

### Is Different Drug Response in Men and Women Caused by Different Symptom Presentation?

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Background: Some gastrointestinal drugs like Alosetron, Tegaserod and probably Omeprazole acts different in men and women. This could be caused by properties related to the drug or different symptom presentation in men and women. Aim: To compare the symptom presentation according to gender in an unselected population of patients with abdominal complaints, consulting in general practice. Material and methods: Following a structured interview about the presence or absence of 20 symptoms, the study population (7273 patients consulting in primary care because of abdominal complaints) reported the presence of a total of more than 35000 symptoms, related to both the upper and the lower gastrointestinal tract. Using principal component analysis the symptom presentation was compared between men and women. Results: 4 principal components were identified, with symptoms representing a factor > 0.5. Women (N = 4102, explaining 37% of the variance): Factor 1: epigastric pain, pain retrosternally, regurgitation, pain in the upper abdomen, pain at night and relief by antacids and food. Factor 2: Bloating, constipation, incomplete evacuation, relief by flatulence. Factor 3: Nausea, vomiting in the morning. Factor 4: pain after meals and dysphagia. Men (N = 3171, explaining 38 % of the variance). Factor 1: as women except relief by food. Factor 2: As women except constipation. Factor 3: as women + relief by vomiting. Factor 4: as women + relief by food. Conclusion: apart from small differences men and women report comparable symptoms, when consulting in general practice because of abdominal complaints.

## T1306

### Evaluation of Autonomic and Enteric Nervous System May Affect the Outcome of Therapy in Patients with GI Motility Disorders

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Purpose: Autonomic Function Testing (AFT) has been advocated as part GI motility testing, to assess autonomic and enteric neural function. However, its ability to guide therapy (tx) and improve outcome is uncertain. We studied 18 consecutive pts (1m, 17f, mean age 43 yrs) presenting with symptoms of dysmotility: 9 receiving AFT guided tx (AFT PTS), and 9 with symptom directed tx (MED PTS). We hypothesized that recommendations (Rx) from AFT testing might alter treatment strategies and improve outcome, over pts that were not tested with AFT. Methods: AFT evaluated sympathetic adrenergic(SAF), vagal cholinergic(VCF), and enteric nervous system function(ENS) as previously reported (Am J Gastroenterol 97(9): 558, 2002). Based on AFT results, therapeutic recommendations were made for each pt. We compared all therapies including GI meds, total medical therapy, and GES device therapy at baseline, short-term (following AFT), and long-term, all follow-up from clinic visits or phone interview. Total Symptom Score(TSS) and subjective assessment of % improvement were used to compare outcomes between the 2 groups at baseline, post-therapy, and long-term. Follow-up was at regular intervals for 24-42 months. Results were compared by paired t-tests and are reported as mean +/- SE. Results: AFT was abnormal (Abn) in 9/9 (100%): 7/9 (77%) with SAF Abn, 8/9 (88%) VCF Abn, and 4/9 (44%) ENS Abn. All pts had therapy changes including meds (n=12) and/or GI electrical stimulation (GES) devices (n=6). GI medical therapy and total medical therapy significantly increased following AFT and remained above baseline over the long-term. Outcomes were improved in AFT PTS based on TSS and % improvement, while MED PTS no improvement(see table). Conclusion: We conclude that AFT provides useful information that may alter treatment strategy for patients with GI motility disorders and the results of these recommendations as shown in this group of patients improve outcomes.

	AFT PTS	MED PTS
GI Therapy Baseline	1.6	-
GI Therapy Post-AFT	3.4	-
GI Therapy Long-Term	3.8	-
Total Therapy Baseline	3.4	-
Total Therapy Post-AFT	5.1	-
Total Therapy Long-Term	9	-
TSS Baseline	11.8	13.2
TSS Post Therapy	7.3	13.8
TSS % Change	35%	0%
Symptom Improvement %	65%	0%

## T1307

### Semilunar Pain - a frequent Cause of Abdominal Distress

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Specific gastroenterologic disorders cannot always be found in patients complaining of abdominal pain. Despite ultrasound, endoscopy, CT, ERCP, and laboratory tests the cause of abdominal pain sometimes remains elusive. In this report, a series of patients is described in whom abdominal pain originated in the abdominal wall. Material and Methods: In 50 consecutive patients without apparent cause for abdominal pain, the point of maximal pain was localized by careful palpation and recorded on a textile fleece after marking the xiphoid, the costal arch, and the umbilicus. Each patient was examined for comorbidity with standard diagnostic tests. Patients with pain in abdominal scars were excluded. Results: Most patients localized their pain with one or two fingertips. Digital palpation revealed small, painful irregularities in the abdominal wall with increasing pain when the patient was asked to sit up in the bed without hands. After questioning, most patients recalled that the pain had been related to a certain type of physical movement. Depending on location, four groups emerged: A) a small painful pit in the linea semilunaris lateral to the musculus rectus abdominis (MRA) (n = 16 right, n = 13 left side); B) localized pain in the midline between the umbilicus and the xiphoid (n = 8); C) localized pain within the MRA (n = 4); and D) painful lower ribs (n = 4). There was

association of A, B, and C with bloating, constipation, sensation of incomplete evacuation, coughing, obesity, exercise (particularly sit-ups), and anxiety. D was associated with anxiety and depression. Defined disorders such as gastroesophageal reflux, cancer, gallstones etc were not associated. Discussion: The most frequent location was in the linea semilunaris, so that the designation "semilunar pain" is proposed. The next most frequent locations were in the midline between xiphoid and umbilicus and at the cartilaginous ribs. The association of the painful rib syndrome with depression has been described before. Abdominal wall distension and straining by bloating, pressing, obesity, and exercise seems to be causative for the pain at these anatomical locations. The very end of this process is frank herniation through the fascia Spigeli and the linea alba, both well-known in the surgical literature. Conclusion: Careful examination of the abdominal wall will reveal well-defined pain syndromes that can be recorded for follow up and verification. Such a diagnosis, though fraught with the risk of missed diagnosis will relieve patients anxiety and can avoid further invasive, diagnostic procedures.

## T1308

### Interobserver Agreement Analysis of a National Inflammatory Bowel Disease Information System (IBDIS)

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Background: The complexity of clinical patterns and the lack of a single differentiating gold standard lead to diagnostic pitfalls in Inflammatory Bowel Disease (IBD). Correct disease classification influences interpretation of epidemiological data, as well as revelation of environmental and genetic determinants. Standards in the documentation of patients with IBD are required to minimize variations in diagnostic and therapeutic procedures. Current classifications of IBD are not based on uniformed parameters and definitions limiting the application in clinical routine and scientific approaches. Methods: For the establishment of an Austrian-wide documentation system (IBDIS) 186 IBD-relevant parameters were selected and included in a data-sheet by 27 representatives of the national working group according to the Delphi method. The parameters are related to demographics, diagnosis, complications, risk factors, pregnancy, surgical and conservative therapy. Variability of parameters was defined and expressed as date (n = 18), binary (n = 50), continuous (n = 8), nominal (n = 24) and ordinal (n = 86). The validity of IBDIS was tested by nation-wide interobserver agreement (IOA) analysis. 16 charts of IBD patients provided from centers in Austria were documented by 18 observers by means of the data-sheet. The strength of agreement was determined using Kappa statistic and considered to be poor if  $K < 0.2$ , fair if  $0.21 < K < 0.4$ , moderate if  $0.41 < K < 0.6$ , good if  $0.61 < K < 0.8$  and very good if  $K > 0.8$ . Results: 24494 single data were obtained to analyze for IOA. In 70% of evaluated parameters IOA was good to very good e.g. diagnosis, ileocolonoscopy, or enteroclysis. Moderate to fair IOA was obtained especially for parameters subjected to potential irregularities of retrospective data collection, such as nicotine consume or joints. Sonography was the single parameter resulting in poor IOA. Our result of very good IOA for CD behavior ( $K = 0.920$ ,  $SEM = 0.068$ ) by predefined IBDIS succeeds in overcoming the difficulties in documentation of this single parameter as previously tested by Steinhart et al. ( $K = 0.353$ ,  $SEM = 0.021$ ). Conclusion: At the first time we present a nation-wide documentation system for patients with IBD (IBDIS), which is validated on each of the included parameters by IOA. IBDIS is a reliable basis for epidemiological, pathogenetical and prognostic relevant studies and should be incentive for the establishment of international standards in IBD documentation.

## T1309

### Quality of Life in Chinese Patients with Inflammatory Bowel Disease: Validation of the Chinese Translation of the Inflammatory Bowel Disease Questionnaire

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BACKGROUND: Health-related quality of life (QOL) is an important outcome measure in inflammatory bowel disease (IBD). The Inflammatory Bowel Disease Questionnaire (IBDQ) is a QOL questionnaire that has not been previously validated on Chinese IBD patients. Such instruments can be unfavourably influenced by cultural differences, societal values, language and idiomatic differences when translated. Reliability and cross-cultural validation of translated questionnaires is therefore mandatory. AIM: To develop and validate a Chinese translation of the IBDQ, specifically determining its construct validity, discriminant ability, reliability and sensitivity to change. METHODS: We developed a Chinese version of the IBDQ (CIBDQ) using the translation back-translation technique. Chinese Crohn's disease (CD) and ulcerative colitis (UC) patients completed the CIBDQ and visual analogue scales (VAS) measuring the 4 domains of systemic, social, bowel and emotional well-being. Patients also completed a validated Chinese SF-36 generic QOL questionnaire, the Crohn's disease activity index (CDAI) or the clinical activity index (CAI) for UC. RESULTS: 135 patients (59 CD, 76 UC) were enrolled, 99 of whom also completed the CIBDQ for a second time. For construct validity, the CIBDQ correlated well with the SF-36 for all 4 domains (Spearman  $r = 0.55 - 0.80$ , all  $P < 0.001$ ), correlated with CDAI ( $r = -0.62 - -0.72$ , all  $P < 0.001$ ) and CAI ( $r = -0.44 - -0.68$ , all  $P < 0.001$ ), and also with the VAS. For discriminant ability, the CIBDQ accurately distinguished between active and inactive disease activity according to the top and bottom tertiles of VAS (Mann Whitney U, for CD all  $P < 0.001$ ; UC  $P = 0.003 - 0.052$ ) and disease activity indices (CDAI all  $P < 0.001$ ; CAI  $< 0.001 - 0.005$ ). The test-retest reliability showed excellent intraclass correlation ( $ICC = 0.76 - 0.92$ , all  $P < 0.001$ ). For sensitivity to change, the CIBDQ was sensitive to changes in disease activity in all 4 domains (Wilcoxon signed rank,  $P = 0.005 - 0.041$ ). The correlation between CIBDQ with the other QOL measurements was stronger for CD than UC. CONCLUSION: The Chinese IBDQ is a valid and reliable test that correlates well with the patients' subjective well-being and also their clinical disease activity. We believe that the Chinese IBDQ will be a useful tool for the assessment of QOL in Chinese IBD patients in clinical trials, health surveys, or for assessment of therapeutic efficacy.