Treatment with Ferric Maltol Associated with Improvements in Quality of Life for IBD Patients with Iron Deficiency Anaemia

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BACKGROUND

- Ferric maltol (FM) is an orally administered complex of ferric iron and maltol that demonstrated efficacy in correcting iron deficiency Anaemia (IDA) in patients with Inflammatory Bowel Disease (IBD) vs. placebo (PBO) during the Phase III, AEGIS study [N=128], [1, 2].
- The AEGIS study was a 12-week, randomised, double-blind, multicentre study with a 52-week open label extension (OLE), during which all patients had the opportunity to receive treatment with FM. (Figure 2)
- Patient health-related quality of life (HRQoL) was measured using the SF-36 questionnaire during the RCT and OLE at baseline, and weeks 12, 36 and 48.
- Meanwhile, the EQ-SD instrument is the measure of HRQoL preferred by health technology assessment (HTA) agencies, such as NICE.
- An established, validated algorithm [3] exists for mapping the SF-36 HRQoL to the EQ-SD patient-preference utility values.
- Though the meaningful difference in EQ-SD scores for IBD has not been established, published estimates in other conditions range from 0.03 to 0.52. [4]

METHODS

- Patient-level data for the 36 questions of SF-36 were used to generate the 8 dimensions of the SF-36 from Version 2, and a previously published algorithm [3] was used to generate the EQ-SD from the 8 dimensions of SF-36.
- Descriptive statistics for the EQ-SD at the week 0 (mean, standard error) were performed.
- Pairwise comparisons were performed using two-sided t-test with significance at p<0.05.
- FM vs. PBO Comparison:
  - EQ-SD scores for the FM and PBO group were compared at week 12 (end of the double-blind period)
- Treatment vs. Baseline:
  - Pooled EQ-SD scores for FM and PBO at week 0 were compared to FM EQ-SD scores at week 36.
  - In addition, pooled EQ-SD scores for FM and PBO at week 0 were compared to pooled EQ-SD scores for FM at week 36 and PBO at week 48, reflecting the delayed start to treatment in that group.
  - Finally, pooled EQ-SD scores for FM and PBO at week 0 were compared to EQ-SD scores of patients during FM treatment: pooled scores at weeks 12, 24, 36 and 48.

RESULTS

- FM vs. PBO Comparison:
  - Baseline mean EQ-SD scores were similar in FM vs. PBO: FM 0.812 (SE: 0.02) vs. PBO 0.797 (SE: 0.02), with a mean difference of 0.01 (SE: 0.03, p=0.622).
  - At week 12 patients on FM had slightly higher EQ-SD scores vs. PBO, although it was not statistically significant: FM 0.844 (SE: 0.021) vs. PBO 0.804 (SE: 0.023) with a mean difference of 0.040 (SE: 0.031, p=0.204) (Figure 2)
- Treatment vs. Baseline:
  - A statistically significant improvement in EQ-SD scores vs. baseline was demonstrated with FM treatment during OLE and the effects were confirmed when accounting for the delay in treatment initiation in the PBO group.
  - FM at week 36: 0.888 (SE: 0.023) vs. pooled FM and PBO at week 0: mean 0.804 (SE: 0.015), mean difference: 0.083 (SE: 0.034, p=0.016) (Figure 3)
  - FM at week 36 pooled with for PBO week 48: mean 0.861 (SE: 0.021) vs. FM and PBO pooled at week 0: 0.804 (SE: 0.015), mean difference: 0.057 (SE: 0.03 p=0.045) (Figure 3)
  - FM-treated patients (pooled weeks 12, 24, 36 and 48): 0.863 (SE: 0.123) vs. FM and PBO pooled at week 0: 0.804 (SE: 0.015), mean difference: 0.059 (SE 0.020, p=0.004) (Figure 3)
  - Mean EQ-SD values for FM at week 36 and the pooled mean utility value for FM at week 36 and PBO at week 48 were similar to published population norms for the general population of the same age: 0.889 (SE: 0.004) [5]

CONCLUSION

This post-hoc evaluation of outcomes from the AEGIS phase III study indicates that ferric maltol has a significantly beneficial effect on HRQoL in patients with IBD and IDA. Mean HRQOL was restored to population norms expected for the patient age profile. [5] The calculated change in HRQoL score was consistent with previous studies that examined the HRQoL burden of IBD (shown in chronic kidney disease), adding to the validity of the demonstrated effect. [6]