 treatment to 40 mg adalimumab (ADA) every other wk (EOW) to 40 mg ADA every wk (EW) to 40 mg ADA EW +2.5 mg/kg azathioprine (AZA)/day at 12, 24, and 36 wks after randomization based on failure criteria (CD Activity Index (CDAI)=200 or decrease <70 points [1 wk pre-randomisation] or <100 points versus baseline [at wk 11, 23, 35] and prednisone use for the CMG; CDAI=150, C-reactive protein=5 mg/L, faecal calprotectin=250μg/g, and prednisone use for the TCG). At 24 and 36 wks, if criteria were not met, patients de-escalated ADA EW to dose of 40 mg ADA EOW. Pts re-escalated if failure criteria were met at the next visit. The primary endpoint (mucosal healing [CD Endoscopic Index of Severity <4] and no deep ulcers at 48 wks post-randomisation) was evaluated in pts who de-escalated-treated. Analyses were performed in pts who completed the study and did not move to rescue therapy. Non-responder imputation was used for missing data.

Results 15 pts in the CMG and 31 pts in the TCG de-escalated treatment during the study. Of those, 2 pts in the CMG and 8 pts in the TCG re-escalated to 40 mg ADA EW. Overall, 54% of pts in the CMG and 61% of pts in the TCG who de-escalated to 40 mg ADA EW ± AZA achieved the primary endpoint (table 1). Of the pts who re-escalated to ADA EW, 0% in the CMG, and 75% in the TCG achieved the primary endpoint (table 1). The overall adverse event rates have been previously reported (Colombel, 2018)

Conclusions Our data suggest that repeated dose optimization based on tight control is a more refined approach resulting in mucosal healing compared with clinical management. Larger data sets are needed to confirm our observation on repeated dose optimization.

Abstract PTH-077 Table 1 Proportion of patients who reached the primary endpoint who de-escalated and/or re-escalated treatment

<table>
<thead>
<tr>
<th>De-escalated and remain de-escalated</th>
<th>CM n/N (%)</th>
<th>TC n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 mg ADA EW to ADA EOW</td>
<td>7/13 (53.8)</td>
<td>7/13 (53.8)</td>
</tr>
<tr>
<td>40 mg ADA EW +2.5 mg/kg AZA/day</td>
<td>0</td>
<td>7/10 (70.0)</td>
</tr>
<tr>
<td>to ADA EOW +2.5 mg/kg AZA/day</td>
<td>Re-escalated</td>
<td></td>
</tr>
<tr>
<td>40 mg ADA EW to ADA EOW to ADA EW</td>
<td>0/2</td>
<td>6/8 (75.0)</td>
</tr>
</tbody>
</table>

REFERENCE


PTH-078 VEDOLIZUMAB POST RESECTION FOR CROHN’S DISEASE: A 4 YEAR REAL WORLD EXPERIENCE

Johanne Brooks*, Mark Tremelling, Norfolk And Norwich University Hospital, Norwich, UK

10.1136/gutjnl-2019-BSGAbstracts.137

Introduction Vedolizumab is a gut specific anti integrin biological therapy that NICE guidance indicates can only be used only in moderate to severe Crohns disease if an anti-TNF has failed, cannot be tolerated or is contraindicated and should be given as a planned course of treatment until it stops working or surgery is needed. There is no documentation regarding vedolizumab post resectional surgery. This audit utilises 4 years of data of using vedolizumab in a tertiary centre and assesses response rates, the use of vedolizumab post surgery and observations regarding TNF naïve and patients with a history of prior cancer on vedolizumab.

Methods Utilising the vedolizumab database from the IBD department, the last 4 years of data was analysed, specifically identifying those who had resectional surgery with vedolizumab post surgery for prevention of recurrence or confirmed anastomotic recurrence. Data included indications for vedolizumab and Rutgeerts scoring at the anastomosis for those who had TI surgery.

Results 81 patients’ data were on the vedolizumab database and their clinical notes were audited by the IBD team. Clinical remission was achieved in 49% of patients in our cohort, with the other 51% having a loss of response, side effects or primary non responders.

37% of those whose Crohns was in remission post vedolizumab were anti-TNF naïve compared to 12% of anti-TNF naïve patients in whom vedolizumab failed.

Conclusions Over 4 years, we achieved clinical remission in 49% of patients with Crohns disease using vedolizumab. 34% of these patients had had resectional surgery for their Crohns disease and were in remission. This real world data indicates that vedolizumab is a useful biological therapy in maintaining remission in patients post resectional Crohns surgery. The data also suggest, in concordance with the current literature, that being anti-TNF naïve affords a better prognosis with vedolizumab, than having failed treatment with an anti-TNF prior to vedolizumab.

REFERENCE