Reviewer's report

Title: Infliximab for pediatric patients with ulcerative colitis: a phase 3, open-label, uncontrolled, multicenter trial in Japan

Version: 0 Date: 06 Jun 2019

Reviewer: Wafaa Al-Qabandi

Reviewer's report:

Comments:

Background:

Line 58: UC is a "rare" inflammatory disease. UC is not considered a rare disease any more. Therefore, it should be mentioned that the disease is considered rare in Japan.

Methods:

Patients:

Line 102: "≥6 episodes/day of bloody diarrhea". Those patients with that much of bloody diarrhea were excluded from the study, why?? This might indicate moderate-sever UC, why were they excluded? Other exclusion factors were OK.

Table 1:

Aminosalicylates used in 19 patients (90.5%) and 5-aminosalicylates used in 17 patients (81.0%). What is the difference between those 2 medications? The available aminosalicylates used in UC patients are usually 5-ASA.

Discussion:

Line 286: "PUCA at 30 weeks (19%), which is lower than other reports". This might indicate that IFX is not affective over time on Japanese patients. It will be interesting to know what was the management plan for those patients. Did they continue IFX maintenance further? Did they receive higher doses or discontinue therapy?

Summary:

This study is uncontrolled with no control group of patients to compare with; therefore, it can't exactly prove the effectiveness of IFX in those patients. However, IFX was proved by multiple previous studies to be effective in the treatment of moderate-severe UC. Therefore, this is a good observational study
that shows the tolerability of IFX in Japanese UC children. As the patients were followed up then the study is good in showing the adverse effects of the drug on those particular patients.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

No

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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Acceptable

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