Endoscopy No. •• / 2018

ENDOS-2017-16036.R2 / Holme

Original Article

Endoscopy assistants influence the quality of colonoscopy

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Short title:

Endoscopy assistants influence the quality of colonoscopy

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Submitted: 7 September 2017

Accepted after revision: 11 January 2018

Copy editor: SF / Deadline at publishers: 30 January 2018 / Typesetting deadline

In brief

An analysis from the Norwegian registry shows that the performance of the

endoscopy assistants (i.e nurses) should be taken into consideration when evaluating

quality in colonoscopy.

Background Colonoscopy performance varies between endoscopists, but little is known about the impact of endoscopy assistants on key performance indicators. We used a large prospective colonoscopy quality database to perform an exploratory study to evaluate differences in selected quality indicators between endoscopy assistants.

Methods All colonoscopies reported to the Norwegian colonoscopy quality assurance register Gastronet can be used to trace individual endoscopy assistants. We analyzed key quality indicators (cecum intubation rate, polyp detection rate, colonoscopies rated as severely painful, colonoscopies with sedation or analgesia, and satisfaction with information) for colonoscopies performed between 1 January 2013 and 31 December 2014. Differences between individual assistants were analyzed by fitting multivariable logistic regression models, with the best performing assistant at each participating hospital as reference. All models were adjusted for the endoscopist.

Results 63 endoscopy assistants from 12 hospitals assisted in 15 365 colonoscopies. Compared with their top performing peers from the same hospital, one assistant was associated with cecum intubation failure, four with poor polyp detection, nine with painful colonoscopy, 16 with administration of sedation or analgesics during colonoscopy, and three with patient dissatisfaction about information given relating to the colonoscopy. The number of procedures during the study period or lifetime experience as an endoscopy assistant were not associated with any quality indicator.

Conclusion In this exploratory study, there was little variation on important colonoscopy quality indicators between endoscopy assistants. However, there were differences among assistants that may be clinically important. Endoscopy assistants should be subject to quality surveillance similarly to endoscopists.

Introduction

There has been much focus on quality indicators in colonoscopy in recent years. Low adenoma detection rates (ADRs) and incomplete examinations are associated with increased risk of post-colonoscopy colorectal cancer [1–3]. Recently, the European Society of Gastrointestinal Endoscopy (ESGE) defined key performance indicators for colonoscopy [4]. Accordingly, performance of individual endoscopists has gained increasing attention, and educating endoscopists and endoscopy leaders improves important colonoscopy quality indicators [5–7].

Less attention has been devoted to the endoscopy assistant. The endoscopist and the assistant work as a team and are mutually dependent on each other. Depending on country, culture, and local routines, the assistant may play an important role in the following activities: informing and preparing the patient for colonoscopy; calming and supporting the patient during the procedure; inserting intravenous cannulas; administering sedation; providing abdominal compression during the examination; and detecting pathology while watching the screen, in cooperation with the endoscopist.

Previous single-center retrospective studies have shown that complication rate, cecal intubation time, and ADR are associated with less experienced endoscopy assistants [8,9]. In a single-center prospective study, the ADR was improved when inexperienced endoscopists were accompanied by an experienced endoscopy assistant [10]. These studies included screening colonoscopies only.

In Norway, outpatient colonoscopies are prospectively recorded in the national quality register Gastronet. We took advantage of this large, prospective database to explore the importance of endoscopy assistants across a range of key performance indicators for colonoscopy in a routine clinical setting.

Methods

All outpatient colonoscopies reported to Gastronet between 1 January 2013 and 31 December 2014 were eligible for analysis in the present study.

Gastronet is the Norwegian quality assurance register for outpatient colonoscopies. Data are captured through two paper forms. The procedure form is completed by the endoscopist immediately after the colonoscopy and contains demographic information (including patient age and sex, and previous abdominal surgery), procedural characteristics including bowel cleansing (Boston Bowel Preparation Scale [BBPS] [11]), use of sedation or analgesia, cecum intubation, cecal intubation time, colonoscopy indication, polyp detection (polyps ≥5 mm), and adverse events that occur before the patient leaves the hospital. Adverse events are recorded as "Yes" or "No." The type of adverse event may be specified as a free-text comment. Each colonoscopy can be traced back to individual endoscopists and endoscopy assistants. In the majority of colonoscopies in Norway, only one person, the endoscopy assistant, accompanies the endoscopist in the examination.

Before leaving the endoscopy suite, patients receive a questionnaire including questions about satisfaction with the information given (yes, slight, moderate, very), satisfaction with bowel cleansing, and adverse events and pain during and up to 24 hours after the colonoscopy (no, slight, moderate or severe pain). The questionnaire contains a field for free-text comments by the patient. All patients are asked to complete the questionnaire the day after the procedure and return the form to the Gastronet secretariat in a prepaid return envelope.

Returning the patient questionnaire is regarded as consent to be registered in Gastronet. Gastronet is approved by the Norwegian Data Inspectorate and ethical approval is waived.

The outcomes of interest in the present study were cecum intubation rate, polyp detection rate (PDR; the number of procedures with detection of polyps ≥5 mm divided by the total number of procedures attended by the endoscopy assistant), painful colonoscopy (dichotomized to severe vs. no or slight or moderate pain), satisfaction with information (not or slightly satisfied vs. moderately or very satisfied), and whether or not sedation or analgesia was given. Administration of sedation or analgesia is not standardized in Norway, and most centers use sedatives and/or analgesics on demand (either before the colonoscopy at the patient's request or during the procedure). Analgesics used include opioids (such as fentanyl, alfentanil and pethidine), and sedatives include benzodiazepines (such as midazolam or diazepam). For the purpose of this study, the use of any of these or any combination of these drugs was termed "sedation."

We excluded assistants who had assisted in fewer than 100 colonoscopies during the 2-year study period, and centers with fewer than 200 recorded procedures. We measured assistants' experience in two ways: lifetime experience and experience during the study period. First, through email correspondence with the assistants' department heads, we obtained lifetime experience measured as years in practice as endoscopy assistants at that particular hospital before 2013 (start of the study period). Experience was categorized as <2 years, 2–4 years, 4–6 years, 6–8 years, 8–10 years, and >10 years. Second, we categorized the experience during the study period (2013–2014) by number of colonoscopies at which they assisted: 100–199, 200–299, 300–399, and 400 or more. In Norway, almost all endoscopy assistants are registered nurses.

Statistics

Categorical variables were analyzed with the chi-squared test. To explore the difference between individual endoscopy assistants, we fitted multivariable logistic regression models with the selected key performance indicator as a binary outcome variable, and endoscopy assistant, endoscopist, patient age and sex, patient pain, sedation, cecal intubation, bowel cleansing quality (BBPS score dichotomized to 1-5 vs. ≥ 6 points) and previous abdominal surgery as covariates. Using a stepwise backward deletion approach, covariates with Wald test P values >0.05 were excluded from the final models. Patient age, sex, endoscopy assistant, and endoscopist were retained in all models regardless of the value of the Wald test. Finally, the impact of the assistants' experience was evaluated by separately introducing lifetime experience and procedure volume as covariates to all models.

The results are presented as scatter plots. The assistant with the most favorable outcome at each hospital was used as the reference in multivariable models. An endoscopy assistant with an outcome odds ratio that was significantly different from the reference assistant at each hospital is indicated in red in the scatter plots. The results are arranged in ascending order for each quality indicator. This implies that the hospital indicators are not consistent between the figures. As each assistant was only working at one hospital, these analyses were performed per center. To further isolate the impact of the endoscopy assistant on the outcome PDR from the endoscopist PDR, we performed stratified analyses within levels of the endoscopist performance (PDR <20%, 20%-30%, and $\geq30\%$) for the individual assistants with suboptimal performance, using the Mantel-Haenzel method to control for strata.

All analyses were performed using Stata version 12 (StataCorp, College Station, Texas, USA), and P < 0.05 was considered statistically significant. We did not adjust

for multiple testing, as adjustment is not strictly recommended in exploratory studies, and this is also reflected in the presentation and interpretation of the results [12].

Results

Of the 23 779 outpatient colonoscopies registered in Gastronet during the study period, 15 365 were available for analysis (**Fig. 1**). A patient response form was received for 10 685 (70%) procedures. A total of 12 centers were eligible for analysis, performing a median of 1818 colonoscopies each during the study period (range 667–2261).

At the 12 participating centers, 63 assistants (median 272 procedures; range 104–996) and 66 endoscopists (median 436 procedures; range 12–1930) were available for analysis. Median lifetime experience for endoscopy assistants was 8 years (range 0–38). Baseline characteristics are presented in **Table 1**.

Assistants' performance

Variations in performance for the key performance indicators between endoscopy assistants at the 12 participating hospitals are presented in **Figs. 2–6**.

The mean center cecum intubation rate was 94% (range 83%–98%; P < 0.001 for difference between centers). One assistant had a significantly lower cecum intubation rate (92%) than the best performing peer at the same hospital (97%) (**Fig. 2**).

The mean PDR for polyps ≥ 5 mm was 23.0% (range 11%–31%; P < 0.001 for differences between centers). Four endoscopy assistants had significantly lower PDRs than the reference assistant at their respective hospital (**Fig. 3**). Details of these assistants are shown in Supplementary **Table e2** (available online).

Patient-reported outcomes

Data on pain were available for 10 559 colonoscopies. The proportion of severely painful colonoscopies was 13%, with large variation between centers (range 5%–19%; P < 0.001). Nine of the assistants had a significantly higher proportion of painful colonoscopies than the assistant with the lowest proportion at each center (**Fig. 4**). Type of colonoscopy (therapeutic vs. diagnostic) or the presence of irritable bowel syndrome (IBS) did not change the results.

Satisfaction with information about the colonoscopy was reported by 8721 patients. Satisfaction was high (91%) with some variability between the centers (range 89%–94%; P < 0.001). Three endoscopy assistants had lower satisfaction scores compared with the reference assistant at their hospital (**Fig. 5**). The inclusion of pain and sedation during the colonoscopy in the multivariable model did not change the results.

Sedation practice

Sedation data were reported for 14 916 colonoscopies. The proportion of patients who received sedation during colonoscopy was 35.0% (range 2%–73%; P < 0.001). A total of 16 endoscopy assistants from seven hospitals had significantly higher sedation rates than the reference assistant at their hospital, adjusted for age, sex, endoscopist, cecum intubation rate, bowel cleansing, and a history of previous abdominal surgery (**Fig. 6**).

Adverse events

There were 112 adverse events recorded by the endoscopists for 13 410 colonoscopies (0.8%; range 0.3%–1.8%; P = 0.01). The number of complications was too low to allow further analyses at the endoscopy assistant level.

Endoscopy assistants' experience

Data for lifetime experience were obtained for 54 out of the 63 assistants in 11 out of the 12 hospitals (13 932 procedures); the number of procedures during the 2-year study period was known for all participating assistants. Neither lifetime experience as an endoscopy assistant, nor procedure volume during the 2-year study period, were associated with any of the outcomes in the multivariable models (data not shown).

Discussion

In most hospitals in Norway, there is little variation in the performance of endoscopy assistants. However, in this exploratory study, we found that at some centers, there are variations among the endoscopy assistants that may be clinically important. Accordingly, quality assurance programs in colonoscopy should include the endoscopy assistants. They should be monitored and undergo quality assessment and training similarly to the endoscopists. It is important to make quality measures at the individual level available to endoscopy leaders in order to both improve quality among those who perform suboptimally, but also to identify those with excellent performance who can serve as teachers and role models. Continuous quality measurements might enable endoscopy leaders to detect sustained suboptimal performance, but also to compare performance at the center level against benchmark thresholds or other hospitals. **Figs. 2–6** enable such comparisons. From our results, endoscopy leaders in some of the study hospitals should clearly take a closer look at the colonoscopy quality at their centers. Both cecal intubation rates (**Fig. 2**) and PDRs (**Fig. 3**) were lower than expected.

The impact of the assistant on colonoscopy quality has not been well studied previously and has focused mainly on the assistant's experience. In two publications from the same center, experienced endoscopy nurses had fewer complications, higher

cecal intubation rates, and higher PDRs [8,9]. However, the association was only evident for very inexperienced nurses (<6 months' experience for cecal intubation and polyp detection, and <2 weeks for complications). We did not detect any differences between the assistants, based either on the number of assisted colonoscopies in the study period, or on lifetime experience as endoscopy assistants. We identified seven endoscopy assistants who started their career during the study period, but found no association with any of the colonoscopy quality indicators. One explanation for the discrepancy between our study and the former two studies, may be that we adjusted for individual endoscopists. It is well known that colonoscopy performance varies between endoscopists [13,14]. Our results indicate that experience should not automatically be regarded as being synonymous with high quality.

Endoscopy assistants are important to the local environment in endoscopy centers. In Norway, sedation practice varies widely [15,16]; there is no standard for sedation during colonoscopy in Norway, which is reflected in the large variation between centers (2%–73% of patients received some kind of medication before or during the examination). Most centers practice sedation on demand. From our results, it seems that not only the endoscopists, but also the assistants, are important in offering sedation during colonoscopy. Interestingly, even if there were large differences between assistants with respect to sedation, there were fewer differences in severe pain experienced by patients. The reason may be that the assistants, together with, but also independently of, the endoscopist, are skilled at detecting patients who may benefit from sedation. One explanation for differences in pain perception in patients might be case-mix, with different rates of polypectomy or proportion of patients with IBS. However, including type of colonoscopy or IBS in the multivariable models did not alter the results.

The strengths of the current study include the prospective registration of real-life data, the large number of assistants involved, the inclusion of multiple hospitals, and adjustment for multiple confounding factors.

To obtain meaningful results at the assistant level, we analyzed our data per center to take into account the endoscopist and the difference in patient population at each center. Because the results should be interpreted within each of the 12 centers by comparing the endoscopy assistant with the best performance of the other assistants at that center, we did not apply methods to adjust for multiple testing (e.g. Bonferroni correction). Therefore, we analyzed the data separately for each individual center. We expect no dependency even if multiple testing was performed. The Bonferroni correction has been criticized for being too conservative and for increasing the probability of false-negative findings [17], and in explorative studies such as the current study, adjusting for multiple testing is not strictly recommended [12].

Cecum intubation rate and ADR (PDR) are the most studied quality indicators, and it is reassuring that there was little variation that could be attributed to the endoscopy assistant. In 4 out of the 12 hospitals, however, there were statistically significant differences among the nurses in PDRs. At one of these hospitals, the PDRs for individual assistants varied between 17% and 29%. This difference is probably clinically meaningful, and the reason for this inequality should be explored at that hospital. Importantly, the difference may be due to unmeasured confounders that do not apply to the endoscopy assistant. Interestingly, the endoscopy assistant with the lowest PDR consistently detected fewer polyps than the endoscopy assistant with the highest PDR when the results were stratified by endoscopist PDR (**Table e2**, available online). This may imply that endoscopists with both high and low PDRs may gain

additional and valuable help from skilled endoscopy assistants in improving their PDR.

There are important limitations to the present study. First, our results should be interpreted with caution as they represent a cross-sectional view of the assistants during a limited period of time. The present study should be considered as exploratory and hypothesis generating, and the results should be confirmed with repeated audits before acting on individual performance. Second, selection bias cannot be ruled out, as the response rate was not 100%. It is important to consider selection and other potential biases when individual performance is considered. The bias may occur both at the endoscopist level (the procedure form was not complete for all colonoscopies), and at the patient level (the response rate was 70%). Furthermore, the hospitals' coverage (the proportion of colonoscopies reported to Gastronet of all the colonoscopies performed at that hospital) has been shown to vary widely (13%–99%) [18]. Even if selection bias due to low coverage seems unlikely in the present study, it cannot be ruled out. Finally, Gastronet covers only about one third of Norwegian hospitals, which may limit generalization of our results [18]. Importantly, the crude rates displayed in the scatter plots may be misleading and should be interpreted with caution. These rates are not adjusted for important confounders such as endoscopist and case-mix. Furthermore, we did not detect any impact of experience as an endoscopy assistant on the performance indicators. It should be noted that experience in the present paper is limited to the experience at that specific hospital. We did not have any information on work experience before the assistants started at the study hospitals. However, we do not think that this limitation has a great impact on our results, as domestic migration within Norway is limited. Polyp histology is not recorded in Gastronet because automatic linkage to pathology results is not possible.

Thus, the PDR in our study is only a proxy for the more common ADR. However, the ADR and PDR are correlated, and the latter is recommended as a performance indicator by the ESGE [4].

It is important to interpret the results of this exploratory study in the context of interindividual variation. The purpose of our analyses, using logistic regression models,
was not to categorize endoscopy assistants into good vs. bad, but rather to show that
there are differences between the assistants, even when multiple confounders are
taken into account. And when there are differences, the reasons should be explored
and action should be taken to ensure equal quality of the endoscopy service regardless
of where the service is provided. This is the core of all quality assurance.

Finally, the performance indicators evaluated in the present study are not specific to measure performance of the endoscopy assistant, and need adjustment for multiple confounders. Future studies should identify and evaluate quality measures that more robustly measure the quality of the assistant. As colonoscopy performance measures are heavily dependent on the endoscopist, the ideal study design would be a randomized trial; in such a trial, each endoscopy assistant should be randomly assigned to different endoscopists in order to effectively control for endoscopist-related confounders. The outcomes, or endoscopy assistant quality indicators, may vary between countries, depending on the role of the endoscopy assistant. Quality indicators may be identified by endoscopy and endoscopy assistant leaders, but also through analyzing data from existing quality registers such as Gastronet. According to our results, pain and sedation are obvious candidates. Quality indicators may also be identified using focus groups, including both endoscopy assistants and patient-representatives. Implementation of endoscopy assistant quality metrics should be an

integrated part of the continuous quality improvement initiatives that should be in place at all endoscopy centers.

In conclusion, this exploratory study showed that at most hospitals in Norway, the endoscopy assistant has little impact on key colonoscopy performance indicators. However, results indicated that there are variations among endoscopy assistants that may be clinically meaningful, and experience is not synonymous with high quality. The endoscopy assistants are important during colonoscopy, and their performance should be monitored in the same manner as for endoscopists. Quality indicators that specifically measure the endoscopy assistant should be identified and evaluated in prospective studies with pre-specified hypotheses. Quality data should be made available to endoscopy leaders in order to facilitate improvement and better patient care.

Competing interests: Dr. Holme has received lecture fees from Norgine and AstraZeneca.

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Fig. 1 Patient flow chart.

- **Fig. 2** Cecal intubation rate. Each marker represents one endoscopy assistant, and shows the cecal intubation rate for their colonoscopies at 12 hospitals. The red marker indicates one endoscopy assistant with lower cecal intubation rate (P < 0.05) than the assistant with the highest cecal intubation rate at that center. The differences between the assistants were obtained from a multivariable logistic regression model, with sex, age, abdominal surgery history and Boston Bowel Preparation Scale score as covariates.
- Fig. 3 Polyp detection rate (PDR). Each marker represents one endoscopy assistant, and shows the average PDR (polyps ≥5 mm) for their colonoscopies at 12 hospitals. The red marker indicates endoscopy assistants with lower PDRs (*P* < 0.05) than the assistant with the highest PDR at that center. The differences between the assistants were obtained from a multivariable logistic regression model, with patient sex and age, cecal intubation rate, endoscopy assistant, endoscopist, and Boston Bowel Preparation Scale score as covariates.
- **Fig. 4** Pain during colonoscopy. Each marker represents one endoscopy assistant, and shows the proportion of their colonoscopies reported to be severely painful by the patient. The red markers represent assistants with a

significantly higher proportion of painful colonoscopy than the assistant with the lowest proportion of painful colonoscopies at that center. The differences between the assistants were obtained from a multivariable logistic regression model, with endoscopy assistant, endoscopist, age, sex, previous abdominal surgery history, Boston Bowel Preparation Scale score, and sedation as covariates.

- Fig. 5 Satisfaction with information about the colonoscopy. Each marker represents one endoscopy assistant, and shows the proportion of patients who were satisfied with the information they received at 12 hospitals. The red markers represent assistants with a significantly lower proportion of satisfied patients than the assistant with the highest proportion of satisfied patients at that center. The differences between the assistants were obtained from a multivariable logistic regression model, with endoscopy assistant, endoscopist, age, sex, previous abdominal surgery history, Boston Bowel Preparation Scale score, and sedoanalgesia (yes/no) as covariates.
- **Fig. 6** Sedation during colonoscopy. Each marker represents one endoscopy assistant, and shows the proportion of examinations with sedation (including analgesics). Red markers represent assistants with a higher proportion of patients with sedation (P < 0.05) than the assistant with the lowest proportion of patients with sedation at that center. The differences between the assistants were obtained from a multivariable logistic regression

model, with endoscopy assistant, endoscopist, age, sex, previous abdominal surgery history, cecal intubation rate, and Boston Bowel Preparation Scale scoreas covariates.

Table 1 Baseline characteristics.

	Patients (n = 15 365)
Sex, n (%)	
Male	7131 (46)
Female	8234 (54)
Age, median (range), years	62 (16–103)
Previous abdominal surgery, n (%)	4248 (28)
Indication for colonoscopy, n (%)	
Symptoms	9998 (65)
Surveillance*	4081 (27)
Other	668 (4)
Unknown	618 (4)
Procedure type, n (%)	
Diagnostic	11 665 (76)
Therapeutic†	2338 (15)
Not specified	1362 (9)
Insufflation gas used, n (%)	
Air	1711 (11)
CO ₂	12 377 (81)
Not specified	1277 (8)

^{*}Post-polypectomy, post-colorectal cancer treatment or dysplasia surveillance for inflammatory bowel disease.

[†]Colonoscopy with treatment (e.g. polypectomy).

Table e2 Polyp detection rate (PDR). Detailed results are displayed for the four centers in which there were differences (P < 0.05 in multivariable regression analyses) between the endoscopy assistant with the highest vs. lowest PDRs. Endoscopists were categorized according to their PDRs: <20%, 20%–30%, and ≥30%. The table shows that the high-detector endoscopy assistant (denoted number 2 in the table), with one exception, detects more polyps than the low-detector assistant (denoted number 1 in the table) when they work with endoscopists with similar PDRs.

	Polyp detection rate		P value
	Endoscopy assistant 1 (Lowest PDR)	Endoscopy assistant 2 (Highest PDR)	_
Center 1			
PDR overall (nurse)	<mark>17%</mark>	<mark>29%</mark>	0.01
PDR (endoscopist)			0.02
<20%	<mark>12%</mark>	<mark>22%</mark>	
20%–30%	<mark>16%</mark>	<mark>32%</mark>	
≥30%	<mark>29%</mark>	<mark>36%</mark>	
Female sex	53%	52%	0.87
Age, mean	60 years	59 years	0.35
BPPS ≥6	91%	94%	0.17
Center 2			
PDR overall(nurse)	21%	33%	0.02
PDR (endoscopist)			0.02
<20%	13%	18%	
20%–30%	15%	35%	
≥30%	40%	40%	
Female sex	52%	57%	0.42
Age, mean, years	59	62	0.01

BPPS ≥6	90%	91%	0.76
Center 3			
PDR overall (nurse)	24%	36%	0.03
PDR (endoscopist)			0.03
<20%	N/A	N/A	
20%–30%	17%	33%	
≥30%	30%	38%	
Female sex	48%	58%	0.12
Age, mean, years	60	62	
BPPS ≥6	94%	96%	0.64
Center 4			
PDR overall (nurse)	28%	31%	0.42*
PDR (endoscopist)			0.09
<20%	5%	17%	
20%–30%	27%	21%	
≥30%	30%	40%	
Female sex	52%	57%	0.23
Age, mean, years	62	61	0.37
BPPS ≥6	96%	98%	0.33

PDR, polyp detection rate; BBPS, Boston Bowel Preparation Scale; N/A, not applicable.

^{*}P < 0.05 in multivariable model only.



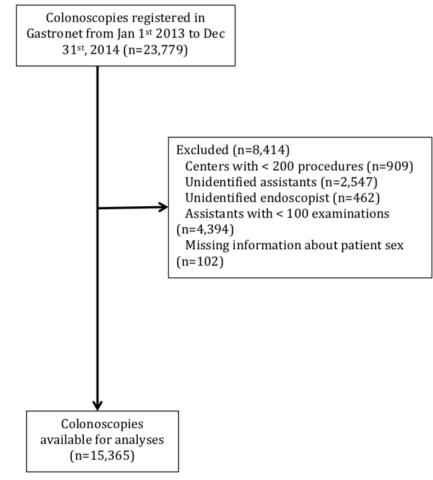


Figure 2A: Cecal intubation rate.

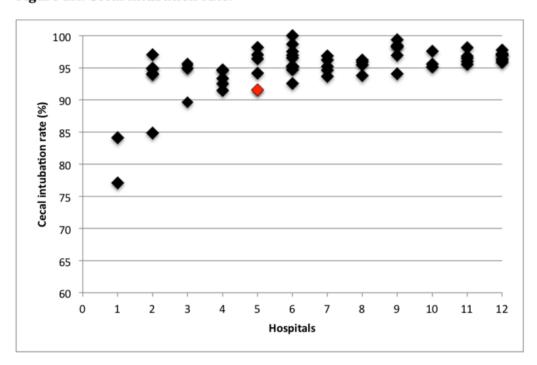


Figure 2B: Polyp detection rate.

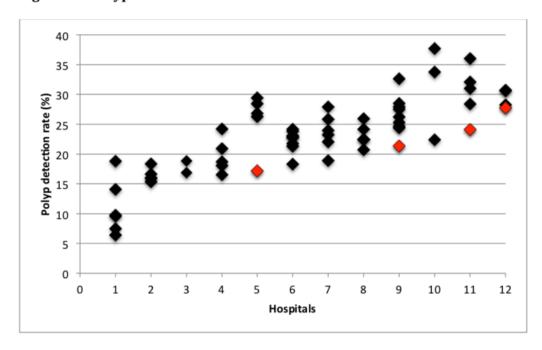


Figure 2C: Pain during colonoscopy.

