https://doi.org/10.33878/2073-7556-2025-24-3-12-21



# Effectiveness of artificial intelligence's system ArtInCol in diagnostic of colorectal neoplasia during colonoscopy: results of multicenter randomised clinical trial

Sergey I. Achkasov[1,2], Yuri A. Shelygin[1,2], Aleksey V. Shabunin[1,2], Irina Yu. Korzheva[2,3], Evgeniy D. Fedorov[4], Yuliya Yu. Kamaletdinova[5], Dmitriy G. Shakhmatov[1,2], Alexey A. Likutov[1], Ilya V. Nazarov[1], Evgeniy V. Gorbachev[4], Airat F. Mingazov[1]

[1]Ryzhikh National Medical Research Center of Coloproctology (Salyama Adilya st., 2, Moscow, 123423, Russia)
[2]Russian Medical Academy of Continuous Professional Education (Barrikadnaya st., 2/1, Moscow, 125993, Russia)
[3]S.P. Botkin Medical Clinical Center of the Department of Health Care of Moscow (2nd Botkinsky passage, 5, Moscow, 125284, Russia)
[4]N.I. Pirogov Medical University (Ostrovitianova st., 1, Moscow, 117321, Russia)
[5]Republican Clinical Oncological Dispensary of the Ministry of Health of the Republic of Bashkortostan (Oktyabrya Avenue, 73/1, Ufa, 450054, Russia)

**ABSTRACT** *AIM: to evaluate the effectiveness of the Russian artificial intelligence system ArtInCol during routine colonoscopy.*
*PATIENTS AND METHODS: from August to December 2024 a multicenter randomized trial was done and included 4 medical institutions and 1,128 patients. The patients were randomized into colonoscopy groups without AI (n = 547) and colonoscopy group using the ArtInCol artificial intelligence system (n = 581). The data was analyzed according to the "intention-to-treat" and «per protocol» types, with the primary endpoint being the frequency of detection of adenomas.*
*RESULTS: the randomized groups were homogenous in all analyzed variables. When comparing the primary endpoint, the detection rate of adenomas (ADR) in the studied group of AI-assisted colonoscopy was 47.2% (95% CI: 43.1–51.2), compared with 41.3% (95% CI: 37.3–45.5) without AI, the effect value was 5.9%, p = 0.048. The average number of detected adenomas was 0.97 (95% CI: 0.85–1.09), versus 0.79 (95% CI: 0.67–0.92) in the control group, which is a statistically significant difference (p = 0.01).*
*CONCLUSION: the study confirm the hypothesis of the effectiveness of the AI — ArtInCol system in order to improve the quality of neoplasm detection during colonoscopy. An increase in the detection rate of adenomas by 5.9% was recorded.*

**KEYWORDS:** *colonoscopy, adenoma, artificial intelligence*

**CONFLICT OF INTEREST:** *the authors declare no conflict of interest*

**FOR CITATION:** Achkasov S.I., Shelygin Y.A., Shabunin A.V., Korzheva I.Yu., Fedorov E.D., Kamaletdinova Y.Yu., Shakhmatov D.G., Likutov A.A., Nazarov I.V., Gorbachev E.V., Mingazov A.F. Effectiveness of artificial intelligence's system ArtInCol in diagnostic of colorectal neoplasia during colonoscopy: results of multicenter randomised clinical trial. *Koloproktologia.* 2025;24(3):12–21. (in Russ.). https://doi.org/10.33878/2073-7556-2025-24-3-12-21

**ADDRESS FOR CORRESPONDENCE:** *Mingazov A.F., Ryzhikh National Medical Research Center of Coloproctology, Salyama Adilya st., 2, Moscow, 123423, Russia; e-mail: mingazov-airat@coloproc.ru*

*Received — 30.04.2025* *Revised — 23.05.2025* *Accepted for publication — 05.08.2025*

## INTRODUCTION

Recently, colonoscopy is the defining method of colorectal cancer screening, which directly affect the detection rate of tumors. At the same time, the medical community faces a number of issues related to the quality of this diagnostic procedure, which in turn directly depends on the qualifications of the endoscopist, the level of equipment and patient-associated factors. It is known that 1 out of 3 large intestine neoplasms can be missed during colonoscopy [1]. Missing adenomas is associated with the development of interval colorectal cancer over the next 5–10 years, with a high

probability of detecting a patient at an advanced stage of the disease [2,3].

The implementation of real-time tumor detection systems based on artificial intelligence (AI) in colonoscopy into clinical practice, according to the literature, makes it possible to improve the effectiveness of endoscopy by identifying more patients with colorectal adenomas, affecting the integral indicators: Adenoma detection rate (ADR) and Polyp detection rate (PDR). Along with this, the use of an AI assistant makes it possible to reduce the proportion of missed small-diameter neoplasms.

In 2023, Russian AI-based medical decision-making system (ArtInCol) for colonoscopy was developed. In the first paper on the results of the developed prototype, the authors stated the accuracy of detection of colorectal neoplasms — 83.2% and sensitivity — 77.2% when analyzing the test sample [4]. After significant improvements, clinical trials and a tandem study were done. An increase in the detection rate of neoplasms of all types (PDR) was found from 40.6% to 56.4% when reviewed using the AI system (ArtInCol) [5].

Taking into account the established trend in the effectiveness of AI systems in colonoscopy, a multicenter randomized trial was done to determine the effectiveness of domestic development (ArtInCol) in high-flow centers.

## PATIENTS AND METHODS

In the period from August to December 2024, a multicenter randomized trial without blinding methods was done. The following centers participated in the study: RNMRC of Coloproctology of the Health Ministry of Russia; S.P. Botkin Medical Clinical Center of the Department of Health Care of Moscow; Moscow State Medical Institution "City Clinical Hospital No. 31 named after Academician G.M. Savelyeva"; the Republican Clinical Oncological Dispensary of the Ministry of Health of the Republic of Bashkortostan. Adult patients who underwent colonoscopy for screening and who gave informed voluntary consent to participate were included.

*Criteria for non-inclusion:*

1. The established fact of the presence of polyps, adenomas and colorectal cancer;
2. Established diagnosis of inflammatory bowel disease (IBD);
3. History of colorectal surgery (including polypectomy);
4. Pregnancy;
5. The patient's refusal to participate in the study at any stage.

*Exclusion criteria:*

1. Poor bowel cleansing (as per the Boston scale less than 6 points / any segment of the large intestine less than 2 points);
2. Newly diagnosed polypous syndrome, IBD;
3. Stenosing large intestine cancer;
4. The inability to perform a total colonoscopy for other reasons.

The study was done in accordance with the ethical requirements set out in the Helsinki Declaration of the World Medical Association (WMA); the Rules of Good Clinical Practice (GCP) of the Eurasian Economic Union (EAEU), the requirements of the Order of the Ministry of Health of the Russian Federation dated April 01, 2016, No. 200n "On approval of the rules of good clinical practice".

The presented study has received official approval from the local Ethics Committee of the RNMRC of Coloproctology of the Health Ministry of Russia (Protocol No. 7/24 dated April 25, 2024), and is also registered in the International Register of Clinical Trials — clinicaltrials.gov (identification number: NCT06469671). Each participant was provided with comprehensive information about the goals, methods, possible risks, and expected benefits of participating in the study. The patients were informed of their right to withdraw or terminate their participation at any time without any consequences for their further treatment.

Randomization was performed by an endoscopist included in the study using the random number method with a parallel distribution of patients into 2 groups in a 1:1 ratio after meeting the

inclusion criteria and signing an informed voluntary consent to participate. Endoscopists participated in the study while complying with the minimum professional experience requirement of 1,000 procedures. A total of 12 specialists of comparable expertise were included in the study. A total of 12 specialists of comparable level of expertise were included in the study. The procedure consisted of performing a colonoscopy using a conventional method up to the dome of the cecum, followed by the removal of an endoscope with additional assistance using an artificial intelligence system. The ArtInCol AI system is a vendor-neutral medical device (RU No. RZN 2024/23409) connected to standard endoscopic equipment. The functioning of the system consists in processing the incoming video stream during the colonoscopy in a compact industrial computer with an AI assistant installed and forming an augmented response picture with the appearance of a 'detection frame' on the monitor in real time in those areas where there is a high probability of finding a neoplasm (Fig. 1).

The system is based on neural network algorithms of computer vision, trained on the archives of the RNMRC of Coloproctology, marked up by specialists of the Endoscopic Diagnostics and Surgery Unit. The mean value of false positives was 1.23 per study. This value was obtained for 35 randomly selected colonoscopies from the presented sample of patients, taking into account the triggering of the model in the form of the appearance of a detection frame lasting at least 3 seconds.

The endoscope was removed for at least 6 minutes in accordance with common clinical practice. The detected neoplasms were recorded regardless of the fact of detection. All detectable formations were additionally examined in narrow-spectrum modes for classification according to the dimpled pattern. If clinically appropriate, which was determined by an endoscopist, the neoplasm was removed or biopsied, followed by a pathomorpholy- among all identified adenomas, with subsequent morphological examination of biopsies among all identified adenomas.

In the control group, a colonoscopy was performed, in accordance with common practice and standards of the procedure, with the exception of using the AI system as a real-time assistant.

The primary endpoint, the detection rate of adenomas (ADR), was estimated as the proportion of patients with detected adenomas from the total number of colonoscopies in the group. The mean number of detected adenomas per colonoscopy (APC) was also analyzed as a secondary endpoint — the calculation was performed for the entire group of patients. The detection rate (PDR) and the mean number of detected polyps per colonoscopy (PPC) were determined in a similar way, taking into account epithelial neoplasms of all types (adenomas, dentate and hyperplastic formations).

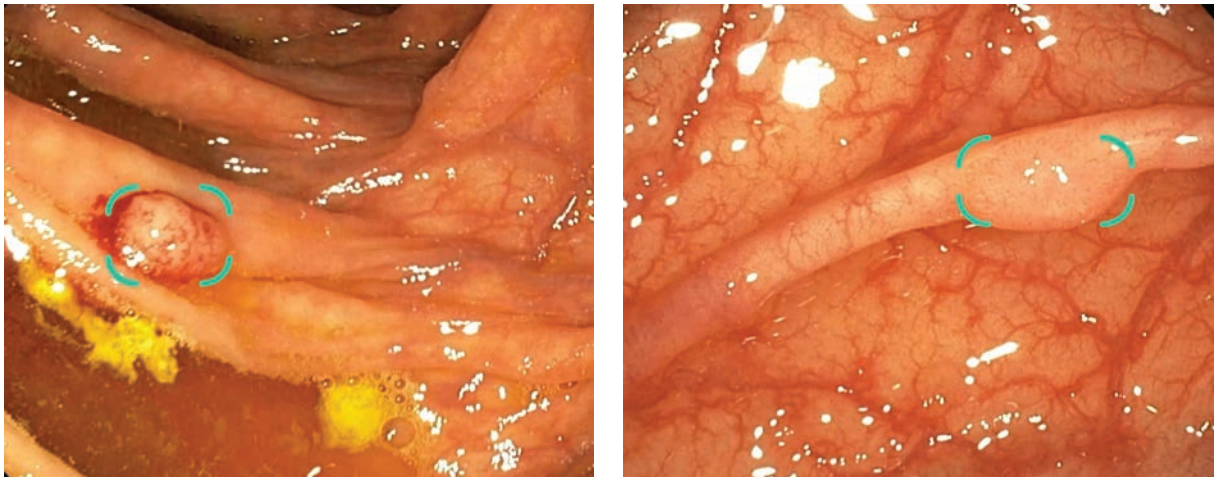

**Figure 1.** *Adenoma detection in the group of AI-assistant colonoscopy*

The hypothesis of the study wasthe advantage of colonoscopy with the use of an AI assistant in the detection rate of adenomas up to 6%, compared with endoscopy without an AI assistant. In accordance with a pre-defined hypothesis, the necessary sample of »1,000 patients were calculated: the set capacity was 80% and the assumed statistical significance was at least 95% to obtain the desired clinical effect value of up to 6% when compared using the criterion $\chi^2$ + 20%, taking into account possible exceptions and data loss. The specified value of the clinical effect is based on the results of a previous tandem study, where the ADR difference was 34.7% vs 40.6% [5].

***Statistical Analysis***

The first stage is a descriptive exploratory analysis. Categorical data are presented in the form of absolute numbers and corresponding fractions (%). Numerical data are checked for compliance with the Gaussian distribution of data using the Agostin-Pearson and Shapiro-Wilk criteria. Numerical data are described with indication of medians and interquartile range (25%, 75%). A comparative analysis of categorical data, including endpoints, was performed using Pearson's $\chi^2$ method. For the values of the ADR and PDR endpoints, a 95% coincidence interval was calculated using Wilson's method and a relative risk with a 95% coincidence interval. Also, by simple calculation, the value of the rate difference at the categorical endpoints was obtained.

When describing secondary endpoints — the number of detected adenomas and neoplasms of all types, the mean value was used in connection with the generally accepted practice for this indicator in the world. In order to avoid violations of the methodology of statistical processing, the median with an interquartile range was used as a measure of the central trend of this indicator, and the average value with a 95% coincidence interval carried a standardized value for readers' perception. The comparison was performed using the nonparametric Mann-Whitney's criterion, as with other numerical variables due to the absence of the Gaussian distribution. In order to verify the degree of influence of various variables on the desired outcome, a univariate analysis was performed, and the odds ratio (OR) values with a 95% coincidence interval were obtained. For the numerical variables associated with the final outcome, a ROC analysis was performed to determine the threshold value for further additional 'per protocol' analysis. The differences were considered statistically significant at $p < 0.05$. Calculations were done using GraphpadPrismv10 software 2.3 (Graphpad Software, USA).

The article was designed in accordance with the criteria for evaluating the quality of presentation of the results of randomized trials CONSORT 2025, with additions for research on new methods using artificial intelligence CONSORTAI 2020 [6,7].

## RESULTS

In the period from August to December 2024, 1,530 patients were selected for inclusion in the study.

Three-hundred thirty-three patients were not included due to non-inclusion criteria. At the same time, 5 endoscopists (out of 12) from different institutions and 1 Center (out of 4) were excluded from further research due to a violation of the research protocol. 1,197 patients were randomized in the participating Centers. The colonoscopy group using the AI system included 606 patients, and the control group included 586 participants. After randomization, according to the results of the colonoscopy performed, 43 patients were excluded from the study due to unsatisfactory bowel cleansing or detected pathology that made it difficult to perform a full examination of the mucous layer of all parts of the large intestine. Also, 26 patients were excluded from the study due to the lack of the required amount of completed data. Detailed information on patient movement is presented in the Consort-flow-chart (Fig. 2).

Both groups were homogenous in main variables (Table 1).

**Table 1.** *Descriptive statistics of the patients*

| Variable | AI–assisted colonoscopy N = 581 | Colonoscopy without AI N = 547 | P |
|---|---|---|---|
| Male<br>Female | 131 (22.5%)<br>450 (77.5%) | 129 (23.6%)<br>418 (76.4%) | 0.68 |
| Age, *Me (Q1, Q3)* | 58 (50, 67) | 55 (50, 66) | 0.13 |
| One-stage cleansing<br>Two-stage cleansing | 165 (28.4%)<br>416 (71.6%) | 141 (25.8%)<br>406 (74.2%) | 0.32 |
| Polyethyleneglycol | 332 (56.9%) | 313 (57.2%) | 0.93 |
| Total cleansing score, *Me (Q1, Q3)* | 8 (8, 9) | 8 (7, 9) | 0.13 |
| Exit large intestine examination time, *Me (Q1, Q3)* | 9 (7, 12) | 8 (7, 11) | 0.54 |
| Afternoon colonoscopy | 338 (58.1%) | 331 (60.5%) | 0.41 |
| Colonoscopy under sedation | 450 (77.4%) | 418 (76.4%) | 0.68 |

*Intention-to-treat Data Analysis*

When comparing the primary endpoint, it was found that the detection rate of adenomas (ADR) in the main group using the AI system was 47.2% (95% CI: 43.1–51.2%), compared with 41.3% (95% CI: 37.3–45.5%) in patients undergoing colonoscopy without an AI assistant (Table 2). The rate difference was 5.9%, $p = 0.048$, relative risk (RR) = 1.14

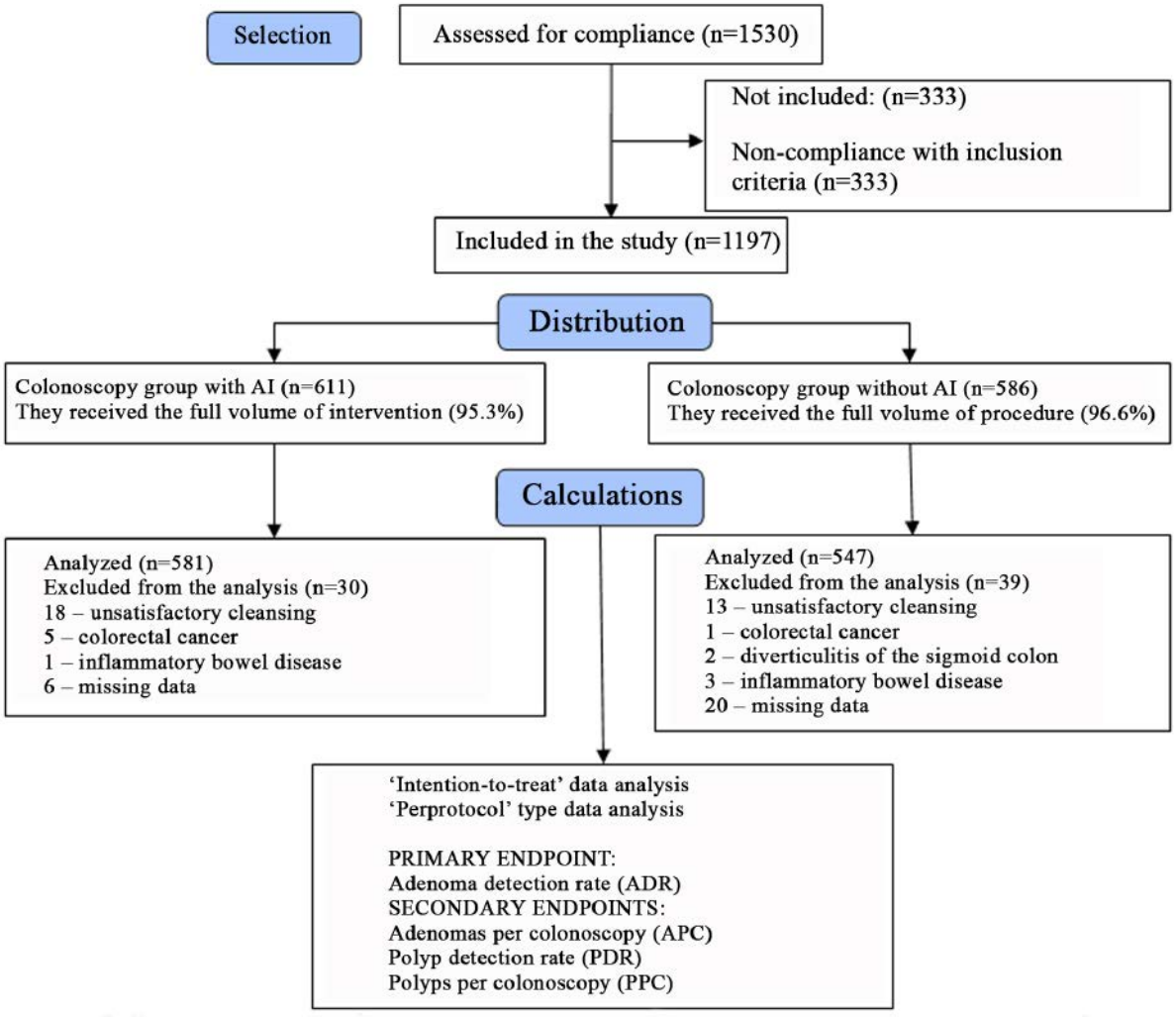


**Figure 2.** *Consort-flow-chart of patients in the trial, endpoints*

**Table 2.** *Descriptive statistics of neoplasia*

| Variable | AI–assisted colonoscopy N = 581 | Colonoscopy without AI N = 547 | P value |
|---|---|---|---|
| ADR | 274 (47.2%) | 226 (41.3%) | 0.048 |
| PDR | 325 (55.9%) | 270 (49.4%) | 0.027 |
| APC | | | 0.011 |
| M (95% CI) | 0.97 (0.85–1.09) | 0.79 (0.67–0.92) | |
| Me (25%, 75%) | 0 (0.1) | 0 (0.1) | |
| PPC | | | 0.004 |
| M (95% CI) | 1.25 (1.12–1.39) | 1.08 (0.87–1.16) | |
| Me (25%, 75%) | 2 (1.3) | 1 (1.2) | |
| The size of adenomas: | | | 0.059 |
| ⩽ 10 mm | 312 (53.7%) | 263 (48.1%) | 0.025 |
| > 10 mm | 37 (6.4%) | 19 (3.5%) | |
| Localization: | | | 0.57 |
| Hepatic flexure | 181 (31.1%) | 162 (29.6%) | 0.034 |
| Transverse colon | 97 (16.7%) | 67 (12.2%) | 0.003 |
| Splenic flexure | 186 (32.1%) | 132 (24.1%) | |
| Classification JNET: | | | 0.11 |
| 1 | 192 (33.1%) | 157 (28.7%) | 0.0001 |
| 2A | 124 (21.3%) | 70 (12.8%) | 0.59 |
| 2B | 2 (0.4%) | 1 (0.2%) | 0.34 |
| 3 | 3 (0.5%) | 1 (0.2%) | |
| Paris Classification: | | | 0.53 |
| 0-Ip | 22 (3.8%) | 17 (3.1%) | 0.42 |
| 0-Is | 162 (27.9%) | 141 (25.8%) | 0.049 |
| 0-IIa | 205 (35.3%) | 163 (29.8%) | 0.94 |
| 0-IIa + c | 3 (0.5%) | 3 (0.5%) | |

(95% CI: 1.01–1.31). At the same time, the secondary endpoint was the mean number of detected adenomas among all the patients (APC) in the AI colonoscopy group was 0.97 (95% CI: 0.85–1.09), vs 0.79 (95% CI: 0.67–0.92) in the control group, $p = 0.011$, effect value = 0.18 (95% CI: 0.04–0.35). The rate of detection of neoplasms of all types (PDR) in the AI-assisted colonoscopy group was 55.9% (95% CI: 51.9–59.9), which is statistically significantly higher than in conventional colonoscopy — 49.4% (95% CI: 45.2–54.5). The rate difference was 6.5%, $p = 0.027$, relative risk = 1.13 (95% CI: 1.01–1.27). The mean number of detected neoplasms of all types (PPC) was 1.25 (95% CI: 1.12–1.39) in the AI-assisted colonoscopy group, vs 1.08 (95% CI: 0.87–1.16), $p = 0.004$, effect value = 0.23 (95% CI: 0.04–0.43).

*Checking the Potential Influence of Factors on the Primary Outcome*

A univariate analysis was performed to determine the effect of descriptive variables on the final outcome — the detection of colorectal neoplasms. It was found that the age of patients, the male gender, the quality of bowel cleansing for colonoscopy in points, as well as the time of day of the colonoscopy significantly affects the probability of detecting tumors of all types (Table 3). According to the earlier comparative analysis, these variables are comparable in both randomized groups, which leads to a low risk of systematic error of interfering factors confounding bias. Additionally, *ROC* curves were constructed to determine the threshold values of numerical variables of age and quality of bowel cleansing by Boston scale for further stratification. For the age variable, the threshold value was £ 40 years, at which the risk of detecting adenomas was lower in this sample (AUC = 0.63 (95% CI: 0.59–0.66), $p = 0.0001$). For the quality of the bowel cleansing as per the Boston scale, the value was 8 points, at which adenomas were detected slightly more often (AUC = 0.55 (95% CI: 0.52–0.59), $p = 0.002$).

**Table 3.** *Univariant analysis of the potential influence of variables on end points*

| Variable | OR (95% CI) | P value |
|---|---|---|
| Age | 0.96 (0.95–0.97) | 0.0001 |
| Male | 1.36 (1.03–1.8) | 0.029 |
| Cleansing regimen | 1.09 (0.78–1.32) | 0.89 |
| Polyethyleneglycol | 0.95 (0.75–1.21) | 0.69 |
| Sedation | 0.89 (0.67–1.18) | 0.43 |
| Cleansing quality in points | 1.14 (1.01–1.29) | 0.038 |
| The colonoscopy starts after 12:00 o'clock | 1.23 (0.97–1.56) | 0.08 |
| Centers: | | |
| 1 | 0.85 (0.57–1.26) | 0.42 |
| 2 | 0.72 (0.46–1.1) | 0.12 |
| 3 | 0.56 (0.16–1.78) | 0.33 |
| Endoscopists | | |
| 1 | 0.82 (0.63–1.05) | 0.15 |
| 2 | 1.01 (0.71–1.44) | 0.94 |
| 3 | 0.56 (0.17–1.78) | 0.33 |
| 4 | 0.72 (0.46–1.1) | 0.13 |
| 5 | 1.18 (0.79–1.79) | 0.41 |
| 6 | 0.85 (0.66–1.05) | 0.17 |
| 7 | 1.31 (0.91–1.43) | 0.12 |

*Per Protocol Data Analysis*

An additional comparative analysis of the endpoints was performed, provided that the stratification (exclusion) of factors associated with a higher probability of detecting adenomas was performed. ADR and PDR did not significantly differ in the groups when performing patient stratification, depending on stratification by factors such as age, gender, and bowel cleansing quality by Boston scale (Table 4).

The analysis of endpoints, depending on the time of colonoscopy (after 12:00 o'clock), revealed an increase in the rate difference of the primary endpoint — ADR to 9.2% and amounted to 47.6% (95% CI: 42.4–52.9) in the AI-assisted colonoscopy group, vs 38.4% (95% CI: 33.3–43.7), $p = 0.015$, RR = 1.24 (95% CI: 1.04–1.48)) without AI. The rate difference when comparing the PDR groups increased to 11.5%, with a value of 56.5% (95% CI: 51.2–61.7) in the AI colonoscopy group, vs 45% (95% CI: 39.7–50.4), $p = 0.003$, RR = 1.25 (95% CI: 1.08–1.46)) without AI. It is important to note that the comparative analysis of these indicators, provided that a colonoscopy was performed in the morning, did not demonstrate a significant difference between ADR and PDR values.

## DISCUSSION

The multicenter randomized trial demonstrates that ArtInCol artificial intelligence system as a colonoscopy assistant significantly increases the detection rate of adenomas and other neoplasms. AI assistant increased the ADR index by 5.9% (47.2% vs 41.3%, $p = 0.048$), which corresponds to the hypothesis of the study. It is important to note that the results of the Russian RCT are consistent with the data of foreign authors, in particular, published over the past 2 years. Thus, in a randomized study by JingLiu et al. (2025), a difference in ADR value was recorded, reaching 10% when using Chinese AI development in the national CRC screening program [8]. The indicated trend is confirmed by generalized data from the largest systematic review devoted to the study of the effectiveness of the use of the AI system known to the relevant community — CADe. Saeed Soleymanjahi et al. published the results of a meta-analysis involving 44 RCTs and 36,201 patients, in which the detection rate of adenomas was 44.7% in the CADe group, vs 36.7% without the use of a colonoscopy assistant, which corresponds to the results of using a developed domestic product [9].

In addition to increasing the ADR index, the results of the RCT raise a number of other important issues related to the implementation of the system in clinical practice. It is worth noting that along with an increase in the detection rate of adenomas, there was a significant increase in the mean number of detectable neoplasia per patient (APC) from 0.79 to 0.97 ($p = 0.011$). This fact indicates that the ArtInCol system not only directly improves the detection of adenomas in the patient, but also contributes to a more scrupulous visualization of the mucous layer, which is more necessary in cases with small or flat adenomas that are often missed during a standard colonoscopy. According to the recent data, 1 out of 3 adenomas can be missed, even when performing colonoscopy in a narrow range, which potentially affects the increased risk of interval colorectal cancer [1]. The design of the domestic RCT did not imply a

**Table 4.** *Per protocol analysis*

| Variable | AI-assisted colonoscopy | Colonoscopy without AI | P value |
|---|---|---|---|
| **Age³ 40 years (n = 1,028)** | | | |
| *ADR* | 262 / 536 (48.8%) | 217 / 492 (44.1%) | 0.12 |
| *PDR* | 310 / 536 (57.8%) | 259 / 492 (52.6%) | 0.1 |
| **Female (n = 931)** | | | |
| *ADR* | 208 / 450 (46,2%) | 182 / 418 (43.5%) | 0.43 |
| *PDR* | 232 / 450 (51.6%) | 210 / 418 (48.1%) | 0.31 |
| **Cleansing quality ³8 points (n = 862)** | | | |
| *ADR* | 208 / 453 (45.9%) | 169 / 409 (41.3%) | 0.17 |
| *PDR* | 253 / 453 (55.8%) | 208 / 409 (50.9%) | 0.14 |
| **The colonoscopy starts after 12.00 o'clock (n = 669)** | | | |
| *ADR* | 161 / 338 (47.6%) | 127 / 331 (38.4%) | 0.015 |
| *PDR* | 191 / 338 (56.5%) | 149 / 331 (45%) | 0.0029 |

revision of the records of colonoscopy, thus, the calculation of the neoplasm skipping index (AMR and PMR) was not performed. The effectiveness of these indicators is confirmed indirectly, through a larger number of detected neoplasms.

Nevertheless, an increase in the immediate indicators of the detectability of neoplasms leads to a decrease in the proportion of missing polyps and adenomas, which is confirmed by current systematic literature reviews when using various types of AI systems [10–12].

An important and unique result of the randomized trial is the fact that the efficiency of using an AI assistant during colonoscopy in the afternoon is increased, which was established during the analysis of endpoints according to the 'per protocol' type. Thus, the ADR difference between the groups increased to 9.2% (47.6% vs 38.4%, $p = 0.015$), and the detection rate of all types of neoplasms (PDR) increased to 11.5% (56.5% vs 45%, $p = 0.003$). This phenomenon is probably due to the natural fatigue of endoscopists in the afternoon, which leads to a decrease in attentiveness and an increase in the likelihood of missing adenomas and small-diameter polyps. The increase in the ADR difference is noteworthy precisely due to a decrease in the proportion of identified patients in the group of patients without the use of AI. Thus, in the afternoon, the AI assistant compensates for the human fatigue factor of the endoscopist by visually detecting neoplasms in real time, ensuring consistently high diagnostic quality. In our opinion, this aspect highlights the important role of AI in raising the standards of endoscopic diagnostics, especially in conditions of high workload for medical staffinhigh volume institutions.

The results section describes the univariate analysis to assess the effect of various descriptive variables on the primary outcome — the detection of colorectal neoplasms. At the same time, it was found that variables such as the age of patients, the male sex, the quality of preparation for colonoscopy and the time of the procedure significantly increased the likelihood of detecting adenomas. However, it is important to note that the percentages of variables statistically significantly associated with the probability of neoplasm detection were comparable between randomized groups in a comparative analysis, which confirms the minimal risk of systematic error confounding bias.

This confirms that the obtained differences in ADR and PDR between the groups are indeed related to the use of an AI assistant and are not subject to bias due to the influence of individual factors. Despite the strict study methodology, it is worthwhile to identify possible systematic limitations and, despite the obvious advantages, the introduction of AI assistants into widespread clinical practice may pose a number of challenges. First of all, RCT was performed in several centers, including the participation of many endoscopists with different levels of expertise, even taking into account the indicated minimal number of routine procedures. During the initial data analysis, 1

center and 5 endoscopists from different institutions were excluded from the final calculations due to violations of the study protocol. Violations of the protocol were associated with an overestimation of the criteria for inclusion in the study and, as a result, an abnormally high value of ADR and PDR. Another possible limitation is the lack of blinding methods in the study, which could lead to some degree of bias in evaluating the results on the part of endoscopists who were aware of the use of an AI assistant and the comparison of their own results. Another limitation is the lack of a follow-up period. Although the study demonstrated improved diagnostic effectiveness, the long-term effects of using AI assistants, such as the effect on interval cancer incidence and patient survival, remain unexplored. Finally, it should be borne in mind that the RCT was conducted in specialized centers with a high level of staff training and the use of expert-class endoscopes. The introduction of AI assistants into routine clinical practice, especially in regions with limited resources, may face additional difficulties, such as a lack of technical support and trained staff. However, this limitation may also help to increase the effectiveness of screening colonoscopy by leveling the class of equipment with an AI assistant.

## CONCLUSION

The results of a multicenter RCT confirm the hypothesis that the ArtInCol AI system is an effective tool for improving the quality of diagnosis of colorectal neoplasms during colonoscopy. An increase in the overall detection rate of adenomas was recorded by 5.9%, as well as by 9.2% during colonoscopy in the afternoon. Taking into account the clinical importance of the results obtained, it is necessary to conduct further multicenter cohort studies in order to determine the degree of influence of the effectiveness of the domestic AI system on the epidemiological indicators of colorectal cancer in a distant prospect.

### AUTHORS CONTRIBUTION

Concept and design of the study: *Airat F. Mingazov, Sergey I. Achkasov, Yuriy A. Shelygin, Aleksey V. Shabunin, Irina Yu. Korzheva, Evgeniy D. Fedorov, Yuliya Yu. Kamaletdinova, Dmitriy G. Shakhmatov, Alexey A. Likutov, Ilya V. Nazarov*

Collection and processing of materials: *Airat F. Mingazov, Aleksey V. Shabunin, Irina Yu. Korzheva, Evgeniy D. Fedorov, Yuliya Yu. Kamaletdinova, Dmitriy G. Shakhmatov, Alexey A. Likutov, Ilya V. Nazarov*

Statistical processing: *Airat F. Mingazov, Evgeny V. Gorbachev*

Text writing: *Airat F. Mingazov*

Editing: *Sergey I. Achkasov, Yuriy A. Shelygin, Dmitriy G. Shakhmatov, Alexey A. Likutov*

### INFORMATION ABOUT THE AUTHORS (ORCID)

Sergey I. Achkasov — 0000-0001-9294-5447
Yuri A. Shelygin — 0000-0002-8480-9362
Airat F. Mingazov — 0000-0002-4558-560X
Irina Y. Korzheva — 0000-0002-5984-5660
Alexey A. Likutov — 0000-0001-5848-4050
Evgeniy D. Fedorov — 0000-0002-6036-7061
Ilya V. Nazarov — 0000-0002-6876-4272
Alexey A. Likutov — 0000-0001-5848-4050
Dmitry G. Shakhmatov — 0000-0001-7964-2126
Yuliya Yu. Kamaletdinova — 0009-0008-5459-7531
Aleksey V. Shabunin — 0000-0002-0522-0681
Evgeniy V. Gorbachev — 0000-0001-7588-1031

## REFERENCES

1. Jahn B, Bundo M, Arvandi M, et al. One in three adenomas could be missed by white-light colonoscopy — findings from a systematic review and meta-analysis. *BMC gastroenterology*. 2025;25(1):170.
2. Wieszczy P, Regula J, Kaminski MF. Adenoma detection rate and risk of colorectal cancer. Best Practice & Research. *Clinical Gastroenterology*. 2017;31(4):441–446.
3. Kaminski MF, Wieszczy P, Rupinski M, et al. Increased Rate of Adenoma Detection Associates With Reduced

Risk of Colorectal Cancer and Death. *Gastroenterology*. 2017;153(1):98–105.
4. Mtvralashvili D.A., Shakhmatov D.G., Likutov A.A., et al. AI-based algorithm for clinical decision support system in colonoscopy. *Koloproktologia*. 2023;22(2):92–102. (in Russ.). doi: 10.33878/2073-7556-2023-22-2-92-102
5. Achkasov S.I., Shelygin Yu.A., Likutov A.A., et al. The effectiveness of endoscopic diagnostics of colon tumors using artificial intelligence: prospective tandem study. *Koloproktologia*. 2024;23(2):28–34. (in Russ.). doi: 10.33878/2073-7556-2024-23-2-28-34
6. CONSORT 2025 Statement: Updated Guideline for Reporting Randomized Trials. Guidelines. *JAMA Network*. URL: https://jamanetwork.com/journals/jama/fullarticle/2832868 (дата обращения: 20.04.2025).
7. Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension | Nature Medicine. URL: https://www.nature.com/articles/s41591-020-1034-x (дата обращения: 20.04.2025).
8. Liu J, Zhou R, Liu C, et al. Automatic Quality Control System and Adenoma Detection Rates During Routine Colonoscopy: A Randomized Clinical Trial. *JAMA Network Open*. 2025;8(1):e2457241–e2457241.
9. Soleymanjahi S, Huebner J, Elmansy L, R, et al. Artificial Intelligence-Assisted Colonoscopy for Polyp Detection : A Systematic Review and Meta-analysis. *Annals of Internal Medicine*. 2024;177-(12):1652–1663.
10. Lou S, Du F, Song W, et al. Artificial intelligence for colorectal neoplasia detection during colonoscopy: a systematic review and meta-analysis of randomized clinical trials. *E Clinical Medicine*. 2023;66:102341.
11. Rizkala T, Hassan C, Mori Y, et al. Accuracy of Computer-aided Diagnosis in Colonoscopy Varies According to Polyp Location: A Systematic Review and Meta-analysis. Clinical Gastroenterology and Hepatology: *The Official Clinical Practice Journal of the American Gastroenterological Association*. 2025;23(4):531–541.
12. Maida M, Marasco G, Maas MHJ, et al. Effectiveness of artificial intelligence assisted colonoscopy on adenoma and polyp miss rate: A meta-analysis of tandem RCTs. Digestive and Liver Disease: Official Journal of the Italian Society of Gastroenterology and the Italian Association for the Study of the Liver. 2025;57(1):169–175.