BSG 2014 abstracts

Introduction The natural history of low-grade dysplasia (LGD) found during colonoscopic surveillance of ulcerative colitis is not clear. The optimum strategy, either continued surveillance or immediate colectomy, is debated. The rate of progression of LGD to more advanced neoplasia has been reported to be as low as 0% after 10 years and as high as 53% after a mean follow-up of 5 years.1,2

Methods All cases of LGD detected at colonoscopy in patients with ulcerative colitis performed between May 1995 and May 2010 were identified, retrospectively, from the pathology database at a single tertiary centre. Endoscopy records and case notes were reviewed and the outcomes for patients undergoing either immediate colectomy or further surveillance endoscopy were included.

Results 22 patients with LGD were identified. 9 patients had endoscopically resectable adenoma – like lesions, and were excluded from further analysis. 13 patients were identified as having unifocal, flat, LGD. The median age was 68 (range 44–87). The median time from diagnosis of ulcerative colitis was 14 years (range 1 to 29 years). All patients were on 5-ASA’s throughout the time period sampled.

8 patients elected to have an immediate colectomy. 5 of 8 resection specimens were negative of LGD, with features of the underlying Ulcerative Colitis. Unifocal LGD was identified in 3 of 8 patients. No advanced neoplasia (HGD or cancer) was identified.

4 patients continued surveillance with a median follow-up of 6.5 years (range 5–9) and a median number of colonoscopies of 5 (range 3–7). LGD was identified on further colonoscopy in 1 patient. This patient then opted for colectomy, but no LGD was identified in the resected specimen. 3 patients had further LGD identified during surveillance endoscopy. The remaining patients had LGD identified at colonoscopies performed outside their scheduled surveillance interval. To date those undergoing surveillance have had no subsequent LGD, HGD or carcinoma.

Conclusion The finding of LGD in patients with ulcerative colitis is associated with a low risk of synchronous or subsequent advanced neoplasia. Continued surveillance may be a reasonable option in this group of patients.

REFERENCES

Disclosure of Interest None Declared.

PTU-068 EFFICACY AND SAFETY OF GRANULOCYTE, MONOCYTE/MACROPHAGE ADSORPTIVE APHESIS IN STEROID-DEPENDENT ACTIVE UC WITH INSUFFICIENT RESPONSE OR INTOLERANCE TO IMMUNOSUPPRESSANTS AND/OR BIOLOGICAL THERAPIES (THE ART TRIAL): WEEK 12 RESULTS

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Introduction Current medical options for patients with refractory steroid-dependent, chronic-active ulcerative colitis (UC) are limited. Immunosuppressants (IS) and biologics carry risks of severe side effects and patients may not respond. The efficacy of of Granulocyte, Monocyte/Macrophage adsorptive (GMA) apheresis with Adacolumn® is supported by an increasing number of randomised controlled trials. The present study intended to generate further data to document efficacy and identify subpopulations of refractory UC that may benefit from GMA apheresis.

Methods This was an uncontrolled, open-label, multicenter trial conducted in the UK, France and Germany. Consecutive eligible patients (age ≥ 18 ≤ 75 years) with steroid-dependent active UC, a Rachmilewitz (CAI) index ≥ 6, an Endoscopic Activity Index (EAI) ≥ 4, and insufficient response or intolerance to IS and/or biologicals were included. Patients received at least 5 weekly GMA aphereses. Evaluation visits were planned at Week 12, 24 and 48. The primary endpoint was the remission rate (CAI ≤ 4) at Week 12 in the Intention-to-treat (ITT) population.

Results We report interim results from the 12 Week visit. The ITT population comprised 84 enrolled and treated patients at cutoff date. At Week 12, 33 (39.3%) subjects had achieved remission. For 30 patients with prior failure of IS and/or biologicals, the remission rate was 30%. Secondary efficacy parameters were clinical response with reduction in CAI of ≥ 3 (47 or 55.9%), steroid-free remission (23%) and steroid-free response (36%). In remitters, EAI dropped from 8.2 to 4.4; in responders from 8.6 to 5.3. Quality of Life improved in parallel. Most subjects had Adverse Events (AEs) of mild or moderate intensity. Six (7.1%) of 85 subjects in the Safety Population experienced serious (SAEs), all in the treatment-emergent period; however none was considered related to study treatment. No new safety signals were seen.

Conclusion This study describes a larger cohort of steroid-dependent moderate-severe active UC patients intolerant or refractory to IS and/or biologicals treated with GMA apheresis. Apheresis was safe and showed benefit in over half of these patients and remission in 39.3% at week 12. Leukocyte apheresis (Adacolumn) for IBD has been reviewed by NICE as suitable for carefully selected patients with IBD, and these results help define this sub-group. Further controlled studies are needed.

Disclosure of Interest None Declared.

PTU-069 740 PATIENT YEARS OF ANTI-TNF SAFETY DATA IN CROHN’S DISEASE PATIENTS

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Disclosure of Interest None Declared.

Abstract PTU-069 Table 1

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<thead>
<tr>
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<th>Mild</th>
<th>Moderate</th>
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<tr>
<td>Ifx</td>
<td>30 (22.6%)</td>
<td>23 (17.3%)</td>
<td>7 (5.2%)</td>
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<tr>
<td>Al</td>
<td>40 (28.3%)</td>
<td>18 (12.8%)</td>
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Results

Median age of pts was 41 (range 20–79) yrs. Total lifetime yrs on anti-TNFs was 740.6 (331.2 on Ifx, 409.4 on Al) yrs. 133 pts were treated with Ifx (75 females), 4 had previously been on Al. Median length of Rx with Ifx was 20 (range 1 dose-still on at 140) months. 98 (73.6%) pts on Ifx were on a concomitant immunomodulator drug. 141 pts were treated with Al (79 females), 53 had previously been on Ifx. Median length of Rx with Al was 33 (range <1-still on at 89) months. 62 (44.0%) pts on Al were on a concomitant immunomodulator.

54 (40.6%) pts had AEs whilst on Ifx (see Table 1 for severity), including lymphoma (2 pts), solid organ tumours (3), pulmonary TB (2), infusion reaction (13), cutaneous side effects (SEs) (7), other infections (12). 33 pts were still on Ifx at the time of this study. 30 pts (22.6%) stopped Ifx due to AEs. 13 pts had an infusion reaction. Pts were most likely to have an infusion reaction at infusion 2 (6 pts).

Overall, 57 (39.7%) pts suffered from AEs on Al (see Table 1 for severity), including solid organ tumours (2 pts), cutaneous SEs (10), neurological symptoms (3) and other viral/bacterial infections (28). 88 pts were still on Al at the time of this study. 21 pts (14.9%) stopped Al due to AEs.

Pts were more likely to suffer from an AE with increasing age (p = 0.041 for Ifx, p = 0.016 for Al). Patients over 50 yrs were more likely to suffer from an AE than those less than 50 (p = 0.015 for Ifx, p = 0.015 for Al). Pts over 70 yrs were more likely to suffer from an AE than those less than 50 (p = 0.041 for Ifx, p = 0.016 for Al). Patients over 50 yrs were more likely to suffer from a moderate or severe AE on Al (p = 0.015 for Ifx, p = 0.015 for Al). Pts over 70 yrs were more likely to suffer from a moderate or severe AE on Al (p = 0.009), there was no relationship for Ifx. Gender, smoking status and use of immunomodulators had no effect on AEs. No significant relationship found between length of Rx and development of AEs. No statistically significant difference found in AEs frequency between Ifx and Al.

Conclusion

This study found that AEs are independent of the length of time on anti-TNFs, but are associated with increasing age of the patient. Patients over 50 yrs are more likely to have an AE on Ifx and Al. Patients over 70 yrs are more likely to have a moderate or severe AE on Al.

Disclosure of Interest

None Declared.

PTU-070

NON-ADHERENCE WITH RECTAL PREPARATIONS IN COLITIC PATIENTS. FACT OR FICTION?

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Introduction

Rectal preparations containing steroids or 5-aminosalicylates are an effective treatment for distal colitis. Nonetheless, it is perceived that this therapy is associated with poor levels of adherence and that patients are not readily accepting of it. This might make gastroenterologists reluctant to prescribe rectal preparations. The patient experience and factors determining adherence with this modality of treatment have not been investigated before. The aim of our survey is to evaluate patient compliance with rectal preparations and explore the possible reasons why compliance is not always achieved.

Methods

A short anonymised survey was distributed over a 3-month period at general gastroenterology and IBD outpatient clinics to patients with a known diagnosis of ulcerative colitis. There were questions on baseline demographics and other details relating to compliance. A free text option was also available for suggestions that could improve compliance.

Results

Over the period November 2013–January 2014, a total of 59 completed surveys were received. 21 of 59 patients (36%) had never been prescribed a rectal preparation. Of the remaining 38 patients with reported experience of rectal preparations, 60% were male with a median age of 45 years. Surprisingly, 76% of these (29 patients) answered ‘yes’ to being compliant with the preparation(s), and they had been prescribed courses ranging from once/day for 2 weeks to thrice/day-long term. 20 patients had been prescribed foam and/or liquid enemas, 8 patients a suppository, and 1 patient a suppository and foam enema. 93% of the compliant patients reported an improvement in their symptoms with the use of rectal preparations. Though compliant, 24% reported ‘yes’ to having difficulties using the rectal preparation citing “insertion difficulties” and “difficulty retaining the fluid” and “at work” as the main reasons. When asked for suggestions to improve compliance, 62% felt reduction of treatment frequency to once/day would help, and 21% felt that better explanation about administration would help. Of the 9 patients who admitted to being noncompliant, 3 had difficulties with administration, 2 experienced pain, and the majority felt that a better explanation about administration would have improved compliance. As expected, the majority of noncompliant patients felt that the rectal preparation had made no difference to their symptoms.

Conclusion

Compliance with prescribed rectal preparations is surprisingly high. This is an encouragement to continue promoting its use. Compliance could be further improved by allowing for patient factors such as work hours and adjusting dosing times, and by dedicating time to explain how the medication should be administered.

Disclosure of Interest

None Declared.

PTU-071

METHOTREXATE THERAPY FOR ULCERATIVE COLITIS IN THE DISTRICT GENERAL HOSPITAL SETTING: A USEFUL SECOND-LINE OPTION FOR PATIENTS


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Introduction

The case for methotrexate (MTX) therapy has been comprehensively compiled in Crohn’s disease, with trials showing its efficacy in both induction and maintenance of remission. By contrast, the evidence remains patchy for ulcerative colitis (UC). BSG guidelines recommend its trial as a second-line agent in those patients intolerant of, or resistant to, azathioprine (AZA) or mercaptopurine (MP). Previous studies show conflicting results for MTX in UC; with response rates between 22–33%, with a high rate of colectomy, 44%, in one of the studies. We aimed to review the clinical effectiveness of MTX in our cohort of UC patients who had previously tried, or failed, with thiopurine therapy.

Methods

A retrospective analysis of patients taking MTX for UC was carried out. Subjects were identified from our inflammatory bowel disease database. All patients had trialled thiopurine therapy prior to MTX. Their outcomes on these treatments, including reasons for discontinuation, were recorded. It is current policy within our department to start with oral MTX (plus folate supplementation), initially 15 mg once weekly, increasing to 20mg or 25mg as necessary. Clinical response at 12 weeks and 12 months was used to assess efficacy of MTX treatment. The primary endpoint was steroid-free remission.

Results

A total of 21 UC patients (male = 62%) were identified. Median age was 61 years (range 21–82). Disease pattern was extensive (43%), left-sided (19%), and recto-sigmoid (38%).