Background and aims

M. Bretthauer1,3,6

A randomized controlled trial screening with an ultra thin colonoscope: Decreased pain during colonoscopy!

Abstracts

Oncology (ESDO)

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May 4–5, 2012

Berlin, Germany

In cooperation with the European Society of Digestive Oncology (ESDO)

Abstracts

Decreased pain during colonoscopy screening with an ultra thin colonoscope: A randomized controlled trial

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Background and aims

Screening colonoscopy for colorectal cancer (CRC) is recommended in several countries, but attendance rates are often low. Fear of pain and time-consuming, costly sedation are barriers for colonoscopy. Development of new colonoscopy equipment decreasing patient discomfort is therefore warranted. This randomized controlled trial investigates performance of an ultra thin colonoscope in CRC screening.

Patients and methods

From March through May 2011 consecutive participants in a population based colonoscopy screening trial were enrolled and randomized to examination with an ultra thin prototype colonoscope (Olympus PCF-Y0014-L) or a standard colonoscope (Olympus CF-H180DI). The prototype colonoscope is equipped with high force transmission (HFT) insertion tube which allows more pushing force and torque than ordinary colonoscopes, and also applies the Olympus passive bending section and responsive insertion technology. We used two versions of the prototype with similar technical features and appearance, but slightly different external and working channel diameters (working channel 2.8 and 3.2 mm; insertion tube diameter 9.2 and 9.5 mm). The main outcome measure was pain during the examination. Participants, who were blinded with regard to the instrument used, rated pain (no, slight, moderate, severe) using a validated questionnaire.

Results

A total of 187 participants were enrolled, 80 (43%) were women. 162 (87%) participants responded to the questionnaire. The study groups were similar regarding baseline characteristics (age, gender, BMI, previous colonoscopy, previous abdominal surgery, responders to questionnaire). Pain scores were significantly lower in the prototype group compared to the standard group (78% vs. 29% of patients with no pain in prototype and standard groups, respectively; *P < 0.001*) (Table 1). Cecal intubation rate was 98% in the prototype group and 92% in the standard group (*P = 0.085*). Sedation was used in 2% and 7% in the prototype and standard groups respectively (*P = 0.12*). Adenoma detection rate was 13% in the prototype groups vs. 24% in the standard group (*P = 0.052*).

Conclusion

The new ultra thin Olympus colonoscope decreases patient pain during screening colonoscopy. This feature may improve compliance and patient satisfaction with screening colonoscopy. Further study is needed to evaluate the lower adenoma detection rate. ClinicalTrials.gov identifier: NCT01370928.

Table 1 Patient pain in the two study groups.

<table>
<thead>
<tr>
<th>Pain</th>
<th>Prototype n = 83 (%)</th>
<th>Standard n = 79 (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>65 (78)</td>
<td>23 (29)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Slight</td>
<td>15 (18)</td>
<td>38 (48)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>2 (2)</td>
<td>9 (11)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>1 (1)</td>
<td>9 (11)</td>
<td></td>
</tr>
</tbody>
</table>

Low yield of advanced neoplasia within six years after negative colonoscopy: A population-based study

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Background and aims

One of the colonoscopy quality indicators is the occurrence of colorectal cancer (CRC) after a negative colonoscopy. Yet little is known on the incidence of advanced neoplasia and its predictors following a negative colonoscopy in daily clinical practice. The aim is to evaluate the quality of colonoscopy in daily clinical practice by investigating the incidence of colorectal cancer and advanced adenomas after negative colonoscopy in a population-based cohort study.

Patients and methods

The initial cohort consisted of all patients that underwent a complete colonoscopy in a three months period in 2005 in Northern Holland. Patients with a negative colonoscopy were followed for the subsequent occurrence of advanced neoplasia. The national Pathology Data System was used to identify patients with advanced neoplasia during six years of follow-up.

Results

In total, 2,812 eligible patients were enrolled. Advanced neoplasia was found in 37 patients (1.3%), of which 12 patients (0.4%) were diagnosed with CRC. Eight patients were diagnosed with CRC 6 to 36 months after negative colonoscopy, two patients within 6 months and two patients after 36 months. Five out of twelve colorectal carcinomas were located in the proximal colon (42%). Twenty-five patients had advanced adenomas after negative colonoscopy; 32 were found within 3 years and 44% were located in the proximal colon. In 6/12 patients with CRC and in 16/25 patients with an advanced adenoma, the procedure indication was surveillance after CRC/ polypectomy. Higher age, but not bowel preparation, sedation or endoscopist’s specialty, were associated with the presence of advanced neoplasia during follow-up.

Conclusion

There is a low yield of advanced neoplasia 6 years after negative colonoscopy in this population-based study. Most advanced neoplasia were found in high-risk patients undergoing surveillance.

Table 1 Patient pain in the two study groups.
Background and aims  Endoscopic mucosal resection (EMR) of large colorectal polyps of more than 2 cm in size using conventional ‘piecemeal’ resection is usually associated with a size-dependent recurrence rate of 10–35%. Furthermore, polyps show a progressive risk of malignant transformation with increasing size. ESD provides an ‘en bloc’ specimen allowing a precise vertical and lateral histopathological evaluation and promises a low recurrence rate (0–3%). However, ESD experience in the ‘Western World’ is limited so far compared to published large series from Japan and Korea.

Patients and methods  From March 2006 to October 2011, 81 patients (ASA 1–4) referred from major practices with ‘laterally spreading tumours’ (LST) of >2 cm in size in the rectosigmoid were treated by ESD and data collected prospectively. One patient with a multifocal recurrent adenoma after EMR and additional surgical full thickness resection received 3 ESDs of 3 distant foci of adenoma. Median patient age 69 years (47–90), 25F, 56 m (69%); 18/81 (22%) had previous local treatment (14× EMR, 6 of the 14 with multiple EMRs; 4× surgical pre-treatment). Location: 43/83 (52%) in the distal, 27 (32%) in the middle and 13 (16%) in the proximal rectum/sigmoid.

Results  74/83 lesions could be resected macroscopically ‘en bloc’ (89.1%). Largest specimen size pinned on cork: median 6.6 cm (2.2–19.0 cm). Histologically a clear adenoma-/tumor-free margin were present in 59/83 (71%). Within the last 6 months all specimens showed tumor-free margins. Histology: 12/83 (14%) malignancies; 8× focal invasive adenocarcinoma (pT1), 2× intramuscosal cancer (pTis), 1× neuroendocrine Ca, 1× smallcell B-cell lymphoma. 71/83 (86%) adenoma (31/71 [44] LG-IEN; 40/51 [56] HG-IEN).

Complications: perforations: in 2/83 ESDs detectable (2.4%); 1× OTSC, 1× vacuum sponge early ion the series); 2/83 free air in CT scan without detectable leak (antibiotics), 1× leakage suspected in the CT scan, but not at subsequent surgery. Fatal: 1× methane gas explosion with colonic perforation → 2× OTSC, emergency surgery. Bleeding: no transfusions but 2× emergency endoscopy+clip. Follow-up: median 446 Tage (0–2044 days; max. 5.6 years). 1× recurrence close to the prior resection site (1.2%) → EMR (LG-IEN; R0).

Conclusion  ESD represents the currently best oncological treatment modality for a safe endoscopic ‘en bloc’ resection of lesions >2 cm in the recto-sigmoid. In our series this was possible in 89% macroscopically and 71% histologically (100% R0 < last 6 month resections). The high rate of 62% of focal malignancies or HG-IEN in the specimen resected of median 6.6 cm and maximum of 19 cm in size, an extremely low recurrence rate of 1.2% in a long term follow-up of up to 5.6 years demonstrate the impressive potential of the procedure even in a European center. R0 resection and complication rate undergo a demonstrable learning curve.

Short-term outcomes and cost evaluation of the first two rounds of a colorectal cancer screening programme based on immunohistochemical faecal occult blood test in a northern Italian province

Background and aims  Colorectal cancer (CRC) screening aims to reduce disease-related mortality by detection of cancers at an earlier stage and by removal of its precursors (adenomatous polyps) at acceptable costs. We assessed both short-term outcomes and costs of the first two biennial rounds of a population-based CRC screening programme using faecal immunochemical test (FIT) in a northern Italian province.

Patients and methods  All residents aged between 50 and 69 years in the pilot province of Lecco were invited by mail to take part in a biennial screening programme using a 1-day non-rehydrated FIT. Those with a positive result were offered colonoscopy. FIT uptake, compliance with colonoscopy, detection rate for cancer and advanced adenomas according to sex and age strata (50–59 or 60–69 years) as well as direct cost analysis was carried out separately for the first and second round of screening.

Results  Among 78083 or 81619 subjects invited to the first and second round of screening, respectively, the corresponding participation rates was 49.6% or 54.4%, and the FIT positivity rate was 6.2% or 5.9%. Detection rates for cancer and advanced adenomas were lower in repeat as compared with first screening (1.6% vs. 2.4% for cancers and 15.8% vs. 17.9% for advanced adenomas, respectively), whereas the positive predictive value (PPV) for cancer and advanced adenoma were quite similar in both rounds. On the whole, 165 adenocarcinomas were detected, of which 161 were staged at initial diagnosis: 52% were stage I and 21% stage II. All cost indicators were slightly higher in the first compared with the second round of screening. The direct cost per cancer or advanced adenoma detection was similar in the two rounds (1101.4 and 1146.0€ at first and second round, respectively) and lower than those previously reported in our and other European countries.

Conclusion  Participation to and diagnostic yield of a FIT based mass-screening programme for CRC in our province are quite satisfactory and similar to what is reported in controlled trials. Most of screen detected cancers are at very early stages; costs of the programme are quite reasonable and do not increase with repeat screening.

Factors related with detection of polyps in screening colonoscopy. Influence of right- vs. leftside polyp location


Background and aims  Colonoscopy and polypectomy plays a central role in colorectal cancer (CRC) prevention. However, some studies suggest lack of efficacy of colonoscopy in the prevention of right-side CRC that could be related to different aspects involving colonoscopy quality. The aim of this study is to know which factors are related with the detection of right and left-side polyps in screening colonoscopy.

Patients and methods  A total of 3288 people have been evaluated in the colonoscopy arm of the ColonPreV study, a randomized trial aimed to compare colonoscopy vs FIT in CRC screening. Polyps were considered as right-sided if they are located in the cecum, ascending or transverse colon. Univariate and logistic regression multivariate analysis were performed in order to evaluate factors related with the finding of colon polyps or CRC and right or left-side polyps.

Results  Polyps or CRC were found in 1564 patients (47.6%). A total of 948 polyps or CRC in their right colon and 516 (39.4%) had only left-side polyps or CRC. In the univariate analysis factors influencing detection of polyps or CRC anywhere in the colon were: hospital, older age, male gender, endoscopists with withdrawal time in normal colonoscopy longer than 6 minutes, cecal intubation, colonic cleansing with sodium fosfate and use of sedation. In the multivariate analysis only withdrawal time (OR 1.79; 95% CI 1.44–2.30), gender (OR 0.42; 95%CI 0.36–0.50), cecal intubation (OR 0.52; 95%CI 0.34–0.79) and use of sedation (OR 2.05; 95%CI 1.27–3.31) were independently associated with detection of colon polyps or CRC. Factors influencing detection of lesions in the right colon were: hospital, withdrawal time longer than 6min, male gender, older age, cecal intubation, use of sedation, use of sodium fosfate, use of propofol in sedation and sedation assisted by anesthetist. In the multivariate analysis, independent factors related with detection of right-side lesions were: male gender (OR 2.42; 95%CI 1.94–3.01), withdrawal time (OR 0.69; 95%CI 0.52–0.91), cecal intubation (OR 1.84; 95%CI 1.04–3.26) and use of sedation (OR 1.15; 95%CI 1.05–1.26). For left-side polyps only the hospital, withdrawal time and male gender were related with its detection.
**Background and aims** Although the adherence to post-polypectomy recommendations is advocated as a quality indicator of colonoscopy programs, prospective data on actual use of surveillance are lacking. The aim of this study was to evaluate the appropriateness of post-polypectomy surveillance colonoscopy on a community-wide basis and to identify factors associated with it.

**Patients and methods** Data on consecutive colonoscopies performed over a 4-week period in 29 endoscopy units in Italy were prospectively collected. For each post-polypectomy surveillance examination, a modified version of the AGA Institute Polyp Surveillance Data Collection Form was filled-in; the time interval between index and surveillance colonoscopy was calculated and compared to guideline recommendations. Proportion of correct prescription and determinants of surveillance timing appropriateness were evaluated as main outcome measures.

**Results** Of 7081 consecutive outpatients, 1218 (17.2%) were referred for post-polypectomy surveillance and 902 were included into the analysis. Surveillance timing resulted correct in 330 subjects (36.6%), anticipated in 490 (54.3%) and delayed in the remaining 82 (9.1%). Low-risk subjects had an anticipated surveillance colonoscopy more frequently than high-risk (67.4% vs. 54.3%, P < 0.001).

At multivariate analysis, determinants of surveillance timing appropriateness were centers with high-volume workload (OR 1.92: 1.41 – 2.63 95% CI), centers providing written recommendation on surveillance interval (OR 1.70; 1.18 – 2.58 95% CI), and surveillance examinations prescribed within a programmatic colonoscopy screening program (OR 2.62: 1.92 – 3.59 95% CI).

**Conclusion** In community practice, post-polypectomy surveillance colonoscopy is often performed earlier than recommended, especially in low-risk subjects. Interventions to reduce unnecessary examinations and to improve adherence to guidelines are advocated, in order to shift resources to screening programs and symptomatic patients.

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**Retroflexion in the proximal colon: A single centre study**

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**Background and aims** Retroflexion in proximal colon has been found to be safe during colonoscopy. Single centre studies have shown improved diagnostic yield [2]. Large studies are necessary to identify the added yield and ascertain if this has to be routinely done. We wanted to assess patient tolerance, success rate, yield and safety of Retroflexion (RF) in proximal colon during colonoscopy.

**Patients and methods** A prospective observational study was carried out by a single endoscopist using standard colonoscope at a tertiary hospital in UK over a 5-month period from September 2011. Patients were assigned to two groups. Group A included patients in whom RF was not planned and Group B with patients we intended to perform RF in proximal colon. Each group had 100 patients with a mean age of 60 years. Comfort score during procedures were recorded between 0 – 4 (with 0 being comfortable and 4 being severe discomfort).

**Results** Procedure completion rates (till caecum or Terminal ileum) were 94% and 97% in Group A and B respectively. In Group A (RF not intended) proximal polyp detection rate (PDR) was 15%, 86% of this group had comfort scores of < 0 or 1. In Group B (RF intended) Retroflexion was successful in 97% of cases, 95% of had comfort scores of 0 or 1. The proximal PDR was 22%. In 40% of these polyps, histology reports were available confirming as adenomatous and histology is awaited in the remainder. There was no difference in the left sided PDR between the groups.

**Conclusion** Retroflexion in proximal colon is technically possible in most cases. It is safe and does not cause any increased discomfort. There is increased proximal polyp detection with Retroflexion.

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**Colorectal cancer in the region with enormously high occurrence rate: the projection of screening program and clinical practice**

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2 Department of Internal Medicine, Central Military Hospital, Prague
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**Background and aims** The national colorectal cancer screening programme in the Czech Republic is extremely high even in those under the age of 50, and the screening rules should be adapted accordingly. The proportion of people with a positive family history is also high. The disproportionately low occurrence of neoplasias among them could be explained by their youth, suggesting they are well informed and seek screening early. The relatively young age of screened people indicates that the campaign should be focused more on those who are older.

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**The impact of a nationwide five-year quality improvement program on colonoscopy practice**

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3 Department of Gastroenterology, Hull and East Yorkshire Hospitals, United Kingdom

**Background and aims** A nationwide quality improvement project for colonoscopy following the plan/do/study/act methodology was set-up in Italy in 2004. The initial prospective evaluation reported disappointing data on colonoscopy indicators. The present study was aimed at prospectively re-assessing performance indicators five years after the implementation of the program.

**Patients and methods** National and regional initiatives to point-out critical issues on colonoscopy were only later recorded and adapted to available programmes. The aim of our multicenter prospective study was to analyze issues of the quality of colonoscopy, the incidence of polyp neoplasias, and the projection of screening.

**Results** A total of 2126 consecutive colonoscopies performed during 2009 – 2010 at four regional tertiary centres in people older than 40 years of age were analyzed. The occurrence rates of adenomas, advanced adenomas, and carcinomas in those <45, 45 – 50, and >50 years were 8.3%, 25.3%, and 48.3%; 3.3%, 10.0% and 31.3%; 1.1%, 2.0%, and 6.8% respectively. Only 59.9% of advanced neoplasias were potentially accessible by sigmoidoscopy. Colonoscopy was performed as a screening procedure in 320-males and 245 females; any between-gender differences were not statistically significant (P = 0.05). A total of 931 (43.8%) patients reported a positive family history. The occurrence rates of advanced adenomas and carcinomas were 6.8% and 2.1%, respectively, figures significantly lower than in other patients (44.6% and 8.5%, respectively, P = 0.001). The mean age in both groups was 47 and 63 years. In screening subgroup, 301 (53.3%) of the 565 patients reported a positive family history. The occurrence rates of advanced adenomas and cancers were 3.3% and 0.9%, significantly less than in people without a positive family history (27.6% and 4.9%, respectively). The mean age of these subgroups was 45 and 52 years. In 245 patients colonoscopy was done after positive FOBT, and in 320 as a primary screening method. The occurrence rate of advanced neoplasias after positive FOBT was significantly higher (21.2% vs. 13.1%, respectively, P = 0.01).

**Conclusion** The rate of neoplasias detected by colonoscopy in the Czech Republic is extremely high even in those under the age of 50, and the screening rules should be adapted accordingly. The proportion of people with a positive family history is also high. The disproportionately low occurrence of neoplasias among them could be explained by their youth, suggesting they are well informed and seek screening early. The relatively young age of screened people indicates that the campaign should be focused more on those who are older.

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**Factors related with detection of left-side polyps are different, and use of sedation improves particularly the detection of right-sided polyps.**
noscopy and educational initiatives (“Train-the-Trainers courses”, “Peer-to-Peer Meetings”, “Hands-on” sessions) to improve the quality performance were promoted. Centers participating to the first round of the project in 2004 were invited to collect data on consecutive colonoscopies in a 2-week period. Cecal intubation and polyp detection rates were calculated and compared with those reported before the quality improvement program implementation (“before-and-after study”).

**Results** Overall, 4452 procedures from 77 centers were evaluated and compared to 3589 procedures performed in the same centers five years earlier. A statistically significant difference between the two rounds of data collections was observed for both cecal intubation (82.6% versus 80.9%, *P* = 0.043) and polyp detection rates (31.3% versus 28.1%, *P* = 0.002). However, only 7 and 5 centers reported a significant improvement for the cecal intubation and polyp detection respectively; 52 centers had a cecal intubation rate constantly under 90%.

**Conclusion** Present data show that colonoscopy in Italy is still far below the quality standards and that a nationwide-based improvement program may not be effective to significantly enhance the quality of colonoscopy in everyday clinical practice. Alternative strategies, such as continuous external assessment of the performances or accreditation processes or local activities of continuous monitoring and feedback should be pursued.

**Prospective evaluation of learning curves of endoscopic submucosal dissection (ESD) in the rectum and colon**

<table>
<thead>
<tr>
<th>Volume of patients examined at center</th>
<th>Number of centers</th>
<th>Aggregated number of patients</th>
<th>Adenoma detection rate, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–50</td>
<td>22</td>
<td>397</td>
<td>40.3</td>
</tr>
<tr>
<td>51–75</td>
<td>37</td>
<td>1913</td>
<td>36.4</td>
</tr>
<tr>
<td>76–100</td>
<td>38</td>
<td>2863</td>
<td>33.9</td>
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<tr>
<td>101–150</td>
<td>41</td>
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<td>32.1</td>
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<tr>
<td>151–200</td>
<td>22</td>
<td>3017</td>
<td>37.2</td>
</tr>
<tr>
<td>201+</td>
<td>25</td>
<td>5607</td>
<td>31.2</td>
</tr>
<tr>
<td>Total</td>
<td>185</td>
<td>17876</td>
<td>33.6</td>
</tr>
</tbody>
</table>

ESDs on isolated stomach; a 2-week observer period in an expert ESD center; 1 supervised ESD on isolated stomach. ESDs were performed unsupervised with insulated-non-insulated knives and the injection of a mixture of hydroxyethyl cellulose, epinephrine, sodium hyaluronate when necessary. Indication for ESD: superficial lesions ≤20 mm. Learning curves for rectal and colon ESD were assessed comparing consecutive blocks of 5 procedures. Primary outcomes: en bloc resection rate; operative time/cm²; perforation rate. Competency definition: en bloc resection rate ≥80%, significant reduction of operative time.

**Results** 30 rectal-ESDs and 30 colonic-ESDs were performed. Colonic-ESD started to be performed after 15 rectal-ESDs. Learning curve of rectal-ESDs showed: 1) en bloc resection rate was 60% in block-1 and 80% in block-2; 2) operative time/cm² significantly decreased after 20 procedures (45 min vs. 16 min; *P* = 0.0079); 3) one perforation (3%) in block-1. Learning curve of colon-ESD showed: 1) en bloc resection rate increased from 20% to 80% after 20 procedures; 2) operative time/cm² significantly decreased after 20 procedures (65 min vs. 8 min; *P* = 0.031); 3) two perforations (8%) in the first two blocks. Colon location was the only negative prognostic factor for ESD en bloc resection (OR 0.28; 95% confidence interval 0.09–0.89).

**Conclusion** After a short training in ESD, an unsupervised endoscopist expert in operative procedures is able to perform rectal-ESD safely but not colon-ESD, which is much more complex with a substantial risk of perforation, and requires a specific skill independent rectal-ESD. However, threshold for competence both of rectal- and colon-ESD was 20 procedures.

**Quality control of colonoscopies in the national colorectal cancer screening programme in the Czech Republic**

<table>
<thead>
<tr>
<th>Table 1 Comparison of adenoma detection rate in different centers.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume of patients examined at center</td>
</tr>
<tr>
<td>--------------------------------------</td>
</tr>
<tr>
<td>1–50</td>
</tr>
<tr>
<td>51–75</td>
</tr>
<tr>
<td>76–100</td>
</tr>
<tr>
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</tr>
<tr>
<td>151–200</td>
</tr>
<tr>
<td>201+</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

For all centers, adenoma detection rate was 31.2% (95% CI 27.8–34.6). The highest average ADR was 44.4% (95% CI 40.7–48.1) in the top position in world statistics of colorectal cancer (CRC) incidence and mortality. Organized screening programme was introduced in year 2000. Quality of screening colonoscopy (SC) has been evaluated based on two indicators—adenoma detection rate (ADR) and caecal intubation rate (CIR). Limit for participation in screening programme is 50 screening colonoscopies per year. The aim of our analysis was to determine whether ADR and CIR of specific examiners correlate with quantity of performed procedures and how these results describe individual colonoscopic screening centers.

**Patients and methods** Data were analyzed from the colorectal cancer screening program in the Czech Republic. Both, endoscopists and screening centers, were divided into five groups according to numbers of patients examined. ADR and CIR of individual examiners and screening centers respectively were calculated.

**Results** In the year 2010, 500 endoscopists in 185 screening centers performed 17876 screening colonoscopies. Average individual ADR and CIR was 33.6% and CIR 95.1% resp. In the group of examiners with least performed SC (1–25 per year) ADR was 33.3%. In examiners with 26–50 procedures per year ADR was 34.9%. In the group with 51–75 examinations per year ADR was 35.2%. In groups with highest numbers of performed procedures (76–150, and more than 150 per year) ADR was 34.8% and 30.8% respectively. ADR correlates with experience of colonoscopic specialists, however in the group with highest counts of procedures, quality did not correlate with quantity. Individual CIR correlates strongly with experience, the group with more than 1500SC per year achieved 96% CIR. In the low volume centers (<50–75 SC per year) total ADR of 36.4% was recorded. In contradicition, centers with the high volume centers SC numbers (more than 200 per year) achieved lowest total ADR (31.2%) (Table 1). Total ADR of endoscopic centers did not correlate with quantities of SC.

**Conclusion** Our analysis shows that even smaller centers are able to maintain high standards of screening colonoscopy and that no changes in minimum requirements for centers to participate are necessary.