Purpose: To assess patient-reported outcomes, including frequency of nighttime heartburn symptoms, level of discomfort with nighttime heartburn symptoms, and quality of sleep, in patients with gastroesophageal reflux disease (GERD).
Methods: Randomized, double-blind, baseline-controlled, two-period, two-treatment crossover study. Placebo was administered during baseline pH measurements. Patients were then randomly assigned to one of the following sequences: pantoprazole/ranitidine (n=12) or ranitidine/pantoprazole (n=19). Patients underwent two 8-day, double-blind treatment periods (pantoprazole 40 mg once daily or ranitidine 150 mg twice daily) separated by at least a 10-day (up to 21-day) washout period. Patients recorded frequency of nighttime heartburn symptoms (number of episodes per day), level of discomfort (1=none to 7=very severe) with nighttime heartburn symptoms, and sleep quality (1=excellent to 7=extremely poor) using daily diaries. Differences between pantoprazole and ranitidine were compared using two-sample t-test or nonparametric Wilcoxon test as appropriate. A P-value < 0.05 in a two-tailed test was considered significant.
Results: On day 1 and 8 during the nighttime (10 pm-8 am) period, the percentage of time that pH was 4 or higher was significantly greater with pantoprazole versus ranitidine ($P \leq 0.004$ and $P \leq 0.007$, respectively). Regardless of period: the frequency of nighttime heartburn symptoms was 0.17 ± 0.37 for pantoprazole versus 0.50 ± 0.55 for ranitidine ($P < 0.01$), the level of discomfort with nighttime heartburn symptoms was 1.20 ± 0.36 for pantoprazole versus 1.62 ± 0.64 for ranitidine ($P < 0.01$), and the quality of sleep was 2.76 ± 0.66 for pantoprazole versus 2.94 ± 0.59 for ranitidine ($P < 0.05$).
Conclusions: Pantoprazole has a significantly positive impact on patient-reported outcomes including frequency of nighttime heartburn symptoms, level of discomfort with nighttime heartburn symptoms, and quality of sleep, in patients with GERD.

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VIRTUAL COLONOSCOPY; REAL MISSES

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Purpose: Virtual colonoscopy (VC) may replace conventional colonoscopy (CC) for colorectal cancer screening if the test characteristics of VC are adequate. We performed a meta-analysis of studies comparing computed tomography (CT) and magnetic resonance (MR) colonography with CC for the detection of colon polyps and cancers.
Methods: Searches of published literature were performed on multiple electronic databases (MEDLINE, PREMEDLINE, EMBASE, and others from 1966 to March 2002) and cross-citation, independently by two authors (A.L. and P.C.). Bibliographic search used specified key words including (colonoscopy, colonography, colography, or pneumocolon) and (CT or MRI). English language studies were selected if they evaluated at least 10 patients with either CT or MR colonography, using CC as the reference standard for the detection of colon polyps and/or cancers. Articles were excluded if the sensitivity and specificity of VC could not be calculated on a per patient basis, or if they used computer-assisted interpretation without radiologist interpretation. Two authors (A.L. and P.C.) independently reviewed and abstracted retrieved studies. Discrepancies in data collection were resolved by consensus. Individual sensitivity and specificity were calculated from contingency data for all selected studies, and separately for MR and CT subgroups. Using the algorithmic meta-analysis method of Midgette and colleagues, we performed weighted summary receiver operator characteristic curve (SROC) analyses if threshold effects were present and calculated the area under the curve (AUC). Otherwise, we pooled test characteristics using random effect models.
Results: Four hundred and forty-seven studies were identified by the literature search, of which 16 met inclusion criteria, including 11 CT studies of 1236 subjects, and 5 MR studies of 316 subjects. Mean sensitivity and specificity were 0.73 (0.61–0.83) and 0.82 (0.72–0.89) respectively for all studies. For CT mean sensitivity was 0.73 (0.57–0.85), mean specificity was 0.81 (0.68–0.89). For MR mean sensitivity was 0.75 (0.47–0.91), mean specificity was 0.82 (0.73–0.89). The AUC was 0.81 for all studies and for CT studies. Significant heterogeneity was noted that might be explained by use of different diagnostic thresholds.
Conclusions: Compared to conventional colonoscopy, virtual colonoscopy results in a 27% rate of missed colorectal lesions. Using current technology, VC is not an adequate screening tool for colorectal cancer.

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THE STUDY FUNDING SOURCE IS ASSOCIATED WITH STUDY QUALITY IN GI RESEARCH

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Purpose: Clinical research in GI is funded by various sources, including private industry, municipalities and professional societies. The effect that the source of the funding for a study has on the quality of the study is not known. The aim of this study was to describe the association between funding source and study quality in the clinical GI literature.
Methods: We reviewed all published articles in 4 leading GI journals (Gastroenterology (Gastro), American Journal of Gastroenterology (AJG), Hepatology (Hep), Gastrointestinal Endoscopy (GIENDO)) to assess funding source for GI research. All articles assessing the effectiveness of a drug therapy or device were included. Data were abstracted on a standardized form. Data abstracted included: journal reference, drug/device being assessed, methodology score (0-100 scale), clinical question, funding source and whether the study outcome favored continued use or identification. Study quality was assessed using a modification of a previously validated methodology scoring system. Quality was determined by assessing 5 attributes: study type, randomization scheme, blinding scheme, whether the study was controlled, and any of the following: sample size calculation, intention to treat analysis or a survival analysis. Funding sources were classified as industry-sponsored, federal/state government-sponsored, national society sponsored or not specified.
Results: A total of 317 papers met the inclusion criteria and underwent abstraction (222 drug therapy papers, 93 device papers). The mean quality of the papers was 65%. Papers published in the journals with the two highest impact factors (Gastro and Hep) had an average methods score of 69% whereas studies published in the other two journals (AJG and GIENDO) had a average methods score of 63%. Drug therapy papers demonstrated significantly higher mean quality scores when compared to device papers (67% vs. 60%, p= .03). Research funded by federal/state sources and research funded by academic professional societies had lower quality than research funded by private industry (64% and 65% vs. 75% respectively, p=.00005).
Conclusions: The funding source of clinical GI research is a predictor of study quality as assessed using a standardized method. Studies funded by private industry tend to have higher quality scores than those funded by governmental sources and professional societies.

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IDENTIFYING IBS PATIENTS USING ROME II SYMPTOM CRITERIA: 3- OR 12-MONTH REPORTING?

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Purpose: To assess the agreement between 3- vs 12-month Rome II IBS symptom criteria and to assess the agreement between the Rome criteria and self-report of a previous medical diagnosis of irritable bowel syndrome (IBS) in an employed U.S. population.