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Colorectal Cancer Screening in Chinese Immigrants: Who Can Deliver the Message?

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Background: Colorectal cancer (CRC) ranks third in cancer incidence and mortality in Asian Americans. Studies on colorectal cancer in Asian Americans suggest that screening rates are among the lowest reported. Barriers to colorectal cancer screening (CRS) in immigrants include language, access and absence of routine health care. The effectiveness of ethnic and culturally specific community outreach on colorectal screening in Chinese immigrants has not been previously reported. This study compares the effectiveness of physician directed compared to lay health educator directed CRS programs in Chinese immigrant communities. Methods: Chinese community based organizations were asked to randomize their clients aged 50 and above into two CRS programs. Physician directed programs used Asian, non-Chinese speaking physicians coupled with a trained medical interpreter for CRC education and fecal occult blood testing (FOBT), while lay educator programs (LHE) used peer educators for education on CRC and FOBT. All participants completed a translated survey on CRS compliance, CRC risk perception and knowledge gained. The effectiveness of each educational program on CRS behavior was assessed by compliance with fecal occult blood testing (FOBT). Results: 260 participants attended CRC programs. The average age was 54; 55% were women, the average years in the US was 10. 80% of participants reported speaking Chinese at home and were of limited English proficiency. 5% of participants in the MD group (n=135) completed the FOBT, compared to 76% in the LHE group (n=125). Overall, 30% were found to have a positive FOBT. 75% in the MD group and 85% in the LHE group reported a gain in knowledge about CRC and CRS. Conclusions: In this study, Chinese immigrants were significantly less likely to comply with FOBT when education was delivered by Asian, non-Chinese speaking physicians. In stark contrast, the same program delivered by a peer educator (a respected member of their community) resulted in an extremely high FOBT compliance. Since no significant difference in knowledge gained between the two groups were reported, these differences cannot be attributed to language barriers. Given the high rates of positive FOBT in this population, this study highlights the importance of community based and community directed education in hard to reach populations.

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Variation in Polyp Detection Rates At Screening Colonoscopy

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Background: Wide variation in adenoma detection rates has been found in the U.K. Flexible Sigmoidoscopy Screening Trial. This variation, attributed to endoscopist performance, has been used to justify the need for establishing quality standards for performance of colonoscopy. Purpose: The objectives of this study were to measure, in a program of screening colonoscopy, variation in polyp detection rates (PDRs) and to identify factors associated with PDRs. Methods: We reviewed summary-level data from endoscopists who performed at least 40 first time screening colonoscopies for the Lilly Colorectal Cancer Prevention Program between 9/1995 and 6/2001. Summary-level data include mean age, mean procedure time (MPT), gender distribution, and % persons with any polyp, any adenoma, any polyp >= 1.0 cm, and multiple polyps. We described the variation in PDRs and used boxplot analysis to identify outliers. Multivariable regression modeling identified factors associated with PDRs and that accounted for some of the variability in PDRs. Results: 2664 screening colonoscopies (1108 [42%] in women, 1556 in men) were performed by 25 endoscopists, whose number of procedures ranged from 40 to 207. Overall mean patient age was 59 years (mean age range, 56 to 62 yr), the mean % women was 42% (range, 29-52%), and MPT was 17.1 minutes (range, 9.7-31 min). Mean PDRs, ranges, number of outliers, and outlier values are in the Table. Regression models that included procedure N, mean age, % women, and MPT accounted for 42% of the variation in PDRs for any polyp, 56% of the variation in PDRs for any adenoma, 37% for large polyps, 36% for > 1 polyp, and 46% for >1 adenoma. In all models, only MPT was significantly associated with PDRs. For the endoscopists with the shortest (9.7 minutes; N=80) vs. longest (31 min; N=56) MPTs, respective PDRs for any polyp, any adenoma, polyps >= 1 cm, > 1 polyp, and > 1 adenoma were 20% vs. 82%, 15% vs. 43%, 0% vs. 12.5%, 7.5% vs. 50%, and 6.3% vs. 25% (all P-values < 0.003). Conclusion: PDRs vary widely among screening colonoscopists, though only a few (high) outliers were identified. Variation in PDRs was significantly associated with MPT, but not with age, gender, or the number of procedures. Further research is needed to understand the reasons for variation, and requires attention to patient risk factors, scope withdrawal time, and quality of the prep.

	Any polyp	Any adenoma	Polyp >= 1cm	> 1 polyp	>1 adenoma
Mean PDR	36%	20%	5.3%	15%	6.8%
PDR range	13-82%	7-44%	0-13%	1.3-50%	1.3-25%
# Outliers	1	2	3	1	1
Outlier values	82%	43%,44%	10%,11%,13%	50%	25%

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The Impact of Literacy On Colonoscopy

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Background and Aims Approximately 20-30% of attempted colonoscopies are incomplete because of poor bowel preparation. This problem is not only costly and wasteful, but increases risks and delays diagnosis and treatment. Although literacy skills are necessary for patients to successfully follow home bowel preparation instructions, they are nearly impossible to assess informally. Our aim was to evaluate the impact of literacy on bowel preparation and completion of colonoscopy, with the ultimate objective of redesigning instructions to be more effective, regardless of patients' literacy skills. Methods We performed a prospective cohort study at a large urban public hospital during the summer of 2005 among patients who presented for outpatient colonoscopy. Before the colonoscopy, literacy was assessed using the 7-minute test of functional health literacy. Using structured interviews, we also gathered information on patients' past history, beliefs, and self-reported behaviors on bowel preparation. Results of the colonoscopy were obtained from the procedure reports. Results The sample of 195 subjects included 64% women, 49% African Americans, and 40% with low literacy skills. 25% of colonoscopies were not completed, primarily (90%) because of poor bowel preparation. Low literacy increased the risk of an incomplete exam 4-fold: 12 % incomplete exams among patients with adequate literacy skills compared to 45% with low literacy skills (p<0.001). Other important predictors of an incomplete exam were: eating lunch or dinner the previous day, not taking the bisacodyl (p=0.001), and not finishing the 1-gallon polyethylene glycol solution (p=0.01). Patients with a past history of colonoscopy (p=0.03) and those who received additional oral instructions from a physician or nurse (p= 0.05) were more likely to have a complete colonoscopy. Low literacy remained the strongest independent predictor of incomplete colonoscopy after controlling for the contribution of all other factors (OR=8.7; 95% CI: 3.4-22.1; p<0.001). Discussion/Conclusion Low literacy accounts for 30% of all incomplete colonoscopies. This important effect is independent of age, gender, ethnicity, and even whether oral instructions supplemented the written instructions. In light of these findings, we must redesign our methods of instructing patients about bowel preparation in order to improve the efficiency and effectiveness of colonoscopy.

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Prevention of Low Dose Aspirin-Associated Gastroduodenal Ulcers and Upper Gastrointestinal Symptoms in Patients Receiving Esomeprazole 20 Mg Per Day

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OBJECTIVE: To assess whether esomeprazole reduces the incidence of ulcers in patients taking low dose (75-325 mg daily) aspirin (acetylsalicylic acid). METHODS: Male or female *Helicobacter pylori*-negative patients ≥60 years with a condition requiring daily low dose aspirin, at risk of developing gastroduodenal ulcers were included in this randomized, double-blind, multicenter, placebo-controlled trial. Patients were excluded if they had upper gastrointestinal symptoms, including heartburn, that required treatment, or if they had erosive esophagitis. Patients with Los Angeles Grade A lesions and without reflux symptoms requiring treatment could be included. Patients were randomized to receive either esomeprazole 20 mg or placebo once daily (qd) for 26 weeks. Patients continued to receive the aspirin dose they were taking when enrolled into the study. The primary outcome variable was the presence of gastric and/or duodenal ulcers at endoscopy over the 26-week period. We present data from endoscopy taken at 26 weeks. RESULTS: A total of 991 patients (57.1% male, mean age 69.3 years, median aspirin dose 100.0 mg, 89.0% taking aspirin for >4 weeks) were included in the intent-to-treat population. Eight patients (1.6%) had developed a gastroduodenal ulcer in the esomeprazole group by 6 months, compared with 27 patients (5.4%) in the placebo group (p=0.0007). This corresponded to a relative reduction of developing an ulcer of 70% when taking esomeprazole rather than placebo. The related life table estimates were 1.8% for esomeprazole and 6.2% for placebo. In patients with Grade A esophageal lesions at baseline and with pre- and post-baseline data, 13 patients (28.3%) in the esomeprazole group had Grade A lesions at week 26, compared with 37 patients (71.2%) in the placebo group (p<0.0001). Resolution of investigator-assessed aspirin-associated upper gastrointestinal symptoms (rated as none to severe) was significantly higher with esomeprazole than with placebo for epigastric pain, burning and discomfort, as well as heartburn and bloating (p<0.05 for all symptoms). Esomeprazole was safe and well-tolerated. CONCLUSIONS: Esomeprazole 20 mg qd is more effective than placebo and is well-tolerated in reducing the risk of developing gastroduodenal ulcers and resolving upper gastrointestinal symptoms associated with low dose aspirin use in patients at moderate-to-high risk of developing ulcers. At risk patients taking low dose aspirin may therefore benefit from co-administration of esomeprazole.

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Effects of Concomitant Aspirin (81 mg qd) On Incidence of Gastric and/Or Duodenal Ulcers in Healthy Subjects Taking Celecoxib Or Naproxen: A Randomized, Placebo-Controlled Trial

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Background: Patients who use nonselective nonsteroidal anti-inflammatory drugs (NSAIDs) or cyclooxygenase-2 (COX-2) selective inhibitors often require concomitant low-dose aspirin (ASA) for cardiovascular (CV) prophylaxis. The impact of the most common prophylactic ASA dose (81 mg qd) on the gastrointestinal (GI) safety profile of COX-2 selective inhibitors remains controversial. Methods: In this multicenter, double-blind, placebo-controlled study, healthy subjects (seronegative for *Helicobacter pylori*) aged 50-75 y were randomized to receive celecoxib 200 mg qd + ASA 81mg qd, naproxen 500 mg bid + ASA 81 mg qd, or placebo + ASA 81 mg qd for 1 week. The primary end point was incidence of gastric and/or duodenal ulcers in subjects treated with celecoxib + ASA compared with naproxen + ASA. Upper GI (UGI) endoscopy was performed at baseline and Day 7 (or early termination). Subjects were excluded if baseline endoscopy revealed >5 erosions in the stomach or duodenum; any gastric, pyloric channel, or duodenal ulcer (≥3 mm diameter); or any esophageal ulcers/erosions. In addition, subjects with any NSAID use within 2 weeks of enrollment were excluded. Results: A total of 662 subjects (mean age, 58 y) were randomized in a 2:2:1 fashion (celecoxib + ASA, n=267; naproxen + ASA, n=264; placebo + ASA, n= 131). There were no significant differences in baseline demographics between groups. A total of 7% (18/257) of evaluable subjects randomized to celecoxib had gastric and/or duodenal ulcers compared with 25.3% (65/257) of those on naproxen and 1.6% (2/129) of those on placebo. Statistical pairwise comparisons by Cochran-Mantel-Haenszel test are shown in the Table. For secondary end points, significantly fewer celecoxib-treated subjects had gastric ulcers (GU) or duodenal ulcers (DU) vs naproxen (GU: 5.8% vs 22.6%; DU: 1.2% vs 7%; *P*<0.001 both comparisons). More celecoxib-treated subjects had GUs vs placebo (*P*=0.016) but there was no significant difference in the incidence of DUs (1.2% vs 0.8%). Conclusion: In a healthy population taking 81 mg qd ASA, celecoxib co-administration

results in more gastric and/or duodenal ulcers than aspirin alone but fewer compared with naproxen. In parallel with a similarly designed trial (but with 325 mg qd ASA), these data suggest that daily ASA doses commonly used for CV prophylaxis do not completely negate the UGI benefit of celecoxib compared with naproxen, as measured by endoscopic ulcer rates.

	Relative risk	95% CI	*P* Value
Celecoxib + ASA vs naproxen + ASA	0.28	0.17-0.45	<0.001
Celecoxib + ASA vs placebo + ASA	4.78	1.12-20.32	0.016
Naproxen + ASA vs placebo + ASA	16.01	3.98-64.46	<0.001

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Effects of Antisecretory Drugs and Nitrates On the Risk of Ulcer Bleeding Associated with NSAIDs and Anti-Platelet Agents

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Background and Aims: After the withdrawal of rofecoxib, an increased prescription rate of some non-selective NSAIDs has been observed, but, according to recent reports, additional prevention strategies are not being followed. In this study we report the effect of antisectory drugs (proton pump inhibitors-PPI; H2-receptors antagonists- H2-RA) and nitrates on the risk of upper gastrointestinal ulcer bleeding (UGIB) associated with NSAID use in clinical practice Methods: Type of Study: hospital-based case-control study with prospective data collection. Setting: A network of 40 general hospitals integrated within the Spanish Association of Gastroenterology. Cases were consecutive patients with UGIB confirmed by endoscopy. Controls matched 2:1 to cases by age (5 years range), hospital and month of interview were individuals with an outpatient visit or hospitalised with a primary diagnosis that was neither an indication nor a known contraindication of NSAID or low dose aspirin treatment. The same structured questionnaire was used in all sites. Relative risk (RR) of UGIB was estimated using logistic regression analysis. Results: 2,777 cases and 5,532 controls have been included. Overall, current use of PPI (RR:0.33; 95%CI:0.27-0.39), H2-RA (RR:0.65; 0.50-0.85) and nitrates (RR:0.52; 0.38-0.70) reduced the risk of developing an UGIB event. The risk reduction was stronger with PPI use among both non-aspirin NSAID (RR: 0.13; 0.09-0.19; vs 0.30; 0.17-0.53 with H2-RA and 0.48; 0.19-1.24 with nitrates) and aspirin users (RR: 0.30; 0.20-0.40 vs. 0.40; 0.24-0.68 with H2-RA and 0.66; 0.44-0.98 with nitrates). Among individual NSAIDs, a similar risk reduction effect with PPI was observed for the 3 most widely used (diclofenac, ibuprofen and naproxen). Among low-dose aspirin users, PPI (RR:0.32; 0.22-0.51) and H2-RA (RR: 0.40; 0.19-0.73)use were associated with risk reduction, while nitrates had a weaker effect (RR: 0.69; 0.36-1.04). In patients taking clopidogrel, only PPI use was associated with a significant risk reduction (RR: 0.19; 0.07-0.49). However, among patients taking anticoagulants neither nitrates (0.67; 0.33-1.34), nor H2-RA (0.88; 0.32-2.45) or PPI use (0.67; 0.37-1.21) were associated with a significant effect on the risk of UGIB event. Conclusion: Treatment with nitrates, H2-RA or PPI is associated with a reduction of the risk of developing UGIB events in patients taking NSAID or aspirin. However, only PPI therapy was associated with a marked and consistent risk reduction among patients receiving all types of agents including non-aspirin anti-platelet agents. Protection was much less apparent in patients on anticoagulant therapy.

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Gastroprotection Gap: A Rising and Dangerous Omission for Elderly Users of NSAIDs with Arthritis

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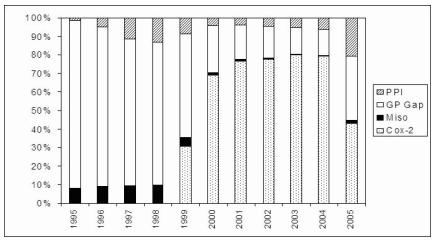
Background: GI complications from NSAIDs have been well-recognized since early 1990s, and were significantly reduced by the use of selective cox-2 inhibitors, concomitant proton pump inhibitors (PPIs) or misoprostol in the early 2000s. Recent media attention on the potential association of cardiovascular events with selective cox-2 inhibitors and market withdrawals resulted in a large decline in the use of these drugs. We report change in prescription patterns in a large cohort of elderly arthritis patients from January 1, 1995 to June 30, 2005. Methods: MediCal, the Medicaid program for California, is the largest Medicaid program in the US, with over 7 million participants per year. All study drugs were available without formulary restrictions or copayments. We studied individuals with physician-diagnosed arthritis who were over 65 years of age and treated with NSAIDs for at least 30 days. Results: Of the total 5,194,765 prescriptions for NSAIDs, 2,634,345 (50.7%) were for selective cox-2 inhibitors. Among the 2,560,420 prescriptions for non-selective NSAIDs, only 1,215,762 (47.5%) had concomitant use of PPI or misoprostol. Figure shows the use of selective cox-2 inhibitors and concomitant PPIs or misoprostol, as a percentage of all NSAID use. The increasing implementation of gastroprotection strategies over the past several years reached a peak in 2004 when the percent of patients not receiving gastroprotection (Gastroprotection Gap) decreased to 14% from 91% in 1995. However, this gap more than doubled to 35% in 2005, following a decline in selective cox-2 inhibitor use, without a commensurate increase in other gastroprotective therapies. Conclusions: An increasing number of elderly users of NSAIDs are again left without gastroprotection. This trend, if left unchanged, will undoubtedly increase morbidity and mortality from NSAID-related complications to levels unacceptable for optimal medical care and deserves immediate public attention.



Gastroprotection (GP) gap in elderly patients 1995-2005. PPI=proton-pump inhibitors, miso=misoprostol, cox-2=selective cox-2 inhibitors

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Improved Gastrointestinal Safety Profile with Lumiracoxib Compared with Naproxen and Ibuprofen in Patients At Least 65 Years Old At Increased Risk of Gastrointestinal Events

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Background: Increasing age is a risk factor for nonsteroidal anti-inflammatory drug (NSAID)-related gastrointestinal (GI) ulcers and associated ulcer complications. Selective COX-2 inhibitors such as lumiracoxib were developed to reduce the risk of GI events. The Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), the largest published GI outcomes study to date, showed a 79% reduction in GI ulcer complications (perforation, obstruction or bleeding) for lumiracoxib compared with naproxen and ibuprofen in the non-aspirin population. Here we report additional analyses on the sub-group of TARGET patients ≥65 years of age. Methods: Patients (n=18 325) aged ≥50 years with OA were randomized to receive lumiracoxib 400 mg once daily (od) (4 times the recommended dose for treatment of OA), naproxen 500 mg twice daily (bid) or ibuprofen 800 mg three times daily (tid) for 1 year. Randomization was stratified by age (50-64, 65-74, ≥75 years) and low-dose aspirin use. The primary endpoint was definite or probable upper GI ulcer complications. Secondary GI endpoints included all definite or probable ulcers (complicated and uncomplicated symptomatic ulcers) and clinically evident major bleeds. Results: In total, 7939 of the TARGET population were ≥65 years (lumiracoxib [n=3980] and NSAIDs [n=3959]), approximately 31% of whom took low-dose aspirin. In patients ≥65 years not taking aspirin (n=5484), there was a significant reduction in ulcer complications in the lumiracoxib group compared with the NSAID group (0.29% vs 1.42% respectively; p<0.0001) and significantly fewer ulcers (complicated and uncomplicated) (0.69% vs 2.62%; p<0.0001). In addition the incidence of clinically evident major bleeds was significantly lower in the lumiracoxib group than in the NSAID group (0.26% vs 0.98%; p=0.0012). In patients ≥65 taking low-dose aspirin, there were no statistically significant differences between treatments. Conclusion: Lumiracoxib 400 mg (od) delivers a consistent GI safety profile that is superior to the NSAIDs naproxen or ibuprofen in patients ≥65 years not taking aspirin.

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A Prospective, Randomized, Controlled Trial of Clear Liquids Vs. Low-Fat Solid Diet as the Initial Meal After Mild Pancreatitis

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Background: Patients recovering from mild acute pancreatitis typically receive a clear liquid diet (CLD) when ready to initiate oral nutrition. The timing of patient discharge frequently depends upon successful advancement to solid food. We hypothesized that initiating feeding with a low-fat solid diet (LFSD) after mild pancreatitis would be well tolerated and would result in a shorter hospital length of stay (LOS). Methods: A sample size of 120 subjects was calculated to have 90% power to detect a one day difference in LOS between two study arms. Exclusion criteria included narcotic use within 6 hours prior to refeeding, an underlying condition that could itself cause poor oral intake or prolonged LOS, inability to monitor the patient post-discharge, pregnancy, and supervision of a patient's care by a study team member. Patients with mild pancreatitis, defined in accordance with the Atlanta symposium, were randomized to receive either a CLD or a LFSD when the responsible medical team determined refeeding was appropriate. The decision to advance a patient's diet and the timing of discharge were determined by the medical team. Patients were monitored daily for dietary intake, recurrence of pain, need to stop feeding, post-refeeding LOS, and for a total of 28 days post-refeeding to capture symptoms or readmission. Post-refeeding LOS (primary outcome) was compared using a t test and need to stop feeding (secondary outcome) was compared with Fisher's Exact test. Results: We randomized 121 patients: 66 to CLD, 55 to LFSD. Baseline characteristics including age, gender, and cause of pancreatitis were similar in both groups. The number of patients requiring cessation of feeding because of pain, nausea or vomiting was similar in both groups (5% for CLD and 9% for LFSD; p= 0.47). There was no difference in 28 day re-admission rates between the two arms. By intention-to-treat, the mean LOS after refeeding was similar in both groups (1.7 +/- 1.9 days for CLD and 1.7 +/- 2.0 days for LFSD; p=0.94). Calorie counts for the first meal consumed were available for 69% of patients and showed significantly lower calories and grams of fat consumed in the CLD arm than in the LFSD arm (mean 177 +/- 106 cal vs 394 +/- 250 cal; 2 +/- 4 gm fat vs 8 +/- 7 gm fat; p<0.001 for both comparisons). Per-protocol analyses and analyses restricted to those with calorie counts provided similar results for both diet tolerability and post-refeeding LOS. Conclusions: Initiating feeding with a LFSD was as well tolerated as a CLD, but did not result in a shorter LOS.