolytic enzymes through the intestine and this confers on it more specificity for pathology in the distal intestinal tract. (Popescu A et al., 2009) We used the rapid immunochemical test HEM-CECK 1 (VedaLab, France) in this study. The patients were provided with clear practical instructions and a stool sampling bottle with a probe attached to the cap. They were informed how to collect a stool sample by scraping the probe over a broad area of the stool surface. The material is placed in the sampling bottle and is collected at the laboratory in the first 24 hours. Patients with a positive result were advised to perform a free of charge follow-up colonoscopy and they were scheduled to the endoscopy unit at the County Hospital Arad. They were instructed about the diet recommendations and colonic cleansing protocol using a split dosing of polyethylene glycol solution. Propofol sedation was used at colonoscopy after prior informed consent.

The following data were registered for each patient: age, gender, the result of the fecal immunochemical test, the colonoscopy report.

RESULTS AND DISCUSSIONS

Between 1 November 2011 and 31 December 2014, 2204 patients performed fecal immunochemical tests. Their mean age was 61.32 years. A number of 865 males (39.25%) and 1339 (60.75%) females were assessed. As in other studies females have a better compliance to the test. The majority of the patients came from the urban area 1656 (75.14%) and only 548 (24.86%) came from the rural parts of our county. This is obviously related to greater distance to the laboratory which will consume patient time and money. Also in the rural area the medium income is lower and because the test is not reimbursed by the health insurance even the modest price of 22 lei can be prohibitive. If the financial barriers are removed due to a national screening program there is hope that the adherence will grow.

In 198 (8.98%) patients with a mean age of 64.8 years the result of the fecal immunochemical tests was positive: 84 males (9.72% reported to the total number of males) and 114 females (Fig.1, Table I). (8.51% reported to the total number of females).
The rate of the patients with positive results was low in those younger than 50 years and it grows with the age. From the total number of 198 patients with positive results at colonoscopy 97 underwent the follow-up colonoscopy. The adherence rate of 48.48% to the colonoscopy is a low one - according to the European guidelines the adherence rate of ≥85% is considered acceptable and >90% is desirable (6). A number of 46 from 84 males (54.76%) and 51 from 114 (44.73%) females performed colonoscopy. Efforts should be made to a better education of the patient who must be informed and repeatedly advised. Also we need a better availability to the endoscopy unit. Providing for free the polyethylene glycol used for colon cleansing may be useful.

In 26 patients (13 males and 13 females) of the 97 who underwent colonoscopy a colorectal cancer was found. Their mean age was 64.61 years. In 30 (30.92%) of the 97 patients who underwent colonoscopy polyps were found. In 97 of them they were 14 (46.67%) males and 16 (53.33%) female with a mean age of 69.5 years.

Summarising from the 2204 patients who performed fecal immunochemical test 198 had a positive result. Only 97 underwent a follow-up colonoscopy. In 56 patients we found a cancer or a polyp. Patients with cancer and polyps tend to be older than the other patients.

In our group no cancer or polyp was detected in patients younger than 50 years. Hence we consider that the age of 50 for beginning the colorectal cancer screening is adequate for our area. In patients aged 75 to 80 years the rate of fecal immunochemical test with positive results is high, so further studies are needed to decide if the screening must be continued till 80 years or not. Older patient are prone to cancer but they usually had some chronic diseases and the decision to screen must be taken in the context of the individual’s health status. Removing financial barriers is an important clue so that anyone could take advantage by screening. That will require substantial resources: trained physicians and nurses, convenient location for laboratory and endoscopy units with adequate equipment.

CONCLUSIONS
Fecal immunochemical test can be an important tool in detection of colorectal carcinoma and preneoplastic lesions and efforts had to be made in order to run a successful screening programme. This is a cheap, non-invasive method able to reduce colon cancer incidence and mortality. Fecal immunochemical test can be an option for a future screening programme in our country.

AUTHOR CONTRIBUTION
All authors have contributed equally to the present work.

REFERENCES
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### Table I. Distribution according to the age and gender of the patients who performed a fecal immunochemical test and patients with positive result

<table>
<thead>
<tr>
<th>Age group</th>
<th>Total number of patients</th>
<th>Total number of patients with positive result</th>
<th>Number of males</th>
<th>Number of males with positive result</th>
<th>Number of females</th>
<th>Number of females with positive result</th>
</tr>
</thead>
<tbody>
<tr>
<td>40-44 years</td>
<td>137</td>
<td>3 (2.19%)</td>
<td>53</td>
<td>1</td>
<td>84</td>
<td>2</td>
</tr>
<tr>
<td>45-49 years</td>
<td>180</td>
<td>6 (3.33%)</td>
<td>71</td>
<td>2</td>
<td>109</td>
<td>4</td>
</tr>
<tr>
<td>50-54 years</td>
<td>219</td>
<td>14 (6.39%)</td>
<td>83</td>
<td>9</td>
<td>136</td>
<td>5</td>
</tr>
<tr>
<td>55-59 years</td>
<td>366</td>
<td>28 (7.65%)</td>
<td>148</td>
<td>6</td>
<td>218</td>
<td>22</td>
</tr>
<tr>
<td>60-64 years</td>
<td>423</td>
<td>39 (9.21%)</td>
<td>153</td>
<td>14</td>
<td>270</td>
<td>25</td>
</tr>
<tr>
<td>65-69 years</td>
<td>343</td>
<td>47 (13.7%)</td>
<td>155</td>
<td>28</td>
<td>188</td>
<td>19</td>
</tr>
<tr>
<td>70-74 years</td>
<td>323</td>
<td>34 (10.52%)</td>
<td>117</td>
<td>12</td>
<td>206</td>
<td>22</td>
</tr>
<tr>
<td>75-79 years</td>
<td>213</td>
<td>27 (12.67%)</td>
<td>85</td>
<td>12</td>
<td>128</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>2204</td>
<td>198 (8.98%)</td>
<td>864</td>
<td>84</td>
<td>1339</td>
<td>114</td>
</tr>
</tbody>
</table>


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