IDDF2021-ABS-0055

ANALYSIS OF EXPOSURE-OUTCOMES OF USTEKINUMAB IN PATIENTS WITH REFRACTORY CROHN'S DISEASE

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10.1136/gutjnl-2021-IDDF.121

Background Ustekinumab (UST), a newly-used biologics targeting p40 subunit of IL12 and IL23 in China, exerts confirmed therapeutic effect in induction and maintenance therapy of refractory Crohn's disease (CD). Therapeutic drug monitoring based on trough and antibody concentration is of core importance when treating patients who lose response to UST. We aimed to analyze UST exposure-response relationship in CD treatment.

Methods We retrospectively enrolled CD patients with UST administration between March 1, 2020 and May 31, 2021 at IBD center of the Sun Yat-Sun Affiliated Sixth Hospital. Baseline characteristic information, biomarker examination, clinical outcomes determined by Crohn's disease activity index (CDAI), and endoscopic outcomes evaluated by a simple endoscopic score for Crohn's disease (SES-CD) at week 16/20 were collected. The optimal UST trough concentration was identified by receiver-operating characteristic curve (ROC).

Results Nineteen eligible patients were finally included, with mean ages as 29.19.1 and mean disease durations as 5.54.7. At study initiation, 89.5% patients had been exposure to prior biologics, 42.1% had previous CD-related surgeries, and 52.6% had a perianal disease. At week 16/20 after UST initiation, clinical response, clinical remission, endoscopic response, and endoscopic remission were 89.5%, 84.2%, 42.2%, and 73.7%, respectively. The cut-off optimal trough concentration of UST was 1.12 µg/mL evaluated by ROC with AUC as 0.78, sensitivity as 87.5%, and specificity as 72.7% (IDDF2021-ABS-0055 Figure 1. Receiver-operating curve analysis for endoscopic remission based on UST trough concentration with optimal UST trough level cut-offs of 1.12 µg/mL). Patients with a UST trough concentration > 1.12 µg/mL had a significantly higher rate of endoscopic remission than those without

Abstract IDDF2021-ABS-0055 Figure 1

Abstract IDDF2021-ABS-0055 Figure 2

(70.0% vs. 11.1%, $P = 0.02$) (IDDF2021-ABS-0055 Figure 2. Clinical and endoscopic outcomes based on UST trough concentration).

Conclusions UST is an effective therapy weapon dealing with refractory CD. Trough concentration of UST above 1.12 µg/mL was associated with endoscopic remission at week 16/20 after UST initiation.

IDDF2021-ABS-0057

OUTCOME OF PER-ORAL ENDOSCOPIC MYOTOMY IN CHILDREN AND ADOLESCENTS WITH ACHALASIA CARDIA: A SYSTEMATIC REVIEW AND META-ANALYSIS

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10.1136/gutjnl-2021-IDDF.122

Background Per-oral endoscopic myotomy (POEM) is an established treatment modality in adult patients with achalasia cardia. Emerging data suggest that POEM may be effective in pediatric cases as well. In this systematic review and meta-analysis, we aim to analyze the outcomes of POEM in children and adolescents with achalasia cardia.

Methods A literature search was performed in Embase, PubMed, Cochrane database for studies pertaining to POEM in pediatric achalasia between Jan 2010 to March 2013. The primary objective of the study was a clinical success (Eckardt≤3). Secondary outcomes included technical success, post-POEM manometry parameters, adverse events and gastro-esophageal reflux (GER) after POEM.

Abstract IDDF2021-ABS-0057 Figure 1

Abstract IDDF2021-ABS-0057 Figure 2

Abstract IDDF2021-ABS-0057 Figure 3

Abstract IDDF2021-ABS-0057 Figure 4

Abstract IDDF2021-ABS-0057 Figure 5

Results A total of 16 studies including 467 children (254-boys, 13.4 ± 3.6 y) were included in the review. Sub-types of achalasia in nine studies ($n=337$) included type I (30.6%), II (63.8%) and III (5.6%). Prior treatment was recorded in 105 (24.4%) cases. Pooled rates of technical and clinical success were 97.1% (95% CI 94.7%-98.4%) and 94.2% (95% CI 91.5%-96.1%), respectively (IDDF2021-ABS-0057 Figure 1. Forest plot demonstrating clinical success). There was a

significant reduction in mean Eckardt score: OR 6.8 (95% CI 6.29-7.25; $p < 0.001$), lower esophageal sphincter pressures (LESP): OR 19.51 (95% CI 17.63-21.40; $p < 0.001$) and integrated relaxation pressures: OR 19.44 (95% CI 13.33-25.55; $p < 0.001$) after POEM (IDDF2021-ABS-0057 Figure 2. Forest plot demonstrating the effect of POEM on mean Eckardt scores; IDDF2021-ABS-0057 Figure 3. Forest plot demonstrating the effect of POEM on mean LESP). Pooled rate of overall adverse events was 18.4% (95% CI 11.1%-28.8%; $I^2 73$), mucosal injury 7.5% (95% CI 4.2% - 12.8%; $I^2 27$) and insufflation related events 11% (95% CI 5.3%-21.7%; $I^2 75$) (IDDF2021-ABS-0057 Figure 4. Forest plot demonstrating adverse events associated with POEM). Reflux esophagitis and symptomatic GER were evident in 22.6% (95% CI 15%-32.5%; $I^2 52$) and was 13.6% (95% CI 10.4%-17.7%; $I^2 20$), respectively (IDDF2021-ABS-0057 Figure 5. Forest plot demonstrating reflux esophagitis after POEM).

Conclusions POEM is an effective procedure in pediatric achalasia. Future studies are required to determine the durability of response and GER after POEM.

IDDF2021-ABS-0058 OUTCOMES OF POEM IN ACHALASIA AND NON-ACHALASIA MOTILITY DISORDERS BEYOND FIVE-YEARS: A LARGE, SINGLE CENTRE STUDY

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10.1136/gutjnl-2021-IDDF.123

Background Per-oral endoscopic myotomy (POEM) is an established modality of treatment in achalasia. However, there is limited data on the long-term outcomes of POEM. In this study, we aim to evaluate the efficacy of POEM in patients with a minimum follow-up of five years.

Methods The data of patients who underwent POEM and completed at least five-years follow-up were analyzed,