

Sustained colonoscopy quality improvement using a simple intervention bundle

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Author Contributions

LN designed data collection tools, undertook data collection, monitored data collection for the whole trial, cleaned the data, and drafted and revised the paper.

JE initiated the collaboration, designed data collection tools, monitored data collection for the whole study and drafted and revised the paper.

PR designed data collection tools and drafted and revised the paper

PB cleaned and analysed the data and drafted and revised the paper.

SD designed data collection tools, undertook data collection and drafted and revised the paper.

RB, SP and SE undertook data collection and drafted and revised the paper.

CJR initiated the collaboration, designed data collection tools, monitored data collection for the whole study and drafted and revised the paper.

Abstract

Background

Unacceptable variation in colonoscopy quality exists. The Quality Improvement in Colonoscopy (QIC) study in 2011 improved quality by introducing an evidence-based 'bundle' of measures into routine colonoscopy practice. The QIC 'bundle' included: minimal cecal withdrawal time of ≥ 6 minutes; hyoscine butylbromide use; supine patient position for transverse colon examination; rectal retroflexion. Colonoscopy quality as measured by adenoma detection rate (ADR) was improved. The current study measured whether these effects led to a sustained change in practice three years following implementation.

Methods

This observational study collected data from eight hospital Trusts (sites) in the United Kingdom for a six-month period, three years following QIC 'bundle' implementation. Use of the antispasmodic, Hyoscine butylbromide, was measured as a marker of 'bundle' uptake. 'Bundle' effectiveness was measured by ADR change. Comparisons were made between data before and immediately after implementation of the bundle.

Results

28615 colonoscopies by 188 colonoscopists were studied. Hyoscine butylbromide use rose from 15.8% pre-implementation to 47.4% in the sustainability phase ($P < .001$) indicating sustained engagement with QIC measures. ADR was higher in the sustainability period compared to pre-intervention, but only reached statistical significance amongst the poorest performing colonoscopists.

Conclusions

The introduction of a simple, inexpensive, pragmatic intervention significantly changed practice over a sustained period. This improved quality as measured by ADR, particularly in poorer performers. QIC demonstrates that an easy to implement quality improvement approach can deliver a sustained change in practice for many years post intervention.

Keywords

Colonoscopy; quality improvement; adenoma detection rate; implementation

Background

Colonoscopy is the gold standard investigation of the lower gastrointestinal tract and is widely performed with over 500,000 procedures performed annually in England and 15 million performed annually in the United States.[1,2] High quality colonoscopy is crucial to ensure adequate mucosal visualisation and maximise detection of pathology. However, variation in quality of colonoscopy exists.[3,4] Adenoma detection rate (ADR) is the most widely used colonoscopy quality indicator and is defined as the proportion of procedures where at least one adenoma is found in a patient, expressed as a percentage.[5–7] Colonoscopists with low ADRs have significantly higher rates of post colonoscopy colorectal cancers and poorer patient outcomes.[8–10] Approaches to improving ADR have included improved optics, devices attached to the colonoscope tip, feedback and leadership training. Several studies aiming to improve ADR through practice change have been undertaken, however only one study has demonstrated significant ADR improvement and this was amongst expert bowel cancer screening colonoscopists.[11,12] These results have not yet been replicated in a non-expert colonoscopist cohort. Multimodal approaches have been adopted to incorporate a number of measures to improve colonoscopy quality. The Endoscopic Quality Improvement Program (EQUIP) combined educational sessions with feedback and demonstrated ADR improvements, however, similar improvements were seen in control groups that received only passive monitoring.[13]

Introducing evidence-based medicine into clinical practice is challenging, with multiple potential barriers including: lack of time for training, perceived lack of time to implement change and uncertainty regarding the impact of change.[14] *Pronovost et al* demonstrated that a ‘bundle’ of interventions could be successfully implemented by combining training, feedback and support to reduce catheter-related bloodstream infections in intensive care units.[15] Using a similar approach, the Quality Improvement in Colonoscopy (QIC) study, previously published in *Endoscopy Journal* changed practice by introducing an evidence-based ‘bundle’ of measures into routine colonoscopy practice (*Figure 1*). Colonoscopy quality

as measured by adenoma detection rate (ADR) was improved.[16] This study is unique in its approach to implementing a bundle of measures in endoscopy.

QIC was a large, multicentre pragmatic study undertaken within the Northern Region Endoscopy Group (NREG), a well organized endoscopy research network in the North East of England.[17] It consisted of central and local training, in addition to anonymized contemporaneous performance feedback. The 'bundle' included a number of evidence-based measures: minimal cecal withdrawal time of ≥ 6 minutes; hyoscine butylbromide use; supine patient position for examination of the transverse colon; rectal retroflexion. Hyoscine butylbromide use (licensed in Europe as an antispasmodic) increased as did ADR, the latter particularly amongst colonoscopists with low baseline ADRs, where ADR almost doubled in the lower quartile of performers.

Our hypothesis was that the effects of the pragmatic QIC intervention would lead to a sustained change in practice (Quality improvement in colonoscopy – sustained, QIC-S). We aimed to evaluate ongoing uptake of the 'bundle' in addition to colonoscopy quality three years following implementation, without delivery of any further interventions or training during the three-year period.

Methods

Data were collected from original study sites on a per-endoscopist basis for a six-month period (January 1st 2014 – June 30th 2014), three years following implementation of the QIC 'bundle.' The sites were all based in North East England and part of the NREG network, including: South Tyneside District Hospital, South Shields, UK; Sunderland Royal Hospital, Sunderland, UK; Cumberland Infirmary, Carlisle, UK; Northumbria Healthcare Trust, UK; County Durham and Darlington NHS Foundation Trust, UK; North Tees and Hartlepool NHS Trust, UK; James Cook University Hospital, Middlesbrough, UK. Patients undergoing bowel cancer screening procedures within the English National Health Service (NHS) have a

much higher adenoma rate as they are all fecal occult blood (FOB) positive. NHS Bowel Cancer Screening Programme (BCSP) colonoscopists were therefore excluded from the study, as it was not feasible to easily distinguish between BCSP and symptomatic procedures in this cohort and higher ADR in FOB positive procedures would have influenced the data. Procedural information was collected, including: total number of colonoscopies; cecal intubation rate (CIR); ADR; hyoscine butylbromide/Buscopan usage rate (BR); colonoscopist specialty and grade; mean patient age; proportion of male patients. All participating units used electronic endoscopy reporting systems, which enabled data collection. All units recorded polyp detection rate (PDR) and hyoscine butylbromide use, however, only one unit routinely reported ADR. Histopathology reporting systems were therefore interrogated to allow ADR calculation.

Comparisons were made across the three phases of data collection; 1. Pre-intervention (pre-QIC) data were collected for three months prior to 'bundle' implementation and demonstrated colonoscopist baseline performance; 2. Post-intervention (post-QIC) data were collected for a duration of nine months following completion of 'bundle' implementation; 3. Sustainability data were collected for a six-month period, three years following implementation of the 'bundle.' (*Figure 2*) The sustainability data was the only fresh data collected for the present study, and was compared with the first two phases of data collection as outlined in the original QIC study.[16]

The primary outcome measure for this study was rate of hyoscine butylbromide (Buscopan) use. This was used as a readily measurable and consistent marker of uptake of the 'bundle,' and therefore of change in practice. It was not possible to measure uptake of other components of the bundle due to inconsistent reporting. Effectiveness of the 'bundle' was measured by change in ADR, defined as the number of procedures in which at least one adenoma was found.

Data were compared across all procedures and by endoscopy unit. Colonoscopists for whom data were available across all three phases of data collection were ranked and analyzed by baseline ADR into four

quartiles. The analysis was performed using multilevel logistic regression. When the data from all units were included in the analysis, three-level models were used, with individual patients contained within colonoscopists, who in turn were nested within units. When the data from each unit was analysed separately, two-level models were used with individual patients nested within colonoscopists. The predictor variable was the time of measurement (pre-QIC, post-QIC, or QIC-S sustainability period).

Sunderland Research Ethics Committee, United Kingdom, waived the need for full ethical review for the original QIC study as it was a service improvement initiative in which all participating units would receive the intervention. As the sustainability phase simply involved collecting data, ongoing local research and development and data access approvals were obtained.

Results

Sustainability data were collected from January 1st 2014 to June 30th 2014 inclusive (*Figure 2*). All original QIC sites participated in the sustainability phase including 12 endoscopy units housed within eight institutions. All of these sites were district general (community) hospitals. 188 colonoscopists performed procedures during the study time frame and were included in the global analyses, however, only 50 colonoscopists performed colonoscopies across all phases of data collection. Colonoscopists performing procedures in all phases were ranked into quartiles according to their baseline ADR.

A total of 28,615 colonoscopies were included for analyses at the level of the colonosocopist, unit and globally; 4,351 pre-intervention, 13,158 post-intervention and 11,106 in the sustainability phase. A total of 14,435 colonoscopies were included in the analyses at quartile level; 2556 pre-intervention, 7252 post-intervention and 4627 in the sustainability phase. The mean patient age in each phase was 60, 61 and 60 years, respectively. The mean proportion of male patients in each phase was 46%, 45% and 47%,

respectively. Within the four quartiles, colonoscopists were comparable by specialty and experience level.

Uptake of the Bundle: Hyoscine butylbromide use

Globally, a significant increase in hyoscine butylbromide use was demonstrated, from 15.8% pre-implementation to 47.4% in the sustainability phase ($P = .006$). This was replicated in all endoscopy units and all quartiles (tables 1 and 2). Overall, the odds of hyoscine butylbromide use were over 11 times higher in the post-intervention phase than in the pre-intervention phase, whilst the odds of hyoscine butylbromide use were over 9 times higher in the sustainability period than in the pre-intervention phase. The largest differences in hyoscine butylbromide use rates were seen in the upper colonoscopist quartiles, where the odds of its use were over 16 times higher in the post-intervention and sustainability phases compared to baseline ($P < .001$).

Effectiveness of the Bundle: Adenoma Detection Rate

A significant increase in ADR was observed rising from 16.0% to 18.0% ($P = .02$) in the first two phases of the study, with a sustained rise in ADR to 18.2% three years following implementation of the bundle ($P = .09$). At the endoscopy unit level, only one endoscopy unit demonstrated a statistically significant change in ADR in the pre-QIC compared to the post-QIC analysis, however; this was not sustained.

(Figure 3)

Where data were available at endoscopist level across all phases of the study, ADR significantly increased from 16.3% pre-intervention to 19.3% post-intervention ($P = .003$) and 18.2% in the sustainability phase ($P = .14$). Although ADR was higher in the sustainability period compared to pre-intervention, this only reached statistical significance in the lowest colonoscopist quartile. Improvement in ADR was most marked in the lower ranking colonoscopist quartiles. *(Figure 4)*

Discussion

Changing practice and implementing evidence-based practice is a challenge. This study reports a simple, pragmatic, inexpensive approach, which led to a major change in practice with sustained results three years after the training intervention. Firstly, uptake of the 'bundle' and therefore change in practice, as measured by hyoscine butylbromide antispasmodic use, was sustained three years following implementation, without need for further study promotion or training sessions. This effect was seen in all units and amongst all colonoscopist quartiles. Hyoscine butylbromide was included as a component of this bundle as it is widely available in Europe and used as an anti-spasmodic to improve mucosal views.[18] As documentation of medication usage is mandatory on endoscopy reporting systems, documentation of hyoscine butylbromide use was the most obvious measure of bundle uptake.

Secondly, this study evaluated the effect of the intervention on ADR. Although global ADR significantly rose immediately following implementation of the 'bundle,' the ongoing improvement in ADR seen in the sustainability phase did not reach statistical significance. Where data were present for all three study periods, a significant, sustained improvement in ADR in the poorest performing colonoscopists was seen, i.e. those with the lowest baseline ADRs and therefore those more strongly associated with post-colonoscopy colorectal cancer. Although ADR fell in the upper colonoscopist quartile between pre-QIC and post-QIC phases, this did not reach statistical significance. A potential explanation for this is regression to the mean as the post-intervention dataset was larger, and similar performance is seen in post-QIC and sustainability phases.

The main limitation of this study was a lack of control group. The rationale for this methodology was that as a pragmatic service improvement project, it was considered important that all units and colonoscopists had access to the intervention, which was based upon evidence for efficacy. Hyoscine

butylbromide is used in Europe as an antispasmodic and whilst it is not available, for example in the United States, it is reported in this context as a marker of engagement with the QIC bundle. The benefits of Hyoscine butylbromide on ADR are inconclusive, due to heterogeneity within current studies.[19] Notably, within the UK there have been recent cautions issued regarding the routine use of Hyoscine butylbromide [20], particularly in patients with pre-existing cardiac disease. In light of this, the authors repeat the guidance that contraindications to the use of Hysocine butylbromide should be carefully considered and accept that in future the raised anxiety regarding its use may influence ongoing uptake of aspects of the QIC bundle. Other components of the bundle are not routinely recorded within the study region and therefore it was not possible to comment on uptake of these components. Some colonoscopists may not have implemented all parts of the bundle but it is an accepted limitation of this study that it was not a randomized trial but a pragmatic study to see if practice could be changed easily. Furthermore, due to limitations in reporting systems across the region, it was not possible to explore potential confounding variables such as procedure indication, bowel preparation, equipment used or endoscopist technique. These factors were not explored in the original QIC study.[16] As this was a 'before and after' study and not a randomised controlled trial, some caution should be taken when interpreting the results; the possibility cannot be excluded that some other event may have caused the change (for example, change in practice or different populations). It was stated in the original paper, but bears repetition, that Hyoscine butylbromide use was taken as marker of bundle compliance and should not be misinterpreted as directly correlating with the change in ADR.

Service improvement projects are often targeted at poorly performing groups. This study demonstrated sustained improvement in ADR, driven by the poorest performing colonoscopists. Within the lowest colonoscopist quartile, ADR was sustained at 15.9%, compared to 8.0% pre-intervention, an almost doubling in performance, which would have moved these endoscopists into the lower middle quartile pre-QIC. Corley et al previously demonstrated that each 1.0% absolute increase in ADR is associated with a relative 3.0% decrease in the risk of interval cancer.[9] More recently Kaminski et al

demonstrated that improving ADR through benchmarking and feedback translates into lower post colonoscopy cancer rates.[10] With this in mind, introducing this 'bundle' into routine colonoscopy practice should improve outcomes by reducing variation in colonoscopy quality.[4]

It is important that evidence-based interventions are included within the 'bundle' to maximise the effect on ADR. Potential barriers to introduction of the 'bundle' into routine practice may include reluctance to change, individual uncertainty as to the effect or necessity of such an intervention and perceived lack of time to introduce the 'bundle.' One way to overcome this may be to introduce this into basic colonoscopy training courses, which are mandatory to achieve complete colonoscopy accreditation in the UK. It is possible that the improvement in the poorest performing endoscopists in this study was not simply limited to bundle implementation and may have occurred due to changes in practice prompted by feedback given in the original QIC study, however, Hyoscine butylbromide use in these groups did rise suggesting implementation of the bundle had a role.

The intervention bundle was viewed as positive by endoscopists and the simple study posters (Figure 1) were reported as a useful reminder.[14]

There is a growing body of evidence for other interventions to improve ADR through improved mucosal visualisation, such as water exchange colonoscopy.[21] Optimising bowel preparation to ensure adequate visualisation is important, however, split dose preparations have not shown significant improvements in ADR.[22,23]

Recent approaches to improving ADR have also focused on technology and devices, in addition to endoscopist characteristics. In addition to high definition colonoscopes, wide-angle colonoscopes have been developed to increase the field of view.[24] Full Spectrum Endoscopy® (FUSE®) is one such example, however, a randomised controlled trial, systematic review and meta-analysis have shown no significant difference in polyp or adenoma detection rate compared to standard colonoscopy.[25–27]

Devices which attach to the tip of the colonoscope have been devised to improve colonic visualisation. The Endocuff Vision™ is a second generation, plastic device with backwards pointing projections which

open colonic folds on withdrawal.[28] Studies have reported a significant increase in ADR (40.9% vs 36.2%) when the Endocuff Vision was used, largely driven by improvements in colorectal cancer screening patients.[29,30] Providing feedback on colonoscopist performance has been shown to significantly improve ADR and caecal intubation rates, as has public reporting of ADR.[31–34] Within the colorectal cancer screening setting, a Polish study introduced leadership training to screening centres with suboptimal performance. [35] When compared with providing feedback alone, those centres which were randomised to leadership training demonstrated larger improvements in ADR.[35] The EQUIP-I, -II and -III studies showed that simple educational interventions and feedback improve ADR. [36,37] The benefit of our approach is that only leads for each site were required to attend training sessions and the effects of the study were ongoing at three years following the intervention, without the need for further training or feedback.

The ‘bundle’ approach to changing practice has been used successfully in other areas of clinical medicine, most notably in reducing catheter related bloodstream infections in the Intensive Care Unit (ICU) setting.[15,38] A sustained response was also seen in this setting. This study is the first within the field of endoscopy to introduce a ‘bundle’ of evidence-based measures to change practice, and furthermore is the first to assess the sustainability of an intervention designed to improve ADR over the medium term.[11] The bundle delivered in this study was based upon the best evidence available at the time of the intervention. Future interventions should consider the most up to date evidence in order to decide the components of the bundle, taking account of the complexity and cost of the interventions and the ease with which they can be implemented.

This was a large size, multi-centre, multi-endoscopist study undertaken in a community-based, non-expert setting and is therefore generalizable to routine colonoscopy practice. NHS BCSP colonoscopists were excluded as screening procedures could not be differentiated and these colonoscopists undergo accreditation exams and are required to demonstrate consistent high quality colonoscopy. It should be noted that ADR in the reported population is lower than in many published colonoscopy series. Bowel cancer screening cases in which all patients are FOB positive and therefore who have a high incidence of

adenomas were excluded and the study included all other indications, hence the lower overall ADR. The factors associated with sustained practice change were not individually evaluated and therefore which measures had the greatest impact cannot be investigated within this study design. Data collection in the sustainability phase was undertaken without ongoing study promotion and therefore reflected true current practice.

The results of this study demonstrate that introducing an evidence-based 'bundle' of measures is an effective way of introducing change into routine colonoscopy practice. Future research in this area should focus on whether the 'bundle' could be modified by introducing further evidence-based measures in addition to studying which educational approaches most readily change practice. Additional study of poorer performers and non-engagers, a particular challenge for quality improvement initiatives, would be of value.

In conclusion, this simple, inexpensive, pragmatic intervention was able to significantly change practice over a sustained period. Whilst accepting that the effect on change in ADR is modest there is evidence for sustained improvement, particularly in poor performers and improving ADR in these colonoscopists has been demonstrated to improve patient outcomes. The primary goal of changing practice was achieved and taking this further to change outcomes is a matter of choosing the best evidence-based interventions to be included within a 'bundle.' Multimodal interventions which target endoscopist, patient, procedure and unit factors will be needed to maximise ADR and minimise post-colonoscopy colorectal cancer.

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Tables and figures


The Quality Improvement in Colonoscopy (QIC) Study

on behalf of the Northern Region Endoscopy Group (NREG)

Remember to ROUTINELY

- 1. Give buscopan on reaching the caecum if not before**
- 2. Take at least 6 minutes to withdraw**
- 3. Use supine to examine transverse colon**
- 4. Retroflex in rectum**

Thank You !






Figure 1: QIC Study Bundle

2010			2011												2012	2013	2014							
Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan-Dec	Jan-Dec	Jan	Feb	Mar	Apr	May	Jun		
Pre-QIC			Implementation			Post-QIC													Sustainability Phase					

Figure 2: QIC data collection timeline

Endoscopy Unit	Hyoscine Butylbromide Use Rate (%)			Odds Ratio:Hyoscine Butylbromide Use (95% CI)			p value pre/sustain-ability
	Pre-QIC	Post-QIC	Sustain-ability	Pre-QIC	Post-QIC	Sustain-ability	
A	11.9	49.0	41.3	1	34.1 (23.1-50.3)	21.6 (14.2-32.8)	<0.001
B	2.6	38.8	28.9	1	35.1 (16.0-77.4)	50.3 (20.3-124)	<0.001
C	13.3	56.3	54.2	1	11.5 (9.30-14.3)	11.1 (8.65-14.1)	<0.001
D	25.4	66.7	39.6	1	9.59 (7.49-12.3)	3.42 (2.63-4.45)	<0.001
E	14.4	44.8	57.1	1	8.22 (6.42-10.5)	15.9 (12.2-20.8)	<0.001
F	24.1	50.7	40.2	1	4.99 (3.78-6.58)	6.74 (4.73-9.61)	<0.001
G	19.5	71.8	57.5	1	12.9 (9.44-17.7)	13.0 (8.88-19.1)	<0.001
H	12.8	59.6	45.0	1	12.8 (8.13-20.1)	6.21 (3.86-9.98)	<0.001
All	15.8	54.4	47.4	1	11.0 (9.89-12.2)	9.67 (8.61-10.8)	<0.001

Table 1: Hyoscine butylbromide usage rate (%) per endoscopy unit

Quartile*	Hyoscine butylbromide use rate (%)			Odds Ratio: Hyoscine butylbromide use (95% CI)			p value pre/sustainability
	Pre-QIC	Post-QIC	Sustainability	Pre-QIC	Post-QIC	Sustainability	
Q1: Upper	19.1	71.7	77.2	1	16.5 (12.6-21.7)	19.2 (14.3-25.8)	<0.001
Q2: Upper Middle	25.6	58.9	57.3	1	7.10 (5.68-8.88)	7.25 (5.74-9.16)	<0.001
Q3: Lower Middle	7.6	36.4	34.3	1	12.1 (8.52-17.1)	6.96 (4.85-10.0)	<0.001
Q4: Lower	9.3	45.9	39.9	1	12.1 (9.06-16.3)	9.87 (7.29-13.4)	<0.001
All	15.5	52.9	52.2	1	11.2 (9.75-12.8)	9.84 (8.53-11.3)	<0.001

Table 2: Hyoscine butylbromide usage rate (%) per endoscopist quartile

* Colonoscopists were divided into four quartiles according to their baseline ADR

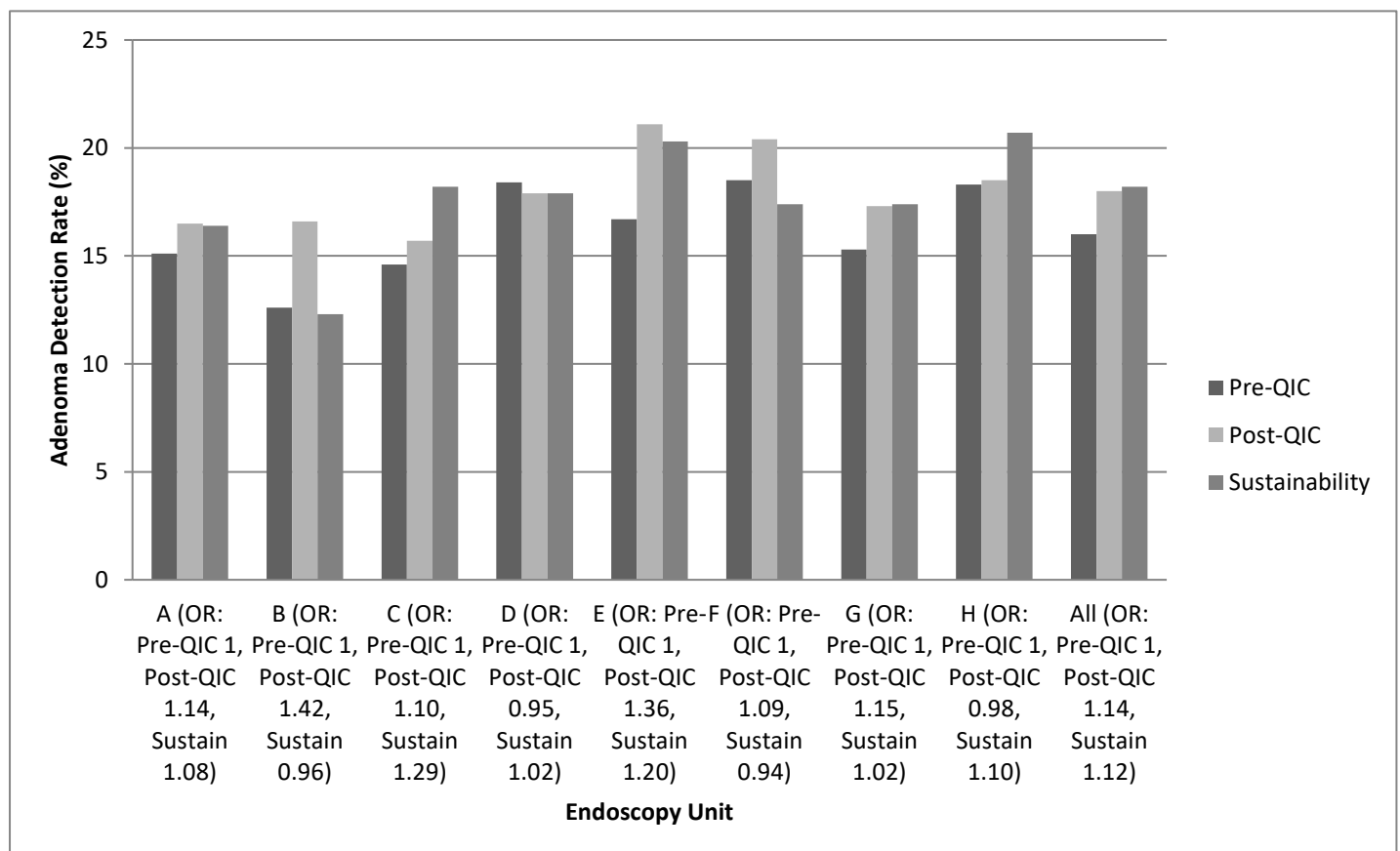


Figure 3: Adenoma detection rate (%) per endoscopy unit

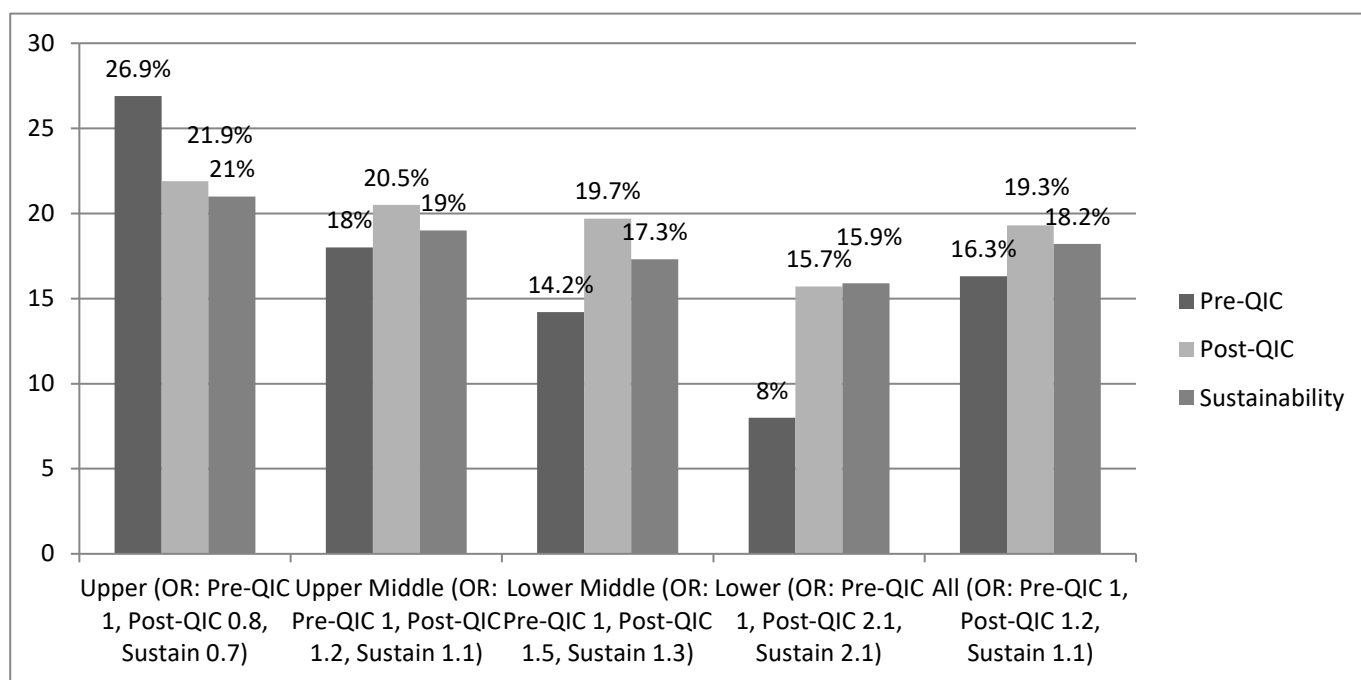


Figure 4: Adenoma detection rate (%) per endoscopist quartile