East Kent Hospitals University NHS
NHS Foundation Trust

Newsround & Future Gazing

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The slides have been reviewed for off label information by Ferring Pharmaceuticals

Disclosures

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- Received speaker fees for conferences and meetings from AbbVie, Ferring and Tillotts Pharmaceuticals
- Attended Advisory Board meetings for AbbVie, Ferring Pharmaceuticals

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Best of 2020/21

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UEGW Virtual 2020

Final results of SPOSIB SB2 Biosimilar

- 1st prospective study of infliximab biosimilar SB2 in patients with IBD
- Safety & efficacy similar to CT-P13
- 192 patients, 57.3% achieved steroid free remission, 13.5% partial response, 29.5% no response
- Rate of steroid free remission increased in patients naïve to both anti TNF's than other TNF's
- Study concluded multiple switches are safe

Macaluso F. SPOSIB SB2 – A Sicilian prospective observational study of patients with inflammatory bowel disease treated with infliximab biosimilar SB2: Final results. Presented at United European Gastroenterology Week Virtual 2020, 11–13 October 2020. Virtual. P0487

Randomised clinical trial: high-dose oral thiamine versus placebo for chronic fatigue in patients with quiescent inflammatory bowel disease

- High dose oral thiamine reduces chronic fatigue in patients with quiescent IBD
- Nurse Led Research
- 40 patients with >3/12 remission Mean FCP 51
- Chronic fatigue >12 on IBDF
- Randomised to high dose thiamine based on weight/sex
- Primary endpoint fatigue improvement of >3 points on IBDF

Palle Bager , Christian Lodberg Hvas , Charlotte Lock Rud , Jens Frederik Dahlerup

IBDF

- What is your fatigue right now 0-4
- What was your highest level of fatigue in the past two weeks 0-4
- What was your lowest level of fatigue in the past two weeks 0-4
- What was your average level of fatigue in the last two weeks 0-4
- How much of your waking time have you felt fatigued in the past two weeks 0-4
  - Score from 0-4, with 0= No fatigue & 4 Severe Fatigue
  - Possible scores 0=None, 1=Some of the time, 2=Often
  - 3=Most of the time, 4= All of the time

  Conclusion – Met primary endpoint

  Thiamine dose 600mg-1800mg daily

High Consumption of Ultra-Processed Foods Associated with the Development of CD

- Crohn's 368 cases, UC 488 cases Mean age 56
- To evaluate the association between UPF consumption and the risk for CD and ulcerative colitis, researchers analyzed 241,252 patients from the Nurses' Health Study and the Nurses' Health Study II.
- Researchers noted no association between consumption of UPFs and emulsifier and risk for UC.
- A higher consumption of UPS products especially ultra-processed grain foods, fat, sauces and emulsifier/thickener-containing foods was associated with increased risk of CD

Stephen B. Hanauer 2021

DDW

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Comprehensive Interdisciplinary Care Program for recently Diagnosed IBD Patients Associated with Lower Healthcare Resource Utilisation

- 182 patients (89 COMPASS-IBD & 93 control)
- Two groups didn’t differ significantly by baseline demographics
- COMPASS-IBD group Access to IBD specialist, nutritionalist, behavioural health specialist & pharmacist
- Control group normal care
- COMPASS-IBD Group less likely to have any ED visit, hospitalisation or follow up in 1 year, more likely to have normal BMI & more clinical remission

Gold S et al May 2021 Abstract 567

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Effectiveness of Ustekinumab for Management of Extra-intestinal Manifestations of Crohn's Disease

- Retrospective study of patients with an active or prior EIM at the of induction of Ustekinumab
- Trend towards higher clinical remission in group with EIM 44.4% 12/27 v non response group 14.3% 2/14

Conclusion

Ustekinumab therapy for Crohn's resulted in an improvement or resolution of EIM in two thirds of patients

Aboubakr A et al 2021

Higher Ant-TNF Drug Concentration is Associated with MRI Healing of Perianal Fistulising Crohn's Disease

- Multi-centre (10 tertiary centres) cross sectional retrospective study of perianal fistulising patients
- MRI disease activity using Van Assche Index
- 193 patients - Infliximab 117, Adalimumab 76
- Optimal trough levels for radiological healing and remission were Infliximab 4.0ug/ml and 6.5ug/ml & Adalimumab 7.2ug/ml and 9.7ug/ml

Conclusion – Higher anti-TNF levels were associated with improved parameters in patients with perianal fistulising Crohn's

Gregorio M et al 2021 Abstract Su437

Frequent disease relapse after withdrawal of infliximab in IBD patients with sustained remission.

- Prior analysis of withdrawal of infliximab inpatients in corticosteroid free clinical remission have demonstrated
- •50% relapse at 1year(Louis et al 2012)
- •18% relapse free survival at 7 years (Reenaersetal 2018)
- Primary Outcome – Relapse free survival
- Secondary Outcomes – Identification of predictors of relapse, Evaluation of response to future therapy
- IBD patients who ceased infliximab due to sustained remission were identified.
- After screening 75 patients were identified. CD:UC = 43:32. F:M = 34:41, median age = 31.3 years

Outcomes after relapse

- 44 total relapses
- 43.1% (19/44) required steroids - 88.6% (39/44) restarted a biologic
- 68.2% (30/44) restarted infliximab

Of those who restarted infliximab

- 17 responded to standard - 3 successful dose escalation
- 4 non responders with ADA - 2 non responders no ADA
- 4 unknown
- **Conclusion – By 24 months after infliximab cessation ,over 75% patients with CD and UC had relapsed. This is despite the majority of patients being in biochemical or endoscopic remission**

H Gordon, J. Murray, F. Tailor, S.A. Goh, J O Lindsay 2021

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What is the future?

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Medication

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Agent	Studies	Main findings
Upadacitinib	U-ACCOMPLISH and U-ACHIEVE: Phase III, placebo- controlled trials of induction therapy in UC	Upadacitinib was superior to placebo for clinical remission, clinical response, endoscopic improvement, endoscopic healing, histologic-endoscopic improvement at Week 8[1,2] Evidence of benefit vs. placebo from Week 2[1,2]
Filgotinib	SELECTION: Phase III, placebo- controlled trial of induction and maintenance therapy in UC	At Week 10 (induction): Filgotinib 200 mg demonstrated superior rates of clinical remission vs. placebo in the overall population, and in both biologic naïve and in biologic-experienced patients (100 mg showed no significant difference vs placebo). Prior biologic therapy was associated with a reduction in clinical benefit[3] At Week 58 in Week 10 responders (maintenance), the treatment benefit (clinical remission) with filgotinib 200 mg was attenuated by prior biologic therapy (but was still significantly different vs. placebo)[3] Improvement in stool frequency and rectal bleeding with filgotinib 200 mg within approximately 7 days[4] Safety data also reported[5]
Risankizumab	ADVANCE and MOTIVATE: Phase III, placebo-controlled trials of induction therapy in CD	Significant difference in rates of clinical remission from Week 4 to Week 12 for risankizumab vs. placebo[6] Significantly more patients in endoscopic remission at Week 12 with risankizumab vs placebo[7] Significant benefits reported on patient-reported outcomes (IBDQ, FACIT-F, SF 36)[8]

Future

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SAFE STAFFING SAVES LIVES

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BRITISH SOCIETY OF GASTROENTEROLOGY

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Questions?

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15th National IBD
Nurse Forum 2021

EVER INCREASING CIRCLES

THE EVOLUTION OF THE IBD NURSING ROLE

FERRING
PHARMACEUTICALS