Introduction PEG based preparations are traditionally seen as the gold standard in cleansing, but they all require a high total fluid intake. NER1006 is the first 1L-PEG 3350 and ascorbate bowel preparation.

Methods This phase 3, randomised, multicentre, colonoscopist-blinded, non-inferiority study assessed the efficacy, safety and tolerability of NER1006, administered either as a 2 day overnight (N2D) or 1 day morning (N1D) split-dosing regimen versus a 2L-PEG 3350 with ascorbate 2 day overnight split dosing regimen (2LPEG) in patients undergoing a colonoscopy. Two alternative primary endpoints were evaluated: overall bowel cleansing efficacy and 'Excellent or Good' cleansing rate in the ascending colon and caecum using the Harefield Cleansing Scale (HCS). Secondary endpoints included hierarchical evaluation of lesion detection rates (key), and cleansing assessment using the Boston Bowel Preparation Scale (BBPS; supportive). Patient tolerability, acceptability and compliance were assessed using questionnaires. Safety was monitored through adverse events and clinical laboratory evaluation. The threshold for statistical significance in this study was $p < 0.025$ and a 10% margin was used to demonstrate non-inferiority vs 2LPEG. Patients were randomised to receive either N2D, N1D, or 2LPEG.

It also demonstrated a superior 'Excellent or Good' cleansing rate in the ascending colon and caecum. As a 2 day overnight split dosing NER1006 demonstrated a superior polyp detection rate in the ascending colon and caecum. The overall tolerability and safety profile of NER1006 was comparable to that of 2LPEG; most TEAEs were mild or moderate in severity and reflected the expected safety profile of the respective treatments.

PTH-001 ENDOSCOPIC MANAGEMENT AND OUTCOMES FOR PATIENTS WITH FOOD BOLUS OBSTRUCTION

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Introduction Food Bolus Obstruction (FBO) often presents as an emergency, with an estimated incidence of 13 per 100 000 population (Longstreth *et al.* Gastrointest Endosc 2001;53:193–8). Endoscopic management is required in many cases, but carries a risk of complications. Our aim was to audit the management and outcomes for patients with FBO admitted to our institution.

Methods We reviewed all cases presenting with FBO to the Emergency Department and/or admitted to the hospital between October 2014 and October 2017. Data was retrieved from the hospital electronic patient records for demographics, duration of stay, performance of endoscopy as well as the endoscopic findings, FBO removal technique and any complications.

Results A total of 160 patients presenting with FBO were identified; 103 (64%) males and 57 (36%) Females, average age of 65 years. Of these, 55 (34%) patients passed the food bolus spontaneously without a referral for endoscopy. Of the 105 (66%) patients who had an endoscopy, data on the time of admission and the time of endoscopy was available for 62 (59%) patients. 11 (18%) patients had endoscopy within 4 hours and 51 (82%) within 24 hours. At endoscopy, an addition 32 (30%) patients were found to have passed the food bolus spontaneously, whilst 72 (70%) needed endoscopic intervention; the push technique was most often employed (33% of cases). Endoscopic therapy was effective in 66 (91.2%) patients. Of the 6 patients in whom initial endoscopic therapy was unsuccessful, 2 patients were intolerant of the procedure (one required an endoscopy under general anaesthetic, and the other patient underwent a repeat procedure the following day successfully); 2 patients had FBO at a high level requiring ENT referral; 2 patients sustained an oesophageal perforation). The underlying pathology was documented as benign stricture/web/Schatzki ring in 20 (19%) of cases, oesophagitis in 12 (11%), oesophageal malignancy in 9 (8%), hiatus hernia in 3 (3%), eosinophilic oesophagitis 1 (1%), oesophageal spasm 1 (1%), Barrett's oesophagus 1 (1%) and candidiasis in 1 (1%); 57 (55%) of patients had no underlying oesophageal abnormality. Endoscopic complications were seen in 4 (4%) patients – mucosal tear in 2 cases and perforation in 2 cases. The duration of hospital stay was 1 day in 136 (85%), 2 days in 16 (10%) and 3 or more days in 8 (4%) of cases.

Conclusion FBO resolves spontaneously in around half of cases. Endoscopic therapy has a high success rate for the remaining patients, but is associated with a small risk of complications.

Abstract ADTH-10 Table 1 (mFAS Population)

	Groups			Confidence Interval (CI), [P value]	
	NER1006 N2D	NER1006 N1D	2LPEG	N2D	N1D
Patients, N	275	275	272		
Primary Endpoints:					
Successful Overall	253	245	238	–4.00%*,	–6.91%*
Bowel Cleansing	(92.0%)	(89.1%)	(87.5%)	[0.055]	[0.328]
(HCS)					
Excellent/Good	87	93	41	8.11%*,	10.32%*,
cleansing in the	(31.6%)	(33.8%)	(15.1%)	[<0.001]	[<0.001]
Ascending Colon/ Caecum (HCS)					
Key Secondary Endpoints:					
ADR* Ascending	11.6%	11.6%	8.1%	–4.80%;12.00%	–4.80%;12.00%
Colon/Caecum				**, [0.106]	**, [0.106]
ADR* Overall	26.6%	27.6%	26.8%	–8.74%;8.02%	–7.65%;9.11%
Colon				**, [0.569]	**, [0.455]
PDR* Ascending	23.3%	18.6%	16.2%	–1.41%;15.47%	–6.12%;10.82%
Colon/Caecum				**, [0.024]	**, [0.268]
PDR* Overall	44.0%	45.1%	44.5%	–8.85%;8.00%	–7.78%;9.09%
Colon				**, [0.579]	**, [0.478]

* 97.5 1-sided CI, ** 95% 2-sided CI, —not applicable

*Adenoma Detection Rate (ADR), Polyp Detection Rate (PDR)

Results Compliance rates were high in all treatment groups. There were no deaths. NER1006 was not associated with any serious treatment-emergent adverse events (TEAEs). The most frequently reported related TEAEs for NER1006 were nausea and vomiting; and for 2LPEG, nausea and abdominal pain.

Conclusions When administered as either a 2 day overnight or 1 day morning split-dosing regimen, and compared to 2LPEG, NER1006 was non-inferior in overall bowel cleansing success.