P247 SAFETY PROFILE OF THE DUODENAL-JEJUNAL BYPASS LINER (ENDOBARRIER): A MULTICENTRE RANDOMISED CONTROL TRIAL

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Introduction The Endobarrier is an endoluminal duodenal-jejunal bypass liner (DJBL) developed by GI Dynamics for the treatment of obese patients with T2DM. It consists of a single use endoscopic implant designed to mimic the effects of gastric bypass but without the risks of undergoing surgery and the possible long-term complications associated with bariatric surgery. We report results of its safety profile in patients receiving the device for one-year duration of therapy as part of the Endobarrier randomised controlled trial (RCT).
Methods The multicentre Endobarrier RCT (NCT02459561) was conducted across two sites in the UK and recruited 170 patients with Type 2 Diabetes and BMI 30–50 kg/m^2. Participants were randomised to receive the DJBL (n=85) for one year or conventional medical therapy, diet and exercise (n=85).
Results A total of 75/85 participants received the Endobarrier implant. There were 19 (25%) early explants (table 1) before the one year period for which the commonest indication for removal was abdominal pain and device migration. There were two GI bleeds and one liver abscess which was managed with antibiotics and drainage with no permanent sequelae.

Abstract P247 Table 1

Early Explants	Frequency
Upper GI Bleeds	2
Abdominal pain	5
Cholestasis/cholecystitis	2
Migration and fistula	1
Migrations	6
Liver abscess	1
Required anticoagulation	1
Withdrew consent	1
Total	**19**

Conclusions The majority of patients received one year of Endobarrier therapy. The early explant rate of 25% is in keeping with previously conducted clinical trials on the Endobarrier. There was one case of liver abscess in the 75 successful implants performed - a complication rate of 1.3% which is similar to post market surveillance data (1%) from GI Dynamics. Liver abscesses still remain a rare but significant complication of Endobarrier therapy.

P248 HELICOBACTER – ARE WE LOSING THE BATTLE?

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Introduction The Nobel Prize winning discovery of Helicobacter Pylori in 1983 heralded a seismic shift in the treatment of peptic ulcer disease. Currently, NICE recommended a PPI, amoxicillin and clarithromycin or metronidazole as the 1st line eradication regimen for H.Pylori. Resistance rates against this regimen for the UK are not known but it is widely held that 1st line eradication is highly effective in clearing H. Pylori. We tested this hypothesis in our local population.
Methods From April 2018 to March 2019, we commenced routine follow up testing 6–8 weeks post eradication with Helicobacter breath testing and performed a retrospective analysis of clearance rates. This was undertaken using online hospital records and the analysis performed using Microsoft Excel.
Results 113 patients were identified who attended for follow up H. Pylori breath testing following first line eradication treatment. Of these, 63 (57.2%) returned negative tests and 47 (42.7%) returned positive breath tests.
Conclusions A failure rate of 42.7% was far higher than expected for our local population and as a result we have held discussions with the Microbiology department and are in the process of altering the first line treatment to improve eradication. This is particularly important given that H. Pylori is now a WHO recognised carcinogen for gastric carcinoma. We are undertaking further analyses on the antibiotic exposure and demographic make-up of the population studied. We suspect that this level of resistance will be similar across the UK but further evidence from other sites is required to prove this.

P249 CONCORDANCE OF HER2 EXPRESSION AND SURVIVAL BASED ON SILVER IN-SITU HYBRIDIZATION(SISH) IN GASTRIC ADENOCARCINOMA

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Introduction Gastric adenocarcinoma(GC) patient selection for antiHER2 therapy is dependent on accurate HER2 status. It is assessed immunohistochemically(IHC) for protein expression and by silver in-situ hybridization(SISH) for gene copy number. This study aimed to evaluate the concordance of HER2 status by IHC/SISH analyses and HER2-SISH based survival.
Methods This prospective study includes 145 GC's(excluding gastro-oesophageal-junction tumours) from the National Hospital of Sri Lanka. HER2-IHC was assessed by DAKO A0485, RealTM Envision system and interpreted using Ruschoff criteria. HER2-SISH was assessed with INFORM HER2 dual ISH DNA Probe Cocktail. Concordance between HER2 IHC/SISH results was determined by Cohens kappa statistics. SISH based survival of GC patients who did not receive antiHER2 therapy, was analyzed by Kaplan-Meier method and log-rank test.