

Providing Patient Education and Support to Ileal Pouch-Anal Anastomosis Patients through the World Wide Web

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Background: Substantive patient education and support about Ileal Pouch Anal Anastomosis (IPAA) is often not readily available. Patients are increasingly turning to the world wide web for their medical and health information. The J Pouch web site was created in 1997 to extend its Philadelphia based network of education and support worldwide. **Aim:** To evaluate the nature of questions asked by patients worldwide concerning IPAA surgery via the World Wide Web. This study analyzed all questions received at our website www.jpouch.org over a 54 month period, from January 1997 through June 2001. **Methods:** A prospective analysis of 585 sequential questions submitted to our website. Questions were catalogued according to their focus: following, anticipating or between surgeries. Emails with multiple questions were sorted according to their primary or first question. A small subset of questions asked fell into an other category. The specific frequency of questions and inquiries are described. **Results:** Since the inception of The Jpouch Web Site in 1997, the number of reported monthly visits or hits has increased from 200 to 750,000. 585 email questions were received from six continents during a 54 month period from January 1997 through June 2001. Of the 585 questions posed, the composite number of questions in each category included: following surgery (67.2%), anticipating surgery (14.4%), in between surgeries (12.3%) and other (6.1%). The most common concerns in the following surgery category included stool frequency/diarrhea (14%), pouchitis (10%) and abdominal/rectal pain (9%). Patients anticipating surgery most commonly had questions about success/complications of the procedure (23%) and selection of a surgeon/hospital (14%); many also sought advice about IPAA surgery for pediatric patients (11%). The most common concerns for patients in between surgery included general procedural questions about future surgeries (32%), take down questions (8%) and rectal bleeding/discharge (7%). The most commonly asked other question was IPAA surgery for other disease states (33%), including Crohns disease, colon cancer, diverticuli, and other diseases. **Conclusions:** Patients who are contemplating, undergoing or have completed IPAA surgery internationally seek information and support. These patients still have many questions and require follow up. The J pouch web site is an effective and much utilized method to provide additional education and support worldwide.

W1336

Bone Mineralization in African-American Children with Crohn's Disease

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Background: Decreased bone mineral content (BMC) and density (BMD) are common in children with Crohn's disease (CD). Healthy African-American (AA) adults have lower incidence of osteoporotic fractures and their bone mineral density appears to be higher than their Caucasian counterparts. We hypothesize that African-American children with CD have different BMC and BMD than Caucasian children with CD. **Methods:** We retrospectively reviewed all the dual energy x-ray absorptiometry (DEXA) scans performed in AA children with CD between 1995 and 2001. Lumbar spine DEXA scans were obtained (Hologic QDR 2000, Bedford MA). Twenty-two AA subjects with CD (6 females), 7 to 20 years of age, were compared with a cohort of 106 Caucasian subjects with CD (45 females) from a previously published study at our institution (Semeao et al, 1999). Height and weight z-scores were calculated from national reference data. BMD z-scores were derived from the Hologic reference data. Means were compared using Student's t test with statistical significance of $p < 0.05$. **Results:** The AA cohort was younger than the Caucasian group (mean age 14.2 ± 3.1 vs. 16.3 ± 4.2 years, $p = 0.028$). There were no significant differences in height z-scores (-0.28 ± 1.2 vs. -0.58 ± 1.2), weight z-scores (-0.34 ± 1.6 vs. -0.49 ± 1.1), disease duration (1 ± 2 vs. 1 ± 1 years) and total exposure to prednisone ($12,620 \pm 22,391$ vs. $9,912 \pm 11,559$ mg) between the groups. There were also no significant differences in BMC (41.7 ± 17.5 vs. 41.6 ± 15.6 g), BMD (0.8 ± 0.19 vs. 0.79 ± 0.15 g/cm²) and BMD z-scores (-0.95 ± 1.2 vs. -1.44 ± 1.1) between the groups. BMD z-scores were also analyzed by gender, male AA subjects were not different from the male Caucasian subjects with CD. Female AA subjects had significantly higher BMD z-scores ($p = 0.009$) than female Caucasian subjects with CD. **Conclusions:** African-American children with CD have BMC, BMD and BMD z-scores similar to Caucasian children with CD. The protective effect of AA ethnic background is not apparent in males with CD.

W1337

Predictive Value of Age at Onset of Disease in Natural History of Ulcerative Colitis (UC)

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Background: The age at onset of disease in UC may help in predicting its natural history. **Aim:** We examined the influence of age at onset of disease with the outcome in terms of disease extent, severity (clinical, colonoscopic and histological), the number of relapses, intensive therapy and requirement for surgery. **Methods:** Patients of UC diagnosed on the basis of clinical history, colonoscopy and rectal biopsy were included in this retrospective study. They were divided in three groups according to age at onset of disease, Group I: <18 yrs, Gr II: 18 to 50 yrs and Gr III: >50 yrs. Outcome measures were severity, extent, number of relapses and treatment taken. **Results:** 578 patients of UC were included. Gr I - 52 patients, Gr II - 474 patients and Gr III - 52 patients. Age range at onset of disease was 3 to 70 yrs. The median duration of follow up was 2 years (Interquartile range: 1 year to 4 years, Range: 1 month to 18 years). The extent was proctosigmoiditis in 31.3%, left sided colitis in 30.5% and pancolitis in 38.3%. There was no significant difference in three age at onset groups when compared for clinical severity ($p = 0.43$), extent ($p = 0.51$), colonoscopic grading ($p = 0.26$), biopsy grading ($p = 0.99$), number of relapses ($p = 0.3$), relapses per year ($p = 0.13$), intensive therapy given ($p = 0.96$), number of times intensive therapy given

($p = 0.76$) and requirement for surgery ($p = 0.7$). **Conclusion:** Age at onset of disease does not predict the natural history of ulcerative colitis as seen in a long-term follow up study.

W1338

Lack of Association between SNPs in the NOD2 Gene and Response to Infliximab Treatment in Crohn's Disease

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LACK OF ASSOCIATION BETWEEN SNPs IN THE NOD2 GENE AND RESPONSE TO INFLIXIMAB TREATMENT IN CROHN DISEASE

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Background: Treatment with infliximab (anti TNF- α monoclonal antibody) has been proven to induce remission in 30-40% of steroid refractory Crohn's disease (CD) patients. Clinical predictors for treatment response are still unknown. The first Inflammatory Bowel Disease (IBD) susceptibility gene (IBD1 on chromosome 16q12) has been recently identified as NOD2, a member of the Apaf-1/Ced-4 superfamily of apoptosis regulators. 3 variants SNP8, SNP12 and SNP13 have been shown to be independently associated with CD susceptibility. **Aim:** To investigate SNP8, SNP12 (both missense mutations) and SNP13 (C insertion producing a truncated protein) in relation to therapeutic efficacy of infliximab. **Methods:** Two multicenter cohorts of active CD patients (CDAI 220-450), from independent clinical trials conducted according to GCP were studied. In both trials patients received open label infliximab (5 mg/kg KG) at study start. The German study (n=90) was used for generation of hypothesis and the ACCENT 1 trial (n=444) for confirmation. Therapeutic response was defined as drop of CDAI of at least 70 points (a), at least 100 points (b) or achievement of remission as CDAI <150 points (c), respectively. The 3 SNPs under investigation were typed by TaqMan technology. **Results and conclusion:** None of the SNPs under investigation were associated with treatment response ($p > 0.5$) in either of the cohorts under investigation. The subsequent negative findings in a two cohort model confirm that mutations in the NOD2 gene do not represent a predictor for therapeutic response to infliximab treatment.

W1339

Infliximab Infusion Reactions: The Influence of Sex and Drugs

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Background: Infliximab infusions in Crohn's patients may be complicated by infusion reactions or other adverse events (AE). Patient risk factors, and the protective effect of concomitant administration of immunomodulators and/or corticosteroids has been postulated, but not conclusively shown. **Methods:** All patients who received infliximab from the 3 year period between 10/1/98 and 9/30/2001 were prospectively entered into the study. Infusion reactions and adverse events were recorded at the day of infusion, as well as by personal or telephone interviews at weeks 1, 3, 7, 12 and then at 3 month intervals following each infusion. Reinfusions reset the schedule of interviews to reflect the most recent infusion. Infusion reactions or AEs were classified as immediate (<24 hours of infusion), 1st Week (>24 hours but <1 week), or 1st Month (>1 week but <1 month). Immunomodulator (6MP/AZA or MTX) and corticosteroid use was recorded. Statistical analysis tests utilized (variable type): Chi-square (dichotomous), Rank-Sum (continuous), Logistic regression (multivariate analysis). **Results:** 271 patients (59% female, mean age 38.3, range 17-71) were infused a total of 1529 infusions (per patient range 1 to 30) over the 3-year period. Concomitant 6MP/AZA was given in 50%, MTX in 10%, and prednisone at daily dose >20mg (Pred) in 12% of infusions. Adverse events were noted within the first 24 hours in 9.4%, between days 1 and 7 in 4.1%, and after the first week in 8.0% of all infusions. See Table. Infusion reactions of any type were less likely in males, and in patients on concomitant 6MP/AZA. There was insufficient statistical power to interpret MTX's trend towards decreasing reactions. Concomitant Pred did not impact immediate (10.0% vs. 9.3%, $p = 0.74$), 1st Week (4.2% vs. 4.1%, $p = 0.95$), or 1st Month (6.3% vs. 8.2%, $p = 0.37$) reaction rates. Immediate infusion reactions were less likely in younger patients ($p = 0.02$). Logistic regression identified gender as an independent predictor of any type of infusion reaction, with age a predictor of only immediate reactions. **Conclusion:** Infliximab infusion reactions in Crohn's patients are much less frequent in men, in younger patients, and with concomitant 6MP/AZA. High dose prednisone did not impart such protection.

Time of AE	Male ¹	Female	6MP	MTX	Neither 6MP or MTX	Pred \geq 20mg	Pred<20mg
Immediate	5.7	11.9	7.5 ²	8.1	12.0	10.0	9.3
1st Week	2.8	5.0	3.1	6.1	4.9	4.2	4.1
1st Month	6.0	9.4	6.5 ³	6.8	10.1	6.3	8.2

¹ $p < 0.001$ Immediate, and $p < 0.05$ for 1st Week and 1st Month, compared to females. ² $p = 0.005$ and ³ $p = 0.022$, both compared to Neither 6MP or MTX. Values shown are percentages.

W1340

Infliximab Therapy for Pediatric Crohn's Disease

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Infliximab, a chimeric monoclonal TNF- α antibody, has proven efficacy in treating adults with Crohn's disease (CD). However, there is little data on its effectiveness in pediatric clinical practice. **Aim:** To assess the safety and efficacy of open-label infliximab for pediatric CD. **Methods:** Medical records were reviewed of all consecutive CD patients (pts) less than 21 yrs of age who had received infliximab. CD diagnosis was based on radiographic, endoscopic