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Retrospektywna analiza wyników badań kolonoskopowych w ramach programu badań przesiewowych dla wczesnego wykrywania raka jelita grubego

PRACA DOKTORSKA

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Pracę wykonano w II Katedrze Chirurgii Ogólnej
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SPIS TREŚCI

WSTĘP

Rak jelita grubego jest jednym z najczęściej występujących nowotworów złośliwych – w Polsce zajmuje pod tym względem 2. miejsce u obu płci, a zachorowalność na ten nowotwór systematycznie wzrasta. Każdego roku rozpoznaje się prawie 16 000 nowych przypadków. Rak jelita grubego lokalizuje się w odbytnicy (30-50%), esicy (15-20%), zstępnicy (6%), poprzecznicy (9%) oraz wstępnicy z kątnicą (14%). Większość raków jelita grubego rozwija się na podłożu gruczolaka uszypułowanego, znacznie rzadziej nieuszypułowanego. Sekwencja gruczolak-rak jest główną drogą prowadzącą do raka, obserwowaną w 85% przypadków raka jelita grubego u ludzi. Rozwój nowotworu odbywa się na przestrzeni lat. W związku z tym istotne znaczenie dla profilaktyki ma wdrożenie badań przesiewowych, które pozwalają na obniżenie częstości występowania raka jelita grubego i spadek śmiertelności z nim związanej. W Polsce podstawową metodą wykorzystywaną w badaniach przesiewowych jest kolonoskopia. Jej główne zalety to duża czułość i swoistość oraz możliwość usuwania zmian prekursorowych, co powoduje, że jest ona narzędziem nie tylko wczesnego wykrywania raka jelita grubego, ale również zapobiegania jego rozwojowi.

W Polsce od 2000 roku realizowany jest Program Badań Przesiewowych dla wczesnego wykrywania raka jelita grubego. Stanowi on część Narodowego Programu Zwalczania Chorób Nowotworowych i jest finansowany przez Ministerstwo Zdrowia. Od tego czasu obserwowany jest stały szybki postęp technologiczny owocujący wprowadzaniem nowych generacji sprzętu endoskopowego, dodatkowego oprzyrządowania, co w połączeniu z doświadczeniem i inwencją endoskopisty umożliwia przeprowadzanie coraz bardziej dokładnej diagnostyki. Na dobre odeszliśmy od endoskopów optycznych, które były wykorzystywane na początku programu badań przesiewowych. Do nowoczesnych technologii wykorzystywanych obecnie w endoskopii należą m.in: wideoendoskopia wysokiej rozdzielczości (HDTV 1080p), obrazowanie w wąskim paśmie światła (Narrow Band Imaging), dwustopniowy system optyczny (Near Focus), zmienna sztywność sondy poprawiająca kontrolę wprowadzania endoskopu oraz system magnetycznej trójwymiarowej nawigacji endoskopu.

Każda procedura medyczna, aby była skuteczna i efektywna oraz bezpieczna dla pacjentów musi być dobrze wykonywana. Jakość w endoskopii pozostaje

obszarem, który ciągle wymaga doskonalenia. W ocenie jakości badania kluczowe znaczenie wydają się mieć obejrzenie przez endoskopistę całego jelita oraz wykrycie i usunięcie wszystkich gruczolaków. Wskaźniki jakości w kolonoskopii są ściśle określone i stanowią je między innymi: częstość wykrywania gruczolaków (adenoma detection rate – ADR), osiągalność kątnicy (cecal intubation rate – CIR) oraz odsetek wykonanych jednoczasowych polipektomii. Obejrzenie całego jelita, z kątnicą włącznie, jest ważne, gdyż wzrasta obecnie częstość raków zlokalizowanych w prawej połowie jelita. Według wytycznych odsetek kolonoskopii przesiewowych z osiągnięciem kątnicy powinien wynosić co najmniej 95%. Natomiast odsetek badań, w których wykryto co najmniej jednego gruczolaka powinien wynosić co najmniej 25% u mężczyzn i co najmniej 15% u kobiet. Innym proponowanym parametrem jakości jest czas wycofywania aparatu, czyli ten, który endoskopista poświęca na obejrzenie błony śluzowej od kątnicy do odbytnicy. Nie powinien być krótszy niż 6 minut.

Wiele czynników wpływa jednocześnie na obniżenie skuteczności badania w aspekcie wykrywalności polipów, przeoczenia zmian nowotworowych, co w rezultacie ogranicza wartość badania przesiewowego. Wśród głównych czynników powodujących niepowodzenie kolonoskopii jako badania zapobiegającego rozwojowi raka jelita grubego wymienia się: niewłaściwe przygotowanie jelita do badania, nieosiągnięcie kątnicy, zbyt szybkie wycofywanie aparatu, nieuwidocznienie polipów znajdujących się za haustracjami jelita, trudności w rozpoznaniu polipów płaskich, nieradykalna polipektomia, czy też brak odpowiedniego nadzoru endoskopowego u chorych z wykrytymi wcześniej gruczolakami.

W ostatnich latach obserwujemy systematyczny wzrost liczby badań kolonoskopowych wykonywanych w ramach skriningu. W związku z tym analiza jakości, parametrów na nią wpływających, w tym szkolenia, czy też indywidualnych możliwości endoskopisty jest niezwykle istotna. W aktualnie spotykanych publikacjach poza ściśle określonymi parametrami jakości poddaje się badaniom wiele różnych parametrów mogących potencjalnie wpływać na końcowy wynik badania przesiewowego. Świadczy to o tym, iż nadal poszukiwane są optymalne rozwiązania zarówno dla pacjentów, jak i lekarzy wykonujących badania przesiewowe. Podkreślany jest m. in. wpływ tolerancji badania na jego jakość. Badania wykonywane w znieczuleniu ogólnym są związane z większą częstością

intubacji kątnicy. Jednak samo znieczulenie ogólne wiąże się to nie tylko z większym odsetkiem powikłań, ale także stanowią istotne zwiększenie kosztów badania, co stoi sprzeczności z założeniami badań przesiewowych, które powinny być ogólnodostępne i racjonalne pod względem finansowym. Dlatego istotne jest, aby dążyć do zwiększenia tolerancji badań w znieczuleniu miejscowym stosując lepszy sprzęt, czy też ulepszać swoją technikę.

Stały postęp technologiczny przyczynia się do wprowadzania nowych generacji endoskopów oferujących wiele wcześniej nie znanych możliwości. Z jednej strony modernizacja polega na przystosowaniu endoskopów do jak najłatwiejszego wykonania badania, co przyczynia się do lepszej tolerancji przez pacjentów. Z drugiej strony nowe możliwości elektroniki oraz precyzyjnej optyki w założeniu dają możliwość dokładniejszej oceny błony śluzowej, określenia charakteru i rozmiarów zmian patologicznych oraz wstępne określenie ich charakteru oraz stopnia złośliwości. Dzięki temu istnieje możliwość podjęcia leczenia równolegle z badaniem diagnostycznym, co może przyczyniać się do skrócenia całego procesu leczenia oraz ewentualnej poprawy wyników tego leczenia.

W związku z tym, iż jako II Katedra Chirurgii Ogólnej Collegium Medicum Uniwersytetu Jagiellońskiego bierzemy czynny udział w badaniach przesiewowych wykonywanych w kierunku wczesnego wykrywania raka jelita grubego, uważamy, że powinniśmy mieć realny wpływ na poprawę jakości badań. Obliguje nas do tego również fakt, iż jesteśmy Ośrodkiem akredytowanym do wydawania certyfikatów umiejętności endoskopowych Towarzystwa Chirurgów Polskich. Dlatego też w ramach cyklu artykułów publikowanych w prestiżowych czasopismach naukowych postanowiliśmy przedstawić wyniki naszych doświadczeń związanych z badaniami endoskopowymi wykonywanymi w ramach skriningu.

Wyniki badań prowadzonych w II Katedrze Chirurgii Ogólnej stanowiły podstawę do napisania niniejszej rozprawy doktorskiej zatytułowanej: „Retrospektywna analiza wyników badań kolonoskopowych w ramach programu badań przesiewowych dla wczesnego wykrywania raka jelita grubego”. Praca doktorska stanowi cykl prac oryginalnych opublikowanych w czasopismach obecnych w bazie PubMed, a także znajdujących się na liście ISI Thomson Reuters. Łączny Impact Factor prac wynosi: 6.002. Jako autor rozprawy doktorskiej jestem pierwszym autorem oraz współautorem prac składających się na wyżej wspomniany cykl.

CELE PRACY

Cel główny:

- Określenie czynników mających wpływ na jakość badania endoskopowego.
- Ocena jakości badań przesiewowych wykonywanych w II Katedrze Chirurgii Ogólnej Collegium Medicum Uniwersytetu Jagiellońskiego

Cele dodatkowe:

- Ocena przydatności rozwoju technik endoskopowych w badaniach przesiewowych oraz ich wpływu na poprawę jakości badań.
- Analiza różnic w jakości badań kolonoskopowych wykonywanych w różnych okresach, z użyciem różnych pod względem zaawansowania technologicznego endoskopów:
  lata 2000 – 2003 - era endoskopów optycznych,
  lata 2004 - 2008 era endoskopów optycznych i wideoendoskopów,
  2009 - 2014 era wideoendoskopów (wykorzystujących technologię HD oraz NBI).
- Ocena roli doświadczenia endoskopisty w jakości wykonanego badania na podstawie porównania badań wykonywanych przez lekarzy rezydentów i specjalistów chirurgii ogólnej w latach 2014- 2018.
- Przedstawienie wyników badań endoskopowych u chorych bezobjawowych.

Publikacje zawarte w rozprawie doktorskiej

Rozprawę doktorską stanowi monotematyczny cykl prac oryginalnych:

I. Tytuł pracy: How to improve the adenoma detection rate in colorectal cancer screening? Clinical factors and technological advancements

Czasopismo: Archives of Medical Science

II. Tytuł pracy: Cecal intubation rates in different eras of endoscopic technological development

Czasopismo: Videosurgery and Other Miniinvasive Techniques

III. Tytuł: Impact of responsive insertion technology (RIT) on reducing discomfort during colonoscopy – randomized clinical trial

Czasopismo: Surgical Endoscopy

IV. Tytuł pracy: Colonoscopy for colorectal cancer screening - is it effective in the hands of a general surgery resident?

Czasopismo: Polish Journal of Surgery

OMÓWIENIE PRAC NAUKOWYCH WCHODZĄCYCH W SKŁAD CYKLU

Publikacja I

Pierwszą pracą wchodzącą w skład cyklu jest artykuł zatytułowany: „How to improve adenoma detection rate in colorectal cancer screening? - clinical factors and technological advancements" opublikowany w czasopiśmie Archives of Medical Science. W związku z tym, iż częstość wykrywania gruczolaków jest jednym z kluczowych parametrów określających jakość kolonoskopii postanowiliśmy się skupić na czynnikach na niego wpływających, w tym zastosowaniu najnowocześniejszych dostępnych technologii endoskopowych. W tym celu przeanalizowaliśmy 24055 badań wykonywanych w latach 2004 do 2008. Pacjentów podzielono na dwie grupy w zależności od stosowanego endoskopu. Grupę I (10405 pacjentów) stanowili chorzy, którzy byli badani standardowymi elektronicznymi endoskopami. W grupie II znaleźli się chorzy (13650 pacjentów), którym wykonywano badanie przy pomocy najnowocześniejszych endoskopów, wykorzystujących m.in.: wideoendoskopia wysokiej rozdzielczości (HDTV 1080p), obrazowanie w wąskim paśmie światła (Narrow Band Imaging), dwustopniowy system optyczny (Near Focus), zmienna sztywność sondy poprawiająca kontrolę wprowadzania endoskopu oraz system magnetycznej trójwymiarowej nawigacji endoskopu. Porównano częstość występowania gruczolaków pomiędzy dwoma grupami, a także inne czynniki wpływające na jakość badania, w tym osiągalność kątnicy, przygotowanie jelita, tolerancję pacjentów na badanie wykonywane w znieczuleniu miejscowym. Wśród najistotniejszych wyników należy wymienić, iż częstość wykrywania gruczolaków była istotnie wyższa w grupie II 31.73% w porównaniu z 29.14% w grupie I ($p<0.001$). Ilość pełnych kolonoskopii, z intubacją kątnicy również była większa w grupie II - 96.68% w porównaniu z grupą I 93.73% ($p<0.001$). Także tolerancja badania była istotnie statystycznie wyższa w przypadku grupy pacjentów badanych zaawansowanymi technologicznie endoskopami. Na podstawie uzyskanych wyników wyodrębniono czynniki, które istotnie wpłynęły na jakość badania, zwiększając tym samym częstość wykrywania gruczolaków (ADR) oraz osiągalność kątnicy (CIR). Należą do nich: płeć męska, wiek, BMI, przygotowanie jelita, tolerancja badania. Również istotny wpływ na jakość badania miał fakt wykonywania kolonoskopii przy użyciu nowego rodzaju endoskopów. Wnioski, jakie

można wyciągnąć na tej podstawie są następujące: czynniki zależne od pacjenta mają niezwykle istotny wpływ na końcowy wynik badania. Również nowe technologie stosowane w najnowszych aparatach zwiększają jakość badania przesiewowego poprzez wpływ na zwiększenie częstości wykrywania gruczolaków oraz zwiększenie osiągalności kątnicy.

Publikacja II

Kolejna praca zatytułowana: „Cecal intubation rates in different eras of endoscopic technological development" została opublikowana w czasopiśmie Videosurgery and Other Miniinvasive Techniques. W tej publikacji główny nacisk został położony na czynnik determinujący jakość, jakim jest osiągalność kątnicy. Kompletne badanie, czyli tzw. pełna kolonoskopia, gdzie oglądamy całe jelito z kątnicą włącznie, jest niezwykle istotna ze względu na wzrastającą częstość zmian o charakterze nowotworowym w prawej części jelita. Poddane analizie zostały wyniki badań 27463 chorych, którzy przechodzili kolonoskopię w ramach programu przesiewowego wczesnego wykrywania raka jelita grubego. Chorzy zostali podzieleni na trzy grupy w zależności od czasu, w którym było wykonywane badanie, a co za tym idzie różnymi endoskopami wykorzystywanymi do badania. Grupa I składała się z 3408 chorych badanych w latach 2000- 2003 z użyciem endoskopów optycznych. Grupę II stanowiło 10405 chorych badanych w latach 2004- 2008 przy pomocy standardowych endoskopów elektronicznych, grupa III to chorzy badani w latach 2009- 2014, gdzie do badania stosowano najnowocześniejsze technologicznie endoskopy. Aby określić wpływ nowych technologii na jakość badania porównano osiągalność kątnicy (cecal intubation rate – CIR), a także czas osiągnięcia kątnicy. Wykazano, iż osiągalność kątnicy zwiększała się wraz z postępem technologii endoskopów używanych do badania przesiewowego. W grupie I osiągalność kątnicy wynosiła 69.75%,w grupie II i III odpowiednio 92.32% i 95.17% ($p< 0.001$). Również średni czas, w którym wykonywano pełne badanie był najkrótszy w grupie III. Pozwoliło to na wyciągnięcie wniosków, iż nowe technologie zastosowane w endoskopach mają istotny wpływ na jakość i efektywność badań przesiewowych wykorzystywanych do wczesnego wykrywania raka jelita grubego.

Publikacja III

Trzecia z publikacji zatytułowana: „Impact of responsive insertion technology (RIT) on reducing discomfort during colonoscopy – randomized clinical trial" opublikowana w Surgical Endoscopy skupia się na analizie jednego z rozwiązań technologicznych stosowanego w najnowocześniejszych endoskopach. Jest to randomizowane badanie kliniczne oceniające korzyści wynikające z implementacji wprowadzania kontrolowanego (ang. Responsive Insertion Technology – RIT) w kolonoskopiach skriningowych wykonywanych w znieczuleniu miejscowym. Technologia RIT ma na celu ułatwienie wprowadzenia aparatu, a także zwiększenie komfortu pacjenta w trakcie badania. Analizą zostało objętych 647 pacjentów. Pacjenci zostali podzieleni na dwie grupy w zależności od rodzaju użytego endoskopu. Grupę I (329 pacjentów) stanowili chorzy, u których zastosowano kolonoskopy wyposażone w RIT, grupę II (318 pacjentów) stanowili chorzy, badani standardowymi aparatami o regulowanej sztywności. Porównano czas, w którym osiągano kątnicę, ilość pętli powstających w czasie badania, częstość stosowania ucisku brzucha przez asystenta w czasie badania oraz dolegliwości bólowe wyrażone w skali VAS. Stwierdzono, iż czas intubacji kątnicy był krótszy w przypadku użycia endoskopów wyposażonych w RIT, wynosił 209 s i 224 s odpowiednio dla I i II grupy ($p < 0.05$). Większa liczba powstających pętli była obserwowana w grupie II- 1.7 vs 1.35 ($p<0.05$). Także pacjenci w grupie II częściej wymagali uciskanie manualnego brzucha w trakcie badania – 2.2 vs 1.7 ($p=0.001$). Chorzy w grupie I zgłaszali mniejsze dolegliwości bólowe w porównaniu z chorymi z grupy II, które oceniono przy użyciu skali VAS – 2.3 vs. 2.6. Pozwoliło to na wyciągnięcie wniosków, iż RIT poprawia manewrowość kolonoskopów, zapewnia lepszą kontrolę nad endoskopem podczas obracania i wprowadzania, a także ułatwia wyprostowanie endoskopu. Sumarycznie skraca to czas intubacji kątnicy, ograniczając również dyskomfort pacjenta.

Publikacja IV

Czwarta z kolei praca będąca częścią cyklu zatytułowana: „Colonoscopy for colorectal cancer screening- is it effective in the hands of general surgery resident?" została opublikowana w Polskim Przeglądzie Chirurgicznym (Polish Journal of Surgery). Niezwykle ważnym elementem podstawowego, współczesnego wykształcenia chirurgicznego są procedury endoskopowe. Pacjenci powinni otrzymywać opiekę na najwyższym możliwym poziomie, jednak chirurdzy będący w trakcie specjalizacji muszą również zdobywać niezbędne doświadczenie. Dlatego w tej pracy naukowej postanowiono ocenić efektywność kolonoskopii wykonywanych przez lekarzy rezydentów w ramach badań przesiewowych wczesnego wykrywania raka jelita grubego. W tym celu porównano wskaźniki jakości badań wykonanych przez rezydentów oraz lekarzy posiadających specjalizację z zakresu chirurgii ogólnej. Analizą objęto 6384 pacjentów, którzy mieli wykonaną kolonoskopię w latach 2014-2018. Pacjentów podzielono na dwie grupy. Grupę I (2268 pacjentów) stanowili chorzy badani przez lekarzy rezydentów, grupę II (4116 pacjentów) stanowili pacjenci badani przez lekarzy specjalistów chirurgii ogólnej. Porównano częstość wykrywania gruczolaków, osiągalność kątnicy oraz tolerancję pacjentów na wykonywane badanie. Jeśli chodzi o osiągalność kątnicy, grupy nie różniły się, cecal intubation rate (CIR) wynosił 95.99% (p=0,994). Nie stwierdzono istotnej różnicy w częstości wykrywania gruczolaków wynosiła ona 29.30% w grupie I oraz 27.66% w grupie II (p=0.203). Badania wykonywane przez specjalistów były lepiej tolerowane przez pacjentów. Tolerancja w czterostopniowej skali była bardzo dobra w 78.98% w grupie lekarzy specjalistów oraz w 75.18% w grupie lekarzy rezydentów (p<0.001). Wyniki pozwoliły na postawienie wniosku, iż lekarze w trakcie specjalizacji są w stanie wykonywać kolonoskopię efektywnie i z jakością nie odbiegającą od wymogów stawianych przez międzynarodowe towarzystwa endoskopowe. Lekarze rezydenci wymagają jednak nadal doskonalenia swoich umiejętności, aby polepszyć komfort pacjentów w trakcie badania i osiągnąć technikę lekarzy specjalistów.

PEŁNA TREŚĆ PUBLIKACJI WCHODZĄCYCH W SKŁAD CYKLU:

How to improve the adenoma detection rate in colorectal cancer screening? Clinical factors and technological advancements

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Abstract

Introduction: Colonoscopy has been widely regarded as the gold standard in colorectal cancer (CRC) screening. Within recent years different endoscopic imaging techniques have been introduced to improve the quality of colonoscopy. The adenoma detection rate (ADR) is the single most important quality indicator for colonoscopy. The aim of this study was to evaluate the quality of CRC screening expressed by ADR in two different eras of endoscopic technology advancement.

Material and methods: We conducted a dual-center study that enrolled 24 055 patients, who underwent colonoscopy as part of a national screening program. Patients were sorted into two groups according to the advancement of endoscopic equipment used for colonoscopic examination: group I– 10 405 patients examined between 2004 and 2008 (standard electronic endoscopes); group II – 13 650 patients examined between 2009 and 2014 (modern endoscopes). The ADR in two different eras and the impact of endoscopic novelties were determined.

Results: The ADR in group I was 29.14%, in group II 31.73% ($p < 0.001$). The overall ADR was 30.88% – 38.80% and 25.95% ($p < 0.001$) for the male and female patients, respectively. The mean adenoma number per colonoscopy was 0.366 (95% CI: 0.357–0.375; $p < 0.001$), 0.337 (0.321–0.352) and 0.380 (0.369–0.392) for patients in group I and group II, respectively.

Conclusions: Our study shows that technological innovation, novel endoscopy devices and diagnostic techniques improve the quality in CRC screening by increasing the ADR. However, we need to determine which of the technologies are supreme to achieve excellence in colorectal cancer screening.

Key words: cancer, adenoma, screening, technology, quality, colorectal, endoscopy, detection, rate, adenoma detection rate.

Introduction

Colorectal cancer (CRC) is the third most common cancer worldwide and the second most common in Europe and the United States. It constitutes approximately 10% of all cancers observed in men and women [1–3]. Over 90% of CRC cases follow an adenoma-to-cancer sequence

over many years [4]. Colorectal cancer screening has been successful in reducing the incidence and mortality of CRC by increasing the proportion diagnosed at an early stage and facilitating removal of pre-neoplastic lesions [5]. Colonoscopy is currently the preferred method for screening, decreasing the incidence of CRC by up to 80% [6, 7]. This beneficial effect is strongly associated with the adenoma detection rate (ADR), which is the single most important quality surrogate for screening colonoscopy. The definition of ADR suggested by the English Bowel Cancer Screening Programme is the number of colonoscopies at which one or more histologically confirmed adenomas is found divided by the total number of colonoscopies performed. According to the most recent European Society of Gastrointestinal Endoscopy (ESGE) recommendations, ADR should be at the minimum level of 25%. The goal of the modern colonoscopy quality improvement is to reduce the operator dependence, and generally to move low-level performers toward high-end performance as rapidly as possible.

Poor cecal intubation rate (CIR) correlates with a low adenoma detection rate, and it is closely associated with an increased risk of post-colonoscopy colorectal cancer (PCCRC). Within recent years different endoscopic imaging techniques have been introduced to improve the quality of colonoscopy and CRC screening. We have witnessed the transition from fiberscopes to videoscopes, which already has significantly increased the diagnostic capability of endoscopes. Following the introduction of videoscopes, the structure of the endoscopes has been changed nowadays. Responsive insertion technology (RIT) combines three technologies, passive bending (PB), high-force transmission (HFT), and variable stiffness, to facilitate the feasibility of the examination, increasing the CIR, and increasing the patient's comfort. The new endoscopes also include narrow band imaging (NBI), near focus (NF) and magnetic endoscopic imaging (MEI) – novelties that are supposed to reduce the adenoma miss rate.

Our aim was to evaluate the quality of colonoscopy expressed by ADR in two different eras of endoscopic technology advancement.

Material and methods

We conducted a retrospective dual-center study in the 2nd Department of Surgery, Jagiellonian University Medical College and the Specialist Diagnostic and Therapeutic Center "Medicina" in Krakow, Poland. The study was approved by the local ethics committee and conducted in accordance with the principles of the Declaration of Helsinki (KBN no. 122.6120.36.2016).

Patients

We selected 24 055 patients aged 40-65 who underwent colonoscopy screening between January 2000 and December 2014 (as part of a national colorectal cancer screening program, which was financed by the Polish Ministry of Health). Patients with a prior history of abdominopelvic surgery, inflammatory bowel disease, active malignancy, and a high anesthetic risk (ASA IV) were excluded from the study. All patients were pre-evaluated before the examination and written informed consent for the procedure was obtained. Bowel preparation was accomplished using verbal and written information. Patients were informed to take a liquid propulsive agent (i.e., 420 g of polyethylene glycol (PEG) in 4 l of water) in the evening prior to the procedure for morning patients and a split-dose regimen for those in the afternoon schedule.

Setting

We used Olympus series colonoscopes (Olympus Optical Co. Ltd, Tokyo, Japan). Patients were sorted into two groups according to the endoscopic equipment used for colonoscopic examination.

Group I included 10 405 patients examined between 2004 and 2008. This era encompasses the use of electronic endoscopes with a standard resolution (CF-Q145, CF-Q165, and CF-Q180).

Between 2009 and 2014, we performed 13 650 colonoscopies using the CF-HQ190L (group II). This was the era of endoscopes with a high-definition resolution, magnetic scope guide, responsive insertion technology (RIT) and narrow band imaging (NBI) with dual focus two-stage optical lens technology (Table I).

Patients' preoperative characteristics including demographics, body mass index (BMI), family history of malignancy and significant comorbidities were determined.

Outcome

Ten experienced endoscopists conducted the procedures, each having independently performed over 1000 colonoscopies, certified by the Polish Society of Surgeons. The ADR was determined as the number of colonoscopies in which one or more histologically confirmed adenomas were found divided by the total number of colonoscopies performed. We compared the adenoma detection rate (ADR) and mean adenoma number per colonoscopy in two successive eras of endoscopic technological development according to the series of the endoscope used. We compared the procedures per room ratio (PPR – a parameter that describes the approximate capacity of procedures per room, representing the mean number of procedures done daily in one

colonoscopy office). Other endpoints of the study influencing the ADR were analyzed: completeness of examination, bowel preparation assessment (5-point scale), and patient tolerance for examination (4-point scale). Pathological results were also presented.

Statistical analysis

All data were analyzed with StatSoft Statistica v.12.5 (StatSoft Inc, Tulsa, Oklahoma, USA). The results are presented as mean ± standard deviation (SD), or median and interquartile range (IQR), when appropriate. The study of categorical variables used Pearson's χ^2 test, or χ^2 with Yates correction when appropriate. The Shapiro-Wilk test was used to check for normal distribution of data. Quantitative data were analyzed with Student's *t*-test (for normally distributed data) or the Mann-Whitney test (for non-normally distributed data). Univariate and multivariate logistic regression models were built including continuous and categorical variables. Results were considered statistically significant when the *p*-value was found to be less than 0.05.

Results

We observed no difference between the groups regarding sex and age ($p = 0.790$ and 0.404, respectively). Body mass index was slightly higher in group II ($p < 0.001$). Family history of malignancy was more prevalent in group II (43% vs. 41.18%, $p = 0.010$). Patients in this group had more significant comorbidities than in group I (21.87% vs. 8.89%, $p < 0.001$). Complete colonoscopies were performed more frequently in group II (96.68% vs. 93.73%, $p < 0.001$) and the adenoma detection rate was higher in group II (31.73% vs. 29.14%, $p < 0.001$) along with mean adenoma number per colonoscopy ($p < 0.001$). Procedures per room ratio (PPR) was comparable ($p = 0.088$). Patients in groups I and II differed slightly, yet statistically significantly, in terms of bowel preparation and tolerance of examination ($p < 0.001$). Bowel preparation assessment was classified as follows: 1 – poor, 2 – substandard, 3 – adequate, 4 – good, 5 – excellent. Patients' tolerance of colonoscopy was described as follows: 1 – severe discomfort, 2 – moderate discomfort, 3 – mild discomfort, 4 – no or minimal discomfort. Basic characteristics and comparison between group I and group II are presented in Table II.

Table III presents univariate logistic regression analysis of influence of selected factors on completeness of examinations. Significant factors were patients' sex, age, BMI, bowel preparation, tolerance and examination performed in group II. They were included in multivariate logistic regression in Table IV. Multivariate logistic regression analysis of the influence of selected factors on completeness of examinations revealed that patients' sex, BMI, bowel preparation, tolerance and colonoscopy performed in the era of modern endoscopes were significant independent factors that resulted in completeness of examinations.

Table I. Parameters of endoscopes used in the study

Endoscopes used in group I (2004–2008)
Olympus CF-Q145: • Diameter: 12.8 mm • Working length: 168 cm • Instrument channel: 3.7 mm • Field of view: 140° • Angulation range: up: 180, down: 180, right: 160, left 160
Olympus CF-Q165: • Diameter: 12.8 mm • Working length: 168 cm • Instrument channel: 3.7 mm • Field of view: 140° • Angulation range: up: 180, down: 180, right: 160, left 160
Olympus CF-Q180: • Diameter: 12.8 mm • Working length: 168 cm • Instrument channel: 3.7 mm • Field of view: 170° • Angulation range: up: 180, down: 180, right: 160, left 160 • Features: variable stiffness technology
Endoscopes used in group II (2009-2014)
Olympus CF-HQ190L: • Diameter: 12.8 mm • Working length: 168 cm • Instrument channel: 3.7 mm • Field of view: 170°, near 160° • Angulation range: up: 180, down: 180, right: 160, left 160 • Features: variable stiffness technology, narrow band imaging (NBI), responsive insertion technology (RIT), scope guide, high definition (HD) (1280 × 1024 pixels)

Univariate logistic regression analysis of the influence of selected factors on the adenoma detection rate (ADR) is presented in Table V. Male sex, age, BMI, bowel preparation, completeness of examinations, patient's tolerance for examination and colonoscopies performed in group II increased ADR. Then significant factors were included in the multivariate logistic regression analysis presented in Table VI: male sex, age, BMI, bowel preparation, completeness of examinations and examinations performed in the modern endoscope era (group II) increased ADR as independent factors.

The overall ADR was 30.88–38.80% and 25.95% for the male and female patients, respectively. The mean adenoma number per colonoscopy was 0.366 (95% CI: 0.357–0.375) – 0.483 (0.466–

Table II. Comparison between groups

Parameter	All	Group I	Group II	*P*-value
Sex M/F, *n* (%)	9007/13841 (39%/61%)	2881/4404 (40%/60%)	6126/9437 (39%/61%)	0.790
Age, mean ± SD [years]	54 ±7	54 ±6	54 ±7	0.404
BMI, mean ± SD [kg/m^2]	26.87 ±4.74	26.56 ±3.9	26.97 ±4.97	< 0.001
Malignancy in family history, *n* (%)	9692 (42.42)	3000 (41.18)	6692 (43.00)	0.010
Significant comorbidity, *n* (%)	4051 (17.73)	648 (8.89)	3403 (21.87)	< 0.001
Full/incomplete examinations, *n* (%)	21875/973 (95.74/4.26)	6828/457 (93.73/6.27)	15047/516 (96.68/3.32)	< 0.001
PPR	10.29±6.88	9.95±6.22	10.46±7.17	0.088
Adenoma detection rate – ADR (%)	30.88	29.14	31.73	< 0.001
Adenoma number per colonoscopy, mean ± SD (95% CI)	0.366 ±0.715 (0.357–0.375)	0.337 ±0.683 (0.321–0.352)	0.380 ±0.728 (0.369–0.392)	< 0.001
Bowel preparation assessment*, *n* (%):				
5	20726 (90.71)	6824 (93.67)	13902 (89.27)	< 0.001
4	377 (1.65)	86 (1.18)	291 (1.87)	
3	712 (3.12)	266 (3.65)	446 (2.87)	
2	271 (1.19)	90 (1.24)	181 (1.16)	
1	67 (0.29)	19 (0.26)	48 (0.31)	
Patient tolerance for exam*, *n* (%):				
4	21838 (95.58)	6988 (95.92)	14850 (95.42)	< 0.001
3	305 (1.33)	117 (1.61)	188 (1.21)	
2	265 (1.16)	63 (0.86)	202 (1.30)	
1	305 (1.33)	117 (1.61)	188 (1.21)	

*PPR – procedures per room, parameter that describes approximate capacity of procedures per room, representing mean number of procedures done daily in one colonoscopy office. *Bowel preparation assessment classification: 1 – poor, 2 – substandard, 3 – adequate, 4 – good, 5 – excellent. **Patient tolerance of colonoscopy classification: 1 – severe discomfort, 2 – moderate discomfort, 3 – mild discomfort, 4 – no or minimal discomfort.*

Table III. Univariate logistic regression analysis of influence of selected factors on completeness of examinations

Parameter	OR	95% CI	*P*-value
Sex, M vs. F	0.43	0.37–0.51	< 0.001
Age, with every year	0.99	0.98–0.99	0.049
BMI, with every 1 kg/m^2	0.93	0.91–0.95	< 0.001
Significant comorbidity	1.05	0.47–2.34	0.905
Bowel preparation assessment, with every grade higher	1.95	1.88–2.02	< 0.001
Patient tolerance for exam, with every grade higher	4.52	4.19–4.87	< 0.001
Group 1 vs. 2	1.95	1.71–2.22	< 0.001

OR – odds ratio, CI – confidence interval.

0.500) and 0.290 (0.280–0.301) for the male and female patients, respectively.

Table VII presents the adenoma detection rate in relation to specific factors that influenced ADR in the logistic regression model.

Tables VIII and IX present comparisons of histopathological findings respectively in distal and proximal colon between groups with *p*-values of inter-group comparisons.

Table IV. Multivariate logistic regression analysis of influence of selected factors on completeness of examinations

Parameter	OR	95% CI	*P*-value
Sex, M vs. F	0.59	0.49–0.71	< 0.001
BMI, with every 1 kg/m^2	0.96	0.94–0.98	< 0.001
Bowel preparation assessment, with every grade higher	2.11	1.94–2.29	< 0.001
Patient tolerance for exam, with every grade higher	4.67	4.28–5.10	< 0.001
Group 1 vs. 2	1.91	1.60–2.27	< 0.001

OR – odds ratio, CI – confidence interval.

Table V. Univariate logistic regression analysis of influence of selected factors on ADR

Parameter	OR	95% CI	*P*-value
Sex, F vs. M	1.82	1.69–1.92	< 0.001
Age, with every year	1.03	1.02–1.04	< 0.001
BMI, with every 1 kg/m^2	1.03	1.02–1.04	< 0.001
Significant comorbidity	1.06	0.98–1.15	0.124
Bowel preparation assessment, with every grade higher	1.19	1.11–1.27	< 0.001
Patient tolerance for exam, with every grade higher	1.31	1.20–1.43	< 0.001
Completeness of examinations	2.09	1.73–2.53	< 0.001
Group 1 vs. 2	1.13	1.05–1.22	0.001

OR – odds ratio, CI – confidence interval.

Table VI. Multivariate logistic regression analysis of influence of selected factors on ADR

Parameter	OR	95% CI	*P*-value
Sex, F vs. M	1.82	1.69–1.96	< 0.001
Age, with every year	1.03	1.02–1.04	< 0.001
BMI, with every 1 kg/m^2	1.02	1.01–1.03	< 0.001
Bowel preparation assessment, with every grade higher	1.17	1.09–1.26	< 0.001
Patient tolerance for exam, with every grade higher	1.06	0.95–1.18	0.271
Completeness of examinations	1.79	1.41–2.26	< 0.001
Group 1 vs. 2	1.13	1.04–1.22	0.004

OR – odds ratio, CI – confidence interval.

Discussion

The single most important outcome to measure the effectiveness of colonoscopy is the ADR, since it is associated with the future risk of CRC occurrence and mortality. Physicians performing screening colonoscopies with ADR below 20% are more likely to have patients subsequently presenting interval cancer [8].

Our results have confirmed some particular circumstances that without a doubt should be maintained to keep the quality of the examinations at the highest possible level. Effective bowel cleansing is one of them. The better the bowel preparation is, the more precise is detection of preneoplastic lesions and the easier is cecal intubation. Poor cleansing of the bowel is associated with prolonged procedures and low ADR. There is heterogeneity among the studies concerning bowel cleansing as to whether split or non-split preparation is more effective. However, tolerance of high volumes of polyethylene glycol (PEG) solution may be low. Splitting the dose may improve it [9]. Authors are now also focusing on the timing of bowel cleansing. The outcome of cleansing appears to be efficient when the examination is commenced within hours of the bowel preparation [10]. The bowel cleansing in our study met the criteria of the European Society of Gastrointestinal Endoscopy, according to which no more than 10% of the examinations should need to be repeated due to inadequate bowel preparation.

Table VII. Comparison of ADR in selected parameters

Parameter	ADR (%)	*P*-value
Sex, F vs. M	25.95/38.80	< 0.001
Age [years]:		
50–55	27.82	< 0.001
56–60	32.08	
61–65	33.43%	
BMI [kg/m^2]:		
< 25	28.17	< 0.001
25–30	31.71	
30–35	34.60	
≥ 35	36.82	
Significant comorbidity, Yes/no	31.96/30.62	0.132
Malignancy in family, Yes/no	31.09/30.82	0.751
Bowel preparation assessment*:		
5	32.26	< 0.001
4	23.86	
3	23.65	
2	30.10	
1	11.54	
Patient tolerance for exam**:		
4	31.32	< 0.001
3	22.19	
2	21.13	
1	18.35	
Complete vs. incomplete examination	31.47/18.01	< 0.001
Group 1 vs. 2	29.14/31.73	0.001

**Bowel preparation assessment classification: 1 – poor, 2 – substandard, 3 – adequate, 4 – good, 5 – excellent. **Patient tolerance of colonoscopy classification: 1 – severe discomfort, 2 – moderate discomfort, 3 – mild discomfort, 4 – no or minimal discomfort.*

Patient-related aspects also have an impact on ADR. Obesity is an independent risk factor of adenoma occurrence. There is a debate concerning body weight and the technical struggle in reaching the cecum during colonoscopy. There is evidence suggesting that both low and high BMI patients are technically demanding for a physician performing the examination [11]. Obesity is also associated with poor bowel preparation, which can subsequently lead to a difficult and prolonged colonoscopy. Our study has revealed that a higher BMI was a factor associated with statistically significantly higher ADR and a higher cecal intubation rate (CIR). It might be due to the low muscle content of a low-BMI patient that may predispose to loop formation and patient intolerance, which leads to unsuccessful colonoscopy. There are studies which revealed that the number of loops formed during the insertion of the endoscope in low-BMI patients is higher than that in obese patients [12].

The ADR varies between men and women. Adenomas are more common in men, which explains our outcome that male sex is an independent factor leading to higher ADR. The American Society for Gastrointestinal Endoscopy (ASGE) recommendations propose that adenomas should be detected in more than 25% of asymptomatic male individuals (> 50 years) and in more than 15% of asymptomatic female individuals (> 50 years) at first. According to studies based on large populations of patients, factors associated with completion of the colonoscopy without sedation include male sex. That explains the higher cecal intubation rate among males in our study [13]. ADR as well as the advanced cancer detection also increases with age. Both men and women with each decade of life after 50 have a statistically higher ADR [14].

Several studies have shown that even certified colonoscopists exhibit variation in the adenoma detection rate. The difference in detecting serrated lesions is even greater than for conventional adenomas. It demonstrates that colonoscopy is a highly operator-dependent procedure [15, 16]. That is why training in differentiation skills is essential.

The benefit of knowing our own ADR may also motivate endoscopic quality improvement, as it has been shown in several interventional studies with the implementation of scheduled personalized ADR report cards [17, 18]. It has been confirmed in recent studies, including a meta-analysis, where patients were undergoing same-day, back-to-back (tandem) colonoscopies, that especially in the right colon polyps are more likely to be missed [19, 20]. Of course failure to reach the cecum leads to low ADR in the right colon as a consequence of excessive loop formation or failure to traverse angulated, fixed, or strictured sigmoids (most commonly among female patients with prior gynecological surgery and patients with advanced diverticular disease). Even if the cecum is intubated successfully, there are factors increasing the adenoma miss rate such as localization behind the folds and flat lesions [21, 22].

Using an effective technique means performing endoscopy with a withdrawal time allowing a physician to keep his ADR level high. There is a strong association of detection of precancerous lesions with withdrawal time. There are studies showing

Table VIII. Comparison of histopathological findings in distal colon between groups

Parameter	All	Group I	Group II	*P*-value
Total number of exams with samples for pathological exam	3501 (15.32%)	1187 (16.29%)	2337 (15.02%)	0.013
Non-neoplastic lesions	1509 (6.60%)	559 (7.67%)	950 (6.10%)	< 0.001
Hyperplastic polyp	422 (1.85%)	141 (1.94%)	281 (1.81%)	0.497
Benign non-epithelial neoplasm	123 (0.54%)	36 (0.49%)	87 (0.56%)	0.532
1–2 Tubular adenomas < 10 mm	1059 (4.63%)	283 (3.88%)	776 (4.99%)	< 0.001
3–4 Tubular adenomas < 10 mm	29 (0.13%)	5 (0.07%)	24 (0.15%)	0.135
≥ 5 Tubular adenomas < 10 mm	3 (0.01%)	0	3 (0.02%)	–
Tubular adenoma ≥ 10 mm	97 (0.42%)	38 (0.52%)	59 (0.38%)	0.122
1–2 Tubular-villous adenomas < 10 mm	58 (0.25%)	24 (0.33%)	34 (0.22%)	0.120
≥ 5 Tubular-villous adenomas < 10 mm	1 (< 0.01%)	1 (0.01%)	0	–
Tubular-villous adenoma ≥ 10 mm	34 (0.15%)	16 (0.22%)	18 (0.12%)	0.057
Villous adenoma < 10 mm	4 (0.02%)	2 (0.03%)	2 (0.01%)	0.810
Villous adenoma ≥ 10 mm	3 (0.01%)	3 (0.04%)	0	–
Polyp with high grade dysplasia < 10 mm	54 (0.24%)	22 (0.30%)	32 (0.21%)	0.211
Polyp with high grade dysplasia ≥ 10 mm	28 (0.12%)	8 (0.11%)	20 (0.13%)	0.862
Invasive adenocarcinoma in polyp	6 (0.03%)	3 (0.04%)	3 (0.02%)	0.607
Non-epithelial malignant neoplasm	1 (< 0.01%)	0	1 (0.01%)	–
Macroscopic adenocarcinoma	70 (0.31%)	23 (0.32%)	47 (0.30%)	0.861

Table IX. Comparison of histopathological findings in proximal colon between groups

Parameter	All	Group I	Group II	*P*-value
Total number of exams with samples for pathological exam	12943 (56.65%)	4618 (63.39%)	8325 (53.49%)	< 0.001
Non-neoplastic lesions	8331 (36.46%)	3086 (42.36%)	5245 (33.70%)	< 0.001
Hyperplastic polyp	1957 (8.57%)	658 (9.03%)	1299 (8.35%)	0.084
Benign non-epithelial neoplasm	44 (0.60%)	17 (0.23%)	27 (0.17%)	0.336
1–2 Tubular adenomas < 10 mm	1483 (20.36%)	413 (5.67%)	1070 (6.88%)	0.006
3–4 Tubular adenomas < 10 mm	44 (0.19%)	13 (0.18%)	31 (0.20%)	0.739
≥ 5 Tubular adenomas < 10 mm	11 (0.05%)	3 (0.04%)	8 (0.01%)	0.996
Tubular adenoma ≥ 10 mm	286 (1.25%)	119 (1.63%)	167 (1.07%)	< 0.001
1–2 Tubular-villous adenomas < 10 mm	148 (0.65%)	64 (0.88%)	84 (0.54%)	0.003
3–4 Tubular-villous adenomas < 10 mm	4 (0.02%)	3 (0.04%)	1 (0.01%)	0.189
Tubular-villous adenoma ≥ 10 mm	107 (0.47%)	52 (0.71%)	55 (0.35%)	< 0.001
Villous adenoma < 10 mm	4 (0.02%)	3 (0.04%)	1 (0.01%)	0.189
Villous adenoma ≥ 10 mm	20 (0.09%)	13 (0.18%)	7 (0.04%)	0.003
Polyp with high grade dysplasia < 10 mm	108 (0.47%)	40 (0.55%)	68 (0.44%)	0.250
Polyp with high grade dysplasia ≥ 10 mm	125 (0.55%)	37 (0.51%)	88 (0.57%)	0.583
Invasive adenocarcinoma in polyp	25 (0.11%)	9 (0.12%)	16 (0.10%)	0.659
Non-epithelial malignant neoplasm	5 (0.02%)	1 (0.01%)	4 (0.03%)	0.928
Macroscopic adenocarcinoma	241 (1.05%)	87 (1.19%)	154 (0.99%)	0.158

a linear correlation between ADR and withdrawal time, proving that a 6-minute withdrawal time is crucial to maintain the quality of the examination [23, 24].

The role of modern colonoscopy is to improve the quality by reducing the operator dependence. Within recent years different types of endoscopic imaging techniques have been introduced to improve the quality in colonoscopy and as a consequence the colorectal cancer screening. Advanced endoscopic imaging is revolutionizing our current methods to diagnose and treat colorectal lesions.

One of the technologies that has become standard in modern endoscopy is high definition (HD). High definition endoscopes have more pixels than standard definition (SD). Improved image quality should improve lesion detection and recognition. High definition not only helps to visualize lesions during a screening colonoscopy, but it also enhances evaluation of post-polypectomy scars at follow-up. A meta-analysis suggested that the implementation of HD produces a 2% to 4% gain in the ADR [25]. In our study ADR in successive eras of endoscopic technological development has risen. The difference in ADR between the analyzed eras is 2.59%, which is an acceptable level according to the literature.

Another optical enhancement technology present in modern endoscopes is filter technology that uses narrow red-green-blue light bands, i.e. narrow band imaging (NBI), to enhance micro-vessel architecture. There are randomized controlled trials (RCTs) showing the improvement in ADR with the use of NBI compared to standard endoscopies. There is also one study suggesting that NBI may improve the learning curve for detecting flat lesions [26, 27]. Initial studies show that this technology has potential to improve ADR, but we definitely need further investigations. In our study we cannot determine what the real influence on ADR in group II was. Not every report contained the Kudo classification describing the found lesion. However, it was possible to use the NBI whenever the physician performing endoscopy had diagnostic doubts.

In our study we performed a multivariate logistic regression analysis of the influence of selected factors on ADR, which showed that patients' tolerance is one of the crucial elements. The modern endoscopes that we used in our study are equipped with tools that increase the tolerance of the patients. The variable stiffness of the endoscope and responsive insertion technology (RIT) are features simplifying endoscope insertion and reducing the discomfort and pain during the examination. Undesired loops are reduced when the RIT endoscope is used, because of the secondary bending section of the endoscope and its flexibility. In conventional colonoscopes, when the scope passes through a sharp flexure in the colon, the force applied by the physician when inserting the scope can sometimes directly push up the wall of the colon because the distal end of the scope bends with a small radius (the so-called stick phenomenon). The bending function is useful for preventing the stick phenomenon, which causes severe pain for patients during colonoscopic insertion in colonic flexures [28, 29]. Reduction of loop formation and auxiliary maneuvers when using RIT reduce the patients' discomfort, leading to higher ADR.

Another technology that has an impact on patients' tolerance is magnetic endoscopic imaging (MEI) commercialized by Olympus as ScopeGuide (Olympus, Tokyo, Japan). Magnetic endoscopic imaging is a non-radiographic imaging technique capable of displaying real-time three-dimensional images of the colonoscope shaft within the abdominal cavity [30]. The main advantage is the possibility to locate the lesions precisely. However, there are RCTs confirming that use of MEI during colonoscopy has the potential to ease cecal intubation, and reduce patient discomfort and dependence on sedation [31]. Also the MEI system appears to be beneficial for inexperienced endoscopists, and it increases the cecal intubation rate. The technology helps to reduce the number of attempts to straighten loops and the duration of looping. However, experienced endoscopists are likely able to recognize and resolve loops quickly without the need for MEI visualization [32].

Colonoscopy is considered to be a gold standard for CRC screening. However, we still have a lot of work to do, especially considering the adenoma miss rate in the right colon. Many lesions are still missed because of the inability to visualize flat lesions and those located behind the fold. A perfect device should be ergonomic, and effective in its results and costs [33, 34]. According to our experience technologies such as HD, NBI, RIT and MEI meet the above-mentioned criteria and enhance the quality of screening endoscopy. There are several technologies present on the market, such as Full Spectrum Endoscopy (FUSE) and devices fixed to the colonoscope tip for the purpose of flattening folds, including a short cap or hood, Endocuff, Endocuff Vision, and Endoring. Our experience with those technologies is initial. Hence, we need more date to determine whether they can improve ADR. So far the data are mixed with regard to their efficacy.

In conclusion, there has been a technological revolution in endoscopy since the beginning of our study in 2004. We showed that technological innovations, novel endoscopy devices and diagnostic techniques as well as patient-related fac-

tors significantly improve the quality of colorectal cancer screening by increasing the adenoma detection rate. Endoscopes of the new era have great potential. However, in the future, we need to determine and standardize which of the technologies are supreme to achieve excellence in colorectal cancer screening.

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Conflict of interest

The authors declare no conflict of interest.

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Cecal intubation rates in different eras of endoscopic technological development

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Abstract

Introduction: *Colonoscopy plays a critical role in colorectal cancer (CRC) screening and has been widely regarded as the gold standard. Cecal intubation rate (CIR) is one of the well-defined quality indicators used to assess colonoscopy.*
Aim: *To assess the impact of new technologies on the quality of colonoscopy by assessing completion rates.*
Material and methods: *This was a dual-center study at the 2nd Department of Surgery at Jagiellonian University Medical College and at the Specialist Center "Medicina" in Krakow, Poland. The CIR and cecal intubation time (CIT) in three different eras of technological advancement were determined. The study enrolled 27 463 patients who underwent colonoscopy as part of a national CRC screening program. The patients were divided into three groups: group I – 3408 patients examined between 2000 and 2003 (optical endoscopes); group II – 10 405 patients examined between 2004 and 2008 (standard electronic endoscopes); and group III – 13 650 patients examined between 2009 and 2014 (modern endoscopes).*
Results: *There were statistically significant differences in the CIR between successive eras. The CIR in group I (2000–2003) was 69.75%, in group II (2004–2008) was 92.32%, and in group III (2009–2014) was 95.17%. The mean CIT was significantly reduced in group III.*
Conclusions: *Our study shows that the technological innovation of novel endoscopy devices has a great influence on the effectiveness of the CRC screening program. The new era of endoscopic technological development has the potential to reduce examination-related patient discomfort, obviate the need for sedation and increase diagnostic yields.*

Key words: *technology, quality, endoscopy, cecal intubation rate, cecal intubation time.*

Introduction

Colonoscopy is widely used for the diagnosis and treatment of disorders of the colon. It allows to visualize the entire large intestine mucosa and distal terminal ileum. It also plays a critical role in colorectal cancer (CRC) screening in many countries and has been widely regarded as the gold standard, decreasing the incidence of CRC by up to 80% and allowing early detection and removal of precancerous lesions [1, 2]. The performance of a 'complete colonoscopy' by passage of the colonoscope along the whole length of the colon to the cecum or terminal ileum is a key parameter for measuring the quality of the procedure. Hence, the cecal intubation rate (CIR) is one of the well-defined quality indicators used to assess colonoscopy [3]. A poor cecum intubation rate is closely correlated

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with a low adenoma detection rate and increased risk of post-colonoscopy colorectal cancer (PCCRC) [4]. However, the CIR not only is a quality indicator but also reveals the endoscopic skills of a physician. Experienced colonoscopists have been shown to intubate the cecum in more than 90% of cases [5]. Reasons for failing to reach the cecum include excessive loop formation and failure to traverse angulated, fixed, or strictured sigmoids. These problems occur most commonly among female patients with prior gynecological surgery and patients with advanced diverticular disease [6, 7]. The chance of reaching the cecum decreases with patients' age and increases with a higher body mass index (BMI). Cecal intubation in a young healthy patient is most likely to be successful [8]. On the other hand, endoscopes have evolved over time through continual improvements. The transition from fiberscopes to videoscopes has significantly increased the diagnostic and therapeutic potential of the endoscopes. Following the introduction of videoscopes, there continued to be numerous technological advances facilitating scope insertion and operation, such as responsive insertion technology (RIT), which is a unique combination of three technologies: passive bending (PB), high-force transmission (HFT), and variable stiffness. Thus, the structure of endoscopes has been altered to facilitate the feasibility of the examination increasing the CIR, reducing the cecal intubation time (CIT) and diminishing patient discomfort during the examination. The new endoscopes also include narrow band imaging (NBI) and magnetic endoscopic imaging (MEI).

Aim

The aim of this study was to assess the impact of new technologies on colonoscopy completion rates. Therefore, we determined the most important colonoscopy quality indicators, the CIR and CIT, in three different eras of technological advancement.

Material and methods

This was a retrospective study at the 2nd Department of Surgery at Jagiellonian University Medical College and at the Specialist Diagnostic and Therapeutic Center "Medicina" in Krakow, Poland. The study enrolled 27 463 patients who underwent colonoscopy as part of a national colorectal cancer screening program, which was financed by the Polish Ministry of Health. Polish citizens ages 50–65 years or 40–65 with a first-degree relative with abdominal cancer took part in the analysis. The inclusion criteria were that patients were between 40 and 65 years of age, were able to provide informed consent, had an indication for colonoscopy as colorectal cancer screening and for whom this was a first or follow-up colonoscopy. We excluded all patients with a prior history of abdominopelvic surgery, inflammatory bowel disease, an active malignancy, and a high anesthetic risk (ASA IV); who were pregnant; who were unable to provide informed consent; and who

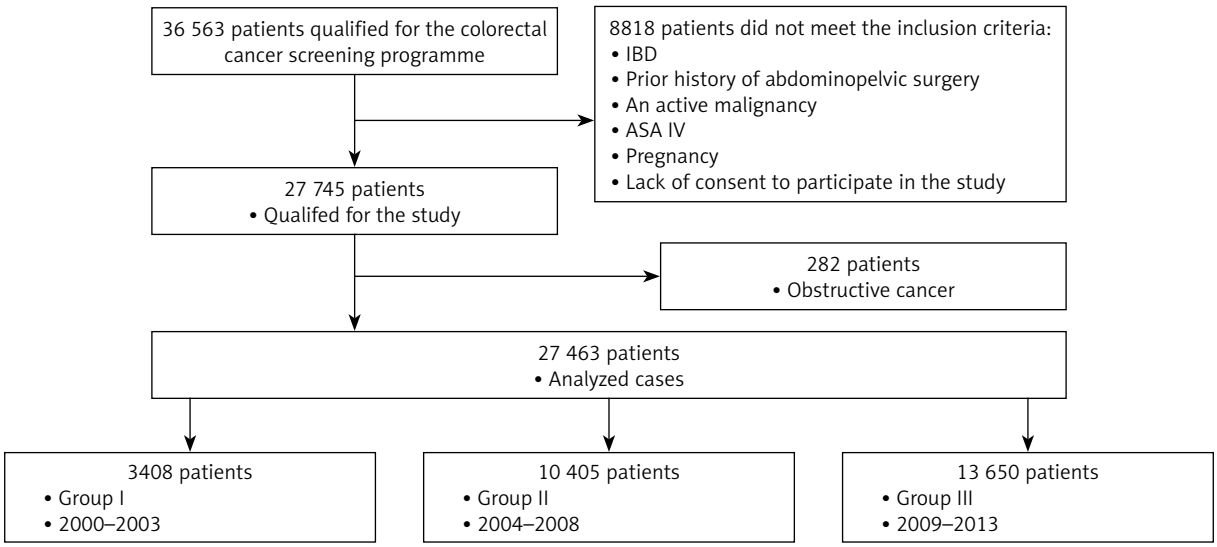

Figure 1. CONSORT diagram of patient enrollment

had obstructive cancer (Figure 1). All of the patients had to personally sign a written consent form before embarking on the study, which was approved by the local ethics committee and conducted in accordance with the principles of the Declaration of Helsinki (KBN no 122.6120.36.2016).

The instruments used in all of the colonoscopies were from the Olympus series (Olympus Optical Co. Ltd, Tokyo, Japan). We compared the cecal intubation rates of three different eras of endoscopic technological development regarding the series of endoscope used. According to the technological era, the patients were divided into three groups. Group I consisted of 3408 patients who underwent colonoscopy between 2000 and 2003. This was the era of optical endoscopes (CF-Q10 and CF-Q20), which had the following parameters: insertion tube diameter: 13.3 mm, biopsy working channel: 3.2 mm, working length: 168 cm, and field of view: 120°. Group II included 10 405 patients examined between 2004 and 2008. This period constitutes the era of electronic endoscopes with standard resolution (CF-Q145, CF-Q165, and CF-Q180), which had the following parameters: insertion tube diameter: 12.8 mm, working length: 168 cm, instrument channel: 3.7 mm, field of view: 140°, and angulation range: up: 180°, down: 180°, right: 160°, and left: 160°. Between 2009 and 2014, we performed 13 650 colonoscopies using the CF-HQ190L (these patients formed group III). This was the era of endoscopes with a high-definition resolution, magnetic scope guide, responsive insertion technology (RIT) and narrow band imaging (NBI) with dual focus two-stage optical lens technology. The endoscopes used in this era had the following parameters: channel width: 3.7 mm, working length: 168 cm, field of view: normal: 170°, near: 160°, outer diameter: 13.2 mm, outer diameter insertion tube: 12.8 mm, max angulation up: 180°, max angulation down: 180°, max angulation right: 160°, and max angulation left: 160°. Ten experienced endoscopists conducted the procedures, each having independently performed over 1000 colonoscopies. Assisting the endoscopists during the colonoscopies were experienced endoscopy nurses, each having participated in more than 2 000 procedures.

The patients were initially placed onto their left side, whereas the endoscopic technique depended on the personal preference and experience of the endoscopist. During the course of the procedure, maneuvers such as manual abdominal pressure, repositioning of the patient, and instrument rotations, twists, stiffening, and straightening were applied where needed. The data collected related to the patient were the age, gender, height, weight, and BMI. Cecum intubation was considered to be attained when the ileocecal valve (Bauhin's valve) and appendiceal entrance were properly identified (Photos 1, 2). The endoscopies were performed under local anesthesia using lidocaine 2% gel topically on the anal canal. All of the patients were given the same bowel preparation guidelines based on the oral ingestion of liquid propulsive agents (i.e., 420 g of polyethylene glycol (PEG) in 4 l of water, taken in 4 doses every 6 h one day before the colonoscopy).

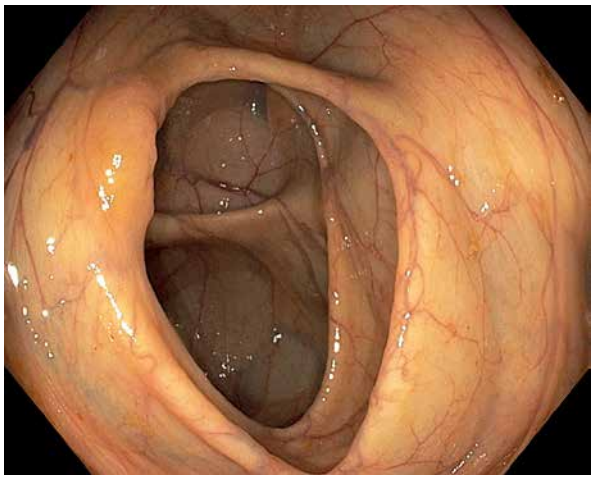

Photo 1. Endoscopic view showing Bauhin's valve

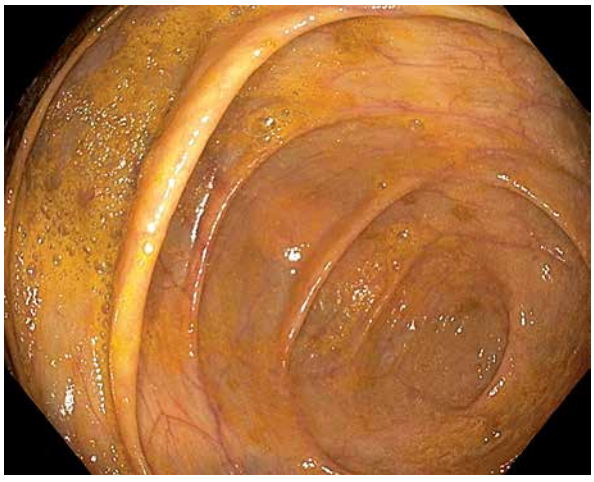

Photo 2. Endoscopic view showing appendiceal orifice

Table I. Characteristics of individuals subjected to colonoscopy in the 3 technological eras

Group	Gender	*N*	Age		BMI	
			Mean	SD	Mean	SD
I	F	2078	54.19	4.20	26.34	4.58
	M	1330	53.94	4.18	27.41	4.44
II	F	6289	54.29	4.31	26.20	3.95
	M	4116	54.16	4.28	27.09	4.32
III	F	8276	54.61	4.41	26.57	4.15
	M	5374	53.87	4.39	27.57	4.19
P-value		0.326	0.151		0.316	

During and after the colonoscopy, data on the procedure-related outcomes, such as the cecal intubation time (CIT) and cecal intubation rate (CIR), were collected. These procedure-related times were recorded by an assistant nurse using the stopwatch function on the endoscopy equipment. Cecal intubation was considered successful through the visualization of colonoscopic landmarks, i.e., the ileocecal valve (ICV) and appendiceal orifice (AO), and the CIT was defined as the time required from the introduction of the colonoscope until it reached the base of the cecum. After the cecum was identified, still photographs of the cecal landmarks were taken.

Statistical analysis

The materials acquired in this study were systematized and analyzed, and the distribution of variables was established. Since the analyzed parameters did not have a normal distribution, nonparametric tests were applied in the analysis. The qualitative variables were compared using the independent χ^2 test.

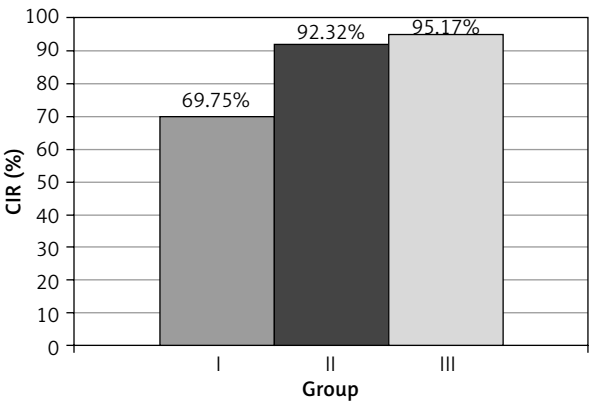

Figure 2. Cecal intubation rate

For comparison of the quantitative variables, the Mann-Whitney test was used. Comparison of quantitative data for more than two groups was done using the Kruskal-Wallis test. The statistical significance threshold was established at $p \leq 0.05$.

Results

A total of 27 463 colonoscopies performed from January 2000 to December 2014 were included in the study. Three groups of patients, each from an era of endoscopic technological development, were compared in terms of age, sex, and BMI. No differences in the distributions of sex, age, and BMI were observed between the groups (Table I).

No complications were observed from any of the procedures included in the study. All of the patients recovered and were discharged from the endoscopy unit.

There were statistically significant differences in the cecal intubation rates between the patients of the subsequent eras of endoscopic technological development. The CIR in group I (2000–2003) was 69.75%, the CIR in group II (2004–2008) was 92.32% and the CIR in group III (2009–2014) was 95.17% (Figure 2).

The mean cecal intubation time of group III, which was 209 s and SD: 93.75 s, was significantly lower than that of group I, which was 250 s and SD: 92.75 s. The mean CIT in group II was 224 s, which had an SD of 103.07 s ($p < 0.05$) (Table II).

Discussion

The cecal intubation rate has become one of the most important indicators of quality in endoscopy procedures. Cecal intubation is defined as a deep

intubation into the cecum with the tip of the endoscope so that it is able to touch the appendiceal orifice. The current guidelines of the European Society of Gastrointestinal Endoscopy (ESGE) and the English National Health Service (NHS) Bowel Cancer Screening Programme (BCSP) expect a completion rate above 90% as a minimum standard. The European Commission guideline also expects a 90% cecal intubation rate (excluding cases with obstructive cancer) [9]. The US Multi-Society Task Force on Colorectal Cancer recommends different benchmarks depending on whether it is a "screening" or "symptomatic" population of patients (95% and 90%, respectively) [10, 11]. Canadian standards set the minimum adjusted CIR at the level of 95% [12]. Over the years, the requirements of the author guidelines regarding the CIR have become stricter. However, it is completely understandable because complete examinations of the colon and rectum are crucial to any endoscopy and especially to a colorectal cancer screening program.

The companies are constantly trying to respond to the expectations of endoscopists to successfully accomplish cecal intubation, inventing equipment that is easier to insert and is applied without patient discomfort [13]. Failure to reach the cecum is not only inconvenient but also expensive for the patient (it requires another endoscopy or a radiological examination such as virtual colonoscopy) [14].

In 2000, we started a national colorectal cancer screening program with simple optical endoscopes. Over the years, we have been introduced to new technologies in endoscopy. Sophisticated technological innovations and advanced endoscopes have been developed in an effort to eliminate the drawbacks of colonoscopy, maximize its ability to detect precancerous lesions and maximize its ability to reach the cecum. Our study has shown that technological improvement has a significant influence on the quality of endoscopy.

We observed differences in the CIRs between the three technological eras. Huge advances in the era of electronic endoscopes (2004–2008) have led us to improve our results of successful cecal intubations from 69.75% to 92.32%. The difference between the era of high-quality advanced endoscopes and standard instruments was also statistically significant. Despite the fact that the total cecal intubation rate in group II was very high in our department (most of the colonoscopies are performed by experienced endoscopists), colonoscopes equipped with a variable stiffness, which are currently used, improve the percentage of cecal intubation [15–18].

Table II. Cecal intubation time

Group	Cecal intubation time [s] Mean ± SD
I	250 ±92.75
II	224 ±103.07
III	209 ±93.75

Another important finding of this study was that the time needed to reach the cecum was reduced in the RIT endoscope group compared with the conventional group and optical endoscopes group. This finding has also already been previously reported [19]. The time differences obtained in our study were small between the RIT group and the standard electronic group but substantial when compared to the optical endoscopes group, and these differences were statistically significant.

One of the major causes of unsuccessful cecal intubation is pain during colonoscopy. The CIR is lower in patients with previous abdominal procedures. It is most often caused by the looping of the instrument during insertion, which causes discomfort by stretching the intestinal mesentery [20–22].

Endoscopies that are performed with the most advanced endoscopes according to our study are most likely to be complete. This result is likely from the use of responsive insertion technology. During the procedure, secondary bending occurs when a section of the endoscope, which is extremely flexible, bends passively, which is beneficial when the sharply angulated sigmoid looping is present. The bending function, which is not present in conventional endoscopes, is useful for preventing the stick phenomenon, which causes severe pain for patients during colonoscopic insertion into splenic or hepatic flexures [23]. Reduced loop formation and auxiliary maneuvers while using the RIT lead to a higher CIR [24]. Another feature of the most advanced endoscopes that might have improved the CIR and CIT is magnetic endoscope imaging (scope guide). According to previous publications, colonoscopies performed using magnetic endoscope imaging demonstrated significantly lower rates of loop formation [25].

We also noted an association between BMI and the technical difficulty in successfully achieving cecal intubation. In our study, a lower BMI was an

independent factor associated with a lower CIR. It is possible that the low fat and muscle content of a low-BMI patient may lead to loop formation and patient intolerance.

Conclusions

We have gone through a technological revolution since the earliest flexible endoscope was presented by Hirschowitz in 1957 at the American Gastroscopy Society annual meeting [26]. Our study shows that technological innovation, novel endoscopy devices and diagnostic techniques have a great influence on the effectiveness of the colorectal cancer screening program. A new era of endoscopic technological development has the potential to reduce examination-related patient discomfort, obviate the need for sedation and increase diagnostic yields. A higher CIR and shorter CIT indicate better endoscope insertability and ergonomics.

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Conflict of interest

The authors declare no conflict of interest.

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Impact of responsive insertion technology (RIT) on reducing discomfort during colonoscopy: randomized clinical trial

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Abstract
Background In many countries, colonoscopies for colorectal cancer screening are performed without sedation due to the cost. Changes in the structure of the endoscopes are designed to facilitate the colonoscopic examination, reduce the duration of the procedure, and improve the imaging of the intestinal lumen. The variable stiffness of the endoscope and the recently introduced responsive insertion technology (RIT) are features aimed at easing colonoscope insertion and reducing the discomfort and pain during the examination. The aim of the study is to analyze whether the new RIT system can improve the practice of colonoscopy under no anesthesia with respect to the widely available variable stiffness colonoscopes.
Materials and methods This analysis included 647 patients who underwent complete colonoscopy in the screening program. All colonoscopies were performed without sedation. Olympus series 180 and 190 endoscopes equipped with a magnetic positioning system were used. Group I included patients who were examined using endoscopes equipped with responsive insertion technology (RIT), and group II included patients who were examined using conventional variable stiffness colonoscopies. The main objective was to evaluate the cecal intubation time, the number of loops, the requirement to apply manual pressure to different areas of the abdomen and the degree of discomfort and pain expressed on a visual analogue scale (VAS). ClinicalTrials.gov number, NCT01688557.
Results Group I consisted of 329 patients, and group II included 318 patients. The mean age of the patients was 58.4 years (SD ± 4.21). Both groups were compared in terms of age, sex, and BMI. The mean cecal intubation time was 209 s in group I and 224 s in group II ($p < 0.05$). Increased loop formation was observed upon endoscope insertion in group II (1.7 vs. 1.35) ($p < 0.05$) and required more manual pressure to the abdomen (2.2 vs. 1.7) ($p = 0.001$). In group I, less discomfort and pain, as graded on a VAS (2.3 vs. 2.6), were noted.
Conclusions The implementation of RIT reduced of the cecal intubation time. The modified structure of the endoscope rendered the colonoscopic examination easier by reducing loop formation upon insertion with a subsequently reduced rate of auxiliary maneuvers.

Keywords Colonoscopy · Colorectal cancer · Responsive insertion technology

Colorectal cancer (CRC) is the third most common cancer and the fourth leading cause of cancer-related death worldwide [1]. Since 2009, mounting evidence from observational studies has demonstrated that colonoscopy screening is associated with reductions in both CRC incidence and mortality [2–5]. Most cases of CRC arise from adenoma via a process known as the adenoma–carcinoma sequence and are therefore amenable to

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screening and early treatment [6, 7]. Approximately 98 % of all colonoscopies in the USA are performed with sedation [8]. Traditionally, sedation involves a benzodiazepine and an opioid. Recently, propofol has been utilized as an alternative option for sedation due to its rapid induction of sedation, faster recovery, lack of active metabolites, and equivalent levels of amnesia. However, in many other countries (e.g., Poland), colonoscopies for CRC screening are performed without sedation due to the costs. The structure of endoscopes has been altered to facilitate feasibility of the examination, reduce the time of its duration, and diminish patient discomfort during examination. Responsive insertion technology (RIT) is a unique combination of three technologies: passive bending (PB), high-force transmission (HFT), and variable stiffness. These technologies work together to improve ease of insertion and operator control, which may help to minimize patient discomfort and enhance procedural efficiency.

PB helps colonoscopes move through acute bends in the colon because the passive bending section is located between the insertion tube and the conventional bending section of the endoscope. When the scope meets resistance, the pressure is redistributed such that the insertion tube automatically bends to adjust to the contours of the colon, thereby potentially decreasing patient discomfort and providing rapid insertion to the cecum.

HFT provides improved operator control for pushing and twisting maneuvers. Whenever the scope is pushed forward or rotated, the pushing force or rotational torque is transmitted in a 1:1 manner down the length of the insertion tube. Thus, the scope reacts more sensitively to physician handling and is easier to maneuver within the colon. This technology features an insertion tube that better transmits the pushing force and torque by reducing the loss of force at the loop, thus helping the device pass the sigmoid colon with less pushing force and torque.

Variable stiffness allows the flexibility of scopes to be incrementally altered by manipulating a flexibility adjustment ring that ranges from 0 to 3. This innovative feature allows the variable stiffness colonoscope (VSC) to be adjusted on a case-by-case basis to meet the unique anatomical needs of the patient and the physician's handling preferences.

The aim of the study was to analyze whether the new RIT system can improve the practice of colonoscopy under no anesthesia with respect to the widely available variable stiffness colonoscopes.

Materials and methods

The analysis was performed between 2014 and 2015 at the Endoscopy Unit in Krakow as a part of a national colorectal cancer-screening program, which was financed by the Polish Ministry of Health. The study was approved by the local ethics committee and was conducted in accordance with the principles of the Declaration of Helsinki. Polish citizens aged 50–65 or 40–65 with a history of abdominal cancer in a first-degree relative took part in the analysis. Inclusion criteria were that patients were between 40 and 65 years of age, able to provide informed consent, whose indication for colonoscopy was colorectal cancer screening, and for whom this was a first or follow-up colonoscopy (Fig. 1). We excluded all patients with suspected significant gastrointestinal bleeding, previous abdominopelvic surgical history, previous colonic resections, known inflammatory bowel disease, or specific conditions that made it theoretically more desirable to use a specific colonoscope (e.g., stenosis, major bleeding), patients with a high anesthetic risk (ASA-4), pregnant women, and patients who were unable to provide informed consent.

Six hundred and sixty-five consecutive endoscopy unit outpatients who were scheduled to undergo colonoscopy screening for CRC were invited to participate in this study upon arrival for their appointment. Eighteen patients with an incomplete colonoscopy due solely to inadequate preparation or sedation were excluded (Fig. 1).

All patients were given the same bowel preparation guidelines based on the oral ingestion of liquid propulsive agents (i.e., 420 g of polyethylene glycol (PEG) in 4 L of water taken in 4 doses every 6 h one day before the colonoscopy). Bowel cleansing quality was graded at the end of the procedure according to the Boston bowel preparation scale.

All colonoscopies were performed by 7 experienced endoscopists ($\geq$1000 colonoscopies), who had previously dealt with endoscopes equipped with RIT and possessed comparable experience in the use of this technology. All endoscopists were assisted by nurses who were responsible for applying manual pressure to different areas of the abdomen to facilitate endoscope insertion. All colonoscopies were performed without sedation. There was no technical possibility to blind the type of endoscope because of their completely different appearance, and clothing of endoscope in a sleeve camouflage would have hampered the performance of colonoscopy thus affecting the study results.

Olympus series 180 and 190 endoscopes equipped with magnetic positioning system were used. Group I included 329 patients who were examined using variable stiffness endoscopes equipped with RIT (Olympus CF-HQ190L, Olympus Optical Co. Ltd, Tokyo, Japan), and group II included 318 patients who were examined using conventional variable stiffness endoscopes (Olympus CF-H180DL, Olympus Optical Co. Ltd, Tokyo, Japan). The mean age of the patients was 58.4 years (SD $\pm$ 4.21). Patients were randomly assigned to two groups as described below. Randomization took place at the endoscopy unit

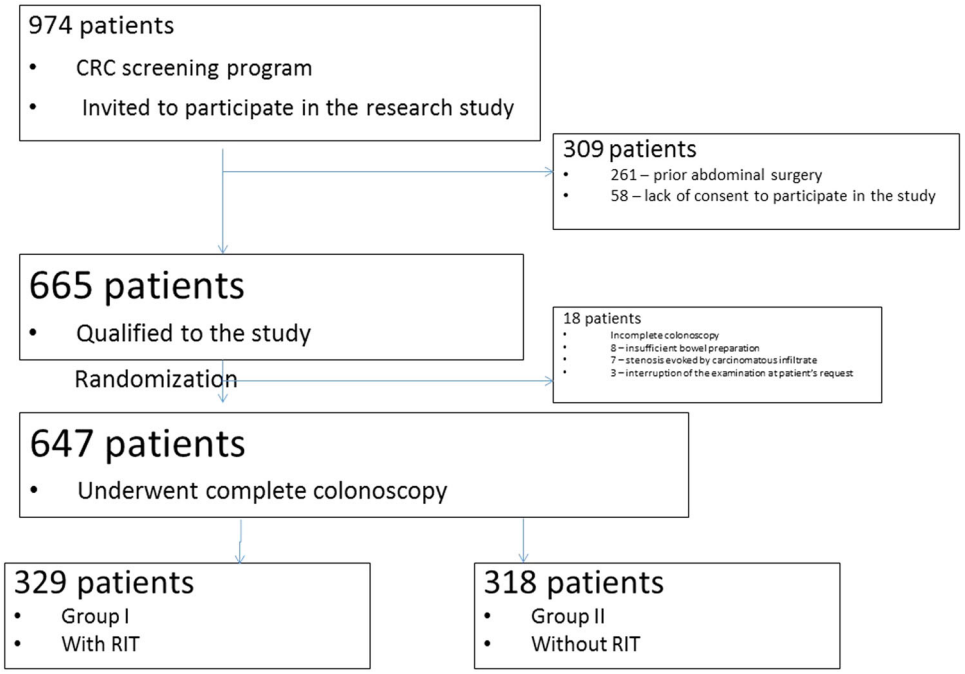

Fig. 1 Consort diagram of patient enrollment

at the study center. A computer-generated list was used for randomization. The randomization sequence was created by the R package "blockrand" with a 1:1 allocation using randomly varying block sizes. To allocate a patient to either the RIT or standard group, a sealed envelope was opened and the randomization card taken out before endoscopy. The endoscopy team did not take part in the randomization allocation process.

The main objectives were to evaluate the cecal intubation (CI) time, the rate of loop formation, the requirement of applying manual pressure to different areas of the abdomen, and degree of discomfort and pain expressed on a visual analogue scale (VAS). Cecal intubation was defined as the time of the insertion of the colonoscope tip to a point proximal to the appendiceal orifice. Loops were identified on the magnetic positioning system display during colonoscopic examination. Additionally, following the colonoscopic examination, the pain perceived by the patient was recorded using a VAS for pain of 0–10. On that scale, the absence of pain corresponds to 0, and the maximum bearable pain corresponds to 10. This parameter was collected by the nursing staff immediately after the colonoscopy (evaluation of intraprocedural pain) and again 15 and 60 min after the colonoscopy (evaluation of postprocedural pain).

Statistics

Continuous variables are expressed as the mean ± SD. Categorical variables were expressed as frequencies and percentages. Differences between the groups of patients (RIT group vs conventional group) were detected using an independent *t* test or Mann–Whitney *U* test for continuous data and the Chi-square test or the Fisher's exact test for categorical data, as appropriate. Univariate and multivariate linear regression models were used to identify factors affecting VAS pain scores during endoscope insertion. Multivariate linear regression with stepwise selection was applied; variables that did not improve the model fit at $p < 0.05$ were discarded. A p-value <0.05 was considered to indicate a statistically significant difference between groups. All statistical evaluations were performed using Statistica version 12 (StatSoft, Tulsa, OK, USA).

Results

Both groups of patients were compared in terms of age, sex, and BMI. No differences in the distribution of sex, age, and BMI were observed between the groups of patients assigned to the novel RIT or conventional endoscope groups (Table 1).

No complications were observed in any of the procedures included in the study. All patients recovered and were discharged from the endoscopy unit. The complete cecal intubation rate was 100 % in both groups. The cecal intubation time was significantly reduced in the RIT endoscope group (group I: mean 209 s, SD 93.75 s) compared with the conventional endoscope group (group II: mean 224 s, SD 103.07 s) ($p < 0.05$) (Table 2).

We evaluated the number of loops encountered during colonoscopy. The number of undesired loops in the shaft of

Table 1 Patients characteristics

Group	Sex	*n*	Mean age	Age SD±	BMI min	BMI max	Mean BMI	BMI SD±
I	F	220	58.86	4.21	17	44	26.44	4.58
	M	109	58.18	4.15	21	42	28	3.81
II	F	224	58.25	4.20	18	40	26.26	4.16
	M	94	57.94	4.30	15	42	27.43	4.29
	$p = 0.329$		$p = 0.146$		$p = 0.306$			

a flexible scope was significantly reduced when the RIT endoscope was used (group I: 1.30, SD 1.00 vs. group II: 1.70, SD 1.10) ($p < 0.05$) (Tables 3).

Significant differences were also noted in the need for the application of manual pressure to the abdomen and the need to change the patient's position. The total frequency of abdominal compressions applied by nurses during endoscopic insertion was reduced in group I (1.67, SD 1.05 vs. 2.17, SD 1.11) (Table 3).

Similar findings were noted concerning the need to change a patient's position (0.27, SD 0.53 vs. 0.46, SD 0.73) (Table 3).

Abdominal pain was assessed using a 10-point VAS. We observed a significant trend of reduced pain in patients in whom colonoscopy was performed with the RIT system (Table 4).

In group I, patients reported less intraprocedural pain during colonoscopic examination (2.33, SD 1.12 vs 2.55, SD 1.12) and less postprocedural pain registered 15 min after completion of colonoscopic examination compared with group II (2.06, SD 1.21 vs 2.14, SD 1.20). However, no significant difference was noted between groups I and II regarding postprocedural pain recorded 1 h after the examination (1.38, SD 0.66 vs 1.37, SD 0.57). Furthermore, we analyzed BMI in relation to loop formation and found that the number of loops was reduced in obese patients (Table 5).

Discussion

The colonoscopic insertion technique remains one of the most difficult endoscopic procedures to master, and the development of a new colonoscope that is easier to insert is anxiously awaited, especially a colonoscope that can be inserted into the cecum without patient discomfort. Non-sedated colonoscopy may be an uncomfortable or painful examination. It is very important for the colonoscopist to understand the structure of the endoscope during its insertion to successfully accomplish cecal intubation with minimal pain. It has been previously suggested that variable stiffness colonoscopes offer an advantage compared with standard adult colonoscopes given its smaller diameter and increased flexibility [9–11]. Therefore, the purpose of our study was to evaluate whether the RIT colonoscopies could further facilitate the practice of colonoscopic examination performed without analgesia.

We did not find publications evaluating the learning curve to achieve competency at colonoscopy with the use of RIT. Theoretically the learning curve could affect the obtained results; however, the participation of experienced endoscopists with comparable experience and knowledge of the different types of endoscopic instruments eliminates the mistake that could change the results of the study.

In our study, we observed no differences between the two types of colonoscope (RIT vs VSC) regarding cecal intubation rate. This result was expected for the following two

Table 2 Cecal intubation time

Group	Sex	Min. cecal intubation time (s)		Max. cecal intubation time (s)	
I	M	70	50	480	520
	F	50		520	
II	M	60	50	610	620
	F	50		620	

Group	Sex	Mean cecal intubation time (s)		SD±	
I	M	221.72	209.29	111.09	93.75
	F	224.62		99.76	
II	M	198.79	223.76	100.37	103.07
	F	214.49		90.07	

Table 3 Comparison of loop formations, number of manual compressions to the abdomen, and changes in patient position during endoscope insertion between two analyzed groups

Group	Sex	Loop formations								Number of manual compressions							
		Min		Max		Mean		SD±		Min		Max		Mean		SD±	
I	M	0	0	4	4	1.4	1.3	1.1	1.0	0	0	6	6	1.77	1.67	1.07	1.05
	F	0		4		1.2		1.0		0		5		1.49		0.98	
II	M	0	0	5	5	1.7	1.7	1.1	1.1	0	0	4	5	2.19	2.17	1.14	1.11
	F	0		5		1.6		1.1		0		5		2.14		1.05	
		$p < 0.05$								$p < 0.05$							

Group	Sex	Changes in patient position							
		Min		Max		Mean		SD±	
I	M	0	0	2	2	0.19	0.27	0.46	0.53
	F	0		2		0.31		0.55	
II	M	0	0	4	4	0.44	0.46	0.78	0.73
	F	0		4		0.46		0.71	
		$p < 0.05$							

Table 4 VAS pain score (at 1, 15 and 60 min after colonoscopy)

Group	Sex	Mean VAS (1 min)		VAS (1 min) SD±		Mean VAS (15 min)		VAS (15 min) SD±		Mean VAS (1 h)		VAS (1 h) SD±	
I	M	1.92	2.33	0.88	1.12	1.88	2.06	1.19	1.21	1.38	1.39	0.73	0.66
	F	2.53		1.17		2.15		1.21		1.39		0.62	
II	M	2.26	2.55	1.15	1.12	1.88	2.14	1.19	1.20	1.34	1.37	0.58	0.57
	F	2.67		1.22		2.25		1.20		1.37		0.56	

Table 5 Comparison of loop formation with BMI in both groups of patients

BMI		Group	Loops [mean]	Loops SD±
<17	Severely underweight	I	0	0
		II	3	0
17–18.49	Underweight	I	2	1.10
		II	3	1.13
18.5–24.99	Normal (healthy weight)	I	1.37	1.41
		II	1.86	0
25–29.99	Overweight	I	1.40	1.05
		II	1.71	1.18
30–34.99	Obese class I	I	1.24	0.97
		II	1.52	0.93
35–39.99	Obese class II	I	1.18	0.87
		II	1.09	0.70
>40	Obese class III	I	0.75	1.50
		II	0.67	0.58

reasons. First, the total cecal intubation rate is very high in our endoscopic clinic because most colonoscopies without sedation are performed by experienced endoscopists [12]. Moreover, in the control group, colonoscopies equipped with variable stiffness were used because these endoscopes were previously demonstrated to improve the percentage of cecal intubation [13]. This result is consistent with the previous reports of skilled technical colonoscopists [14–16].

An important finding of this study was that the time needed to reach the cecum was reduced in the RIT endoscope group compared with the VSC group. This finding has also been reported in previously published studies [13, 17]. The time differences obtained in our study were small and therefore of doubtful clinical relevance. Nevertheless, the differences were statistically significant.

One of the major causes of pain during colonoscopy involves the looping of the instrument during insertion through the sigmoid colon, which causes discomfort by stretching the mesentery [18–20]. The number of undesired loops in the shaft of a flexible scope in our study was significantly reduced when the RIT endoscope was used, and less manual pressure to the abdomen was required. This result is likely because the secondary bending section of the endoscope bends only passively and is extremely flexible. This feature is useful in the presence of sharply angulated sigmoid looping. In conventional colonoscopes, when the scope passes through a sharp flexure in the colon, the force applied by the physician when inserting the scope can sometimes directly push up the wall of the colon because the distal end of the scope bends with a small radius—commonly known as the stick phenomenon. The bending function is useful for preventing the stick phenomenon, which causes severe pain for patients during colonoscopic insertion in splenic or hepatic flexures [21]. Reduced loop formation and auxiliary maneuvers when using RIT contribute to a reduction in patient discomfort. We demonstrated that the mean pain score, as rated by the patients, was significantly reduced in patients undergoing unsedated colonoscopy with RIT compared with VSC. This reduction in pain could be attributed to less stretching of the sigmoid colon loops by the flexible intubation tube acquired from the most flexible mode, thereby reducing both the number of auxiliary maneuvers applied (PB and HFT combined) and the recurrent loop formation by the stiffened colonoscope using the stiffest mode (VS) (Figs. 2 and 3).

Abdominal pain during colonoscopy can be affected by multiple factors. Loops caused by the colonoscope may lead to mesenteric stretching that is often associated with discomfort or pain. In addition, endoscope passage through angled colonic flexures, duration of the study, aggressive movements of the endoscope, and gas used for bowel insufflation have also significant impact. Intestinal wall tension is sensible during examination, and for a short time

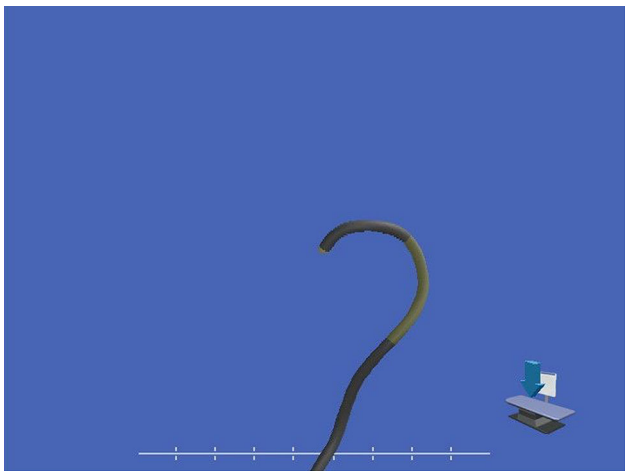

Fig. 2 MEI: mild endoscope passage through the splenic flexure with use of RIT

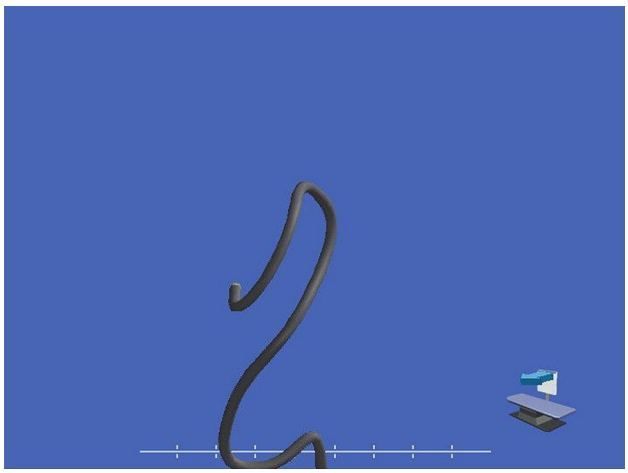

Fig. 3 MEI: acute angle of endoscope passage through the splenic flexure using conventional technology (flexure under tension)

afterward, while the procedure time and gas pressure left in the intestine appear to have a greater effect on the persistence of the postprocedural pain. Thus the application of carbon dioxide insufflation instead of air reduces pain and bloating not only during but also after colonoscopy [22]. This is reflected in our results, where it has been shown that facilitation of the endoscope passage to the cecum due to RIT usage significantly reduces pain during examination and within a short period afterward. The association between body weight and the technical difficulty in achieving CI during colonoscopy has been a topic of debate. Conflicting evidence suggests that both lean and obese subjects present a challenge to the endoscopist during colonoscopy [23–26]. Obesity has been independently associated with poor bowel preparation, which can subsequently lead to a difficult and prolonged colonoscopy. In our study, a lower BMI was an independent factor associated with significant discomfort during colonoscopy. It is

possible that the low muscle content of a low-BMI patient may predispose to loop formation and patient intolerance. Our study revealed that the number of loops formed during the insertion of the endoscope was greater in slender low-BMI patients; however, RIT did not alter patient tolerance.

In addition, we must emphasize the safety of the RIT endoscope because no complications associated with its use were noted in the study.

The limitations of this study are the necessity to purchase RIT-equipped endoscopes which are more expensive than the earlier generations. Another limitation is that all endoscopists must be familiar with the skillful use of variable stiffness technology. A criticism of the study is also that, due to the nature of the test, it could not be double-blinded. The endoscopists knew with which colonoscope they were performing the test as it was simply impossible to hide the type of endoscope from them. It should be emphasized that only experienced endoscopists participated in this study and their skillfulness is proved by the efficient cecal intubation time in the control group, which is significantly shorter as compared to the literature [27]. This was certainly influenced by the routine use of magnetic positioning system and the exclusion from the study patients after prior abdominal surgery.

In conclusion, RIT combines three unique technologies: high-force transmission (HFT), passive bending (PB), and variable stiffness. These technologies improve endoscope insertability and ergonomics. Through the use of RIT, the endoscope offers improved operator control when maneuvering and moves more easily through the colon. New RIT instruments allow a favorable colonoscopy with regard to completeness and time required for cecum intubation and significantly reduces discomfort in unsedated patients. These features suggest that RIT is the preferred improvement for unsedated patients undergoing total colonoscopy regardless of the skills of the examiner who can appropriately manipulate this novel device. The use of this technology should also facilitate to conduct colonoscopy under sedation, making it easier to pass the endoscope through the intestine and reduce cecal intubation time.

Compliance with ethical standards

Disclosures Miroslaw Szura, Artur Pasternak, Rafal Solecki, Maciej Matyja, Antoni Szczepanik, and Andrzej Matyja have no conflicts of interest or financial ties to disclose.

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POLSKI PRZEGLĄD CHIRURGICZNY

ORYGINALNY ARTYKUŁ

Colonoscopy for colorectal cancer screening - is it effective in the hands of a general surgery resident?

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ABSTRACT:

INTRODUCTION: Colonoscopy is considered to be a gold standard for colorectal cancer (CRC) screening. Endoscopy training is an essential component of general surgery training program. Patients should receive care at the highest level possible, nevertheless residents need to gain experience. The aim of our study was to evaluate the effectiveness of colonoscopy performed by general surgery residents by comparing quality indicators between surgical trainees and consultants

MATERIALS AND METHODS: The analysis included 6384 patients aged 40-65 who underwent screening colonoscopy between October 2014 and February 2018. The patients were divided into two groups: group I - patients examined by residents, group II - patients examined by board certified general surgeons. Quality indicators such as cecal intubation rate, adenoma detection rate and patient tolerance scale were compared between the two groups.

RESULTS: Group I comprised 2268 (35.53%) and group II 4116 (64.47%) patients. The overall cecal intubation rate (CIR) was 95.99%, equal for the both groups (p=0.994). There was no statistically significant difference in adenoma detection rate: 29.30% in residents group and 27.66% among consultants (p=0.203). Patient tolerance for exam was very good (4-point scale) in consultants group in 78.98% of cases and in 75.18% cases among residents (p<0.001).

CONCLUSION: Within a proper learning environment general surgery residents are able to perform high quality and effective screening colonoscopy. However, residents need to continue the progress in their technique to improve patient tolerance in order to reach the proficiency of the consultant.

Introduction

Colorectal cancer (CRC) is one of the leading causes of mortality and morbidity worldwide. It is the second most common cancer in Europe and the second most common cause of cancer-related deaths. CRC develops from precancerous polyps in

the colon or rectum and is both preventable and treatable when it is diagnosed early and with the removal of premalignant polyps. Colonoscopy plays a critical role in early detection and removal of precancerous lesions and it has been considered to be the gold standard tool of screening with a high sensitivity and specificity [1,2,3].

Measurable quality indicators/parameters for endoscopy have been selected and formulated. Complete colonoscopy, which is defined by passage of the colonoscope along the whole length of the colon to the cecum or terminal ileum is a one of the crucial measures of the procedure quality. It is addressed by cecal intubation rate (CIR) [4]. CIR is not only a quality indicator but it also delivers the information about the skills of physician performing examinations. Minimum standard of cecal intubation rates greater than 90% has been endorsed by the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG) [5].

Another priority quality indicator is adenoma detection rate (ADR). It is the percentage of patients aged ≥50 years undergoing first-time screening colonoscopy who have one or more conventional adenomas detected and removed. European Society of Gastrointestinal Endoscopy (ESGE) recommendations state that an experienced colonoscopist should have the ADR at the minimum level of 25% [6,7]. High ADR is associated with decreased interval colorectal cancer.

Endoscopy training is an essential component of general surgery training program. According to current recommendations screening programs agree a minimum lifetime experience for their screening colonoscopists and set a minimum benchmark for their annual number of screening examinations. It is recommended that minimum lifetime experience of 1000 colonoscopies and a minimum annual number of 150 screening colonoscopies would be sufficient for a physician to take part in CRC screening [8,9] .

In an attempt to further standardize surgical training, the Polish Board of Surgery now requires that residents provide evidence that they are certified in flexible endoscopy. This prospective study was aimed to determine whether, through a structured curriculum, junior level residents could conduct competent and safe screening colonoscopy

The aim of our study was to evaluate the quality and the effectiveness of colonoscopy performed by general surgery residents by comparing quality indicators between surgical trainees and consultants performing CRC screening.

Materials and methods

We conducted a dual-center study in the 2nd Department of Surgery, Jagiellonian University Medical College and the Specialist Diagnostic and Therapeutic Center “Medicina” in Cracow, Poland. The study was approved by the local ethics committee and conducted in accordance with the principles of the Declaration of Helsinki (KBN no 122.6120.36.2016).

Patients

We selected 6384 patients aged 40-65 who underwent colonoscopy screening between October 2014 and February 2018 (as a part of a national colorectal cancer-screening program, which was financed by the Polish Ministry of Health). Patients with a prior history of inflammatory bowel disease, active malignancy, and a high anesthetic risk (ASA IV) were excluded from the study. All patients were pre-evaluated before the examination and the written informed consent for the procedure was obtained. Patients were informed to take liquid propulsive agent (i.e., 420 g of polyethylene glycol (PEG) in 4 L of water) in the evening prior to the procedure for morning patients and a split-dose regimen for those in the afternoon schedule.

Setting

We used Olympus series colonoscopes (Olympus Optical Co. Ltd, Tokyo, Japan). Patients were sorted into two groups according to the experience of the physician performing the colonoscopy.

Group I included 2268 patients examined by surgical trainees i.e. general surgery residents, that have already obtained Endoscopic Skills Certificate from the Society of Polish Surgeons.

Group II included 4116 patients examined by board certified general surgeons (each of whom has performed more than 5000 colonoscopies).

Patients' preoperative characteristics including demographics, body mass index (BMI), family history of malignancy and significant comorbidities were determined.

Outcome

ADR was determined as a number of colonoscopies at which one or more histologically confirmed adenomas is found divided by the total number of colonoscopies performed. We compared ADR between the two groups of patients.

Cecal intubation was defined as deep intubation into the cecum with the tip of the endoscope being able to touch the appendiceal orifice. Cecal intubation rate was another quality indicator that we assessed between the two groups.

Another endpoints of the study that potentially differ between two groups were analyzed: patient tolerance for exam (4-point scale), localization of lesions

Statistical Analysis

All data were analyzed with Statsoft STATISTICA v.12.5 (Statsoft Inc, Tulsa, Oklahoma, USA). The results are presented as mean ± standard deviation (SD), median and interquartile range (IQR), when appropriate. The study of categorical variables used the Pearson's chi-square test, chi-square with Yates correction when appropriate. The Shapiro-Wilk test was used to check for normal distribution of data. Quantitative data were analyzed with t-student test (for normally distributed) and Mann-Whitney's (for non-normally distributed data). Univariate and multivariate logistic regression models were built including continuous and categorical variables. Results were considered statistically significant when the p-value was found to be less than 0.05.

Results

We observed no difference between the groups regarding sex and BMI (p=0.089 and 0.607, respectively). There was a slight difference in median age between the two groups: 62 vs 63 respectively (p<0.001). Family history of malignancy was not different (8.73% vs. 8.60%, p=0,860).

Basic characteristics and comparison between group I and group II including past medical history are presented in Table I.

Table I. Basic groups characteristics

	All	Residents	Consultants	p-value
N (%)	6384 (100%)	2268 (35.53%)	4116 (64.47%)	-
Males/Females (%)	3154/3230 (49%/51%)	1153/1115 (51%/49%)	2001/2115 (49%/51%)	0.089[1]
Median age (IQR)	62 (60-64)	62 (59-64)	63 (60-65)	**<0.001**[2]
Median BMI (IQR)	27.55 (24.91-30.49)	27.68 (25.07-30.80)	27.47 (24.85-30.48)	0.067[2]
Malignancy history	552 (8.65%)	198 (8.73%)	354 (8.60%)	0.860[1]
Previous colonoscopy	1013 (15.87%)	415 (18.30%)	598 (14.53%)	**<0.001**[1]
Lower gastrointestinal tract bleeding/Anemia	91 (1.43%)	65 (2.87%)	26 (0.63%)	**<0.001**[1]
Nonintentional weight loss	19 (0.30%)	16 (0.71%)	3 (0.07%)	**<0.001**[1]
Changes in bowel movements routine	47 (0.74%)	32 (1.41%)	15 (0.36%)	**<0.001**[1]
Medications	1112 (17.42%)	438 (19.31%)	674 (16.38%)	**0.003**[1]
Aspirin	983 (15.40%)	389 (17.15%)	594 (14.43%)	**0.004**[1]
Sintrom/Acenokumarol/Warfin	72 (1.13%)	29 (1.28%)	43 (1.04%)	0.469[3]
Plavix/Clopidogrel/Areplex/Trombex/Plavocorin	43 (0.67%)	30 (0.73%)	13 (0.57%)	0.570[3]
Smoking	1181 (18.50%)	396 (17.46%)	785 (19.07%)	0.112[1]
Operations	2691 (42.15%)	949 (41.84%)	1742 (42.32%)	0.710[1]
Cardiovascular comorbidity	660 (10.34%)	246 (10.85%)	414 (10.06%)	0.322[1]
Pulmonary comorbidity	241 (3.78%)	88 (3.88%)	153 (3.72%)	0.743[1]
DM2	700 (10.96%)	224 (9.88%)	476 (11.56%)	0.039[1]
Chronic kidney disease	33 (0.52%)	15 (0.66%)	18 (0.44%)	0.311[3]

[1] chi-square Pearson's test
[2] Mann-Whitney's test
[3] chi-square with Yates correction

The overall cecal intubation rate (CIR) was 95.99%, equal for the both groups (p=0.994). There was no statistically significant difference in another quality indicator adenoma detection rate. Complete ADR was 28.23%, 29.30% in residents group and 27.66% among consultants (p=0.203). The results are presented in Table II.

Table II.

	All	Residents	Consultants	p-value
Cecal intubation rate	6128 (95.99%)	2177 (95.99%)	3951 (95.99%)	0.994[1]
ADR	1516 (28.23%)	543 (29.30%)	973 (27.66%)	0.203[1]
General anesthesia	616 (9.65%)	201 (8.86%)	415 (10.08%)	0.114[1]
Tolerance for exam (local anesthesia)				**<0.001[1]**
poor	180 (2.82%)	87 (3.84%)	93 (2.26%)	
medium	336 (5.26%)	148 (6.53%)	188 (4.57%)	
good	912 (14.29%)	328 (14.46%)	584 (14.19%)	
very good	4956 (77.63%)	1705 (75.18%)	3251 (78.98%)	

[1] chi-square Pearson's test

Localization of changes is presented in Table III.

Table III. Localization of changes

	All	Residents	Consultants	p-value
Caecum	120 (1.88%)	57 (2.51%)	63 (1.53%)	**<0.001[1]**
Ascending colon and hepatic flexure	247 (3.87%)	106 (4.67%)	141 (3.43%)	
Transverse colon	149 (2.33%)	54 (2.38%)	95 (2.31%)	
Splenic flexure and descending colon	142 (2.22%)	59 (2.60%)	95 (2.31%)	
Sigmoideum	1046 (16.38%)	715 (31.53%)	331 (8.04%)	
Rectum	672 (10.53%)	513 (22.62%)	159 (3.86%)	

[1] chi-square Pearson's test

Table IV presents univariate and multivariate logistic regression analysis of influence of selected factors on cecal intubation rate. Significant factors were patients' sex, tolerance for examination and bowel preparation.

Table IV. Univariate and multivariate logistic regression model of factor potentially influencing cecal intubation rate			
	OR	95% CI	p-value
UNIVARIATE			
Residents vs. specialists	1.00	0.99-1.01	0.823
Males/Females	1.84	1.42-2.40	**<0.001**
Age	1.00	0.98-1.02	0.855
Obesity	1.23	0.93-1.64	0.152
Previous colonoscopy	0.86	0.62-1.18	0.347
LGI Bleeding/Anemia	1.87	0.46-7.64	0.383
Nonintentional weight loss	1.91	0.001-11.53	0.734
Changes in bowel movements routine	1.34	0.001-173.57	0.910
Medications	1.05	0.74-1.48	0.796
Aspirin	1.05	0.75-1.46	0.791
Anesthesia	2.44	1.33-4.49	0.004
Tolerance for exam	4.97	4.37-5.66	**<0.001**
Bowel preparation R	1.08	1.07-1.08	**<0.001**
Bowel preparation M	1.07	1.06-1.08	**<0.001**
Bowel preparation L	1.07	1.04-1.09	**<0.001**
MULTIVARIATE			
Males/Females	1.20	0.74-1.93	0.463
Anesthesia	1.79	0.65-4.98	0.262
Tolerance for exam	2.12	1.65-2.72	**<0.001**
Bowel preparation R	1.07	1.05-1.08	**<0.001**
Bowel preparation M	1.00	0.99-1.02	0.602
Bowel preparation L	1.08	1.03-1.13	**<0.001**

Table V presents univariate and multivariate logistic regression analysis of influence of selected factors on adenoma detection rate. Significant factors were: cecal intubation rate, patients' sex, tolerance for examination and bowel preparation.

Table V. Univariate and mulitivariate logistic regression model of factor potentially influencing ADR			
	OR	95% CI	p-value
UNIVARIATE			
Residents vs. specialists	0.92	0.82-1.04	0.199
Males/Females	0.50	0.45-0.57	**<0.001**
Age	1.03	1.01-1.05	**0.003**
Obesity	1.28	1.12-1.45	**<0.001**
LGI Bleeding/Anemia	1.14	0.68-1.91	0.625
Nonintentional weight loss	1.13	0.35-3.69	0.839
Changes in bowel movements routine	1.17	0.57-2.38	0.672
Medications	1.04	0.90-1.21	0.561
Aspirin	1.02	0.74-1.39	0.920
Anesthesia	1.20	0.98-1.47	0.083
Tolerance for exam	1.38	1.25-1.52	**<0.001**
Cecal intubation rate	3.48	2.23-5.44	**<0.001**
Bowel preparation R	1.02	1.01-1.02	**<0.001**
Bowel preparation M	1.01	1.01-1.02	**<0.001**
Bowel preparation L	0.99	0.98-1.01	0.444
MULTIVARIATE			
Males/Females	0.53	0.47-0.60	**<0.001**
Age	1.03	1.01-1.43	**<0.001**
Obesity	1.23	1.08-1.40	**0.002**
Tolerance for exam	1.17	1.05-1.30	**0.006**
Cecal intubation rate	1.67	0.87-3.23	0.122
Bowel preparation R	1.01	1.00-1.03	**0.018**
Bowel preparation M	1.01	1.00-1.02	0.131

Discussion

Endoscopy training has been one of the essential components of general surgery residency program in Poland. It is also required by the Association of Polish Surgeons (AJS). The importance of endoscopic training during residency has been well documented by graduates and program directors [10,11].

Recently, in 2014 the Polish Ministry of Health accepted new general surgery residency program, with increased up to 100 gastrointestinal endoscopies required for graduating residents to perform. However, the AJS has more strict requirements for board certification. In order to get the AJS accreditation candidates have to perform at least 100 colonoscopies and 50 polypectomies. To perform colorectal cancer screening colonoscopy a physician needs to have either the above mentioned

certification or graduation from general surgery or gastroenterology, alternatively. Currently, the international endoscopic societies tend to resign from arbitrary numbers and state that competency level should be based on more objective criteria [12].

It has been already demonstrated that surgeons can perform high-quality endoscopy with low rates of complications. Reports, including prospective studies confirm that colonoscopies performed by surgeons are at the highest quality, with the results comparable to those done by gastroenterologists [13,14]. According to our knowledge there is only a few studies comparing outcomes in endoscopy between residents and consultants. We have not found any reports concerning particularly CRC screening colonoscopy and differences in performance between those two groups of physicians.

At both institutions, where our study took place residents with adequate experience, after the acceptance of the head of the department, performed examinations without a direct supervision. A board certified surgeon, who is a supervisor, was present in the endoscopy department and was always willing to assist when needed. This sort of solution gives a resident a chance to make autonomic decisions, but at the same time a possibility to use the knowledge of a more experienced colleague. We have not noticed any inconvenience concerning our work system so far. When there is an indication to stop the examination before reaching the cecum (i.e. severe pain or potential risk of perforation) trainees do not force the colonoscopy. The patients are referred to CT scan, CT colonoscopy or barium enema, when required. To keep the highest possible quality level we follow the rule of a minimum 6 minutes withdrawal time that has been recently reported and is considered as a standard because of its correlation with ADR [15,16].

Our study has shown that there are statistically significant differences concerning patients tolerance between the two groups. Colonoscopies performed under local anesthesia by residents were not tolerated as well as the ones performed by the consultants. 75.18% examinations were rated as very good in a matter of tolerance vs 78.98% performed by consultants. There are reports stating that patients undergoing colonoscopy performed by surgeons are more likely to report pain than patients examined by gastroenterologists [17]. But we have not met any paper

distinguishing pain reports between the residents and consultants. Higher discomfort may have influence on completion rates. Evaluating patient tolerance is also questionable. The physician and the patient opinions may vary in terms of the comfort during the procedure. In our paper we have analyzed results reported by the physicians.

Our study showed that results of CRC screening colonoscopy and its quality is comparable between residents and consultant specialists. Slightly lower patient tolerance of the examinations performed by trainees did not affect completion rates. There were no statistically significant difference between cecal intubation rate in the groups: 95.99 % among residents and 95.99 % among consultants. CIR outcomes in both of the groups meet the recommendations of European Commission and National Health Service Bowel Cancer Screening Programme in England (NHSBCSP), where 90% CIR is a minimum [18]. Residents and board-certified surgeons at our institution also meet stricter requirements of the US Multi-Society Task Force on Colorectal Cancer, where a benchmark for screening population is set to 95% [19].

The ADR between the two study groups showed no statistically significant difference. It exceeds the minimum standards described in the literature, such as the American Society for Gastrointestinal Endoscopy (ASGE) recommendations, which state that adenomas should be detected in more than 25% of the asymptomatic male patients and in more than 15% of the females [20]. ADR calculated as described in methods section was overall 28.23%, and did not differ groups significantly neither in chi-square nor in univariate logistic regression. ADR of residents was 29.30% and of consultants 27.66% (p-values respectively 0.203 and 0.199). There is a possibility that this 1.64% difference between ADRs came from that the consultants have more experience with narrow band imaging (NBI) that enhances micro-vessel architecture and determines the decision not to remove hyperplastic polyps [21]. However, not every report contained Kudo classification describing detected lesion, so it is hard to determine what was the real influence of NBI on ADR.

To sum up, in our study residents did not diverge from the consultant surgeons in terms of quality in screening colonoscopy. The factors describing CRC screening

have been maintained at the highest level. Of course it is unquestionable that residents require proper training methods before having a possibility to become independent from their supervisors. Our training methods as described above are accepted internationally and similar studies have confirmed their successfulness [22,23]. At the same time patients undergoing screening colonoscopy are provided with the best possible medical care. Residents before performing independent examinations need a proper education provided by our consultant, but as soon as physicians enter CRC screening program their results are monitored. Polish Ministry of Health keeps auditing the quality of CRC screening, so it is impossible to lower the desired standards in the accredited institutions. There are several limitations to our study. It has been limited to two departments, where physicians performing examinations work in university centers having accreditations to issue certificates of competency in endoscopy. To have a larger perspective more data from non-academic centers is required. However, our study describes a large number of screening endoscopic examinations. Our results may become a foundation to improve the quality and training of general surgery residents.

Conclusion

Within a proper learning environment general surgery residents are able to perform high quality and effective screening colonoscopy. Examinations carried out by residents have the same value as the ones performed by board certified surgeons. However, there is a room for improvement in patient tolerance in order to reach the proficiency of the consultant.

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Authors have no conflicts of interest or financial ties to disclose

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STRESZCZENIE W JĘZYKU POLSKIM

Wstęp:

Rak jelita grubego jest jednym z najczęściej występujących nowotworów złośliwych – w Polsce zajmuje pod tym względem 2. miejsce u obu płci, a zachorowalność na ten nowotwór systematycznie wzrasta. Większość raków jelita grubego rozwija się na podłożu gruczolaka uszypułowanego, znacznie rzadziej nieuszypułowanego. Sekwencja gruczolak-rak jest główną drogą prowadzącą do raka, obserwowaną w 85% przypadków raka jelita grubego u ludzi. W związku z tym istotne znaczenie dla profilaktyki ma wdrożenie badań przesiewowych, które pozwalają na obniżenie częstości występowania raka jelita grubego i spadek śmiertelności z nim związanej. W Polsce podstawową metodą wykorzystywaną w badaniach przesiewowych jest kolonoskopia. Jej główne zalety to duża czułość i swoistość oraz możliwość usuwania zmian prekursorowych, co powoduje, że jest ona narzędziem nie tylko wczesnego wykrywania raka jelita grubego, ale również zapobiegania jego rozwojowi.

W Polsce od 2000 roku realizowany jest Program Badań Przesiewowych dla wczesnego wykrywania raka jelita grubego. Od tego czasu obserwowany jest stały szybki postęp technologiczny owocujący wprowadzaniem nowych generacji sprzętu endoskopowego, dodatkowego oprzyrządowania, co w połączeniu z doświadczeniem i inwencją endoskopisty umożliwia przeprowadzanie coraz bardziej dokładnej diagnostyki. Odeszliśmy od endoskopów optycznych, które były wykorzystywane na początku programu badań przesiewowych. Do nowoczesnych technologii wykorzystywanych obecnie w endoskopii należą m.in: wideoendoskopia wysokiej rozdzielczości (HDTV 1080p), obrazowanie w wąskim paśmie światła (Narrow Band Imaging), dwustopniowy system optyczny (Near Focus), zmienna sztywność sondy poprawiająca kontrolę wprowadzania endoskopu oraz system magnetycznej trójwymiarowej nawigacji endoskopu.

Każda procedura medyczna, aby była skuteczna i efektywna oraz bezpieczna dla pacjentów musi być dobrze wykonywana. Wskaźniki jakości w kolonoskopii są ściśle określone i stanowią je między innymi: częstość wykrywania gruczolaków (adenoma detection rate – ADR), osiągalność kątnicy (cecal intubation rate – CIR). Według wytycznych odsetek kolonoskopii przesiewowych z osiągnięciem kątnicy powinien wynosić co najmniej 95%. Natomiast odsetek badań, w których wykryto

co najmniej jednego gruczolaka powinien wynosić co najmniej 25% u mężczyzn i co najmniej 15% u kobiet. Innym proponowanym parametrem jakości jest czas wycofywania aparatu, który nie powinien być krótszy niż 6 minut.

W ostatnich latach obserwujemy systematyczny wzrost liczby badań kolonoskopowych wykonywanych w ramach skriningu. W związku z tym analiza jakości, parametrów na nią wpływających, w tym szkolenia, czy też indywidualnych możliwości endoskopisty jest niezwykle istotna. Nadal poszukiwane są optymalne rozwiązania zarówno dla pacjentów, jak i lekarzy wykonujących badania przesiewowe. W związku z tym, iż jako II Katedra Chirurgii Ogólnej Collegium Medicum Uniwersytetu Jagiellońskiego bierzemy czynny udział w badaniach przesiewowych wykonywanych w kierunku wczesnego wykrywania raka jelita grubego powinniśmy mieć realny wpływ na poprawę jakości badań. Dlatego też wyniki badań prowadzonych w II Katedrze Chirurgii Ogólnej stanowiły podstawę do napisania niniejszej rozprawy doktorskiej zatytułowanej: „Retrospektywna analiza wyników badań kolonoskopowych w ramach programu badań przesiewowych dla wczesnego wykrywania raka jelita grubego". Praca doktorska stanowi cykl czterech prac oryginalnych: I. How to improve the adenoma detection rate in colorectal cancer screening? Clinical factors and technological advancements, II. Cecal intubation rates in different eras of endoscopic technological development,
III. Impact of responsive insertion technology (RIT) on reducing discomfort during colonoscopy – randomized clinical trial, IV. Colonoscopy for colorectal cancer screening – is it effective in the hands of a general surgery resident?.

Cele:

I. Ocena jakości kolonoskopii oraz czynników na nią wpływających na podstawie ADR w dwóch różnych erach technologicznych
II. Ocena wpływu nowych technologii w endoskopii na podstawie parametru osiągalności kątnicy.
III. Analiza wpływu technologii kontrolowanego wprowadzania endoskopu (RIT) na wyniki kolonoskopii wykonywanych w znieczuleniu miejscowym.
IV. Ocena wyników kolonoskopii wykonywanych w ramach program badań przesiewowych przez lekarzy w trakcie specjalizacji z chirurgii ogólnej.

Materiał i metody:

I. Przeanalizowano 24055 badań wykonywanych w latach 2004 do 2008. Pacjentów podzielono na dwie grupy w zależności od stosowanego endoskopu. Grupę I (10405) stanowili chorzy, którzy byli badani standardowymi elektronicznymi endoskopami. W grupie II znaleźli się chorzy (13650), którym wykonywano badanie przy pomocy najnowocześniejszych endoskopów. Porównano częstość występowania gruczolaków pomiędzy dwoma grupami, a także inne czynniki wpływające na jakość badania, w tym osiągalność kątnicy, przygotowanie do jelita, tolerancję pacjentów na badanie wykonywane w znieczuleniu miejscowym.

II. Poddane analizie zostały wyniki badań 27463 chorych, którzy przechodzili kolonoskopię w ramach programu przesiewowego wczesnego wykrywania raka jelita grubego. Chorzy zostali podzieleni na trzy grupy w zależności od czasu, w którym było wykonywane badanie, a co za tym idzie różnymi endoskopami wykorzystywanymi do badania. Grupa I składała się z 3408 chorych badanych w latach 2000- 2003 z użyciem endoskopów optycznych. Grupę II stanowiło 10405 chorych badanych w latach 2004- 2008 przy pomocy standardowych endoskopów elektronicznych, grupa III to chorzy badani w latach 2009- 2014, gdzie do badania stosowano najnowocześniejsze technologicznie endoskopy. Porównano osiągalność kątnicy (cecal intubation rate – CIR), a także czas osiągnięcia kątnicy pomiędzy grupami.

III. Analizą zostało objętych 647 pacjentów. Pacjenci zostali podzieleni na dwie grupy w zależności od rodzaju użytego endoskopu. Grupę I (329 pacjentów) stanowili chorzy, u których zastosowano kolonoskopy wyposażone w RIT, grupę II (318 pacjentów) stanowili chorzy, badani standardowymi aparatami o regulowanej sztywności. Porównano czas, w którym osiągano kątnicę, ilość pętli powstających w czasie badania, częstość stosowania ucisku brzucha przez asystenta w czasie badania oraz dolegliwości bólowe wyrażone w skali VAS.

IV. Analizą objęto 6384 pacjentów, którzy mieli wykonaną kolonoskopię w latach 2014-2018. Pacjentów podzielono na dwie grupy. Grupę I (2268 pacjentów) stanowili chorzy badani przez lekarzy rezydentów, grupę II

(4116 pacjentów) stanowili pacjenci badani przez lekarzy specjalistów chirurgii ogólnej. Porównano częstość wykrywania gruczolaków, osiągalność kątnicy oraz tolerancję pacjentów na wykonywane badanie.

Wyniki:

I. ADR był istotnie wyższy w grupie II 31.73% w porównaniu z 29.14% w grupie I ($p<0.001$). CIR również był większy w grupie II - 96.68% porównaniu z grupą I 93.73% ($p<0.001$). Także tolerancja badania była istotnie statystycznie wyższa w przypadku grupy pacjentów badanych zaawansowanymi technologicznie endoskopami.

II. CIR zwiększał się wraz z postępem technologii endoskopów używanych do badania przesiewowego. W grupie I CIR wynosił 69.75%,w grupie II i III odpowiednio 92.32% i 95.17% ($p< 0.001$). Również średni czas, w którym wykonywano pełne badanie był najkrótszy w grupie III.

III. Czas intubacji kątnicy był krótszy w przypadku użycia endoskopów wyposażonych w RIT, wynosił 209 s i 224 s odpowiednio dla I i II grupy ($p < 0.05$). Większa liczba powstających pętli była obserwowana w grupie II- 1.7 vs 1.35 ($p<0.05$). Pacjenci w grupie II częściej wymagali uciskanie manualnego brzucha w trakcie badania – 2.2 vs 1.7 ($p=0.001$). Chorzy w grupie I zgłaszali mniejsze dolegliwości bólowe w porównaniu z chorymi z grupy II, wg skali VAS – 2.3 vs. 2.6.

IV. CIR wynosił 95.99% ($p=0,994$) dla obu grup. Nie stwierdzono istotnej różnicy w częstości wykrywania gruczolaków wynosiła ona 29.30% w grupie I oraz 27.66% w grupie II ($p-0.203$). Tolerancja w czterostopniowej skali była bardzo dobra w 78.98% w grupie lekarzy specjalistów oraz w 75.18% w grupie lekarzy rezydentów ($p<0.001$).

Wnioski:

I. Czynniki zależne od pacjenta mają niezwykle istotny wpływ na końcowy wynik badania. Nowe technologie stosowane w najnowszych aparatach zwiększają jakość badania przesiewowego poprzez wpływ na zwiększenie częstości wykrywania gruczolaków oraz zwiększenie osiągalności kątnicy.

II. Nowe technologie zastosowane w endoskopach mają istotny wpływ na jakość i efektywność badań przesiewowych wykorzystywanych do wczesnego wykrywania raka jelita grubego.

III. RIT poprawia manewrowość kolonoskopów, zapewnia lepszą kontrolę nad endoskopem podczas obracania i wprowadzania, ułatwia wyprostowanie endoskopu. Skraca to czas intubacji kątnicy, ograniczając również dyskomfort pacjenta.

IV. Lekarze w trakcie specjalizacji są w stanie wykonywać kolonoskopię efektywnie i z jakością nie odbiegającą od międzynarodowych wytycznych.

STRESZCZENIE W JĘZYKU ANGIELSKIM

Introduction:

Colorectal cancer (CRC) is the second most common cancer in Poland including men and women. Over 85% of CRCs follow an adenoma-to-cancer sequence. Colonoscopy is widely used for the diagnosis and treatment of disorders of the colon. It also plays a critical role in colorectal cancer screening in many countries and has been widely regarded as the gold standard, decreasing the incidence of CRC by allowing early detection and removal of precancerous lesions.
Since 2000 in Poland colorectal cancer screening program has been introduced by the Polish Ministry of Health. CRC screening has been successful in reducing the incidence and mortality.

Since the beginning of the national screening program different endoscopic imaging techniques were introduced. We have witnessed a technological evolution started by the transition from fiberscopes to videoscope. Nowadays, high definition (HD) resolution endoscopes are used in everyday practice Following the introduction of videoscopes, the structure of the endoscopes has been changed nowadays. Responsive insertion technology (RIT) combines three technologies: passive bending (PB) and variable stiffness are supposed to facilitate the feasibility of the examination. The new endoscopes also include narrow band imaging (NBI), near focus (NF) and magnetic endoscopic imaging (MEI).

Every procedure, especially screening hast be safe and effective. Quality in endoscopy needs to be constantly improved. One of the key quality indicators is associated with the adenoma detection rate (ADR). The definition of ADR is the number of colonoscopies at which one or more histologically confirmed adenomas is found divided by the total number of colonoscopies performed. According to the recommendations ADR should be at the minimum level of 25% for men and 15% for women. Complete colonoscopy is another key parameter for measuring the quality of the procedure. Cecal intubation rate (CIR) is one of the well-defined quality indicators used to assess colonoscopy. A poor cecum intubation rate is correlated strictly with a low adenoma detection and increased risk of post–colonoscopy colorectal cancer (PCCRC). Another important aspect of effective colonoscopy is a 6-minute withdrawal time.

Number of patients undergoing screening colonoscopy is constantly growing. Hence, the analysis of parameters influencing quality, endoscopy training is crucial. We are still seeking for the factors, that could improve our performance.

In the 2nd Department of General Surgery, Jagiellonian University Medical College we perform colonoscopy for colorectal cancer screening. We are an academic center with an accreditation to issue certificates of competency in endoscopy. It obliges us to play a leading role in a search for better quality. It has inspired me to write a PhD thesis entitled: 'Retrospective analysis of colorectal cancer screening colonoscopies' consisting of four published papers:

I.How to improve the adenoma detection rate in colorectal cancer screening? Clinical factors and technological advancements, II. Cecal intubation rates in different eras of endoscopic technological development, III. Impact of responsive insertion technology (RIT) on reducing discomfort during colonoscopy – randomized clinical trial,

IV. Colonoscopy for colorectal cancer screening - is it effective in the hands of a general surgery resident?.

Aims:

I. To evaluate the quality of colonoscopy expressed by ADR and clinical factors in two different eras of endoscopic technology advancement.

II. To assess the impact of new technologies on colonoscopy quality by assessing completion rates.

III. The aim of the study is to analyze whether the new RIT system can improve the practice of colonoscopy under no anesthesia with respect to the widely available variable stiffness colonoscopes.

IV. To evaluate the effectiveness of colonoscopy performed by general surgery residents by comparing quality indicators between surgical trainees and consultants

Materials and methods:

I. The study enrolled 24055 patients aged 40-65 who underwent colonoscopy as a part of a national CRC screening program. Patients were sorted into two groups according to the advancement of endoscopic equipment used for colonoscopic examination. Group I: 10405 patients examined between 2004 and 2008 (standard electronic endoscopes).

Group II 13650 patients examined between 2009 and 2014 (modern endoscopes). The ADR, completeness of examination, bowel preparation assessment (5-point scale), patient tolerance for exam (4-point scale) in two different eras of technological advancement and the impact of endoscopic novelties were determined

II. The cecal intubation rate (CIR) and cecal intubation time (CIT) in three different eras of technological advancement were determined. The study enrolled 27 463 patients who underwent colonoscopy as part of a national CRC screening program. The patients were divided into three groups: group I - 3408 patients examined between 2000 and 2003 (optical endoscopes); group II - 10 405 patients examined between 2004 and 2008 (standard electronic endoscopes); and group III - 13 650 patients examined between 2009 and 2014 (modern endoscopes).

III. Analysis included 647 patients who underwent complete colonoscopy in the screening program. All colonoscopies were performed without sedation. Group I included patients who were examined using endoscopes equipped with responsive insertion technology (RIT), and group II included patients who were examined using conventional variable stiffness colonoscopies. The main objective was to evaluate the cecal intubation time, the number of loops, the requirement to apply manual pressure to different areas of the abdomen and the degree of discomfort and pain expressed on a visual analogue scale (VAS).

IV. The analysis included 6384 patients aged 40-65 who underwent screening colonoscopy between October 2014 and February 2018. The patients were divided into two groups: group I - patients examined by residents, group II - patients examined by board certified general surgeons. Quality indicators such as cecal intubation rate, adenoma detection rate and patient tolerance scale were compared between the two groups.

Results:

I. The ADR in group I was 29.14%, in group II 31.73% ($p < 0.001$). The overall ADR was 30.88% – 38.80% and 25.95% ($p < 0.001$) for the male and female patients, respectively. The mean adenoma number per colonoscopy was 0.366 (95% CI: 0.357–0.375; $p < 0.001$),
0.337 (0.321–0.352) and 0.380 (0.369–0.392) for patients in group I and group II, respectively.

II. There were statistically significant differences in the CIR between successive eras. The CIR in group I (2000-2003) was 69.75%, in group II (2004-2008) was 92.32%, and in group III (2009-2014) was 95.17%. The mean CIT was significantly reduced in group III

III. Group I consisted of 329 patients, and group II included 318 patients. The mean age of the patients was 58.4 years (SD ± 4.21). Both groups were compared in terms of age, sex, and BMI. The mean cecal intubation time was 209 s in group I and 224 s in group II ($p < 0.05$). Increased loop formation was observed upon endoscope insertion in group II (1.7 vs. 1.35) ($p < 0.05$) and required more manual pressure to the abdomen (2.2 vs. 1.7) ($p = 0.001$). In group I, less discomfort and pain (VAS: 2.3 vs. 2.6) were noted.

IV. Group I comprised 2268 (35.53%) and group II 4116 (64.47%) patients. The overall cecal intubation rate (CIR) was 95.99%, equal for the both groups ($p=0.994$). There was no statistically significant difference in adenoma detection rate: 29.30% in residents group and 27.66% among consultants ($p=0.203$). Patient tolerance for exam was very good (4-point scale) in consultants group in 78.98% of cases and in 75.18% cases among residents ($p<0.001$).

Conclusions:

I. There has been a technological revolution in endoscopy since the beginning of our study in 2004. Technological innovations, novel endoscopy devices and diagnostic techniques as well as patient-related factors significantly improve the quality of colorectal cancer screening by increasing adenoma detection rate. However, we need to determine and standardize which of the technologies are supreme to reach the excellence in colorectal cancer screening.

II. Our study shows that the technological innovation of novel endoscopy devices has a great influence on the effectiveness of the CRC screening program. The new era of endoscopic technological development has the potential to reduce examination-related patient discomfort, obviate the need for sedation and increase diagnostic yields.

III. The implementation of RIT reduced of the cecal intubation time. The modified structure of the endoscope rendered the colonoscopic examination easier by reducing loop formation upon insertion with a subsequently reduced rate of auxiliary maneuvers

IV. Within a proper learning environment general surgery residents are able to perform high quality and effective screening colonoscopy. However, residents need to continue the progress in their technique to improve patient tolerance in order to reach the proficiency of the consultant.

UNIWERSYTET
JAGIELLOŃSKI
W KRAKOWIE

OPINIA
nr. 122.6120.36.2016 z dnia 25 lutego 2016 roku

Na zebraniu w dniu 25 lutego 2016 r. Komisja zapoznała się z wnioskiem z dnia 15 lutego 2016 r.
złożonym:
przez kierownika tematu: **prof. dr hab. med. Kazimierz Rembiasz**
zatrudnionego w: **II Katedra Chirurgii Ogólnej UJCM**
31 – 501 Kraków, ul. Kopernika 21

oraz jego merytorycznym uzasadnieniem dotyczącym przeprowadzenia eksperymentu medycznego pt. „Retrospektywna analiza wyników badań kolonoskopowych w ramach programu badań przesiewowych do wczesnego wykrywania raka jelita grubego".

Komisja Bioetyczna
Uniwersytetu
Jagiellońskiego

Do wniosku dołączono:
1. Protokół badania.
2. Życiorys naukowy wnioskodawcy.
3. Lista piśmiennictwa.
4. Oświadczenie o braku załączenia formularza informacji dla pacjenta, formularza zgody uczestnika badania, formularza o ochronie danych osobowych.
5. Oświadczenie o realizacji projektu w ramach prac badawczych UJ/UJCM.

Komisja wyraża pozytywną opinię w sprawie przeprowadzenia wnioskowanych badań - na warunkach określonych we wniosku oraz dodatkowo zastrzegając:
1/ obowiązek przedstawienia Komisji:
- wszystkich zmian w protokole mających wpływ na przebieg oraz ocenę badania,
- zawiadomienia o przyczynach przedwczesnego zakończenia badania,
- sprawozdania w toku przeprowadzanych badań - co sześć miesięcy,
- raportu końcowego.

Badanie może być prowadzone do dnia 25 lutego 2017 roku.
Skład i działanie Komisji zgodne z GCP oraz wymogami lokalnymi.
Lista członków Komisji biorących udział w posiedzeniu stanowi załącznik do niniejszego dokumentu.

Kraków, dnia 25 lutego 2016 r.

Przewodniczący
Komisji Bioetycznej UJ

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PRACA I

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Kraków, dnia 4 czerwca 2018

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OŚWIADCZENIE

Jako współautor pracy pt.

"How to improve the adenoma detection rate in colorectal cancer screening? Clinical factors and technological advancements"

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(podpis współautora)

Kraków, dnia 4 czerwca 2018

Dr hab. n. med. Michał Pędziwiatr
(tytuł zawodowy, imię i nazwisko)

OŚWIADCZENIE

Jako współautor pracy pt.

„Colonoscopy for colorectal cancer screening - is it effective in the hands of a general surgery resident?"

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Kraków, dnia 4 czerwca 2018

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OŚWIADCZENIE

Jako współautor pracy pt.

„Impact of responsive insertion technology (RIT) on reducing discomfort during colonoscopy – randomized clinical trial"

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(podpis współautora)

Kraków, dnia 4 czerwca 2018

Dr hab. n. med. Antoni Szczepanik
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„Impact of responsive insertion technology (RIT) on reducing discomfort during colonoscopy – randomized clinical trial"

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