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CZECH REGISTRY OF IBD PATIENTS - A FIRST REPORT OF ITS EXISTENCE

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Background: Creating the patient's database is necessary for availability of up to date informations on the large group of IBD patients. Aim and method: 1. elucidate a current situation in the field of IBD in the Czech Republic; 2. ensure a prospective follow-up of patients; 3. allow a high-level cooperation with international institutions (e.g. ECCO); 4. offer a posibility to create compatible databases in each cooperating center. The database was set up on the basis of a cooperation between centers participating in the Czech IBD Working Group. In order to avoid many drawbacks that could arise during creation of a database, a well-proven Danish system (DCCD) was adopted and modified for our conditions.
Results: The fundamentals of the Registry are as follows: 1. Every patient fulfilling the criteria of IBD can be entered. Simultaneously, retrospective data are collected. 2. Subsequently, all visits are documented using the standardized forms. Disease activity and therapy are the essential informations that are taken. Occasional events (e.g. surgery) are reported if happen. 3. The data are collected in a written and then digitalized. The identity of each patient can not be disclosed. 4. Each center can arbitrarily use it's own data. When data from more centers will be used, each center must agree. 5. The Registry is funded by contributions from pharmaceutical companies. Another sources, like grants, or contributions from the Czech Society of Gastroenterology, will be requested. The Registry started in April 2006; since then, 388 IBD patients have been enrolled in 9 centers out of 18 planned. The descriptive data from the Registry will be presented biannually at the meetings of the Working Group.
Conclusion: The Czech IBD Registry has recently been established. It is believed that it improves cooperation between Czech centers and extends possibilities of collaboration with foreign and international institutions.

P045
THE USE OF AZATHIOPRINE FOR THE TREATMENT OF INFLAMMATORY BOWEL DISEASES IN CLINICAL PRACTICE: A MULTICENTER, RETROSPECTIVE STUDY

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Background: Azathioprine is the most commonly used immunomodulatory drug in Inflammatory Bowel Diseases (IBD). Literature data suggests its efficacy in inducing and maintaining remission of Crohn's disease (CD) and ulcerative colitis (UC); however, important toxicities may limit its use.
Aim: to evaluate the use, the therapeutic and side effect profiles of azathioprine in a large series of IBD patients.
Methods: we reviewed 3353 case histories of IBD patients; the analysis has been performed on 569 patients (280 UC, 281 CD, 8 indeterminate colitis; 307 men) whose clinical data were considered to be exhaustive. Azathioprine has been administered at an initial dosage of 1,5-2,5 mg/kg daily.
Results: indications for treatment were: steroid-dependence in 334/569 (58.7%), steroid-resistance in 111/569 (19.5%), fistulae in 27/569 (4.7%), prophylaxis after surgical resection in 20/569 (3.5%), other in 77/569 (13.5%). Side effects have been observed in 147/569 (25.8%); the main were: myelotoxicity in 42/147 (28.6%), liver toxicity in 26/147 (17.7%), pancreas toxicity in 23/147 (15.6%). Optimal efficacy was observed in 258/569 (45.3%), partial efficacy in 103/569 (18.1%), inefficacy in 85/569 (14.9%), while in 123/569 (21.6%) the effect has not been assessable due to short time of assumption and/or early withdrawal due to side effects. Azathioprine has been discontinued in 246/569 (43.2%): side effects in 99/569 (17.4%), long-standing assumption in 18/569 (3.2%), patient's decision in 35/569 (6.2%), inefficacy in 45/569 (7.9%), other in 49/569 (8.6%). It has been discontinued because of side effects after a mean time of 11 months (range 1-118 months). Azathioprine has been continued during pregnancy in 14/262 women (5.3%) without negative effects on outcomes.
Conclusions: in our series, azathioprine confirms its clinical usefulness and its acceptable safety profile in managing complicated IBD patients. However, its use appears to be complicated by quite a number of side effects, some of them leading to drug discontinuation.

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PREGNANCY IN IBD PATIENTS

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Aim of the study: To recognize the influence of IBD on course of pregnancy, childbirth in one tertial IBD centre in the past five year period. Methods and patients: The retrospective analysis of 44 pregnant IBD pts. (13 UC and 31 CD). We observed activity of IBD in conception, frequence and severity of relapses in the course of gravidity, medical therapy during gravidity, time of childbirth and rate of malformations.
Results: 39 pts (89%) were in remission at the time of conception. Out of them, 4 pts (10%) experienced severe relaps in course of gravidity (3 UC 1 CD). One patient aborted at 20th week of gravidity (CD) and 1 relapsed within childbed. 5 pts (11%) concieved during flare up of the disease, 2 of them went to the remission at 10th and 12th week of gravidity, 1 aborted at 10th week of gravidity, 1 (CD) underwent surgery intervention (ileocolic resection) at 12th week of gravidity due to massive bleeding and in last 1 patient the activity continued over the whole time of gravidity. Majority of pts was treated with combined medical therapy. The most frequent combination was mesalazine with azathioprine. No malformation occurred in any patient.
Conclusions: Active disease at time of conception increased risk of unfavourable course of gravidity. The relaps of disesase during gravidity was more frequent in pts sufferring from UC than CD. The conventional medical therapy in gravidity was save and didn`t increase the risk of malformation.

P047
SAFETY AND EFFICACY OF ORAL, COLONIC-RELEASE, LOW MOLECULAR WEIGHT HEPARIN-MMX™ FOR THE TREATMENT OF MILD TO MODERATE LEFT-SIDED ULCERATIVE COLITIS: PRELIMINARY REPORT OF A PILOT STUDY

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Introduction: efficacy of heparin and low-molecular-weight-heparins (LMWHs) in UC has been suggested. The multimatrix oral formulation MMx™ (Cosmo Technologies Ltd, Ireland) allows the release of active drugs to the left colon, avoiding systemic absorption and side effects. Parnaparin is the LMWH chosen to be carried in the MMx™ formulation.
Aim: to assess the safety and the efficacy of three different oral dosages of Parnaparin-MMx™ in mild-to-moderate left-sided UC.
Methods: 10 UC patients (4 with 70 mg, 4 with 140 mg and 2 with 210 mg, once daily) enrolled. All had relapsed during maintenance therapy with mesalamine and had a DAI $>$ 4 and $<$ 10 and an EAI $>$ 2. All patients received Parnaparin-MMx™ while continuing mesalamine treatment at a stable dose for 8 weeks. CAI was assessed at time 0 and at 1, 2, 4, 6 and 8 weeks. EAI and DAI were assessed at time 0 and week 8. A strict clinical and laboratory follow-up, including assessment of clotting parameters and anti-factor Xa activity, was performed.
Results: 1 patient of low-dose group retired from the study for clinical deterioration. No relevant side effects were observed. Slight and transient increases in CK and ALT were observed in two patients. No interference with haemostasis parameters was observed nor increased rectal bleeding. Statistical analysis was performed by means of Student's paired "t" test. Mean ($\pm$ SD) final CAI and DAI are significantly lower than basal CAI and DAI (4.6 ± 1.6 vs. 2.1 ± 2.0; $p<0.02$) and (7.4 ± 1.3 vs. 4.2 ± 2.7; $p<0.006$), respectively. A trend towards a reduction in EAI was also noted (7.8 ± 1.7 vs. 6.0 ± 4.1; $p=0.22$).
Conclusions: oral Parnaparin-MMx™ appears to be a safe and effective treatment option in mild to moderate ulcerative colitis. Controlled studies are warranted to confirm its therapeutic effect.