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Retrospective comparison of G-EYE balloon-colonoscopy with standard colonoscopy for increased adenoma detection rate and reduced polyp removal time

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ABSTRACT

Background and study aims The newly introduced G-EYE colonoscope (G-EYE) employs a balloon, installed at the bending section of a standard colonoscope (SC), for increasing adenoma detection and stabilizing the colonoscope tip during intervention. This retrospective work explores the effect of introducing G-EYE into an SC endoscopy room, in terms of adenoma detection and polyp removal time.

Patients and methods This was a single-center, retrospective study. Historical data from patients who underwent colonoscopy prior to, and following, introduction of G-EYE into a particular endoscopy room were collected and analyzed to determine adenoma detection rate (ADR), adenoma per patient (APP), and polyp removal time (PRT), in each of the SC and G-EYE groups.

Results Records of 1362 patients who underwent SC and 1433 subsequent patients who underwent G-EYE colonoscopy in the same endoscopy unit by the same endoscopists were analyzed. Following G-EYE introduction, overall ADR increased by 37.5% ($P<0.0001$) from 39.2% to 53.9%, the serrated adenoma rate increased by 47.3% from 27.9% to 41.1% ($P<0.0001$), and the APP increased by 50.6% from 0.79 to 1.19 ($P<0.0001$). The number of advanced adenomas increased by 32.7%, from 19.6% to 26.0% of all adenomas ($P<0.0001$). With G-EYE, average PRT was reduced overall by 29.5% ($P<0.0001$), and particularly for endoscopic mucosal resection (EMR) by 37.5% for polyps measuring ≥ 5 mm to ≤ 20 mm ($P<0.0001$) and by 29.4% for large polyps > 20 mm ($P<0.0001$).

Conclusions Introduction of G-EYE to an SC endoscopy room yielded considerable increase in ADR and notable reduction in PRT, particularly with the EMR technique. G-EYE balloon colonoscopy might increase the effectiveness of colorectal cancer screening and surveillance colonoscopy, and can shorten the time of endoscopic intervention.

Introduction

Colonoscopy is considered the “gold standard” in prevention of colorectal cancer (CRC), which is one of the most lethal cancers, with annual incidence of approximately 140,000 cases and 50,000 CRC-related deaths in the United States alone [1–3]. The detection and real-time removal during colonoscopy of precancerous colonic polyps, most frequently adenomas [4, 5],

prevents CRC associated with such lesions. Nonetheless, a meaningful percentage of adenomas are missed in standard colonoscopy (SC), resulting in interval cancers [6, 7]. This shortfall of SC gave rise to various detection enhancement technologies for improved polyp detection, such as the FUSE 330-degree view-angle colonoscope [8–10], the Endocuff [11–14] and Endorings [15] disposable attachments, and the G-EYE balloon [16–18]. The adenoma miss rate of SC was demonstrated in back-to-back studies in which each subject underwent two subsequent colonoscopies in the same session. In such studies where both first and second procedures were SC, it was indicated that 18 % to 24 % of adenomas were missed by the first SC [6]. In similar studies in which the first colonoscopy was SC and the second procedure was performed with one of the detection enhancement technologies mentioned above, the reported SC adenoma miss rates ranged from 37.6 % to 48.3 % [8, 14, 15, 17]. As part of the clinical effort for reducing the adenoma miss rate and increasing the quality of screening and surveillance colonoscopy, several quality indicators were developed and utilized in clinical studies to measure the quality and effectiveness of colonoscopy. Adenoma detection rate (ADR), defined as the percentage of screened patients in whom at least one adenoma is detected, is considered one of the most important indicators for quality in colonoscopy, as each 1.0 % increase in ADR was found to be correlated with a 3.0 % decrease in risk of CRC [19]. The effect of the above-mentioned detection enhancement technologies on ADR was investigated in numerous clinical studies [10–13, 18], and analyzed in meta-analyses comparing ADR enhancement of these different enhancement technologies [20, 21], which highlighted in particular the mechanical fold-flattening effect of the Endocuff and G-EYE devices. The G-EYE device which is the subject of the present work (Smart Medical Systems Ltd., Israel) is a standard colonoscope (of any brand and model) onto which a reusable, re-processable balloon is integrated at its bending section. Withdrawal of the colonoscope in the colon with the G-EYE balloon moderately inflated centralizes the image in the colon lumen and flattens colonic folds, to provide enhanced visualization of the colon, thereby reducing adenoma miss rate and increasing ADR, as reported in published clinical studies [17, 18]. In addition, the G-EYE balloon can be inflated during intervention to anchor and stabilize the colonoscope's tip in front of a lesion to be treated (e. g., a polyp to be removed), aiming to facilitate accurate and effective operation. Similar use of inflated endoscopic balloons for stabilization during endoscopic therapy is reported in the literature, including the use of double-balloon endoscope (Fujifilm Corporation, Japan) [22, 23], single-balloon endoscope (Olympus Medical, Japan) [24], and Bi-Lumen balloon attachment (Lumendi, United States) [25, 26].

The present work aimed to explore, retrospectively under "real-world conditions" of daily practice in a particular endoscopy unit, the effect of the G-EYE balloon, compared to standard colonoscopy, in two aspects: (1) detection rate, primarily measured by ADR; and (2) efficiency of intervention, measured by polyp removal time (PRT).

Patients and methods

Study design

This study was an observational, retrospective, single-center study. The study was registered at clinicaltrials.gov (NCT04767971). The aim of this study was to compare colonoscopy detection and intervention parameters of G-EYE and SC in one endoscopy unit (Helios HSK Wiesbaden, Germany), in which the G-EYE balloon was installed on the Standard Colonoscopes. This study was based on digital reports (E&L, Germany) of endoscopic procedures performed between March 2015 and October 2019. Procedure data from patients who underwent colonoscopy prior to, and following, introduction of G-EYE into this endoscopy unit, were collected and analyzed to determine ADR, adenoma per patient (APP), polyp removal time (PRT), and other procedural parameters in the SC and G-EYE groups. The colonoscope models used in the G-EYE procedures were identical to the standard colonoscope models used in the SC procedures prior to balloon installation. All colonoscopes used in this study were high-definition endoscopes of either Pentax Medical (EC-i10 and G-EYE i10 colonoscopes, applying iSCAN1 mode during withdrawal of the colonoscope) or Fujifilm Corporation (EC-760 R and G-EYE 760 R colonoscopes, applying LCI mode during withdrawal). For G-EYE colonoscopy, the balloon was inflated during withdrawal and was also inflated to anchor the colonoscope tip to the colon during polyp removal. Only patients examined by two particular endoscopists, who are experienced in both SC and G-EYE colonoscopy (all authors), were included under the study, to eliminate physician-related bias and any learning-curve effect. Propofol sedation was used for all patients. Device insertion time, net withdrawal time (without intervention time), PRT and total procedure time were measured.

All endoscopists involved in the study were highly experienced endoscopists with more than 5000 colonoscopies experience before entering the study period.

All detected polyps, except for rectal lesions with endoscopic features of hyperplastic pathology, measuring 2 mm or greater, were endoscopically removed or biopsied and subjected to histological evaluation. Polyp removal technique (biopsy, snare or EMR) was noted, and was chosen according to the type and size of lesion and as per European guideline favoring EMR in the removal of large polyps. Polyps were classified by size ("diminutive" [2–5 mm], "small" [5–20 mm] or "large" [> 20 mm] and according to Paris and Kudo classification [27, 28]. Polyp detection rate (PDR) was defined as the percentage of subjects in whom at least one polyp was found. ADR was defined as the percentage of subjects in whom at least one adenoma was found. Adenoma was defined as adenoma and/or sessile serrated adenomas/polyp (SSA/P) or traditional serrated adenomas. Advanced adenomas were defined as adenomas which were either ≥ 10 mm in diameter, included a villous component, harbored high-grade dysplasia or were cancerous.

Time of polyp removal was measured from the last image of the intact polyp until the first image of the fully resected polyp was captured. Time for polyp retrieval was not part of the interventional time.

▶ **Fig. 1** Left: G-EYE System. Right: G-EYE balloon integrated on a standard colonoscope NaviAid SPARK²C inflation system.

Safety parameters and adverse events (AEs) were assessed during the procedure and by phone call interview during the 48– to 72-hour post-procedure follow-up period.

Participants

Subjects included in the study were patients referred to screening or surveillance colonoscopy based on the German guideline for colon cancer screening. Exclusion criteria included previous colonic surgery (except for appendectomy), known inflammatory bowel disease or acute colonic inflammation (e. g., diverticulitis, ischemic colitis), history of radiation therapy of the abdomen or pelvis, hereditary cancer syndromes, incomplete colonoscopy, insufficient bowel preparation, and emergency procedures.

G-EYE device

The G-EYE device (Smart Medical Systems Ltd., Israel) is a standard colonoscope (of any brand and model) (▶ **Fig. 1**), onto which a reusable balloon is integrated at the distal bending section. The G-EYE balloon adds up to 0.3 mm to the diameter of the colonoscope (when deflated), and does not affect its maneuverability and angulation. The G-EYE balloon is inflated by a dedicated inflation system (NaviAid SPARK²C, Smart Medical Systems Ltd., Israel). Withdrawal of the G-EYE colonoscope with the balloon moderately inflated during colonoscopy, stretches and unfolds haustral folds, centralizes the optics within the colon lumen, and prevents uncontrolled bowel slippage. This combined effect demonstrated substantial increase in ADR [18] and meaningful reduction in miss rate [17], compared to SC. During interventional procedure (e. g., polypectomy), the balloon can be inflated to anchor and stabilize the colonoscope's tip in the colon to enable accurate and controlled access to the lesion under treatment.

Study endpoints

The study included two primary endpoints, ADR and average PRT, in each group (G-EYE versus SC). Secondary endpoints included the number and type of polyps and adenomas detected, procedure times, EMR time by polyp size, and safety parameters.

Enrollment and bias elimination

This study included subjects which underwent colonoscopy in the Helios HSK Wiesbaden endoscopy unit between March 2015 and October 2019. G-EYE balloons were installed on the colonoscopes of the endoscopy unit in the beginning of January 2017, thus SC was used for all subjects prior to January 2017 ("SC group," 1362 subjects), and all subjects after this date went through G-EYE colonoscopy ("G-EYE group," 1433 subjects). This eliminates bias of the endoscopists since only SC procedures were included prior to G-EYE introduction, and only G-EYE procedures were included thereafter.

Statistical analysis methods

Continuous variables were summarized by the mean and standard deviation (SD) and compared using two-sample *t*-test or the Wilcoxon rank sum test, as appropriate. Binary data were summarized by count and percentage and compared using the Chi-squared test. Count variables are summarized using mean and are compared using over-dispersed Poisson model. Distribution of PRT time, using EMR, for small and large polyps, is summarized using selected quantiles and a smoothed histogram using kernel density.

Statistical analyses were performed using JMP Pro Statistical Discovery, version 16.0.0 (SAS Institute Inc., Cary, North Carolina, United States). $P \leq 0.05$ was considered statistically significant. Nominal *P* values are presented.

Results

A total of 2795 subjects, who underwent colonoscopy from March 2015 to October 2019 and complied with the study enrollment criteria were included in the study. Of them, 1362 underwent SC (from March 2015 to December 2016) and 1433 underwent G-EYE colonoscopy (from January 2017 to October 2019). The two groups exhibited similar gender proportion ($P = 0.2439$) and a 1.1-year younger G-EYE mean population age ($P = 0.0005$ due to the large sample size, though not considered to be clinically meaningful) (▶ **Table 1**). G-EYE colonoscopy exhibited a significant increase in ADR over SC, with an ADR of 53.9 % in the G-EYE group and 39.2 % in the SC group (a 37.5 % increase, $P < 0.0001$; ▶ **Table 2**, primary endpoint). ADR by adenoma type/stage was higher in the G-EYE group compared to the SC group as well, with increase of 32.7 % for advanced adenomas, 47.3 % increase in serrated adenomas, and 43.1 % increase in flat adenomas ($P < 0.0001$ for all; ▶ **Table 2**). A similar increase was observed in PDR, with 57.2 % in the G-EYE group and 42.3 % in the SC group (a 35.2 % increase, $P < 0.0001$; ▶ **Table 2**). Per-lesion analysis was aligned with the per-patient ADR and PDR results, where APP increased by 50.6 % ($P < 0.0001$) from 0.79 in the SC group to 1.19 in the G-EYE group (▶ **Table 2**). APP increase with G-EYE was consistent per adenoma size distribution (▶ **Table 2**) for diminutive adenomas (< 5 mm) and small adenomas (≥ 5 mm to ≤ 20 mm), with respective increase of 50.6 % (from 0.496 to 0.747, $P < 0.0001$) and 70.2 % (from 0.188 to 0.320, $P < 0.0001$). An APP increase with G-EYE (16.0%, from 0.106 to 0.123) was noted for large adenomas

▶ **Table 1** Baseline parameters and procedure times, by type of colonoscopy.

Outcome parameters	SC	G-EYE	*P* value
Demographics			
N	1,362	1,433	N/A
Female (%)	64.1 %	62.0 %	0.2439[1]
Mean age (years)	64.5	63.4	0.0005[2]
Procedural times, mean (SD), min.			
Total examination time	22.5 (7.3)	24.0 (7.5)	< 0.0001[3]
Insertion time	4.4 (1.9)	4.3 (1.8)	0.7378[3]
Withdrawal time	7.6 (0.98)	7.7 (0.99)	< 0.0001[3]

SC, standard colonoscope; SD, standard deviation.
[1] Pearson Chi-squared.
[2] *t*-test for two independent samples.
[3] Wilcoxson sum rank test.

▶ **Table 2** Detection rates and adenoma characterization, by type of colonoscopy.

Outcome parameters	SC	G-EYE	% difference	*P* value
Total number of subjects and adenomas/polyps				
Number of patients, N	1,362	1,433	N/A	N/A
Number of adenomas, N_a	1,076	1,705	N/A	N/A
Number of polyps, N_p	1,387	2,187	N/A	N/A
ADR, adenoma per patient and adenomas characterization				
Polyp detection rate (PDR) (%)	42.3 %	57.2 %	35.2 %	< 0.0001[1]
Adenoma detection rate (ADR) (%)	39.2 %	53.9 %	37.5 %	< 0.0001[1]
Polyps per patient (PPP)	1.02	1.53	50.0 %	< 0.0001[2]
Adenomas per patient (APP)	0.79	1.19	50.6 %	< 0.0001[2]
Advanced adenomas, n/N_a (%)	211/1076 (19.6 %)	444/1705 (26.0 %)	32.7 %	< 0.0001[1]
Serrated adenomas, n/N_a (%)	300/1076 (27.9 %)	701/1705 (41.1 %)	47.3 %	< 0.0001[1]
Flat adenomas, n/N_a (%)	314/1076 (29.2 %)	712/1705 (41.8 %)	43.1 %	< 0.0001[1]
Flat adenoma detection rate (%)	15.6 %	33.9 %	116.9 %	< 0.0001[3]
Adenoma, distribution according to size, n (average per patient)				
Diminutive, size < 5 mm	676 (0.496)	1,071 (0.747)	50.6 %	< 0.0001[2]
Small, ≥ 5 mm to ≤ 20 mm	256 (0.188)	458 (0.320)	70.2 %	< 0.0001[2]
Large, > 20 mm	144 (0.106)	176 (0.123)	16.0 %	0.2920[†]

SC, standard colonoscopy; ADR, adenoma detection rate; PDR, polyp detection rate; PPP, polyps per patient.
[1] Pearson Chi-squared.
[2] Over-dispersed Poisson.
[3] Fisher's exact test.

(>20 mm) as well, which is clinically meaningful though not statistically significant due to limited number of large adenomas (*P* = 0.2920). Similarly, polyp per patient (PPP) value increased by 50.0 %, from 1.02 with SC to 1.53 with G-EYE colonoscopy (*P* < 0.0001; ▶ **Table 2**).

EMR rate per polyp size was similar in both groups, with respective EMR rates for small and large polyps of 43.0 % and 100 % in the SC group and 50.2 % and 100 % in the G-EYE group (▶ **Table 3**).

▶ **Table 3** Polyp removal time (PRT) and technique, by type of colonoscopy.

Outcome parameters	SC	G-EYE	% difference	*P* value
Overall average polyp removal time (PRT) (by all techniques – snare, EMR, biopsy), mean (SD), min.				
Overall average PRT	4.4 (2.5)	3.1 (1.3)	-29.5 %	<0.0001[1]
Number and proportion of polyps removed by EMR, per size of lesion, n (%)				
≥ 5 mm to ≤ 20 mm	110 (43.0 %)	230 (50.2 %)	16.7 %	0.063[2]
> 20 mm	144 (100 %)	176 (100 %)	0.0 %	1
Mean EMR time of polyps of size range: ≥ 5 mm to ≤ 20 mm, mean (SD), min.				
Mean EMR time	7.2 (1.9)	4.5 (2.3)	-37.5 %	<0.0001[3]
Mean EMR time of polyps of size range: size > 20 mm, mean (SD), min.				
Mean EMR time	10.2 (2.5)	7.2 (2.3)	-29.4 %	<0.0001[3]

PRT, polyp removal time; SC, standard colonoscopy; SD, standard deviation; EMR, endoscopic mucosal resection
[1] *t*-test, averaging polypectomy time for each patient having more than one polyp.
[2] Chi-square.
[3] *t*-test.

▶ **Table 4** EMR time percentiles for small and large polyps, by type of colonoscopy.

Outcome parameters	SC	G-EYE
EMR time percentiles for polyps of size range: ≥ 5 mm to ≤ 20 mm, min		
Median EMR time	7.15	4.10
75th percentile EMR time	8.10	5.25
90th percentile EMR time	10.10	7.50
EMR time percentiles for polyps of size range: size > 20 mm, min.		
Median EMR time	9.95	7.10
75th percentile EMR time	12.40	8.30
90th percentile EMR time	13.30	9.70

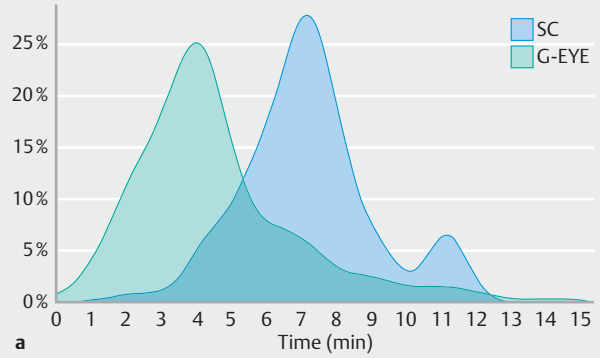
EMR, endoscopic mucosal resection; SC, standard colonoscopy.

With respect to procedural times (▶ **Table 1**), average insertion time was similar in both groups (4.4 min with SC vs. 4.3 min with G-EYE, $P = 0.7378$), and average withdrawal time in the G-EYE group was 6 seconds longer than in the SC group (7.7 min vs. 7.6 min, $P < 0.0001$). Average total examination time in the G-EYE group was 1.5mins. longer than in the SC group (24.0 min vs. 22.5 min, $P < 0.0001$), due to removal of excess polyps.

Average PRT in the G-EYE group was 29.5 % shorter than in the SC group (3.1 min vs. 4.4 min, $P < 0.0001$; ▶ **Table 3**, primary endpoint). Focusing in particular on EMR technique, G-EYE demonstrated substantial PRT reduction over SC, 37.5 % reduction (from 7.2 min to 4.5 min, $P < 0.0001$; ▶ **Table 3**) and 29.4 % reduction (from 10.2 min to 7.2 min, $P < 0.0001$; ▶ **Table 3**) of mean EMR time for small polyps ≥ 5 mm to ≤ 20 mm) and large polyps (> 20 mm), respectively. This substantial polypectomy time reduction in the G-EYE group is attributed to the balloon stabilization effect. Differently calculated, taking the G-EYE group as baseline, the inability to anchor and stabilize the colonoscope's tip during EMR polypectomy in standard colonoscopy, extends the average polypectomy time by 60.0 % for small polyps (≥ 5 mm to ≤ 20 mm) and by 41.7 % for large polyps (> 20 mm).

Median, 75th and 90th percentiles of EMR times were shorter as well with G-EYE as compared to SC, for both small and large polyps (▶ **Table 4**). Distribution of EMR time by polyp size provides additional comparison between SC and G-EYE (▶ **Fig. 2**), a smoothed histogram presenting EMR time in the two arms, for small polyps (▶ **Fig. 2a**) and for large polyps (▶ **Fig. 2b**). For small polyps, the histograms of SC and G-EYE are generally displaced, with SC histogram exhibiting extended EMR times and EMR median time value of 7.2 min, 60 % longer than the G-EYE EMR median time of 4.5 min. This effect is in correlation with the percentile results in ▶ **Table 4**, in which the 90th percentile EMR time for G-EYE (7.50 min) is comparable to the median EMR time for SC (7.15 min). Differently stated, for polyps ≥ 5 mm to ≤ 20 mm, almost 90 % of the G-EYE EMR procedures can be performed in a time equal to, or shorter than, the median SC EMR procedure time, which corresponds to 50 % of such polyps removed by the standard colonoscope. As further seen in ▶ **Fig. 2a**, the SC histogram exhibits a bimodal shape, with a certain polyp population entailing more challenging EMR procedure and thus requiring extended polypectomy time. This bi-modality does not exist in the G-EYE histogram. The histogram shapes and percentile results for polyps of size > 20 mm, presented in ▶ **Fig. 2b** and ▶ **Table 4**, are consistent with the results for small polyps, whereas the time required for SC to remove 50 % of the EMR polyps (SC median EMR time, 9.95 min) is sufficient for the G-EYE to remove over 90 % of such polyps (G-EYE 90th percentile EMR time, 9.70 min). Due to the stabilization effect of the G-EYE balloon during therapy, it takes a considerably shorter time to perform complex polypectomies with G-EYE compared to SC.

No AEs occurred in any of the G-EYE or SC procedures.



▶ **Fig. 2** EMR time distribution histograms for SC and G-EYE, smoothed using Kernel estimation for polyps **a** ≥ 5 mm to ≤ 20 mm and **b** > 20 mm.

Discussion

Screening and surveillance colonoscopy include two complementary capacities in CRC prevention, detection of precancerous polyps and removal of such polyps during the procedure. Adenoma miss rate is negatively impacting detection [6], which results in interval cancers as demonstrated in a cohort-based study which reported a 6 % interval cancer rate following colonoscopy with no finding in CRC patients [7]. ADR is currently considered a principal indicator for detection quality in colonoscopy, being inversely correlated with the risk for interval CRC following screening colonoscopy [29]. Removal and biopsy of detected polyps is critical both in preventing the risk for cancer associated with such polyps, and in determination of the follow-up surveillance protocol of the patient. While most polyps can be readily removed, some polyps pose a challenge due to size, shape, morphology or location (e. g., behind flexures or haustral folds). Balloon stabilization of the endoscope tip in the intestine during polyp removal or other interventional operations was found effective in facilitating accurate and controlled operation [22–26].

The present study investigated the effectiveness of the G-EYE balloon device in screening and surveillance colonoscopy by exploring its two relevant capacities, detection yield and polypectomy efficiency, in comparison to SC. In this study, detection yield was primarily measured by ADR (first primary endpoint), and efficiency of polyp removal was primarily measured by removal time (PRT, second primary endpoint). This study reflects the daily use of the G-EYE system in a specialized center. While previous publications discussed the operation of the G-EYE device under controlled conditions in randomized, multicenter settings [17, 18], the current study explored the G-EYE system under routine "real-world" conditions in a particular endoscopy unit. The large cohort of 2795 patients provides statistically powered data, which can be validated against the results obtained in previous, controlled randomized studies. The current study was performed by two highly skilled endoscopists, having substantial previous experience in both G-EYE and SC techniques, as reflected in the short insertion times of approximately 4:20 min and in the ADR level, which exceeded the recommended 25 % threshold [30] in both groups.

Nonetheless, use of the inflated G-EYE balloon significantly increased ADR (by 37.5 %), from 39.2 % in the SC group to 53.9% in the G-EYE group. In particular, ADR of advanced adenomas, serrated adenomas, and flat adenomas was significantly higher in the G-EYE group. Per-lesion analysis was in line with the per-patient ADR results, showing a significant increase in APP by using the inflated G-EYE balloon during colonoscope withdrawal (1.19 adenoma per patient with G-EYE), as compared both with SC in this study (a 50.6 % increase over the SC APP of 0.79) and with previous SC studies, reporting an APP range of 0.42–0.5 [31]. The G-EYE balloon effect of increasing detection rates (both ADR and APP), demonstrated in this study, revalidates the outcome of a published 1,000 patient study which demonstrated a 28 % increase in ADR (from 37.5 % to 48.0 %) and a 47.1 % increase of APP (from 0.68 to 1.00) of G-EYE over SC [18]. This present study demonstrates that the G-EYE is a valuable technique for routine use in daily practice of endoscopy centers, for increasing colonoscopy detection rates and preventing interval cancers. As demonstrated in this study, the significant increase in all detection parameters was observed with G-EYE as compared to SC notwithstanding the high skill level and experience of the endoscopists involved. It may be concluded that the fold-stretching effect of the balloon allows the endoscopists to leverage their skill level as it reveals more mucosal surface for inspection by the endoscopist. This study showed that even expert users can achieve higher detection rates by taking advantage of the effect of the G-EYE balloon.

The current study examined, for the first time, the effect of G-EYE balloon stabilization on the efficiency of endoscopic intervention. Because polypectomy and PRT were selected as the representative interventional operation and metrics, the utilization of data generated in routine daily use of the SC and G-EYE colonoscopes was very suitable. Intervention time, and polypectomy time in particular, pose challenges to the daily routine and workflow of any endoscopy unit. Complex polypectomies and EMR operations take a considerable time, and generally cannot be anticipated in advance of the procedure, because lengthy interventional operations and related complications often develop during an intervention session. This introduces uncertainty and limits the predictability of the procedure, and must be taken into consideration in workflow planning and scheduling of patients. The outcome is decreased throughput and reduced efficiency of the endoscopy unit. As

demonstrated in the PRT results of this study, due to colonoscope tip stabilization of the inflated G-EYE balloon during intervention, overall average polypectomy time is significantly shorter with G-EYE as compared to SC (by 29.5 %), with particularly significant time reduction in the EMR polypectomy of small polyps (≥ 5 mm to ≤ 20 mm, 37.5 % reduction) and large polyps (> 20 mm, 29.4 % time reduction). In addition, as observed in the G-EYE group of this study, balloon stabilization facilitated a more accurate and complete intervention, as it allowed better positioning and visibility during interventional sessions. The observed impact of the G-EYE balloon on endoscopic intervention goes beyond time reduction, to increased effectiveness of the interventional session. In terms of ease of use, the ability to instantly inflate or deflate the balloon, upon need during the procedure, is a valuable attribute, in contrast to mechanical attachments (e. g., Endocuff, Endorings) which are placed over the colonoscope tip prior to, and remain throughout the entire duration of the procedure.

Of particular importance is the comparative EMR time distribution in the SC and G-EYE groups, as exhibited in the histograms in ▶ **Fig. 2**, demonstrating a saddle-shaped, right-shifted histogram of SC as compared to the generally gaussian-shaped, shorter peek time G-EYE histogram. The descent of the G-EYE histogram at longer EMR times while the SC curve is still ascending, aligns with the percentile results (▶ **Table 4**) evidencing that EMR time required for removal of 50 % of the polyps in standard colonoscopy, is sufficient for removal of approximately 90 % of the polyps in G-EYE colonoscopy.

This outcome implies that the G-EYE colonoscopy is significantly more predictable and plannable than SC. Accordingly, daily routine use of G-EYE colonoscopy may be relevant and effective for increasing throughput, capacity and efficiency of the endoscopy unit. While this study focused on polypectomy as a representative intervention, it is expected that the balloon stabilization effect remains valid for any other type of interventional operation, such as coagulation, clipping, ESD and so forth.

There are several limitations to this study. First, it was retrospective and observational. Second, the colonoscopy procedures of the two compared techniques (SC and G-EYE) were performed in different (consecutive) time intervals. Third, it was a single-center study.

This retrospective study involved only highly experienced endoscopists. However, there are published data available [18], which show that endoscopists with less experience do benefit from this technique.

The resection times for polyps were significantly shorter with use of G-EYE. However, we have no data available to show the recurrence rate for resected polyps, which is a limitation of this retrospective analysis. However, this is currently the largest study exploring the use of G-EYE colonoscopy in daily routine. The large cohort of this study enhances the results and outcomes of the present work.

Conclusions

In conclusion, this study showed that the G-EYE device detects significantly more adenomas than SC, and facilitates considerable reduction in PRT. The meaningful increase in ADR and APP demonstrated in this study in a routine-usage environment is consistent with findings from previous randomized, controlled, multicenter trials. The inflated G-EYE balloon provides, beyond a fold-stretching effect that accounts for increased detection yield, stabilization of the colonoscope's tip during polyp removal, and thereby, better access and positioning, resulting in a more accurate and shorter intervention. The ability to instantly inflate or deflate the balloon as needed during the procedure makes this attribute particularly useful. Daily usage of the G-EYE as the default colonoscopy device has the potential to significantly reduce the incidence rate of interval cancers while increasing an endoscopy unit's throughput and efficiency in daily routine.

Competing interests

The authors declare that they have no conflict of interest..

Clinical trial

clinicaltrials.gov
NCT04767971
TRIAL REGISTRATION: observational, retrospective, single-center study NCT04767971 at clinicaltrials.gov

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