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Implementing capnography to help improve patient safety during procedural sedation: Quality improvement in a high-volume gastroenterology department

--Manuscript Draft--

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Abstract:	Objective: Respiratory compromise is a major cause of adverse events during procedural sedation; continuous monitoring is vital for identifying and halting decompensation. We performed a quality improvement (QI) investigation to assess patient safety during procedural sedation in gastroenterology and the impact of implementing capnography monitoring. Patients and Methods: Sedation-related adverse events and interventions were prospectively recorded during the endoscopic procedure and in recovery. Assuming rates in published literature, power analysis determined that at least 1,332 patients were required to show a 20% improvement in patient safety. Recorded sedation-related adverse events (mild and severe oxygen desaturations, bradycardia, and tachycardia) and interventions were anonymized and aggregated to evaluate the QI. Patient safety under current care was determined before capnography (Medtronic) was implemented in combination with training. Results: Between February–April 2018, a baseline (1,092 patients) for outcomes under current care was completed, with 11.45 events per 100 procedures recorded.

	Between May–July 2018, 1,044 procedures including capnography monitoring were performed with 5.08 events per 100 procedures recorded. The distribution of ASA scores and procedure types between baseline and capnography were comparable. The absolute difference between baseline and capnography was -6.4 events per 100 procedures (95% CI -4.1, -8.7; p ≤ 0.0001). The 55% reduction in adverse events surpassed the 20% improvement in patient safety set as the goal of this QI. After multivariate regression, the adjusted odds ratio for events after implementation of capnography was 0.46 (95% CI 0.32, 0.66). Conclusions: Addition of capnography to current care significantly decreased procedure-related safety events.
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Dear Editor,

Submission of an original research article entitled "Implementing capnography to help improve patient safety during procedural sedation: Quality improvement in a high-volume gastroenterology department" to *The European Journal of Gastroenterology & Hepatology*.

This manuscript describes a quality improvement assessment (QIA) undertaken at the UZ hospital, Leuven. The aim was to understand whether introducing capnography monitoring could improve on our standard of care for non-anaesthesiologist-led procedural sedation during endoscopy. Including over 1,000 patient both before and after introduction of capnography monitoring, this QIA represents one of the largest studies of capnography to date and the largest with results from real-world practice.

The results of this QIA are likely to be of interest to your readership as we show that with additional monitoring and education, a substantial reduction in adverse patient safety events can be achieved. In our practice, a 55% reduction was recorded. Of interest is that the greatest reduction in adverse events was seen in the recovery room as opposed to during endoscopy itself. Overall, we found the capnography monitoring could improve patient safety with cost neutrality over the assessment period. Cost of monitoring were offset by savings in care costs.

Following successful implementation of capnography monitoring, we provide some guidance from our own learnings to other hospitals and departments who may wish to consider their own QIA. Given the increase in patient safety obtained and the current drive for improving care in a cost-effective manner, we feel that the readership of *Endoscopy* will have an interest in the outcomes of this QIA.

We would like to emphasize that according to Belgian legislation and our Independent Research Bureau (IRB), QIA projects are not regarded as interventional studies, and do not require an internal or external ethics approval. At all times, all patients undergoing conscious sedation received maximal standard of care with the equipment that was available. In addition, capnography monitoring is an established technology and there was no prospective patient assignment nor randomization.

If the manuscript is of interest, we look forward to working with the peer-reviewers on any updates and improvements.

All authors have given written consent for the submission to *The European Journal of Gastroenterology & Hepatology.*

Yours sincerely

Rhodri Saunders, on behalf of all authors

1. Implementing capnography to help improve patient safety during procedural sedation: Quality improvement in a high-volume gastroenterology department

1-1. Short title

Capnography monitoring during procedural sedation

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1-3. Conflict of interest and funding disclosures

The QI and the preparation of this manuscript was supported by Medtronic. RB received speaker's honorarium and research support from Medtronic, not related to the content of this paper or the research conducted in this paper. RB is supported by a grant of FWO Vlaanderen. RTT is an employee and RS the owner of Coreva Scientific, which has received consultancy fees from Medtronic. At the time of this QI, RW was an employee of Medtronic.

1-4. Word count

3,691 excluding tables, figures and references

2. Abstract

Objective: Respiratory compromise is a major cause of adverse events during procedural sedation; continuous monitoring is vital for identifying and halting decompensation. We performed a quality improvement (QI) investigation to assess patient safety during procedural sedation in gastroenterology and the impact of implementing capnography monitoring.

Patients and Methods: Sedation-related adverse events and interventions were prospectively recorded during the endoscopic procedure and in recovery. Assuming rates in published literature, power analysis determined that at least 1,332 patients were required to show a 20% improvement in patient safety. Recorded sedation-related adverse events (mild and severe oxygen desaturations, bradycardia, and tachycardia) and interventions were anonymized and aggregated to evaluate the QI. Patient safety under current care was determined before capnography (Medtronic) was implemented in combination with training.

Results: Between February–April 2018, a baseline (1,092 patients) for outcomes under current care was completed, with 11.45 events per 100 procedures recorded. Between May–July 2018, 1,044 procedures including capnography monitoring were performed with 5.08 events per 100 procedures recorded. The distribution of ASA scores and procedure types between baseline and capnography were comparable. The absolute difference between baseline and capnography was -6.4 events per 100 procedures (95% CI -4.1, -8.7; $p \leq 0.0001$). The 55% reduction in adverse events surpassed the 20% improvement in patient safety set as the goal of this QI. After multivariate regression, the adjusted odds ratio for events after implementation of capnography was 0.46 (95% CI 0.32, 0.66).

Conclusions: Addition of capnography to current care significantly decreased procedure-related safety events.

2-1. Key words

Real-world evidence; Quality Assurance, Health Care; Value-based healthcare; Respiratory Insufficiency; Endoscopy; Evidence-Based Practice

3. Manuscript

Introduction

There is a growing body of evidence that capnography is beneficial for patients receiving moderate sedation,[1,2] though its value as a ubiquitous monitoring modality for moderate sedation in gastroenterology is questioned.[3] A review of 2,132 patients receiving gastrointestinal endoscopy under anaesthetist-managed sedation found that 23% had unplanned events related to the procedure, with 15.4% having a significant adverse unplanned event during the procedure itself.[4] One relatively common adverse event during sedation is oxygen desaturation.[5,6] The patient impact of minor oxygen desaturation (<90%) is debated, but unchecked descent along the respiratory compromise cascade can, in rare cases, result in catastrophic patient harm or death.[4,7] Oxygen desaturation is typically preceded by changes in patient ventilation, with studies showing changes in ventilation over 30 seconds before arterial oxygen desaturation is noted.[9] It is changes in ventilation that capnography monitoring aims to identify. As such, it can provide an early warning of patient compromise and allow for timely action to be taken. This is one reason why capnography is considered as part of standard of care for the monitoring of patients under deep sedation.[10]

This is the situation at the UZ Leuven, where capnography is used for monitoring of deep sedation by anesthesiologists but not as standard during moderate sedation in the endoscopy unit. In preparing to standardize the hospital's sedation protocols, the question of capnography's utility and value during procedural, moderate sedation was raised. As others have noted, the initial, direct cost of adding capnography monitoring in a high-volume department can be substantial,[3] although there is suggestion that it can be cost-effective by reducing the incidence of adverse events and, hence, eliminating some care costs.[11] It may mean that capnography monitoring could play a role in value-based care, where the focus is on improving quality of care (patient outcomes) and reducing waste (either monetary or resources).

We undertook a quality improvement (QI) investigation to determine whether implementing ubiquitous capnography monitoring during procedural sedation at UZ Leuven would be of benefit to patient outcomes at a reasonable cost. The findings of our QI investigation are intended to provide substantial real-world data to assess the utility of implementing capnography monitoring in a high-volume gastroenterology department performing moderate sedation. Reporting is aligned with "*Standards for reporting implementation studies (StaRI)*" guidance.[12]

Material and methods

Implementation and quality improvement

Implementation science considers whether and how effective interventions can be implemented in routine practice to improve patient health.[12] A commitment to improving health and its provision is integral to modern-day medicine and the undertaking of QI programmes is a central aspect of this.[13] QI requires taking generalizable scientific evidence and applying it in a local setting to assess whether improvement in a measurable target can be achieved.[14] Measurable targets in the context of procedural sedation have been discussed by Mason (2012) and Ward (2017).[15,16] In this instance, the utility of implementing capnography monitoring on patient safety in the endoscopy unit of UZ Leuven, Belgium, was investigated. The department sees over 27,000 patients annually, including undertaking approximately 12,000 procedures involving moderate sedation.

Sedation monitoring practice

At the start of this undertaking, the standard of care for monitoring patients under sedation in our department was pulse oximetry, blood pressure, and heart rate monitoring performed by the endoscopist and the assisting nurse. To assess its impact on patient safety, we subsequently implemented capnography monitoring using the CapnoStream™ 35 portable respiratory monitor (Medtronic) during both the procedure and recovery. Monitoring in the recovery room was performed until the patient was assessed and approved for discharge.

Quality improvement primary target

The primary outcome was the incidence, events per 100 procedures, of mild oxygen desaturation, severe oxygen desaturation, bradycardia, and tachycardia. Multiple events of the same type in the same patient were counted as only a single event. The target was a 20% reduction in the primary outcome. Based on published rates of events,[1,5] power calculation with the type 2 error (beta, ß) set to 80% determined that 666 or 844 patients per group were required with a type 1 error (alpha, α) of 90% and 95% respectively.[17] Given the high volume of the department, the department's QI team decided to target 1,000 patients per group to increase the likelihood of a statistically significant outcome and to better inform future decisions on standard of care.

Patients

All consecutive patients undergoing procedural, non-propofol sedation in the department during the assessment period were included. Propofol sedation is standardly performed by anaesthetists in our department and they use capnography as standard of care on their mobile anaesthesia units. Non-propofol sedation included those performed with midazolam or midazolam and meperidine. Procedures included were colonoscopy, bronchoscopy, echo-endoscopy, proctology, gastroscopy, or combined gastroscopy and colonoscopy. As a before-and-after assessment of capnography implementation, there was no prospective assignment of patients to study groups. There were no exclusion criteria for this QI. Of note, all gastrointestinal procedures both gastroscopies and colonoscopies are performed with CO_2 insufflation.

Recorded data

The data recorded were adverse events as defined by the World Society of Intravenous Anaesthesia (SIVA),[15] including mild and severe oxygen desaturation, bradycardia, tachycardia, prolonged apnoea, airway obstruction, cardiovascular shock/collapse, cardiac arrest/absent pulse, and other. Furthermore, it was noted whether the adverse events occurred during the procedure or during recovery from sedation. Additional parameters recorded were the perioperative risk level defined by the American Society of Anesthesiologists (ASA) score, the sedative used, SIVA-defined interventions used, and the procedure duration. The patient's age and sex were not recorded to minimize data collection in line with EU data-protection regulations, as their inclusion may have allowed for easier identification of individual patients from the data collected.

Data collection & security

Data were initially recorded on paper by a member of the sedation team. Afterwards, data were entered into an Excel™ data-collection tool with password-restricted access to the resulting analysis. No personal data of patients were collected and no transfer of data outside of the EU occurred. The analysis team only ever presented results in aggregate form to interested parties.

Training and education

Before undertaking the baseline recording, a comprehensive education program on patient safety and monitoring during procedural sedation was provided to all physicians, nurses, and other relevant staff in the department. At this time, the staff were introduced to the data-collection forms and the purpose of QI. Once the baseline phase was complete, results were not shared with the care team in order to minimize potential bias before completing the capnography assessment phase. Prior to use of capnography monitoring, further clinical education on the role and purpose of capnography monitoring was provided by the device manufacturer and frequent follow up and support was offered by clinical educators.

The training consisted of small group training (1-5 per group) with nursing staff to review the basics of capnography, the importance and utility of capnography in procedural sedation, and a deep dive into capnography waveforms. The training covered normal, hypoventilation, hyperventilation, apnea, airway obstruction and shallow breathing waveform examples and reviewed a step-by-step algorithm of what to do if an abnormal waveform is observed. This was followed by a two-week wash-in period, where capnography was used but no data collection took place. During the initial procedures utilizing capnography monitoring, trainers assisted in the setup of the device, demonstrated alarm settings and basic button functionality, and answered questions and explained monitor outputs during the entire procedure. During the two-week wash-in period, a clinical specialist repeated the capnography training and provided new resources including a clinical algorithm for capnography waveforms.

Data analysis

The primary outcome, the difference in incidence per 100 procedures between the baseline and capnography phases, was evaluated using a two-proportion z-test. Tests were also performed for the primary outcome when stratified by ‘periprocedural’ or ‘recovery’ states. The mean procedure time before and after capnography implementation was assessed using a two-tailed t-test. For all tests, the Holm–Bonferroni correction was used to account for potential multiplicity.

The impact of potential confounders on the primary outcome was assessed via a logistic regression model (binomial distribution) including the procedure (1 to 6), ASA level (1 to 4), sedative used (1 or 2), supplemental O_2 (yes/no), and capnography (yes/no) to predict the primary outcome. Subsequently, the adjusted odds ratio for capnography use was calculated. These analyses were performed in R (version 3.6.3) using the packages “stats” (version 3.6.3) and "oddsratio" (version 2.0.0).

When assessing events by procedure type or patient ASA classification, the incidence of events for 100 procedures was evaluated and only general descriptions of outcomes are reported. No statistical testing was performed due to potential for confounding these in smaller stratified populations. The relative risk of events in the capnography group compared with the baseline group was calculated and is presented in the associated figures. For these relative-risk analyses, no strategy was applied to account for multiplicity and any results should be considered only as an indication of a potential real effect that needs to be confirmed in prospective studies.

In all cases, any indication of statistical significance does not dictate clinical relevance. The impact of results on clinical practice in UZ Leuven is discussed, but it is up to individual readers to determine whether such results will have clinical relevance in their own practice.

To assess the economic impact of the QI, average costs of capnography and its comparator were calculated based on current costs in Belgium and the costs of adverse events were taken from the literature (using France as a proxy).

Ethics considerations

According to Belgian legislation and our Independent Research Bureau (IRB), QI projects are not regarded as interventional studies. More specifically and at all times, all patients undergoing conscious sedation received maximal standard of care with the equipment that was available: this was standard monitoring when capnography was not available and capnography when it was available for a limited time period in the hospital. In addition, capnography monitoring is an established technology and there was no prospective patient assignment nor randomization. As such, this project qualified according to our hospital quality management as a QI project and not as a study that needed IRB approval. Therefore, no internal or external ethics approval was required for the collection and analysis of the aforementioned data that were anonymized.

Neither patients nor the public were involved in the design, conduct, reporting, or dissemination plans of this QI. Notices were in place in the department to inform patients of an ongoing QI. Results may be included in hospital communications accessible to the public, depending on the outcomes and implications for care.

Results

Data from 1,092 consecutive patients receiving non-propofol sedation were recorded between February 19th and April 12th 2018, which constituted the baseline group. For the capnography group, data from 1,044 consecutive patients receiving non-propofol sedation were recorded between May 7th and July 9th 2018. The distributions of procedures and ASA levels did show differences between the baseline and capnography groups (Table 1). The number of patients experiencing at least one adverse event was 100 (9.2%) in the baseline group and 54 (5.2%) in the capnography group. Incidence of adverse events per 100 procedures is reported in Figure 1.

Primary target outcome

In the baseline group, there were 11.45 primary-outcome events per 100 procedures, the majority of which were oxygen desaturations (Figure 2A). In comparison, there were 5.08 primary-outcome events per 100 procedures recorded in the capnography group. Capnography reduced the combined incidence of mild oxygen desaturation, severe oxygen desaturation, bradycardia, and tachycardia by 55.7% (Figure 2A). The corresponding risk ratio was 0.43 (95% CI 0.31 to 0.58) with an absolute difference between groups of -6.4 (95% CI: -4.1 to -8.7; $p<0.0001$) primary-outcome events per 100 procedures. The improvement in the primary outcomes far exceeded the target of a 20% reduction. With respect to patient outcomes, there were nine escalations of care (extended hospital stay or ward transfer) in the baseline group, including one transfer to intensive care. In the capnography group, no patient required an escalation of care.

Capnography monitoring reduced the risk of adverse events across all procedures, except for proctology, for which no adverse events were reported in either the baseline or capnography groups (Figure 3A). For patients classified as ASA 1, 2, or 3, an adverse-event rate reduction of around 50% was apparent after implementing capnography (Figure 3B).

In multivariable analysis, capnography was the most reliable predictor ($p = 0.000036$) of the primary outcome, whereby presence of capnography predicted that the primary outcome was avoided. Other factors significantly associated with the primary outcome

were ASA 2 (p = 0.023) and procedure 6 (gastroscopy & colonoscopy, p = 0.015), both of which predicted that the primary outcome would occur. The adjusted odds ratio for the primary outcome was 0.462 (0.319, 0.663) with capnography, 1.61 (1.08, 2.44) for ASA 2, and = 2.90 (1.14, 6.46) for combined gastroscopy and colonoscopy.

Adverse events by location

Locations were the operating room during the procedure or subsequently the recovery room. During the procedure, the difference in adverse-event incidence per 100 procedures between baseline and capnography groups was -26.9% (Figure 2B). Albeit being a greater improvement than was the target, it did not reach significance at the 5% level. During recovery from sedation, the adverse-event incidence was 5.32 and 0.95 per 100 procedures in the baseline and capnography groups respectively. This 82% reduction of adverse-event incidence was significant ($p<0.0001$) with the corresponding relative risk for capnography being 0.17 (95% CI 0.08 to 0.36). The use of SIVA-defined interventions during the recovery phase was also significantly lower with capnography monitoring than without, the relative risk being 0.15 (95% CI, 0.06 to 0.37).

Regarding escalations of care, which only occurred in the baseline group, the majority of these (7 of 9, 78%) occurred in the periprocedural period. Six of these were associated with mild (5 patients) or mild and severe oxygen desaturation (1 patient) events, the remaining patient experienced prolonged apnea (> 60 seconds). During recovery, the two escalations of care recorded were associated with an unconscious patient and a patient experiencing both mild and severe oxygen desaturation.

Procedure duration

The introduction of capnography did not impact substantially on the length of procedure in most cases. Only colonoscopy (+2 minutes, p = 0.009) and bronchoscopy (+2.7 minutes, p = 0.006) showed a significant difference, with use of capnography adding to the duration of the procedure.

Holm-Bonferroni adjustment for multiple comparisons

Of the nine items tested for significance, three would be considered as statistically significant after adjustment under the Holm-Bonferroni method. These, in order of rank, are the reduction in the primary outcome during recovery, reduction in the primary outcome (periprocedural and recovery combined), and increased time for bronchoscopy procedures.

Economic outcomes

Outside of this QI, use of capnography monitoring would require purchase of filter lines. Whether this cost would be offset by improved patient safety and reduced need for escalation of care was assessed. Costs for ward stays were taken from the hospital records, whereas costs for adverse events were derived from published literature (Table 2). Our estimates found that addition of capnography was approximately cost neutral, even if all patients were monitored (no stratification). For every 100 patients, the estimated cost difference was a saving of approximately EUR 55 when using capnography (Table 3).

Discussion

Capnography monitoring measures carbon-dioxide in the patient's breath and provides an indicator for the functionality of their ventilation, perfusion, and metabolism. There is plentiful evidence that capnography monitoring can detect apnoea and significantly reduce the incidence of subsequent adverse events in the respiratory compromise cascade.[18][1] To date, the largest trials of capnography monitoring during procedures in gastroenterology included 757 patients,[5] well below the 2,136 patients included in this analysis. Although potentially not of the evidence-value of clinical trial data, e.g. as is provided by the ColoCap study,[5] our data provides one of the largest, single-center assessments of capnography monitoring. At baseline, the adverse-event incidence with current care was 11.45 events per 100 procedures. This rate is generally lower than that reported in clinical trials,[5,6] and higher than those in retrospective studies.[19,20] Our prospectively collected, real-world data suggest that sedation-related adverse events are more common than many expect but that the burden is not too acute.

When outcomes were stratified by procedure type and ASA level, all strata showed reduction in adverse events in the capnography group. The relative risks calculated (Figure 3) shows that the 95% confidence intervals did not cross parity only in those strata accounting for >300 patients, demonstrating the importance of having a sample of sufficient size to inform clinical decision making.

For the capnography group, a notable difference in the incidence of adverse events was observed between procedure and recovery. During the procedure, capnography was associated with a risk ratio for adverse events of 0.84 (95% CI 0.57 to 1.23). For recovery, the risk ratio for adverse events was 0.17 (95% CI 0.08 to 0.36), a ~5-fold reduction. When investigating the utility of capnography monitoring for nurse-administered propofol sedation, Slagelse et al. observed a similar phenomena. The cumulative incidence of oxygen desaturation events in both the control and capnography arms were similar to around 20 minutes, but after this point events were only observed in the control arm.[21] Two potential explanations for this observation exist. First, from a clinical perspective, stimuli from the procedure prompt patient awareness, pain, and a stressor response that could promote ventilation; the lack of these stimuli in recovery may result in respiratory depression as the sedatives used are still in effect. Second, from a care perspective, there may be a marked difference in the closeness of monitoring between the procedure and recovery. During the procedure, an individual is assigned to monitoring and maintaining the patient's health status on a one-to-one basis; once in the recovery room, one nurse is responsible for supervising 12 patients simultaneously. In this context, the early warnings of ventialtory insufficiency provided by capnography may help the nurses to optimize their care provision to patients most in need of their help.

A monitor is only effective if carers respond appropriately to the information that it provides. It is important to recognize that clinical education is of paramount importance when introducing new technologies and that the quality of the education program most likely impacted the program results. The device manufacturer provided a robust clinical education program consisting of e-learning modules, presentations and a hands-on demonstration on how to respond clinically to different capnography waveforms and pulse-oximetry values in the procedure suite to all team members. One member of the nursing staff also had extensive prior experience with capnography and was a proponent of the QI, having such an 'internal resource' may have been extremely beneficial to other staff. The value of training and internal buy-in cannot be underestimated. Still, it is unlikely that training on patient safety during procedural sedation alone (without capnography) would have driven the same results. Staff interpreted and acted on information provided by

capnography, particularly in the recovery room where the patient-to-staff ratio is higher and requires the staff to be supported by appropriate monitoring technologies.

Since direct cost collection was not a part of this QI but the overall cost of care was of interest to the hospital, the associated costs for each adverse event and escalation of care was estimated. Overall, it was estimated that the introduction of capnography in all patients would be essentially cost neutral. For every 100 procedures performed, the department would expect a saving of EUR 55 once the capital cost of equipment is accounted for. The lack of direct cost collection as part of this QI is a limitation, but it was out of scope to accurately determine the full resources required to treat each adverse event. The results, by design, reflect only the clinical practice of UZ Leuven. As a reflection of current care, no randomization or extensive inclusion/exclusion criteria were applied. There is, thus, no simple nor intended method to extrapolate these results to other clinical settings. The strength of the presented work is the demonstration of real-world benefit of capnography monitoring in a large group on non-selected patients.

The findings of this QI might spark an interest in the exploration of the value of capnography in settings outside of deep sedation. Such approaches to data collection and assessment are also particularly relevant today with the growth of value-based healthcare. The measurement of outcomes and costs in a real-world setting is important to all stakeholders (patients, clinicians, administrators, insurance, and regulators) to inform and drive decisions on the adoption of new technology. As the costs of healthcare burgeon, there may be reluctance to invest in new technology. However strong its evidence base, there are always concerns that effectiveness and cost-effectiveness may not transition directly from controlled trials to real-world use. That is to question, whether the effectiveness of an intervention can (1) be maintained outside the trial setting and (2) result in sufficient cost or resource savings to make implementing cost neutral over a specified period of time. QI, as undertaken here, allows for technology that is new to the department to be assessed in real-life practice with limited risk to the hospital, department, and patients. Given our experiences and the QI outcomes, we encourage other groups to consider this approach to extending and optimizing clinical practice in their local setting.

Conclusion

Use of capnography monitoring reduced the incidence of adverse events during moderate sedation in endoscopy by 55.7%. Overall, capnography was a benefit to patient safety in our department, with benefits achieved without increasing the costs of care.

Disclosures

The QI and the preparation of this manuscript was supported by Medtronic. RB received speaker's honorarium and research support from Medtronic, not related to the content of this paper or the research conducted in this paper. RB is supported by a grant of FWO Vlaanderen. RTT is an employee and RS the owner of Coreva Scientific, which has received consultancy fees from Medtronic. At the time of this QI, RW was an employee of Medtronic.

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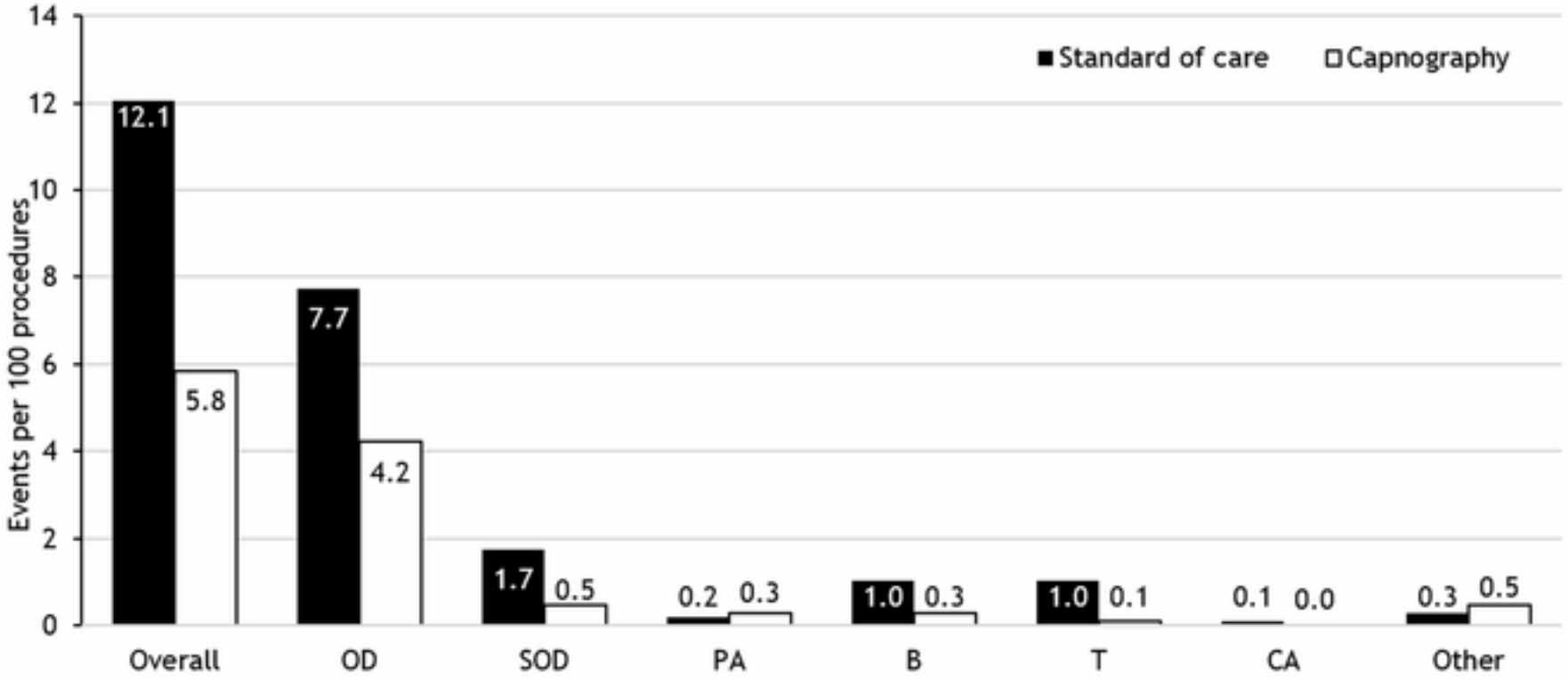
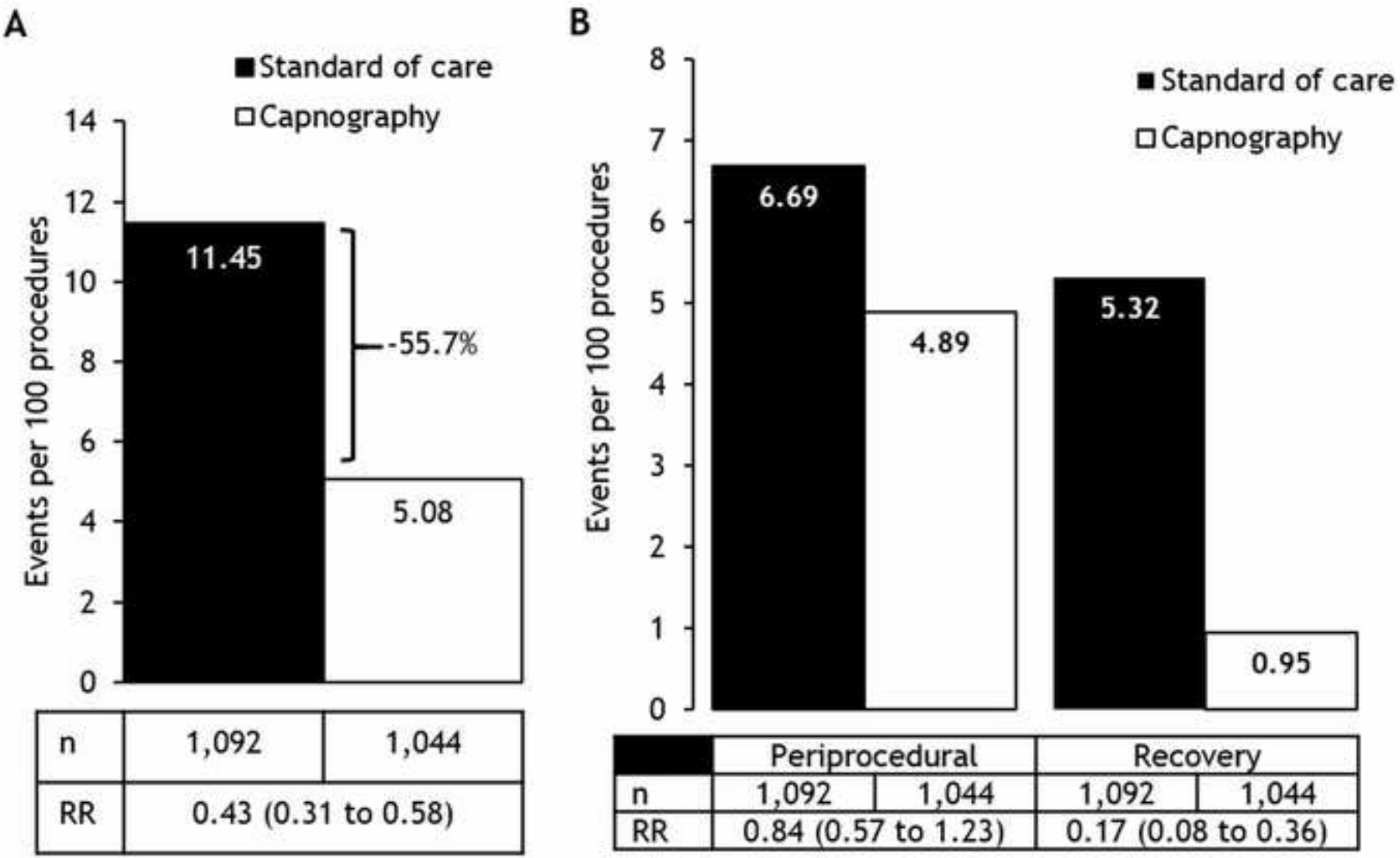
5. Figure legends

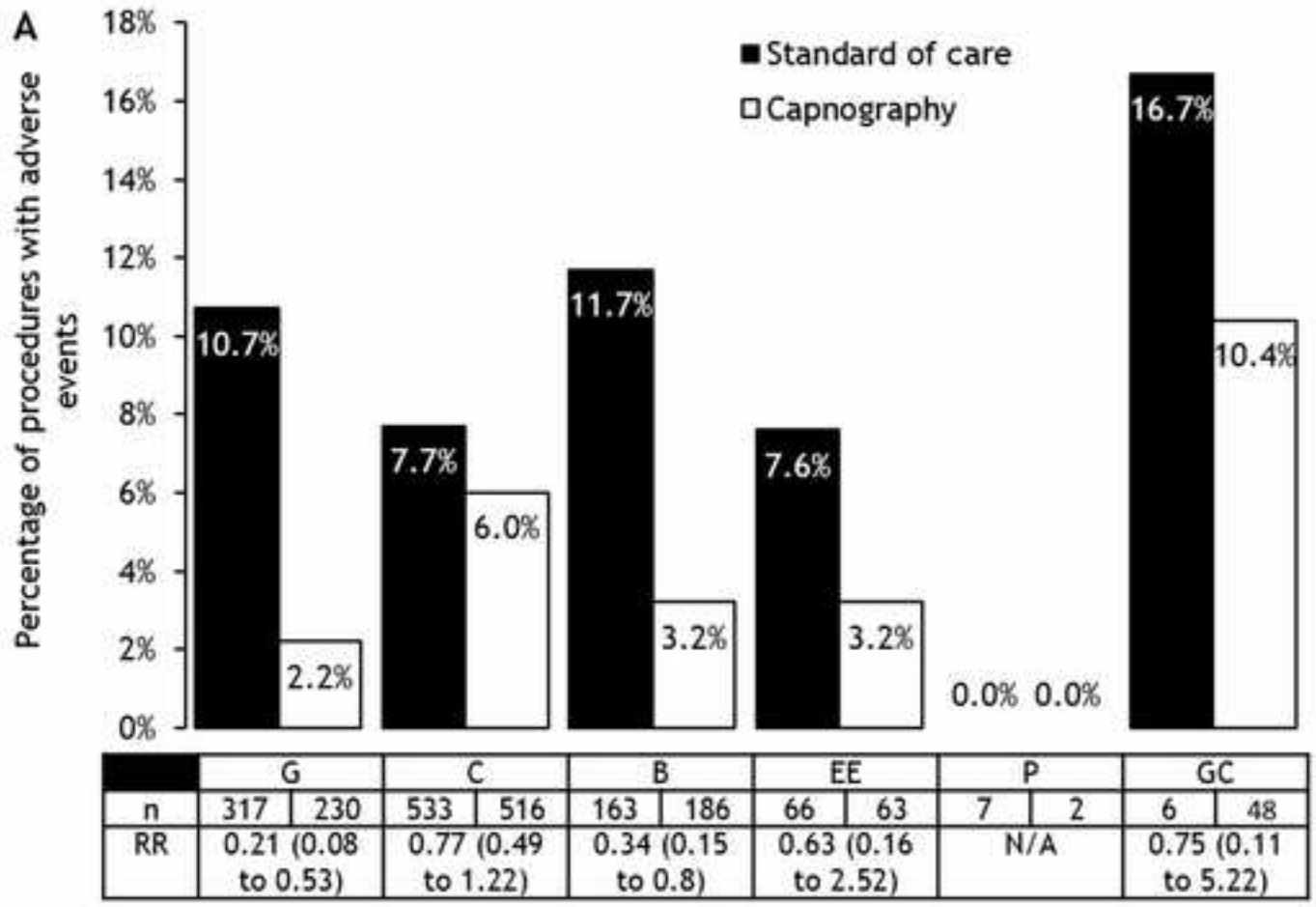
Figure 1. Incidence of types of adverse events. OD: oxygen desaturation, SOD: severe oxygen desaturation (<75%), PA: prolonged apnoea, B: bradycardia, T: tachycardia, CA: cardiac arrest, Other: pain, vertigo, dizziness, not specified, short apnoea.

Figure 2. Primary QI outcome: Adverse events incidence comparing standard of care with capnography monitoring. (A) Overall incidence and (B) incidence separated by periprocedural and recovery phase. Adverse events include mild and severe oxygen desaturation, bradycardia, and tachycardia. n: number of patients, RR: risk ratio, statistical significance ($p<0.05$) marked with *.

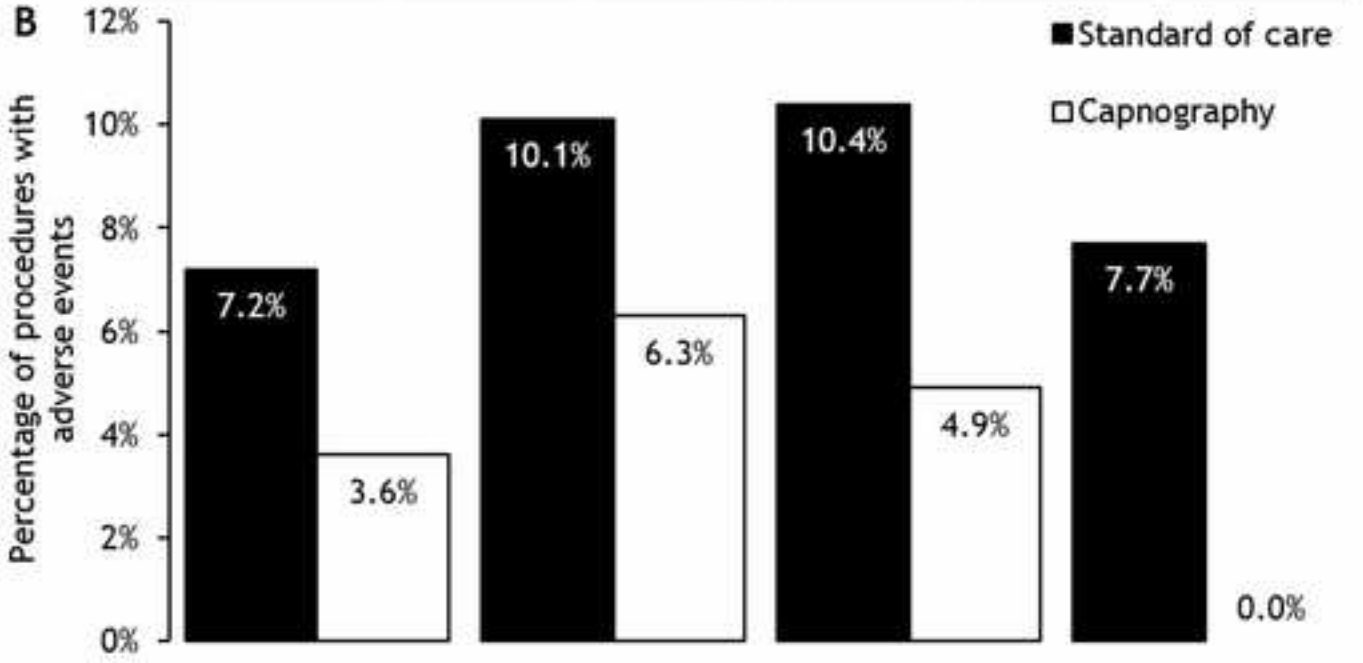
Figure 3. Adverse event rates stratified by (A) procedure and (B) patient ASA risk level. Adverse events include mild and severe oxygen desaturation, bradycardia, and tachycardia. G: gastroscopy, C: colonoscopy, B: bronchoscopy, EE: echo-endoscopy, P: proctology, GC: gastroscopy & colonoscopy, n: number of patients, ASA: American Society of Anesthesiologists, RR: risk ratio, statistical significance ($p<0.05$) marked with *.







	G		C		B		EE		P		GC	
n	317	230	533	516	163	186	66	63	7	2	6	48
RR	0.21 (0.08 to 0.53)		0.77 (0.49 to 1.22)		0.34 (0.15 to 0.8)		0.63 (0.16 to 2.52)		N/A		0.75 (0.11 to 5.22)	



	ASA risk level 1		ASA risk level 2		ASA risk level 3		ASA risk level 4	
n	359	338	556	592	164	103	13	11
RR	0.41 (0.2 to 0.83)		0.63 (0.42 to 0.94)		0.47 (0.18 to 1.2)		N/A	

Table1. Summary of patient and procedure characteristics for the QI population. Significance testing was performed via a Chi-squared test.

Characteristic	Baseline	Capnography	Difference	Significance
		N (%)	Percentage	p-value
Procedure	N (%)		points	
Gastroscopy	317 (29.03)	230 (22.03)	7.02	<0.01
Colonoscopy	533 (48.81)	515 (49.33)	-0.52	0.81
Bronchoscopy	163 (14.93)	186 (17.81)	-2.87	0.07
Echo-endo	66 (6.04)	63 (6.03)	0.01	0.99
Proctology	7 (0.64)	2 (0.19)	0.45	0.11
Gastro-Colo	6 (0.55)	48 (4.60)	-4.04	<0.01
ASA level				
1	359 (32.88)	338 (32.38)	0.5	0.81
2	556 (50.92)	592 (56.70)	-5.78	<0.01
3	164 (15.02)	103 (9.87)	5.15	<0.01
4	13 (1.19)	11 (1.05)	0.14	0.76

Table 2. Costs associated with a hospital stay, adverse events and monitoring.

Category	Costs
General ward	€ 664.30
Intensive care unit	€ 2,015.00
Oxygen desaturation (mild)	€ 19.25
Oxygen desaturation (severe)	€ 55.00
Bradycardia	€ 11.00
Tachycardia	€ 43.00
Cardiac arrest	€ 3,934.11
Code blue	€ 146.80
Capnography	€ 9.00

Table 3. Comparison of overall costs between Capnography and the current standard of care.

Costs are shown per 100 procedures.

	Total Costs	Care (incl. adverse events)	Monitoring
Standard of care	€1,159.07	€ 1,159.07	€ -
Capnography	€1,103.43	€ 203.43	€ 900.00
Cost change	-€ 55.64	-€ 955.64	€ 900.00

Manuscript Text file in Word-only 1 single version (All Text Pages, including Title Page, References and Figure Legends, Abstract