

fistulas. Re-operation in all cases was carried out without significant adhesion formation complicating the procedures. **Conclusions:** Intestinal fistulas following CS and IPIC can be best treated with immediate re-operation. This allows resumption of intraperitoneal chemotherapy, if necessary. Rarely, late fistulas can be treated with catheter drainage, however, at a cost of prolonged hospitalization. Prolonged ileus and SBO can be treated with NG decompression with resolution in most cases. Routine peritoneal fluid cultures may identify early fistulas but not late fistulas. Parenteral nutrition initiated immediately p.o. is mandatory.

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Are Major Cancer Operations in the Very Elderly Worthwhile?

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BACKGROUND: Advanced patient age may be considered a contraindication to referring elderly patients with gastrointestinal malignancies for surgical intervention. Our goal was to determine whether elderly cancer patients ≥ 80 years of age are able to safely undergo major abdominal surgical procedures and derive a clinical benefit. **METHODS:** We conducted a retrospective study of all patients ≥ 80 years of age who underwent a major oncologic procedure with curative intent between June 1990 and July 1999. **RESULTS:** 111 patients fit the above criteria with 16 excluded due to insufficient follow up. Of the 95 patients evaluated, 62 had standard intestinal resections (SR) for cancer of the colon ($n = 59$) or small bowel ($n = 3$). 33 patients, 18 male and 15 female with a mean age 83.8 ± 3.5 years, underwent major oncologic resections (MR) that included 13 low anterior resections and 4 abdominoperineal resections for rectal cancer. 2 patients had an esophagectomy and 5 had a gastrectomy for adenocarcinoma of the esophagus and stomach, respectively. 9 patients underwent a pancreaticoduodenectomy for cancer of the pancreas, duodenum, or bile duct. 38.7% of the MR patients had documented coronary artery disease and 25.8% had a previous cancer diagnosis. The median hospital stay was 11 ± 2.2 days in the MR group and 9 ± 4.8 days in the SR group. The median overall survival was 25 and 27 months and the median disease free survival was 22 and 26 months in the MR and SR groups, respectively. With a median follow up of 20.9 months, the three year overall and disease free survival for the MR patients were $60.4 \pm 10.2\%$ and $76.2 \pm 9.8\%$ respectively. Evaluating all 95 patients ≥ 80 years of age, 16.8% had complications and 3 patients (3.2%) died in the perioperative period. **CONCLUSIONS:** These data suggest that selected patients aged ≥ 80 years of age are able to undergo a major abdominal cancer operation with curative intent with an acceptable perioperative morbidity and mortality. Advanced age alone should not be a contraindication to major oncologic resections.

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Willingness to Pay for Relief of Gastroesophageal Reflux Disease

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BACKGROUND: Gastroesophageal reflux disease (GERD) is associated with extensive use of prescription medication. Value to the consumer of these medications may differ based not only on price but also on amount of relief or presence of side effects. Willingness to pay (WTP) is one method that can be used to assess the value of medications to consumers by quantifying the willingness of individuals to exchange money for goods and services. **METHODS:** This study assesses the WTP of GERD patients for complete symptom relief via prescription medication. We used a discrete choice exercise (DCE) to assess trade-offs between four attributes: time to relief (in days), amount of relief, presence of side effects, out-of-pocket costs. Patients were presented with a series of 16 choices between two products characterized by varying levels of these attributes. In addition, patients completed two quality of life instruments (SF-12, QOLRAD), a symptom severity scale, and a set of socio-demographic questions. All questionnaires were administered via computer self-report. **RESULTS:** A total of 205 patients with GERD at five outpatient sites completed the WTP exercise. The majority were female (62%), married (74%), and employed outside the home (69%). Consistency rate for the DCE was extremely high (99.8%), indicating that patients were internally consistent in their choices between the two products. A random effects probit model was used to analyze the DCE data. Results demonstrated that these patients were willing to pay \$1.88 for a 1 day decrease in time of onset of relief, \$60.78 for a unit increase in amount of relief (from little to some or from some to complete), and \$49.14 for the elimination of side effects. Further analysis will assess WTP by income, insurance status, employment status, and other socio-demographic variables as well as by quality of life and disease severity. **DISCUSSION:** Results of this study demonstrate that individuals can comprehend discrete choice questionnaires and provide consistent results. Thus, DCE is a feasible method with which to estimate WTP for changes in the levels of attributes of GERD medications. Patients appear to be willing to pay for positive changes in amount of relief and lack of side effects. These findings may have important implications for pricing and reimbursement strategies for new prescription medications. Results of WTP analyses can be used in cost-benefit studies and serve as a useful tool for HMOs and other regulatory organizations in determining resource allocation.

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Health-Related Quality of Life Improves with GERD Symptom Resolution: Treatment Effects by Baseline Severity

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BACKGROUND: Effective medical treatment of gastroesophageal reflux disease (GERD) is associated with the resolution of heartburn symptoms and improvements in health-related quality of life (HRQL). We evaluated the effectiveness of omeprazole versus ranitidine in providing complete relief from heartburn symptoms and improving subjective feeling of well-being and distress by severity of heartburn symptoms. **METHODS:** This is a secondary analysis of baseline and follow-up heartburn symptoms and HRQL scores from two clinical trials (total

$n = 1222$) comparing omeprazole and ranitidine for acute symptomatic treatment of GERD. Heartburn symptoms were measured using patient diaries or patient reported HRQL outcome measures. HRQL was assessed using the Psychological General Well-Being Index (PGWB) in two clinical trials. Resolution of heartburn was defined as no heartburn reported during the assessment period. Disease severity was defined by the heartburn item of the Gastrointestinal Symptom Rating Scale (GSRS) or patient diary data. **RESULTS:** Controlling for baseline severity, a greater proportion of omeprazole treated patients reported complete heartburn resolution compared with ranitidine treated patients across the two clinical trials. Differences in the proportion of patients resolved were statistically significant at 8 weeks (Cochran-Mantel-Haenszel; $p = 0.0002$ and $p < 0.0001$). For both of these clinical trials, mixed-model analysis of variance demonstrated a statistically significant interaction between baseline heartburn severity, treatment regimen, and duration of therapy for mean total PGWB scores ($p = 0.0608$ and $p = 0.0166$). **CONCLUSIONS:** Omeprazole appears to be more effective than ranitidine in resolving heartburn symptoms and improving HRQL in patients with GERD.

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Sufficient Control Of Heartburn In Endoscopy Negative Heartburn Trials.

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Background: For patients with endoscopy negative heartburn the main objective of treatment is symptom improvement and symptom control. In clinical trials the severity and frequency of heartburn are routinely assessed at clinical visits and used for defining responders. The aim of this study was to relate post-treatment symptom assessments to the patients' perception of sufficient heartburn control. **Methods:** Symptom data from a placebo controlled omeprazole trial in patients with heartburn as the predominant symptom and with a macroscopically normal esophageal mucosa have been evaluated. All 509 patients had at least 2 days of heartburn the last week prior to inclusion and a history of heartburn for at least 12 months. Heartburn was assessed pre-treatment and after 2 and 4 weeks of treatment. Referring to the last week, severity of heartburn was assessed as none, mild, moderate or severe and frequency of heartburn recorded as zero, 1, 2-4, 5-6 or 7 days. Patients were asked, after 2 and 4 weeks of treatment, 'Does the study medication give sufficient control of your heartburn?' with the only alternatives 'Yes' or 'No'. **Results:** After 4 weeks 99% (170/171) of patients with no heartburn, 46% (101/219) with mild heartburn, 1/80 with moderate heartburn and 0/20 with severe heartburn, said that treatment gave sufficient control of their heartburn. The acceptance of mild heartburn depended on the heartburn frequency and to some extent also on the pre-treatment severity/frequency. Mild heartburn for 5 days or more was rarely accepted (10%, 7/67 patients). Mild heartburn for 2-4 days after 4 weeks was accepted more often by patients who pre-treatment presented with daily moderate/severe heartburn (67%, 12/18) than by those with mild and less frequent pre-treatment heartburn (17%, 5/30). One day with mild heartburn at 4 weeks was accepted by around 90% (70/76) of the patients, even among those with mild and less frequent pre-treatment heartburn. This pattern was already observed after 2 weeks of treatment. **Conclusion:** From this study and in the clinical setting patients with initially moderate or severe daily heartburn accept up to 4 days a week of mild heartburn during ongoing treatment. Patients with a less severe initial symptomatology accept mild heartburn episodes if the frequency does not exceed once a week. Under these circumstances patients consider given treatment as adequate with sufficient symptom control.

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Concomitant Use of Proton Pump Inhibitors and Metabolically Competing Drugs, and the Risk of Drug-Drug Interaction Induced Adverse Events

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OBJECTIVE: To evaluate adverse events (AE) due to potential drug-drug interactions between certain proton pump inhibitors (PPIs) and metabolically competing drugs (MCDs) in a managed care environment, and to examine the impact of adverse events (AE) due to such interactions on medical costs. **METHODS:** A retrospective cohort analysis using PharMetrics' Integrated Outcomes database. Patients receiving one of the MCDs (benzodiazepines, carbamazepine, cisapride, clarithromycin, cyclosporine, diclofenac, digoxin, disulfiram, erythromycin, estrogens, ibuprofen, itraconazole, ketoconazole, nifedipine, oral contraceptives, propranolol, theophylline, phenytoin, oral steroids, or warfarin) during 1996-1998 were allocated into two study groups, based on the presence or absence of a PPI prescription (lansoprazole, omeprazole) within 30 days of the MCD prescription. Adverse events considered to be related to the drug-drug interaction, were compared across the two cohorts. Additionally, medical charges for patients with an AE were compared those with no AE, to determine their financial impact. **RESULTS:** 530,168 patients were identified, with 7% being included in the MCD + PPI cohort and 93% in the MCD only cohort. Overall, patients taking a MCD + omeprazole or lansoprazole were 9 times more likely to have an AE than patients in the MCD only cohort. Specific examples: patients taking warfarin + PPI were 2.19 times as likely to have a warfarin-related AE than patients taking warfarin alone ($p < 0.0001$), and patients taking phenytoin + PPI were 2.7 times as likely to have a phenytoin-related AE than patients on phenytoin alone ($p < 0.0001$). For patients who did not experience an AE during the study period, medical costs increased \$360 over time, compared to a \$7,326 increase for patients who did have an AE ($p < 0.0001$). **CONCLUSIONS:** Patients concurrently prescribed omeprazole or lansoprazole and a MCD are at an increased risk of experiencing adverse events related to the MCD. Drug-interaction related adverse events for patients taking omeprazole or lansoprazole and a metabolically competing drug significantly increases the overall costs of medical management.