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Long-term outcome of patients with ulcerative colitis and first course of intravenous corticosteroids

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Background: Although the early outcomes of ulcerative colitis (UC) after a first course of corticosteroids are well known, data on long-term disease evolution are scarce. Our aim was to evaluate long-term clinical outcomes of patients with moderate or severe attacks of UC after the first course of intravenous corticosteroids. We estimated outcomes according to whether they were admitted to UC and those directly treated with intravenous corticosteroids.

Methods: All episodes of patients with active UC admitted to Tampere University hospital between January 2007 and January 2016 were identified and retrospectively reviewed from patient records. Only patients who were admitted first time with intravenous corticosteroids were included. Treatment outcome was compared between episodes which failed to outpatient oral corticosteroids and those directly treated with intravenous corticosteroids.

Results: Total of 216 episodes were included, 40% of patients had failed to outpatient oral corticosteroids, in 45% UC was diagnosed during this treatment period and 15% were without previous oral corticosteroids. Only 64% of those who had failed oral corticosteroids had response to intravenous corticosteroids, the other groups the results were 90% and 81%, respectively. 94% of the non-responders were treated with intravenous cyclosporine of which 85% responded, thiopurine was used as maintenance therapy. Three of those who had failed oral corticosteroids and one who had undiagnosed disease needed emergency colectomy.

6 months after treatment period 28–32% of patients were on steroids but there was no difference between the groups. Later nearly two-thirds required further corticosteroid therapy. The colectomy rate was almost twofold among those who failed oral corticosteroids, (31% vs. 15.35 -18.8%) during the follow-up time, median 6.2 years (0-9.6). The proportion of patients that reached response at the end of follow-up was 45.2% (14/31). When we compared the short-term response by induction regimen we did not find differences (14/21 vs. 8/10 iv, p = 0.4). A total of 7 patients (22.6%) needed maintenance dose escalation.

Conclusions: UST showed clinical benefit in these CD refractory patients. No differences were found in short-term response by induction regimen (sc or iv).

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Ustekinumab use in Crohn’s Disease: Does short-term effectiveness correlate to induction regimen?

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Background: Efficacy of ustekinumab (UST) in Crohn’s disease (CD) has been demonstrated in clinical trials. If real-world symptomatic response and remission are different depending on the induction regimen (sc or iv) is still unknown.

Methods: A retrospective, observational study was conducted in three Spanish hospitals. Response was defined as decrease of HBI ≥3 points and remission as HBI <4. Response and remission were assessed after induction, at 6 and 12 months and at the end of follow-up.

Results: Until September 2017, 31 CD patients were treated with UST. Twenty-one patients (67.7%) received sc UST (90 mg, 0, 1, 2, 3) and 10 (32.3%) iv (6 mg/kg) induction followed by UST sc (90 mg sc/8 w) maintenance treatment. Median treatment duration was 19.3 months (3–64). Among these 31 patients (18 female, median age 39.4 years, median disease duration 10.8 years), 24 (77.4%) had failed to 2 or more anti-TNF agents and 6 to one. At time of UST introduction, 7 (22%) patients received immunosuppressant (IS) and 11 (35.4%) steroids. Short-term response after induction was achieved by 22 patients (71%). Response at 6 and 12 month were 80% (16/20) and 70.5% (12/17). Remission at 6 and 12 month were 50% (10/20) and 58.5% (10/17). The proportion of patients that reached response at the end of follow-up was 45.2% (14/31). Among these, 76 (20%) had response to infliximab but non-remission after one year of infliximab treatment. In total, 376 Crohn’s disease patients received infliximab. Among these, 76 (20%) had response to infliximab but non-remission as evaluated after one year of scheduled infliximab maintenance therapy. The majority of these patients (64%) had non-remission due to luminal symptoms, or mucosal activity, or both; whereas 36% had either isolated or concomitant perianal fistulising activity (Figure). After another year of continued infliximab therapy, the vast majority (54/76; 71%) experienced no additional therapeutic benefit, still having response but non-remission. Only 25% (19/76) obtained remission, whereas 4% (3/76) developed secondary treatment failure (Figure). Infliximab therapy beyond two years (median follow-up 150 weeks, Interquartile range 102–237) resulted in a
higher proportion of patients improving (39.5%); however, nearly half of the patients (46.1%) still failed to improve further. In a subgroup of patients (n = 21) who discontinued infliximab while having response but non-remission, half (n = 11) experienced disease flare after median 22 (IQR: 12–31) weeks from last infliximab administration, whereas the other half had no disease change or actually improved.

Flow-chart and classification of patients with response but non-remission to infliximab after one year and their status after two years of therapy

Conclusions: Most patients with response but non-remission after one year of infliximab therapy did not attain remission despite continued long-term infliximab therapy. Considering the growing evidence of the clinical importance of achieving remission (clinically and endoscopically), these patients have an unmet medical need.

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Switching between anti-TNF originator and biosimilar in patients with inflammatory bowel disease: Can it be recommended? A systematic review

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Background: It is not known in detail whether it is possible to switch from infliximab reference medicinal product (Remicade®) to biosimilar (CT-P13) in patients with inflammatory bowel disease (IBD) without any detrimental effects on safety and efficacy. Our aim was to review the effectiveness and safety of switching from a reference medicinal product to a biosimilar, focusing on the experience of switching between Remicade® and CT-P13 in patients with IBD.

Methods: Electronic and manual search in PubMed and international conferences (ECCO, UEGW, and DDW) up to September 2017.

Results: We identified 24 studies evaluating the switching between Remicade® and CT-P13 in 1326 IBD patients. Most studies were retrospective and generally included a low number of patients; only one was randomised. Effectiveness was evaluated only by clinical assessment, but not endoscopically. Follow-up ranged from 1.5 to 12 months, being 6–12 months in most studies. Disease control (no disease worsening after switching) was confirmed in most of patients (weighted mean, 88%; 95% CI = 86–89%). When only studies including a more homogeneous follow-up from 4 to 8 months were included, this figure was 90% (89–92%). When a subanalysis was conducted only for Crohn’s disease, the proportion of patients maintaining disease control after switching was 86% (82–89%); the corresponding figure for ulcerative colitis was 93% (89–96%). No unexpected adverse events were reported in any of the studies. When evaluated, no differences in adverse events before and after switching were reported either. Furthermore, no differences in adverse events between patients with and without switching were confirmed (in those studies including these two subpopulations). Finally, in the only randomised controlled trial study performed up to now (the NOR-SWITCH trial), the frequencies of reported adverse events were not different between patients with and without switching.

Conclusions: The risks of switching from Remicade® to biosimilar CT-P13 seem theoretical and are not supported by the limited real-world safety experience so far. On the contrary, an increasing number of publications have shown that there seems to be no safety or efficacy concerns about switching. Therefore, switching from infliximab originator to biosimilar in patients with IBD may be considered acceptable.

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Anthropometric measures in adolescents with inflammatory bowel disease: A population-based study

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Background: Growth impairment is common in paediatric inflammatory bowel disease (IBD) patients. Nevertheless, a controversy exists regarding disease impact on final adult height. We investigated the impact of IBD on anthropometric measures, including weight, height and body mass index (BMI), at late adolescence in a cross-sectional, population-based study.

Methods: A total of 1144213 Jewish Israeli adolescents who underwent a general health examination from 2002 to 2016 at a median age of 17.1 years (interquartile range 16.9–17.4) were included. IBD cases were stratified into Crohn’s disease (CD) and ulcerative colitis (UC). Patients were also sub-grouped based on age at IBD diagnosis.

Results: Overall, 2372 cases of IBD were identified out of 1144213 persons examined (0.2%). CD accounted for 68% of IBD cases. Both UC and CD patients had significantly lower weight and BMI compared with controls. Differences in near-final height were not statistically significant for either disease compared with controls (Females: 162 cm vs. 161.7 cm vs. 161.5 cm, Males: 174 cm vs. 173.7 cm vs. 173.6 cm for controls, UC and CD, respectively). Subgroup analysis showed that patients with CD diagnosed at age<14 years were significantly shorter than those diagnosed at age >14 years (CD: 172.9 cm vs. 173.9 cm for males, 160.5 cm vs. 161.8 cm for females, p < 0.05). The same was true for UC (173.9 cm vs. 173 cm for males, 161.6 cm vs. 160.9 cm for females, p < 0.05).

Conclusions: IBD adolescents were leaner compared with the general population. No overall difference was noted in near-final height. Younger age at diagnosis is associated with slightly (though significantly) reduced near-final height.