bleeding or perforation. In spite of initial endoscopic appearance of complete resection f/u EGD reveals residual adenoma in every fifth case which can however be endoscopically re-treated.

S1398

Adherence to ASGE & ACG Task Force Quality Guidelines: Inadequate Colonoscopy Report Documentation Is Common in Transcription-Based Reporting Systems

Chakri Panjala, Benjamin P. Dalton, Neal C. Patel, Massimo Raimondo, David S. Loeb, Kenneth R. Devault

Background & Aim:Effectiveness of colonoscopy depends on preparation quality, adequate visualization and diligent examination of the colon. This is necessary to optimize the effectiveness of recommended intervals between screening and surveillance examinations. The American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG) task force published quality indicators for colonoscopy performance at each stage: pre-procedure, intra-procedure and post-procedure (GIE. Volume 63, No. 4: 2006 S1) in hopes of improving the quality of endoscopic care. Compliance is most often assessed by reviewing procedure documentation. In addition to meeting quality guidelines, the endoscopy report is used to guide future screening and surveillance intervals. Inadequate documentation therefore leads to poor patient care in addition to impaired cost effectiveness. In this study we review the variations in our transcription-based colonoscopy reports. Methods:This is a retrospective chart review of patients who underwent colonoscopy. Following data were extracted from their colonoscopy reports. Pre-procedure: indications, consent, surveillance intervals; intra-procedure: preparation documentation, cecum identification and photo documentation, polyp detection rate, withdrawal times, biopsies in chronic diarrhea; post-procedure: complications rate and management, post procedure follow up.Results:A total of 400 random colonoscopy reports performed in the months of July and August, 2009, by 20 different endoscopists, were reviewed. The median age of the patients was 62 yrs (17-88 yrs); M: 203; F: 197). Results, mainly noted deficiencies, are in the enclosed table.Conclusions:A review of our transcription-based colonoscopy reports identified the following areas for improved documentation; 1-Documentation of colon preparation, 2-photo documentation of cecum, 3-recording withdrawal time, 4-describing polyp characteristics and 5-documentation of post-procedure follow-up. We believe standardized templates and electronic and automated documentation at the time of procedure itself will translate into higher standards and increase adherence to ASGE and ACG task force guidelines.

Table 1

Total procedures reviewed	400
Indication (multiple in some cases)	Screening: 198 Surveillance: 134 Symptomatic: 159
Referral	GI: 19.5% (78) Non-GI: 78% (313) Undocumented: 2.5% (9)
Colon preparation	Undocumented: 34.5% (138)
Cecal landmarks and intubation	Undocumented: 4.75% (19) h/o surgery: 9
Photo documentation	Undocumented: 84% (336)
Withdrawal time	Undocumented: 84.5% (338) Median: 11 min (7- 61)
Polyp detection & characteristics	Detection rate: 41% (164) Median # of polyps: 2 (1-10) Location documentation: 100% Size documentation: 100% Flat/sessile/ pedunculated - Undocumented: 60% (99)
Post-procedure follow up (up to 2 weeks)	GI: 18.75% (75) Non-GI: 60.75% (243) Undocumented: 20.5% (82)

S1399

A Phase IB Study of the Safety and Efficacy of Multiple Doses of CNS 7056 in Volunteers Undergoing Colonoscopy, Including Reversal With Flumazenil

Mark T. Worthington, Laurie Antonik, D. Ronald Goldwater, Jacqueline Mazza, Isaac C. Fleming, James Lees, Karin Wilhelm-Ogunbiyi, Keith M. Borkett, Mack C. Mitchell

Fast onset/rapid clearance endoscopic sedation (FORCES) is increasingly popular. Propofol is typically administered by anesthesiologists due to a narrow therapeutic index and a lack of reversal agents. A novel benzodiazepine, CNS 7056, is metabolized by tissue esterases (not cytochrome P450) with a faster onset, a shorter duration, and more rapid recovery profile than other available drugs. We performed the first study of CNS 7056 as sedation for colonoscopy. Method: 51 healthy volunteers were enrolled in a Phase 1b study to evaluate the safety and efficacy of CNS 7056 during colonoscopy. All procedures were performed without supplemental oxygen. To assess reversibility, 6 volunteers received 0.25 mg/kg CNS 7056 followed by placebo or flumazenil using a double-blind cross-over design on 2 consecutive days. With reversal agent administered 3 min after CNS 7056,sedation levels were measured serially, with no colonoscopy performed. For colonoscopy, 3 cohorts of 15 volunteers each were given fentanyl 50 μg, followed by 0.04, 0.075 or 0.10 mg/kg CNS 7056. The colonoscopy was started when subjects reached adequate sedation (MOAA/S $\leq$ 3), and up to 6 additional doses of 0.04 mg/kg CNS 7056 given to maintain sedation (MOAA/S $\leq$ 4) for 30 min. Sedation was also measured via standard scales including Bispectral index and Aldrete score. Success was defined as complete colonoscopy, 3 successive MOAA/S $\leq$ 4, no requirement for alternative sedation or supplemental ventilation, and sedation for 30 min. Results: Flumazenil rapidly reversed CNS 7056 sedation (1.3 v 16.3 min for placebo) without resedation. 10/15, 15/15 and 9/14 patients in the 0.04, 0.075 & 0.10 mg/kg dosing groups achieved complete success as defined. 1 subject at 0.10 mg/kg was insufficiently prepped. Failures were inability to sedate in 9/10 and 1/10 with hypotension and SaO2 $<$ 90%. SaO2 was maintained above 90% otherwise at all doses on ambient air. A MOAA/S of 5 (no lethargy) was achieved in 11.1$\pm$4.77 min after the last injection in all subjects with a successful procedure (all doses) and no resedation. Aldrete scores $\geq$9 (wide awake and functional) were achieved in 23.9$\pm$12.31, 24.1$\pm$17.20, and 23.0$\pm$13.07 min in the respective dosing groups. Conclusion: CNS 7056 has the attributes of a good FORCES agent, with results comparable to recent studies of other drugs. It is easily reversible and provided safe and adequate sedation in 34/45 subjects undergoing colonoscopy. Further studies are needed using standard colonoscopy patients under more typical conditions prior to widespread clinical use. The PD/PK results of this study are now being used to optimise the dose regimen for a Ph IIb study.

S1400

Renal Risks of Sodium Phosphate Tablets for Colonoscopy Preparation: A Review of Adverse Drug Reactions (ADRs) Reported to the Food and Drug Administration (FDA)

Eli D. Ehrenpreis, Deepak Parakkal, Rumi Semer, Hongyan Du

Background: Sodium phosphate-containing colonoscopy preparations are known to cause renal failure by the development of calcium-phosphate nephropathy. Although Fleet's Phospho-Soda has been removed from the US market, sodium phosphate tablets, sold as Osmoprep and Visicol, remain available. Because there are few reports of renal ADRs from tablets, fluid consumption is predictable and patient acceptance is high, prescription of these agents continue.Purpose of the study: To review renal ADRs reported from sodium phosphate colonoscopy preparations, including tablet forms.Methods: The FDA ADR database is available for public access. Individual reports were downloaded as ASCII files and analyzed using a database created with the Access program (Microsoft Corp., Redmond, WA). Data was queried for all sodium phosphate preparations. Cases analyzed included reports of renal ADRs as defined by the authors. Search terms included renal impairment, increased blood urea nitrogen, increased creatinine, hemodialysis, glomerular filtration rate decreased, creatinine clearance decreased, phosphate nephropathy, renal tubular necrosis, nephropathy toxic, dialysis, renal injury and renal tubular disorder. Patient age, gender and body weight were compared to data for the general population in the National Health and Nutrition Examination Survey (NHANES). Results: A total of 1,967,150 files were extracted from the FDA website for 2004, 2005, 2006, 2007, 2008 and first 6 months of 2009. 869 patients with renal ADRs were identified (75 % females) with 719 cases from liquid and 150 from tablet preparations. Body weight data was available for 288 cases. Increasing numbers and percentages of renal ADRs were reported from tablet preparations each year peaking in 2008. In 2006, 9 of 74(12%) renal ADRs were from tablets. In 2007, 40 of 181 (22%) and in 2008, 46 of 148 (31%) renal ADRs were reported from tablet preparations. Mean body weight for adult females (age 20 years and older) with renal ADRs secondary to tablet preparations was 68.37 kg, compared to the national average weight of 74 kg for the same age group ($p=0.003$). Conclusion: This study shows that rare, but underappreciated renal ADRs occur from tablet forms of sodium phosphate colonoscopy preparations. Females of lower body weight represent the highest risk group for renal ADRs from tablet forms of sodium phosphate.

S1401

The Prone 12 O'Clock Position Reduces Ileal Intubation Time During Colonoscopy Compared to the Left Lateral 6 O'Clock (Standard) Position

Arjuna P. De Silva, Ravindu S. Kumarasena, Suramya P. Keragala, Kaiubowila V. Udayapushpa, M. A. Niriella, A. S. Dassanayake, Arunasalam Pathmeswaran, H. J. De Silva

Introduction Ileal intubation is the gold standard for evidence of a complete colonoscopy. However, despite evidence of clinical benefit, ileoscopy is not always attempted due to perceived technical difficulty. Although several studies have previously reported on the time taken for ileal intubation, such timings have not been standardized. Aim To compare time taken for ileal intubation

using a new position - the prone 12 o'clock position (PP) - with the standard method (left lateral 6 o'clock position-LLP). Methods We first performed a pilot study using fluoroscopy to determine the best patient position for the most direct (end-on) approach to the ileo-caecal valve. The prone 12 o'clock position appeared to be the best position. We then randomized consecutive patients having colonoscopy, aged 18-80 years and who were not pregnant, to undergo ileoscopy in the standard position or the prone 12 o'clock position. After the ileo-caecal valve was identified during colonoscopy, ileal intubation time was standardized and defined as the time taken for the tip of the colonoscope to be maneuvered from the mid-point of the caecum to entering the terminal ileum.Results Colonoscopy was performed on 150 patients [82 females, mean (SD) age 53 (16) years]. 75 patients were randomized for ileal intubation in the PP and 75 patients in the LLP. Overall, the ileum was successfully intubated in 145 (96%) patients [74 (98.7%) in the PP and71 (94.7%) in the LLP]. The mean (SD) ileal intubation time was 26.4 (63) seconds in the PP and 96.9 (112) seconds in the LLP ($p<0.0001$; Student t-test). The ileum was abnormal in 11 (7.5%) patients: 6 in the PP group and 5 in the LLP group. Conclusions During colonoscopy, the prone 12 o'clock position gives a more direct approach to the ileo-caecal valve and significantly reduces ileal intubation time when compared to the standard left lateral 6 o'clock position.

S1402

Interobserver Variability and Accuracy of High-Resolution Endoscopic Diagnosis for Intestinal Metaplasia Among Experienced and Non-Experienced Endoscopists

Yil Sik Hyun, Dong Soo Han, Joong Ho Bae, Hye Sun Park, Sang Bong Ahn, Tae Yeob Kim, Chang Soo Eun, Yong Cheol Jeon, Joo Hyun Sohn

Background and Aims: Gastric cancer is the second highest cause of cancer-related deaths worldwide. Intestinal metaplasia (IM) has been known to be a premalignant lesion or condition; however there is no gold standard for diagnosing IM. Although several useful techniques combined with the aid of endoscopy have been suggested to accurately diagnose IM, the cost-effectiveness of these modalities has been questioned. Recently, a widely used high-resolution endoscopy made it possible to observe even the mucosal pit pattern and improve diagnostic accuracy of mucosal lesions. The aim of this study was to assess the interobserver variability and accuracy of the high-resolution white-light endoscopy as a diagnostic tool for IM. Methods: A total of 50 cases (31 histopathologic IM) were selected from 1596 cases, of which 1 case consisted of 4 high resolution still images. Afterwards, the selected cases were sent for interpretation to five experienced and five non-experienced endoscopists; answers were composed of only three types (IM, gastritis, or others). The interobserver agreement was measured by intraclass correlation analysis while the diagnostic accuracy was analyzed using histopathology as reference standard. Results: The interobserver agreements of experienced (κ=0.316) and non-experienced endoscopists (κ=0.354) were poor. Experienced endoscopists had better diagnostic accuracy (76% vs 60%), positive predictive value (85.2% vs 70%) and negative predictive value (65.2% vs 50%) than non-experienced endoscopists.Conclusion: A high-resolution endoscopy is not a reliable diagnostic tool for IM because of the poor interobserver agreement. The diagnostic accuracy of experienced endoscopists is higher compared with non-experienced endoscopists. For a more reliable and accurate diagnosis of IM, additional diagnostic modalities apart from high resolution endoscopy are required, as well as a professional endoscopic education.

S1403

Assessment of Colonoscopy Reporting in a Multicenter Study Using the ASGE Quality Assurance Task Force Guidelines

Jerome Sint Nicolaas, Vincent De Jonge, Onno Van Baalen, Frank Ter Borg, Johannes T. Brouwer, Han Geldof, Sjam. Ganesh, Antonie J. P. Van Tilburg, Monique E. Van Leerdam, Ernst J. Kuipers

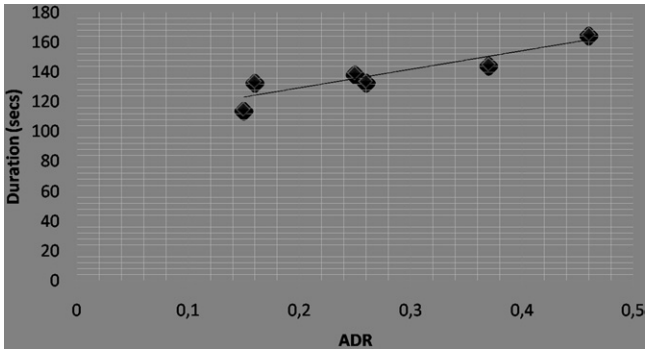
IntroductionTo adopt continuous quality assurance (QA) initiatives for colonoscopy, it is important to identify quality indicators concerning technical performance which can be monitored in clinical practice. Quality of colonoscopy cannot be measured or improved if data are not properly captured and recorded. The ASGE therefore defined quality indicators for colonoscopy reporting. The aim of this study was to assess to what extent these indicators were reported in daily practice.MethodsColonoscopy reports were reviewed in 7 endoscopy centers (1 academic, 6 general, 200 consecutive reports per site) from March to April 2009. Data captured included patient demographics, colonoscopy indication, medical history, procedural characteristics (i.e. cecal intubation, quality of preparation, findings) and interventions. Although 3 out of 7 hospitals perform pre-colonoscopy assessments and report on medical history and informed consent in the patient file, we did not capture these data and only reviewed the colonoscopy report.ResultsA total of 1,442 reports (male: 46%; mean age: 58 yrs ±16) were collected. Written consent is not obligatory in our environment and none of the reports had data about consent procedure. ASA-classification was also not included in the reports. Medication usage and relevant history for cardiovascular disease or surgery were reported in respectively 7%, 14% and 34% of reports.Digital rectal examination was reported in 50%. In 33% the quality of preparation was not mentioned. The extent of the bowel examination was reported in 96% and cecal intubation was achieved in 90%. Cecal landmarks were photo documented in 69% of cases. Photo documentation of the colon was provided in 75% of the reports. Retroflexion of the endoscope in the rectal ampul was recorded in 28%. Total procedure time could not be extracted in 78%. In total 1,306 polyps were found in 531 patients. Polyp characteristics including size, anatomical location and morphology were reported in respectively 50%, 75% and 44%.Perforation occurred in 1 patient (0.07%), bleeding after polypectomy in 1% of all procedures. Interventions for adverse events such as clip placement or argon plasma coagulation were reported in 60% respectively 27% for bleeding.ConclusionsUsing the ASGE guidelines for endoscopy reporting as a standard, relevant information regarding colonoscopy performance is lacking or insufficient in a large proportion of Dutch clinical practice. This is likely to reflect the overall situation in a considerable proportion of European practices. To contribute to continuous QA in colonoscopy, a standard approach for reporting in key indicators needs to be encouraged.

S1404

Association Between Visual Gaze Patterns and Adenoma Detection Rate During Colonoscopy

Cristina Almansa, Muhammad W. Shahid, Susanne Preissler, Michael B. Wallace

Eye tracking technology makes possible to follow a person's gaze and record the resulting visual gaze pattern (VGP). Research studies have found differences in VGP when comparing subjects of different experience levels performing a given task. For colonoscopy withdrawal time, washing and optical factors are associated with quality as measured by higher adenoma detection rates (ADR), but there is no data on VGP. We hypothesized that different VGP were associated with higher ADR. Aims: To quantify the VGP for endoscopists observing standardized colonoscopy videos and describe the association between VGP and ADR. Methods: We previously measured the ADR for 18 endoscopists in our center from 2006-07 during 2502 colonoscopies. For this pilot study we selected 6 endoscopists, 2 with the lowest, 2 highest, and 2 average ADR. They watched 3 videos under similar conditions while their VGP was recorded by an eye tracking system (ASL Mobile Eye, Beford, MA). The videos were displayed on a standard high definition endoscopy monitor and corresponded to uncompressed HD segments from 3 normal colonoscopy withdrawals. We calculated the percent of gaze in each of 9 segments of the screen: 8 peripheral and 1 central. We compared the percent of gaze time in the central vs. peripheral screen according the rate of ADR with student test and linear regression. Results: The 3 groups of endoscopists had ADRs of 15%(low), 26%(average), and 41%(high). All subjects spent more gaze time in the central portion of the screen compared to the periphery (73.2 ± 8.6 vs. 26.8 ± 8.6; $p<.0001$). ADR was associated with percentage of gaze time ($R=.624$) and total gaze time in the central screen ($R=.917$) (figure 1). Conclusions: In this pilot study, there appears to be an association between VGP and ADR. High adenoma detectors tend to focus on the central portion of the screen, whereas low detectors move their gaze more broadly across the screen. If confirmed in a larger sample, these data can be used to retrain low ADR endoscopists and test whether this improves colonoscopy quality



Time in central screen related to ADR