

Su1042

### Trends in Clinic Visits and Hospitalization in Pediatrics Inflammatory Bowel Disease Patients: A 20-Year Follow-up Study

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**Background:** The incidence of IBD in children has dramatically increased over the past 20 years. **Objective:** To examine the trends over time of clinical visits and hospitalization of children diagnosed with IBD attending the same clinical facility during the past 20 years. **Methods:** A retrospective investigation was conducted on a cohort of children with IBD registered in the IBD registry at Texas Children's Hospital between 1988 and 2008. The diagnosis of IBD was based on clinical, radiological, endoscopic, and histological examinations. The date of each in/out patient visit for each participant and the date of hospitalization as well as demographic data and the IBD subtype were recorded allowing the total number of visits and the interval between visits for each child to be estimated from the date of diagnosis of IBD to the last follow-up visit. We calculated the number of visits/patient/year. **Results:** There were 490 children eligible for the analysis with 3387 visits. The median of visits significantly dropped between the periods 1988-1994 to 2000-2008 (16.3 + 6.6 vs. 3.7 + 1.9, respectively,  $p=0.0001$ ), as well as the median of visits/patient/year dropped (4.3 + 2.6 vs. 2.8 + 1.5), respectively;  $p=0.04$ ). The median number of follow-up years dropped from 6.2 + 2.4 the period 1988-1994 to 1.4 + 0.6 during 2000-2008;  $p=0.0001$ . The overall number of patients seen was four times higher in the last study period compared to the first period, 59 vs. 227 patients, respectively. Sixteen patients out of the 54 patients were hospitalized during the first period (30%) vs. (21%) during the later period (OR=2.1, 95%CI= 1.0-5.5,  $p=0.042$ ). IBD subtype, age, gender, ethnicity did not have an effect on the median duration of outpatient visits or hospitalization. **CONCLUSIONS:** Over the 20 years study period, outpatient clinical visits per patient/year due to IBD in children dramatically dropped as did the frequency of hospitalization despite a significant increase of children diagnosed with IBD during the same period. It is likely that this reflects improvement in the treatment of IBD among children. Subsequent studies should examine the effect of specific treatments on visits and hospitalizations

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### Gastric Acid Suppressive Therapy and Community-Acquired Pneumonia, Etiology and Outcome

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**Background.** Community acquired pneumonia (CAP) is an infection of the pulmonary parenchyma that can be caused by various microbial pathogens. Co-morbidity and medication are related to specific pathogens. Patients on gastric acid suppressive therapy have an increased risk to develop CAP. We aimed to assess whether there are specific pathogens independently associated with gastric acid suppressive therapy and its impact on infection severity. **Methods.** From December 2007 to January 2010, all subjects consulting the emergency care unit of a general hospital in the south of the Netherlands with a suspected CAP were prospectively registered. Each patient underwent chest radiography. Sputum, urine, nose swabs and blood samples were obtained for microbial culture, antigen detection and polymerase chain reaction techniques, respectively. To study the severity of CAP upon presentation, the validated CURB-65 score was calculated. Furthermore, we assessed hospital or intensive care admission, length of hospitalization and in-hospital mortality. We evaluated the association between use of acid suppressive therapy and microbial aetiology of CAP and severity of illness with logistic regression analysis. **Results.** The final cohort comprised 463 patients with CAP, defined as presence of infiltrate on chest radiography and/or microbial aetiology. Overall 136 patients (29%) used acid suppressive therapy, mainly proton pump inhibitors (97%). Patients with acid suppressive therapy more frequently had an infection with *Streptococcus pneumoniae* (28% vs. 14%) and *Haemophilus influenzae* (10% vs. 6%), and less frequently with *Coxiella burnetii* (8% vs. 19%) or H1N1 influenza A virus (2% vs. 7%) in comparison to those without acid suppressive therapy. After adjustment for baseline differences, the risk of proton pump inhibitor users being infected with *S. pneumoniae* was 2.18 times (95%Confidence Interval(CI): 1.2-3.6) higher compared to those not on acid suppressive therapy. Patients using more than one defined daily dose of a PPI had a 1.48-fold increased risk of a *S. pneumoniae* infection compared with patients using the defined daily dose (95%CI:1.1-2.0). No risk between PPI use and any other microbial pathogen was found. Patients with acid suppressive therapy had on average higher CURB-65 scores, longer hospital stay and subsequently a case fatality rate of 11% vs. 4% compared to those not using acid suppressive therapy. **Conclusions.** Proton pump inhibitor therapy predisposes with community acquired *S. pneumoniae* pneumonia, and was associated with higher morbidity.

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### Effect of *Helicobacter pylori* Treatment on Gastroesophageal Reflux Disease (GERD): Meta-Analysis of Randomized Controlled Trials

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**Background:** Gastroesophageal reflux disease (GERD) is a multifactorial disorder characterized by reflux of acidic gastric contents into the esophagus leading to tissue damage and symptoms. The role of *H. pylori* in the pathogenesis of GERD is controversial. Some studies indicate a protective role, whereas others fail to show any beneficial effect. Therefore, we performed a meta-analysis on the effect of *H. pylori* treatment on symptomatic and endoscopic changes associated with GERD. **Methods:** MEDLINE, Cochrane Central Register of Controlled Trials & Database of Systematic Reviews, PubMed, and recent abstracts from major conference proceedings were searched (11/2010). Randomized controlled trials (RCTs) comparing *H. pylori* treatment versus no treatment on symptomatic as well as endoscopic changes with GERD were included. Standard forms were used to extract data by two independent reviewers. The effects of *H. pylori* treatment were analyzed by calculating pooled estimates for new onset or changes in symptoms or endoscopic reflux esophagitis. Separate analyses were

performed for each outcome by using odds ratio (OR) or weighted mean difference (WMD) by fixed and random effects models. Publication bias was assessed by funnel plots. All were graded by Jadad score. Heterogeneity among studies was assessed by calculating I<sup>2</sup> measure of inconsistency. **Results:** Twelve trials met the inclusion criteria (N=6043). Trials were of adequate quality (Jadad score  $\geq 2$ ). No significant heterogeneity was noted for the primary outcome. A statistically significant lower incidence of esophagitis was noted in the non-treated (4.06%) versus the treated group (5.99%) (OR 1.49; 95% CI: 1.03-2.16,  $p=0.04$ ). Non-significant effect was noted in symptomatic GERD (OR 0.95; 95% CI: 0.81-1.12,  $p=0.58$ ). Funnel plot revealed no publication bias. **Conclusions:** There was a significant increase in new-onset or worsening esophagitis in the group treated for *H. pylori* compared to control. Therefore, *H. pylori* may have a protective role in GERD.

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### Lubiprostone Plus PEG-Electrolytes vs. Placebo Plus PEG-Electrolytes for Outpatient Colonoscopy Prep: A Randomized, Double-Blind Placebo-Controlled Trial - Final Analysis

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**Introduction:** Colonoscopy is the gold standard for colon cancer screening. Many patients have difficulty tolerating large volumes of fluid particularly PEG-electrolytes. Lubiprostone, a chloride pump activator FDA approved for constipation had been anecdotally used in patients unable to tolerate a full gallon of PEG-electrolytes(PEG). **Objective:** The primary objective of the study was to evaluate the efficacy of lubiprostone (vs. placebo) plus PEG as a bowel cleansing prep for colonoscopy. The secondary objective was to evaluate the effectiveness of lubiprostone in reducing PEG volume. **Method:** Randomized, double-blind, placebo-controlled design. Patients scheduled for screening colonoscopy were randomized 1:1 to either lubiprostone 96 mcg in divided doses (Group A) or placebo (Group B) in divided doses plus one gallon of PEG. All patients were instructed to stop PEG after having two clear bowel movements. Five endoscopists trained using 20 historical patients used the Ottawa scale and ranked colon cleanliness from 0-4 and fluid quantity from 0-2. Group comparisons were done using a two-sided two-sample t-test. A one-way ANCOVA was used to test for treatment effect and this model was extended to a multiple regression looking at confounding factors. Cochran-Armitage trend test was used to evaluate tolerance of preparations. **Results:** 158 patients were randomized however only 123 patients completed the study and were included in the analysis. 57 patients were in the lubiprostone group (Group A) and 66 were in the placebo group (Group B). Baseline group characteristics were similar. There was no difference in overall colon cleanliness (Group A-1.24 vs. Group B-1.38) or segmental cleanliness. The volume of PEG ingested was similar in both groups. For both groups, the volume of PEG ingested approached significance as a predictor of improved score ( $p = 0.054$ ). There was no difference in how the groups tolerated the lubiprostone or PEG. **Conclusions:** Lubiprostone plus PEG was similar to placebo plus PEG in colon cleansing and volume of PEG consumed. The volume of PEG consumed showed a trend towards improving the quality of the colon cleansing.

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### Factors Impacting the Refill Adherence of and Persistence to Adalimumab Therapy in Swedish Patients With Crohn's Disease

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**Aim:** To examine factors affecting refill adherence and persistence to adalimumab therapy in Swedish patients with Crohn's disease (CD). **Methods:** This was a retrospective cohort study of the Swedish National Board of Health and Welfare database of dispensing records of adalimumab from July 6, 2005, to September 30, 2009, for patients with CD. For each patient, the medication possession ratio (MPR) was calculated as the days of supply dispensed (excluding the last dispensing record) divided by the number of days between the first and last dispensing records. Then patients were identified as adherent (MPR  $\geq 0.8$ ) vs. non-adherent (MPR  $< 0.8$ ). A logistic regression was conducted, where the outcome variable was adherence (yes/no) and the independent variables included age group, gender, dispensing device, prescriber's specialty, and prescriber's practice setting. A patient was considered non-persistent if the gap between any 2 dispensing records minus the days of supply dispensed with the former record was greater than 180 days. A Cox proportional-hazards model was conducted, where the outcome variable was non-persistence (yes/no) and the independent variables were the same as in the logistic regression. Kaplan-Meier survival analyses were performed to compare cumulative incidence of non-persistence for independent variables. **Results:** Of 1,083 patients, the average MPR was 0.93 with an average follow-up time of 445 days, where 790 (89%) were identified as adherent (MPR  $\geq 0.8$ ) and 837 (77%) were identified as persistent. The 1-year Kaplan-Meier persistency rate was 82%. Compared with those using a syringe, patients using a pen as the dispensing device were more likely to be adherent, with an odds ratio (OR) of 1.78 (95% CI: 1.14, 2.78). Patients whose prescribers worked in a gastroenterology center were more likely to be adherent than patients whose prescribers worked in an internal medicine center, with an OR of 1.70 (95% CI: 1.04, 2.79). In addition, patients using a pen were less likely to be non-persistent than those using a syringe, with a hazard ratio (HR) of 0.74 (95% CI: 0.56, 0.97). Patients whose prescribers worked in a gastroenterology center were less likely to be non-persistent than patients whose prescribers worked in an internal medicine center, with an HR of 0.64 (95% CI: 0.48, 0.86). Compared with female patients, male patients were less likely to be non-persistent, with a HR of 0.75 (95% CI: 0.57, 0.97). Furthermore, Kaplan-Meier survival analyses revealed similar results. **Conclusions:** Use of the adalimumab pen as the dispensing device and being treated in a gastroenterology center had a positive impact on Swedish patients' refill adherence and persistence to adalimumab. Male patients had better persistency.