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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/m². 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.

arly Explants	Frequency
Jpper GI Bleeds	2
Abdominal pain	5
holestasis/cholecystitis	2
Aigration and fistula	1
ligrations	6
iver abscess	1
lequired anticoagulation	1
Vithdrew consent	1
otal	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.

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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.

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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.

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Results Of the 69 gastrectomies and 76 biopsies, 8.3% (n=12) were HER2-IHC positive (n=7, +2 and n=5, +3). HER2-SISH positivity was 4.8%(n=7). All IHC+3 were SISH positive, while two, +2 were SISH positive. Concordance for IHC 0, +1, +3 were 100%. There was a significant overall correlation (kappa=0.72, p<0.001) between HER2-IHC and HER2-SISH indicating substantial concordance. The mean overall survival of HER2-SISH negative and positive patients were 41.7(0–210) and 14.6(3–51) weeks respectively. The mean duration of follow up was 40.4 weeks (range 0–210). Survival was significantly poor(p=0.018) with HER2-SISH positivity.

Conclusions HER2-IHC was well concordant with HER2-SISH for 0, +1, +3 scores and could be used for treatment and prognostication in low resource settings. HER2-IHC+2 without gene amplification may be due to transcriptional activation by other genes or post-transcriptional events, mandating further evaluation by SISH. Survival of GC patients is significantly affected by HER2-SISH positive status.

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PERSONALISED MEDICINE: IS THIS THE WAY TO COMBAT HELICOBACTER PYLORI (HP) ERADICATION FAILURE?

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Introduction Antibiotic-resistant HP varies in different geographical areas. A recent review of international guidelines suggest evidence-based locally relevant treatment strategies. Within the United Kingdom, hospitals develop local antibiotic guidelines as per local resistance rates. However, Public Health England (PHE) recommendation for treatment regimes in primary care remains to be clarithromycin and metronidazole-based regimes for patients with dyspepsia who are HP positive. The Gastrointestinal Bacteria Reference Unit (GBRU), PHE is the national reference laboratory which tests all HP cultures in England. We aimed to look local HP secondary resistance data from 3 different units in London and compared whether variation in specimen collection practice impacted on rates of HP culture positivity.

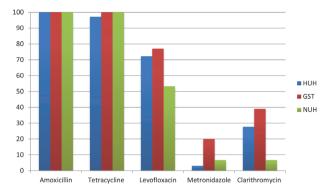
Methods We compared culture data from 3 different units in London. Due to differences in the local databases used, the date ranges of data collected was varied.

We obtained 34 months data between March 2016 and December 2018 from Homerton University Hospital (HUH). There were no local guidelines at HUH regarding number of biopsy samples taken and samples were transported to the lab routinely.

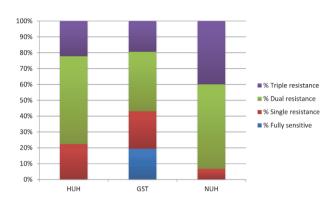
Culture data from Guys & St Thomas' Hospital (GST) was for 10 months between January to October 2019. At least 4 to 6 samples were taken on Monday to Thursday morning lists to ensure samples are sent to reference lab urgently.

Culture data from Newham University Hospital (NUH) was for 12 months from October 2018 to October 2019. At least 6 gastric biopsy samples were taken on a dedicated endoscopist's list on a weekday morning and samples were urgently transported by taxi to the laboratory.

Results 122 gastric biopsy samples were sent in HUH and 36 isolated HP, giving a 29.5% positive culture rate.



Abstract P250 Figure 1 Phenotypic HP sensitivities by hospital



Abstract P250 Figure 2 Percentage of antibiotic resistance by hospital

112 gastric biopsy samples were sent in GST and 72 isolated HP, giving a 64.2% positive culture rate.

34 gastric biopsy samples were sent in NUH and 15 isolated HP, giving a 44.1% positive culture rate.

Conclusion 38% of UK's foreign born population live in London. Variation in concentrations of migrant communities within a city can lead to variations in antimicrobial resistance. Our results are skewed towards resistant isolates as patients having gastroscopy and cultures taken for HP sensitivity would have had multiple courses of antibiotics. They suggest a benefit in tailoring local second line antimicrobial guidelines to local resistance rates. Given the lack of amoxicillin resistance, we recommend penicillin allergy testing for patients who report allergy.

Pancreas and neuroendocrine

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THE UTILITY OF FDG PET/CT IN THE DIAGNOSIS AND MANAGEMENT OF IGG4 RELATED DISEASE

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Introduction IgG4 related disease (IgG4-RD) is a rare immune mediated fibroinflammatory condition that can affect nearly any organ. Pancreaticobiliary (PB) manifestations include autoimmune pancreatitis (AIP) and

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