Autumn Meeting

Park Avenue Hotel, Belfast.
Friday 18th October, 2019

usg Ulster Society of Gastroenterology

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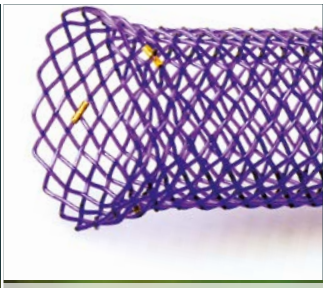

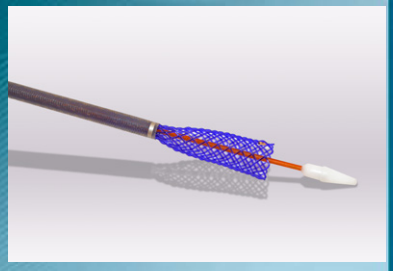

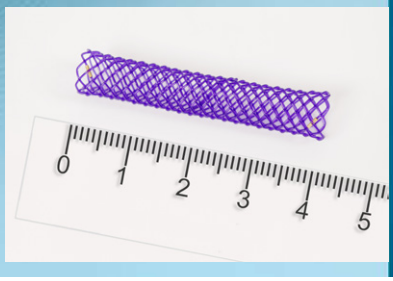

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- Diameter 8. Available lengths 40/60mm

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Diameter 8-10 Delivery System 11.8Fr Length 60mm

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Welcome to Autumn USG 2019

Dear Colleagues,

Welcome to all our colleagues, friends and members of the USG. I am flattered and honoured to be elected as president of USG. I would like to pay tribute and thank Peter Watson for all his previous work and we wish him well in his new work project.

This affords me the great opportunity of leading USG and with the support of the excellent committee and yourselves I hope to continue the sound ethos that the USG presents.

For this meeting I hope that you will agree that we have established a nicely balanced programme. Mr.Tan Arulampalam Laparoscopic & General Surgeon from Colchester Hospital is one of the leading Surgeons in this field and I feel certain that his presentation on 'Locally advanced Colrectal cancer' will be informative as well as educational.

Prof Duff Bruce Consultant Bariatric Surgeon will follow with 'a current update on Bariatric Cancer' which should be worth waiting for.

One of our leading local Dieticians Julie Ann Kidd will deal with issues relating to the dietetic approach to the bariatric surgery patient.

Dr Oliver Brain from the John Radcliffe Hospital is another major coup for USG and his contribution on Immunotherapy induced Colitis will certainly be interesting.

Not to forget our local Sp Regs who will present papers and reports at this meeting.

I would also like to welcome our nursing groups and hope that they will have a very successful parallel meeting. Sincere thanks here to Brendan Byrne for attracting a very good programme. The agenda is filled with people who are well known and should make for an excellent meeting.

Finally a word of thanks to our friends in industry without whose continued support we would not be in a position to convene our present meeting levels.

Tim McAdam
President USG

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USG Autumn Meeting

Friday 18th October, 2019

Programme

8.00	**Registration**
9.20	**Welcome** **Mr Tim McAdam** USG President
9.30	**Oral Free Papers 1 – 3**
SESSION 1	**Lower GI** Chair: Mr Tim McAdam
10.00	***Locally Advanced Colorectal Cancer - 'Watch and Wait'*** **Mr Tan Arulampalam** Laparoscopic & General Surgeon Colchester Hospital, Essex, UK
10.40	**Tea/Coffee break** **Meet the Industry**
11.10	**Oral Free Papers 4 – 5**
SESSION 2	**Lower GI** Chair: Dr Phillip Hall
11.30	***Immunotherapy induced colitis*** **Dr Oliver Brain** Consultant Gastroenterologist John Radcliffe Hospital, Oxford, UK
12.10	**USG Bursary recipients** - **Dr John McGoran** (Speciality registrar in Gastroenterology) - **Mr Andrew McGuigan** (Speciality registrar in Surgery)
12.30	**Lunch** **Meet the Industry**
SESSION 3	**Upper GI** Chair: Dr Shivaram Bhat
13.30	**MDT corner – trainee led case discussion** Lower GI Upper GI HPB
13.45	***Bariatric surgery – update on current practice*** **Prof Duff Bruce** Consultant Upper Gastrointestinal & Bariatric Surgeon BMI Albyn Hospital, Aberdeenshire, Scotland
14.30	***Dietetic approach to the bariatric surgery patient*** **Julie Ann Kidd** Clinical Lead Dietitian Belfast Health and Social Care Trust
14.50	**Tea and Coffee**
15.00	**USG Business meeting** ***Service update - Transformation of endoscopy services*** **Mr Tim McAdam** USG President
16.00	**Closing remarks**

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Ferring Pharmaceuticals Ltd. Tel: 0800 111 4126. Email: medical@ferring.com

References: 1. Danese S, *et al. J Crohns Colitis.* 2019;13 (supplement 1):296–297. **2.** Cortiment 9 mg, Prolonged Release Tablets. SmPC. **3.** Entocort CR 3 mg Capsules. SmPC. **4.** Budenofalk 3 mg Gastroresistant Capsules. SmPC. **5.** Budenofalk 9 mg Gastro-resistant Granules. SmPC. **6.** Brunner M, *et al. Br J Clin Pharmacol.* 2006;61(1):31–8. **7.** Fiorino G, *et al. Curr Med Chem.* 2010;17(17):1851–7. **8.** Travis SPL, *et al. Gut.* 2014;63:433–41. doi:10.1136/gutjnl-2012-304258. **9.** Sandborn WJ, *et al. Gastroenterology.* 2012;143:1218–1226. **10.** Rubin D, *et al. J Crohns Colitis.* 2017;11(7):785–791.

Date of preparation: June 2019. Job Code: COR/439/2018/UKa(1)c

Nurses Programme

USG 18 October 2019 at Park Ave Hotel, Belfast

9.30 - 10.00 **Sean Dooher**
Emcompass Programme Manager
South Eastern H&SC Trust
Dr Matthew Costley
Core Medical Trainee
South Eastern H&SC Trust
"Emcompass abstract to reality"

10.00 - 10.30 **Dr Carolyn Adgey**
Registrar
Royal Victoria Hospital, Belfast
"Small Bowel transplant - An Overview"

10.30 - 11.00 **Tea/Coffee Break**

11.00 - 11.30 **Mr Kevin McCallion**
Consultant Colorectal Surgeon
Ulster Hospital Dundonald
"Management of large colonic Polyps"

11.30 - 12.00 **Dr Maurice Loughrey**
Consultant Gastrointestinal Pathologist
Royal Victoria Hospital, Belfast
"Endoscopy meets pathology: where are the problems?"

Biographical Sketches

Sean Dooher – encompass Programme Manager South Eastern H&SC Trust, employee of HSCNI for 20 years including WHSSB, Belfast Trust, BSO and SE Trust survivor of such implementations as Theatre Management System, Diamond, Unisoft and Business Services Transformation Programme(HRPTS FPL) to name a few.

Dr Matthew Costley entered ST4 in Dermatology in August 2019. He is a NIMDTA ADEPT fellow working with the encompass programme for the next year.

Dr Carolyn Adgey is a final year gastroenterology registrar currently working in the Belfast trust. She graduated from Queens University Belfast in 2008 and has trained as a gastroenterology registrar in Northern Ireland. She completed a 1 year clinical fellowship in small bowel transplantation, intestinal failure and nutrition in Addenbrookes Hospital, Cambridge in 2017.

Mr Kevin McCallion is a Consultant Colorectal Surgeon In the Ulster Hospital Dundonald, Graduating Queens in 1992, completing his colorectal fellowship in Toronto in 2003 and took up his Consultant post in Dundonald in 2004.

Dr Maurice Loughrey is a consultant gastrointestinal pathologist, Royal Victoria Hospital, Belfast. His primary interests are the pathology and biology of colorectal cancer, precursor polyps and colorectal cancer screening. He is lead author of related pathology guidelines from the Royal College of Pathologists (UK), the International Collaboration for Cancer Reporting (colorectal cancer datasets) and the NHS Bowel Cancer Screening pathology programme.

Brendan Byrne qualified as an RCN in 1991. He has worked in Endoscopy for 25 years and has been a Nurse Endoscopist since 2001 with Bowel Screening accreditation in 2009 and currently works in the South eastern Trust

The Northern Ireland Practice and Education Council for Nursing and midwifery (NIPEC) was established by the Northern Ireland Assembly in 2002 under the Health and Personal Social Services Act as an NDPB (Non Departmental Public Body) to support the development of nurses and midwives by promoting high standards of practice, education and professional development. NIPEC also provides advice and guidance on best practice and matters relating to nursing and midwifery.

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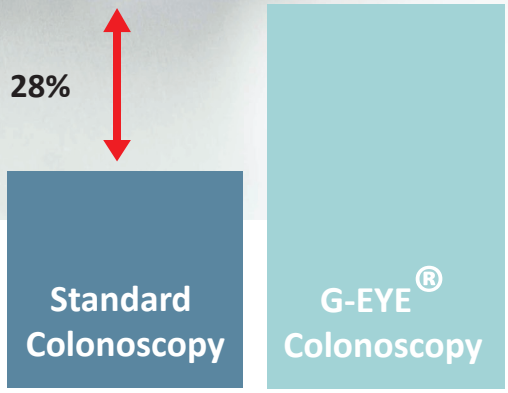

G-EYE® colonoscopy is superior to standard colonoscopy for increasing adenoma detection rate: an international randomised controlled trial

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References:
Shirin H, Shpak B, Epshtein J, et al. G-EYE colonoscopy is superior to standard colonoscopy for increasing adenoma detection rate: an international randomised controlled trial. Gastrointest Endosc. 2018; Chen Y, Duan YT, Xie Q, et al. Magnetic endoscopic imaging vs standard colonoscopy: meta-analysis of randomised controlled trials. World J Gastroenterol. 2013;19(41):7197-204.

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USG Executive Committee

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Mr Tim McAdam
Consultant Colorectal Surgeon
Belfast Trust

Honorary Secretary:
Dr Shivaram Bhat,
Consultant Gastroenterologist
Craigavon Area Hospital

Honorary Treasurer:
Dr Philip Hall,
Consultant Gastroenterologist
Belfast Trust

Member:
Dr Helen Coleman
Senior Lecturer in Cancer Epidemiology
Centre for Public Health
Queens' University Belfast

Organising Team

Michael Dineen
Chief Exec ISG /
Event Organiser USG

Cora Gannon
Administrator ISG/USG

ESGE DAYS DUBLIN 2020

We are excited and honoured that ESGE Days 2020 (European Society of Gastrointestinal Endoscopy) is coming to Dublin on April 23-25, 2020. Registration will open this Thursday, August 1, 2019. If you are an ISG member, you can take advantage of a reduced rate to register for the congress – a discount of €180. This is yet another reason to become a member of the ISG if you are not already one! Nurses (ESGENA members) and young endoscopists can register for €130. Group registrations will be opening soon and if you register a group of over 16 people, there will be a 10% discount.

Tony Tham
President, Irish Society of Gastroenterology
Consultant Gastroenterologist, Ulster Hospital

Spring Meeting 2019

Natalie Phillips DR Falk Pharma and Shivaram Bhat, USG Secretary

Fiona Ross and Sarah Jane Kelly Cardiac Services
with Katrina Battisti, Liz Hand and Nicola Halliwell

Brian Osborne and Michelle Casey Fleetwood Healthcare
with Anne McKeown

Nigel Trudgill and Eugene Campbell

Peter Watson USG President, Philip Hall USG Treasurer
and Conor Braniff

Spring Meeting 2019

Helen Coleman, Paul Springthorpe Takeda , Shivaran Bhat, Andy Nichol Takeda, Peter Watson USG President and Mark Hull

Peipei Liu and Yasemin Adali

Philip Hall, Conor Braniff and Claire Jones

Tim Harding and Abraham Varghese

Andrew Kunzmann, Una McMenamin and Helen Coleman

Biographical Sketches

Mr Tan Arulampalam
Laparoscopic & General Surgeon
Colchester Hospital, Essex, UK

Professor Tan Arulampalam qualified as a Doctor in 1992 from St Bartholomew's Hospital (University of London). He completed his basic surgical training at St Bartholomew's Hospital and was appointed to the higher surgical training scheme in London in 1996. After completion of his training he undertook a Fellowship with Professor Cristiano Hüscher in Rome and was appointed Consultant Laparoscopic GI Surgeon at Colchester General Hospital in November 2003.

He has performed over 500 laparoscopic colorectal resections as well as a full range of advanced laparoscopic biliary, GI, emergency and hernia surgery. He was a Preceptor in Laparoscopic Colorectal Surgery for the Association of Laparoscopic Surgeons of Great Britain and Ireland.

Professor Arulampalam was awarded a Doctorate by the University of London in 2003 for his research and subsequent thesis on the role of Positron Emission Tomography in Colorectal Cancer Imaging. He has continued his research interests in PET, colorectal cancer and laparoscopic surgery since taking up his appointment. He has been an honorary senior lecturer at the University of Essex and has held the post of Reader (Associate Professor) in Surgery at Anglia Ruskin University. He has supervised 5 post graduate MDs and raised over £2 million in funds to support clinical and training at Colchester Hospital and the ICENI Centre. In 2019 he was appointed to the post of Visiting Professor of Surgery at the School of Medicine, Anglia Ruskin University.

As Clinical Director of the ICENI Centre, Mr Arulampalam has taken an active role in training, both on courses in Colchester, as well as mentoring surgeons at their own hospitals. He is on the faculty at the European Surgical Institute in Hamburg, regularly lecturing and training in laparoscopic colorectal surgery. He continues to publish his work in peer-reviewed journals and was on the editorial board of the Annals of the Royal College of Surgeons of England. He also acts as a medical advisor to the national charity Bowel Cancer UK and was network lead for the Department of Health Bowel cancer Awareness campaign. He has worked on Department of Health projects on Enhanced Recovery Programmes and is a trainer on the National Laparoscopic Colorectal training programme.

As Chairman of the Association of Surgeons of Great Britain and Ireland International Development Committee working towards establishing closer links between the surgical fraternities of developed and developing nations for exchange of ideas and opportunities. In addition, to these activities he has also been a regular advisor to BBC Drama working on Holby City as well as working on other shows such as Law and Order, Harley Street, Dalziel and Pascoe and Silk.

Mr Arulampalam is Honorary Treasurer of the Association of Laparoscopic Surgeons of Great Britain and Ireland He is Chair of the Research Sub Committee of the European Association of Endoscopic Surgeons. His interests include clinical management of colon and rectal cancer, hernia surgery, artificial intelligence and healthcare process engineering as well as clinician wellbeing.

Dr Oliver Brain
Consultant Gastroenterologist
John Radcliffe Hospital, Oxford, UK

Dr Oliver Brain is a Consultant Gastroenterologist in the Translational Gastroenterology Unit at Oxford University Hospitals NHS Trust. Dr Brain completed his clinical training at St Bart's and The Royal London Medical School. His postgraduate training in Gastroenterology and Internal Medicine was at the John Radcliffe Hospital, Oxford. His research training and DPhil into the function of Crohn's disease susceptibility genes was undertaken at the Weatherall Institute of Molecular Medicine in Oxford.

Dr Brain has sub-specialist interest in Inflammatory Bowel Disease and GI inflammation. He is currently local PI for four multicentre interventional IBD studies, and two multicentre observational IBD studies. He is also Chief Investigator for the PRISE (PRedicting Immunotherapy Side-Effects) study, which is prospectively analysing the immune and microbial biology of this novel enterocolitis.

Prof Duff Bruce
Consultant Upper Gastrointestinal & Bariatric Surgeon
BMI Albyn Hospital, Aberdeenshire, Scotland

Duff Bruce is a graduate of Robert Gordon's College and the University of Aberdeen, and has 30 years experience in General Surgery, gained in the UK, Australia and USA. His surgical interests include laparoscopic bariatric (weight loss) procedures and surgery (first time and revision), laparoscopic anti-reflux and hiatus hernia surgery, laparoscopic gallbladder surgery, laparoscopic and open hernia repairs, gastroscopy, colonoscopy and the management of abdominal symptoms. He introduced laparoscopic inguinal hernia repair to the North of Scotland.

In 2001, he completed a Fellowship in oesophageal physiology at the Kech Medical School of the University of Southern California in Los Angeles. Since 2002, he has worked in Aberdeen as a consultant general surgeon with special interests in gastro-oesophageal reflux, gastroparesis, laparoscopic surgery and metabolic and weight loss surgery. He is a local NHS practitioner and a visiting Professor at Robert Gordon University, Aberdeen.

Duff Bruce is one of the leading exponents of bariatric surgery and anti-reflux surgery in Scotland and has interests in clinical management and modernisation of services.

Areas of interest

Bariatric surgery; weight loss surgery; laparoscopic gastric band insertion; laparoscopic sleeve gastrectomy; laparoscopic gastric bypass; laparoscopic single anastomosis gastric bypass; laparoscopic mini-gastric bypass; revision stomach

surgery; revision bariatric surgery; insertion of intra-gastric balloon; insertion of Orbera 365; gastroparesis; swallowing problems; gastric pacing; laparoscopic gastric pacemaker insertion; insertion Enterra device; gastro-oesophageal reflux; hiatus hernia surgery; laparoscopic anti-reflux surgery; laparoscopic fundoplication; gallstone surgery; laparoscopic cholecystectomy; laparoscopic surgery; endoscopic diagnostics; diagnostic laparoscopy; gastroscopy; colonoscopy; hernia surgery; laparoscopic hernia surgery; laparoscopic inguinal hernia repair; laparoscopic femoral hernia repair; umbilical hernia repair; pilonidal sinus surgery

Julie Ann Kidd
Clinical Lead Dietitian
Belfast Health and Social Care Trust

Julie-Ann graduated from the University of Ulster in 2002 with a BSc(Hons) in Human Nutrition and Dietetics. She works in both the NHS and private sectors in bariatric surgery. She leads on the delivery of a dietetic bariatric surgery service in the Belfast Health and Social Care Trust. Julie-Ann is trained in motivational interviewing and behaviour change helping patients achieve their long term goals. Julie-Ann manages a team of dietitians in the Royal Victoria Hospital in Belfast. She was PRO for the Northern Ireland Branch of the British Dietetic Association and has been involved in TV and radio interviews and has written many articles representing dietetics.

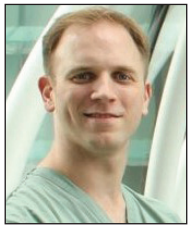
USG Committee Members

Mr Tim McAdam
USG President

I am a Consultant Colorectal Surgeon and clinical Lead in Belfast Trust having worked as a Consultant in Aberdeen for 6 years. I was a medical student in QUB and trained in North of Scotland and England. My main interests are management of colorectal cancer, member of specialist endometriosis team and pelvic floor disorders. I am a faculty member for RCSEd surgical skills, NOTSS, RCSEng strategies in emergency surgery. I am a recognised national trainer for laparoscopic colorectal surgery.

Dr Shivaram Bhat
Consultant Gastroenterologist
Hon Secretary USG

Dr Shivaram Bhat is a consultant Gastroenterologist at Craigavon Area Hospital in Northern Ireland. He graduated from Queens University Belfast medical school (2002) with subsequent postgraduate training in Northern Ireland and a clinical fellowship at the John Radcliffe Hospital in Oxford. During his postgraduate training he completed a PhD researching cancer progression in Barrett's oesophagus. His clinical and research interests include inflammatory bowel disease and early detection of GI cancer. He is a bowel cancer screening endoscopist and is the IBD lead for the Southern Health and Social Care Trust.



Dr Philip Hall
Consultant Gastroenterologist
Belfast Trust
Hon Treasurer USG

Dr Philip Hall has recently been appointed consultant gastroenterologist within the Belfast Trust. He graduated from Queens University Belfast in 2008 and completed gastroenterology training in Northern Ireland. He has a Masters degree in Clinical Education.
He completed an advanced therapeutic endoscopy fellowship in St Michael's Hospital, Toronto in 2017 and has interests in upper GI therapeutics, ERCP and quality improvement.

Dr Helen Coleman
Senior Lecturer
Queen's University Belfast

Dr Helen Coleman is a Senior Lecturer in Cancer Epidemiology at the Centre for Public Health at Queen's University Belfast, and previously studied there during her PhD and postdoctoral research projects. She has also spent time conducting research at Vanderbilt University, Nashville, TN, USA, Ulster University, and at the MRC-Human Nutrition Research centre in Cambridge, England. Dr Coleman's general research interests are in cancer epidemiology, particularly modifiable risk factors for progression from pre-cancerous conditions to cancer and factors associated with recurrence or survival after a cancer diagnosis. She is also involved in health services research projects that aim to optimise how individuals are treated and followed-up after a diagnosis of a pre-malignant condition or cancer, including analysis of Northern Ireland Bowel Cancer Screening data. Her strong interests are in cancers of the digestive tract, especially colorectal polyp/cancer, and oesophageal adenocarcinoma/ Barrett's oesophagus epidemiology.

Oral Presentations - USG Meeting 2019

Ref. No.	Authors	Title	Time
101	Peipei Liu	Proton Pump Inhibitor And Histamine-2 Receptor Antagonist Use And Risk of Gastric Cancer In Two Population-based Studies	9.30
102	Oliver Reed	Fully Covered Self Expanding Metal Stents in the Management of Complex Biliary Stone Disease	9.40
103	Una McMenamin	Prediagnostic Concentrations of Circulating Sex Hormones and Risk of Oesophageal and Gastric Cancer	9.50
104	Gary Morrison	Collateral Thinking - A case of ectopic variceal bleeding (withdrawn)	11.10
105	Andrew Spence	Creation of a Northern Ireland Barrett's Oesophagus Treatment Registry	11.20

Nicola Halliwell, Michael Gibbons, Brendan Byrne, Elizabeth Hand and Katrina Battisti

Rebecca O'Kane and Gary Morrison

Tim McAdam and Damian McKay

Ms Claire Jones-Speaker

Dr Andrew Murdock Speaker

Helen Coleman and Peter Watson

ORAL PRESENTATIONS

ABSTRACT 19A 101

Proton Pump Inhibitor And Histamine-2 Receptor Antagonist Use And Risk Of Gastric Cancer In Two Population-based Studies

Authors:
P Liu, ÚC McMenamin, BT Johnston, CR Cardwell
Departments/Institutions:
Centre for Public Health ICS-B Building, RVH Site, Grosvenor Road, Belfast, BT12 6BJ
Introduction:
Proton pump inhibitor (PPIs) and histamine-2 receptor antagonist (H2RAs) are commonly used medications. Recently, there have been concerns that PPIs and H2RAs could increase gastric cancer risk.
Aim:
To investigate PPI and H2RAs and gastric cancer risk in two large independent study populations.
Methods:
We conducted a nested case-control study within the Primary Care Clinical Informatics Unit (PCCIU) database. Each gastric cancer case was matched to up to five controls. Conditional logistic regression model was used to calculate odds ratios (ORs) and 95% confidence intervals (CIs). We also conducted a prospective cohort study within the UK Biobank in which medication use was identified from self-report at baseline and cox regression was used to calculate hazard ratios (HRs) and 95% CIs.
Results:
In PCCIU, there were 1,129 gastric cancer cases and 5,394 matched controls. PPI users had higher gastric cancer risk (unadjusted OR=1.45 95%CI 1.25, 1.68; adjusted OR=1.49 95%CI 1.24, 1.80) but this was most marked for PPI use of under 6 months (adjusted OR=1.84 95%CI 1.43, 2.38) and was attenuated after excluding prescriptions in the 2 years before diagnosis (adjusted OR=1.13 95%CI 0.91, 1.40). Similar findings were observed for H2RAs. In UK Biobank, 250 gastric cancer cases occurred in 471,529 participants. PPI use was associated with gastric cancer (unadjusted HR=1.53, 95%CI 1.10, 2.12) but this was not apparent after adjustments for potential confounders (adjusted HR=1.28, 95%CI 0.86, 1.90).

ABSTRACT 19A 102

Fully Covered Self Expanding Metal Stents in the Management of Complex Biliary Stone Disease

Authors: O. Reed, T. Tham, J. Eccles, G. Caddy
Institution: Division of Gastroenterology, Ulster Hospital, Dundonald BT16 1RH, Belfast, Northern Ireland, United Kingdom

Introduction: There is some evidence from a few case series that fully covered self-expanding metal stents (FCSEMS) can help in the management of difficult retained bile duct stones

Method: We reviewed our own data and experience in the use of FCSEMS. The data was searched over a 4 period from our endoscopic reporting system as well as patient outcomes and complications from the Northern Ireland Electronic Care Record.

Results: Biliary FCSEMS were inserted in 33 patients (11 male and 22 female) with a mean age of 76.8(range of 31 to 92) over a 4 year period over 67 procedures. Successful duct clearance occurred in 70% (23) of these patients with mean stent duration of 12 weeks. Patients underwent fewer ERCPs after FCSEMS were inserted with an average of 0.95 ERCPs post FCSEMS versus an average of 2.58 procedures from first diagnosis to completion of treatment. 5 patients in this group had prior cholecystectomy.
The duct was not cleared in 30%(10) of patients. 8 of these subsequently were referred for surgery and 2 for SpyGlass electrohydraulic lithotripsy.
In this group of patients 2 developed pancreatitis, 2 had an episode of biliary sepsis, 2 stents migrated proximally (which were successfully removed) and 2 stents became impacted, one of these was able to be removed endoscopically and the other required surgery. 1 patient required admission due to pain post procedure. The incidence of complications was therefore 13.4%.

Conclusion: In difficult common bile duct stones cases FCSEMS can help to achieve a high biliary stone clearance rate.

Conclusions: Overall, we found little consistent evidence of an association between PPI or H2RA use and gastric cancer risk.

ABSTRACT 19A 103

Prediagnostic Concentrations Of Circulating Sex Hormones And Oesophageal/Gastric Cardia Adenocarcinoma In Men: A Prospective Cohort Study In The UK Biobank

Úna Mc Menamin[1], Peipei Liu[1], Andrew Kunzmann[1], Helen Coleman[1,2,] Brian Johnston[2], Chris Cardwell[1]
Departments/Institutions:
[1]Centre for Public Health, Queen's University Belfast, Belfast, Northern Ireland.
[2] Centre for Cancer Research and Cell Biology, Queen's University Belfast, Northern Ireland
[3] Department of Gastroenterology, Royal Victoria Hospital, Belfast Health & Social Care Trust, Belfast, Northern Ireland.
Introduction:
Incidence of oesophageal adenocarcinoma (OAC) and gastric cardia adenocarcinoma (GCA) show a strong unexplained male predominance which has led to the hypothesis that sex hormones may be involved in their development.
Aim:
To determine the impact of circulating sex hormones on risk of OAC/GCA in men.
Methods:
We included 219,425 men enrolled in the UK Biobank between 2006-2010. Serum samples were obtained at baseline and sex hormone concentrations were quantified using chemiluminescent immunoassay. Incident cases of OAC/GCA were identified through linkage to UK cancer registries. Sex hormone levels were categorised into quartiles and adjusted hazard ratios (HR) and 95% confidence intervals (CIs) were estimated using age-dependent Cox proportional hazards models. We adjusted for potential confounders including smoking, alcohol, body mass index deprivation, and diabetes.
Results:
During 8 years of follow-up, 340 OAC/GCA cases were indentified. We observed no significant differences in the risk of OAC/GCA in men who with the highest levels of testosterone (HR 0.94, 0.68, 1.31, Ptrend=0.95), free testosterone (HR 0.84, 0.62, 1.13, Ptrend=0.22) or sex homrmone-binding globulin (HR 1.21, 95% CI 0.84, 1.74, Ptrend=0.14) compared to those with the lowest levels. Similarly, no associations were noted for oestradiol comparing the highest to the lowest concentrations (HR 1.12, 95% CI 0.67, 1.88, Ptrend=0.53). Results were similar when analyses were stratified by cancer site.
Conclusion:
We found little evidence of associations in the first prospective cohort study of circulating sex hormones and risk of OAC/GCA. Further large prospective investigations are required to replicate these findings.

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naloxegol

NICE recommended[1]

THE KEY TO UNLOCKING **OPIOID-INDUCED CONSTIPATION** IS TO TREAT THE SOURCE, NOT JUST THE SYMPTOM

In patients who previously did not respond adequately to a laxative...

MOVENTIG 25MG ONCE-DAILY TABLET:

- Offers relief **within 8 hours** of the first dose.[2]
- Increases spontaneous bowel movements (SBM) from **1.2 to 4.8 per week**.[3]

1.2 SBMs at baseline

4.8 SBMs over 12-week study with MOVENTIG 25mg

When symptoms persist after four days of laxative treatment, move to MOVENTIG.[4]

Visit: www.targetOIC.co.uk

For the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s)[4]

REFERENCES: 1. NICE Technology appraisal guidance [TA345]. Published July 2015. Available at: www.nice.org.uk/guidance/ta345/chapter/1-Guidance (last accessed September 2019). **2.** Tack J, Lappalainen J, Diva U, Tummala R, Sostek M. Efficacy and safety of naloxegol in patients with opioid-induced constipation and laxative-inadequate response. United European Gastroenterology Journal. 2015;3(5):471-480. **3.** Data on file, DOF-UK-029-v1 MOVENTIG. **4.** MOVENTIG Summary of Product Characteristics.

PRESCRIBING INFORMATION (prepared June 2019.)

Moventig® ▼ (naloxegol oxalate) 12.5mg and 25mg film-coated tablets

Consult Summary of Product Characteristics (SmPC) before prescribing.

Indication: Opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s) (concurrent OIC symptoms of at least moderate severity while taking at least one laxative class for a minimum of four days during the previous 2 weeks). **Dosage and administration:** Recommended 25 mg once daily. Take on empty stomach at least 30 minutes prior to first meal of day or 2 hours after first meal of day. Crushed tablets can be mixed with water (120ml) and drunk immediately or administered via a nasogastric tube (CH8 or greater). ***Renal impairment:*** Moderate or severe renal impairment starting dose 12.5mg. Discontinue if side effects impact tolerability. Increase to 25mg if well tolerated. ***Hepatic impairment:*** Use in severe hepatic impairment not recommended. ***Moderate CYP3A4 inhibitors:*** Starting dose 12.5mg, can be increased to 25mg if well tolerated. ***Paediatric population (<18 years):*** Safety and efficacy not yet established. **Adverse effects:** Consult SmPC for full list of side effects. *Very Common:* Abdominal pain, diarrhoea. *Common:* Nasopharyngitis, headache, flatulence, nausea, vomiting, hyperhidrosis. *Uncommon:* Opioid withdrawal syndrome. Not known: Hypersensitivity, Gastrointestinal perforation. **Contraindications:** Hypersensitivity to active substance or any of the excipients or any other opioid antagonist. Patients with known or suspected gastrointestinal (GI) obstruction or patients at increased risk of recurrent obstruction. Patients with underlying cancer who are at heightened risk of GI perforation, such as those with underlying malignancies of gastrointestinal tract or peritoneum, recurrent or advanced ovarian cancer or vascular endothelial growth factor (VEGF) inhibitor treatment. Concomitant use with strong CYP3A4 inhibitors. **Warnings and precautions:** Cases of gastrointestinal perforation have been reported in the post-marketing setting, including fatal cases when naloxegol was used in patients who were at an increased risk of gastrointestinal (GI) perforation. Naloxegol must not be used in patients with known or suspected gastrointestinal obstruction or in patients at increased risk of recurrent obstruction. Use with caution in patients with any condition which might result in impaired integrity of the gastrointestinal tract wall. Advise patients to discontinue therapy and promptly report if unusually severe or persistent abdominal pain develops. Use with caution in patients with clinically important disruptions to the blood brain barrier and observe for potential CNS effects. Discontinue if interference with opioid-mediated analgesia or opioid withdrawal syndrome occurs. Use with caution in patients taking methadone. If opioid withdrawal syndrome is suspected the patient should discontinue Moventig and contact their physician. Use with caution in patients with a recent history of myocardial infarction, symptomatic congestive heart failure, overt cardiovascular (CV) disease or with a QT interval of ≥500msec. Use with caution in OIC patients with cancer-related pain. Use of naloxegol with another opioid antagonist (e.g. naltrexone, naloxone) should be avoided. **Use in pregnancy and lactation:** Not recommended. **Legal category:** POM. **Marketing Authorisation numbers:** Moventig 12.5mg x 30 tablets EU/1/14/962/001; Moventig 12.5mg x 30 x 1 film-coated tablets EU/1/14/962/008; Moventig 25mg x 30 tablets EU/1/14/962/005; Moventig 25mg x 30 x 1 film-coated tablets EU/1/14/962/010. **Further information available on request from the Marketing Authorisation holder:** Kyowa Kirin Holdings B.V., Bloemlaan 2, 2132NP Hoofddorp,The Netherlands.

For the United Kingdom:

NHS cost: Moventig 12.5mg, 30 tablets, £55.20; Moventig 25mg, 30 tablets, £55.20.

Adverse Events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse Events should also be reported to Kyowa Kirin Ltd. on +44 (0)1896 664000, email medinfo@kyowakirin.com

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Adverse Events should be reported. Information about adverse event reporting can be found at www.hpra.ie. Adverse Events should also be reported to Kyowa Kirin Ltd. on +44 (0)1896 664000, email medinfo@kyowakirin.com

Kyowa KIRIN

Date of preparation: September 2019 **Code:** KKI/UKIRE/MOV/0099

Spring Meeting 2019

Sudheer George Jacob, Brian McLaughlin MSD, Fiona Ross and Breda McKee AbbVie

Mark Devoy and Claire Kelly Boston scientific with Abraham Varghese

Shane Dunseith, James McDaid and Paul Kavanagh Sword Medical

Ethna McFerran, Andrew McGuigan, Yasemim Adali and Peipei Liu

Leanne Stratton, Rachel Rutherford and Oliver Reed

Philip hall and Mark Devoy Boston Scientific

Eugene Campbell and Paula Norris Norgine

Carol Ramsey Janssen and Shane Dunseith

ABSTRACT 19A 104 - CASE STUDY (withdrawn)

Collateral Thinking – A case of ectopic variceal bleeding

Authors:
G.Morrison, A.Collins, R.McCorry
Departments/Institutions:
Liver Unit, 1st Floor East Wing Royal Victoria Hospital Belfast

Introduction
We present a rare and challenging case of a patient with alcohol related liver cirrhosis suffering ectopic variceal haemorrhage. The various levels of investigation and management are explored before a multidisciplinary effort prevents exsanguination.

Case Series
A 57 year old man with Child Pugh class A6, MELD 10 alcohol related liver cirrhosis suffered several episodes of frank umbilical bleeding over a four day period. Subsequently developing anaemia that required blood transfusion. Initial management with a surgical oversew of the umbilical vessels proved unsuccessful. CT images confirmed cirrhosis and portal hypertension with impressive collateral vessels within an umbilical hernia. He was managed as per gastro-intestinal variceal haemorrhage with transfusion of packed red cells, Terlipressin and prophylactic antibiotics. Despite this 48 hours post admission he had further significant haemorrhage with haemoglobin dropping from 113 g/L (130 – 180 g/L) to 62 g/L.
Following work-up with echocardiogram, interventional radiology used CT fusion images to successfully deploy a transjugular intrahepatic portosystemic shunt (TIPSS) and embolise the culprit vessel via microcatheter leading to cessation of bleeding.

Discussion
Ectopic variceal bleeding accounts for up to 5% of all variceal bleeds with mortality reaching 40%. Treatment is generally guided by local expertise due to absence of large studies. Surgical interventions such as suture haemostasis and cauterisation in addition to medical treatments such as vasoconstrictors (terlipressin) and beta blockers have demonstrated mixed success. In parastomal bleeding, radiological interventions including TIPSS and embolization with sclerotherapy have been documented. A greater than 50% reduction in pressure gradient has been demonstrated to protect from rebleeding.

Figure 1, CT showing sizeable umbilical varices (white arrowhead)

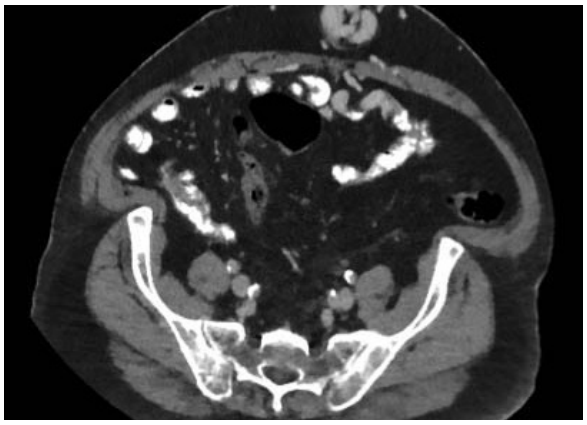
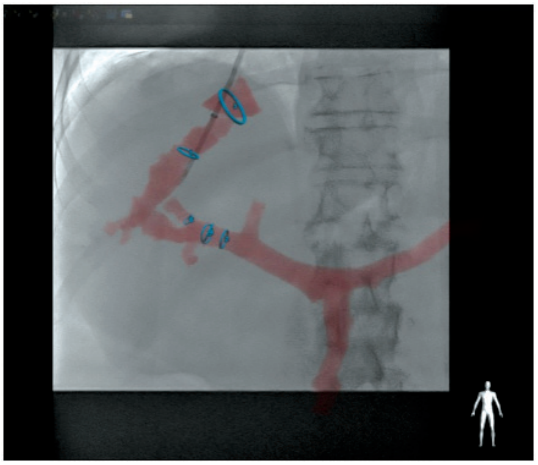


Figure 2, CT guided fusion imaging assisting TIPSS insertion



ABSTRACT 19A 105

Creation of a Northern Ireland Barrett's Oesophagus Treatment Registry

Authors:
AD Spence[1], HG Coleman[2], D McManus[3], P Hall[1], I Mainie[1]
Institutions:
[1]Department of Gastroenterology, Belfast City Hospital, Belfast Health and Social Care Trust, Belfast
[2]Cancer Epidemiology Research Group, Centre for Public Health, Queen's University Belfast, Belfast
[3]Department of Pathology, Royal Victoria Hospital, Belfast Health and Social Care Trust, Belfast

Introduction:
Barrett's oesophagus is a premalignant condition which can develop into oesophageal adenocarcinoma. Endomucosal resection (EMR) and radiofrequency ablation (RFA) are endoscopic treatments aiming to reduce the risk of transformation to cancer.

Aim:
Create a registry of EMR and RFA Barrett's oesophagus treatments for linkage with the Northern Ireland Barrett's oesophagus registry.

Method:
All EMRs and RFAs for Barrett's oesophagus from 2008-2019 were identified using endoscopy software in the Belfast Trust. Pathology data were identified from the Belfast Trust Laboratory (Lab Centre) for biopsies obtained from each treatment and any previous or subsequent endoscopies. The number of patients deceased and those who developed cancer were determined. Time trends were analysed to determine the frequency of procedures year on year.

Results:
From January 2008 to February 2019 274 patients with Barrett's oesophagus underwent a total of 362 EMRs and 383 RFAs in the Belfast Trust. There were an average of 1.3 EMRs and 1.4 RFAs per patient. On at least one oesophageal biopsy, 72% of patients had evidence of high grade dysplasia, 45% had intramucosal adenocarcinoma and 2% had invasive adenocarcinoma. 31 (11%) patients underwent surgery for oesophageal cancer and 40 (15%) patients have died. There is a progressive increasing number of EMR/RFA treatments from 2008-2019.

Conclusions:
The introduction of EMR/RFA has resulted in an increasing proportion of patients with Barrett's oesophagus undergoing treatment to reduce risk of adenocarcinoma. This new database will be combined with the Northern Ireland Barrett's oesophagus registry for further study.

Spring Meeting 2019

Meeting of minds

USG Speakers

Audience View

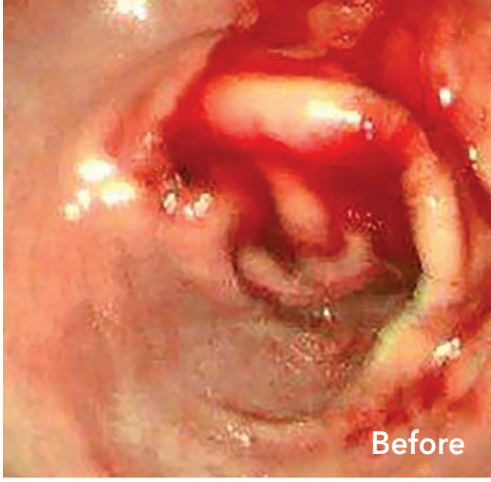
Eileen Fox and Bernie McGrath with Michelle Casey Fleetwood Healthcare

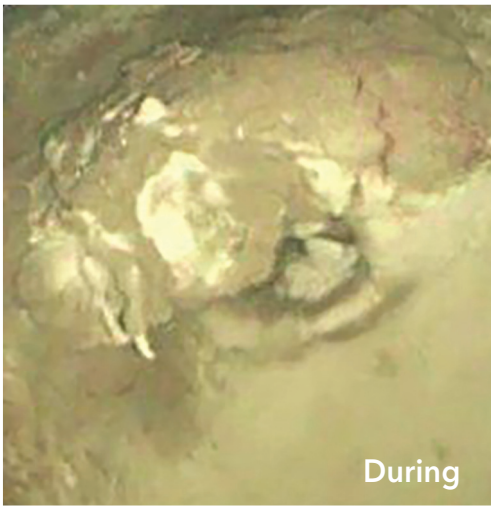
Una McMenamin, Damien McManus,
Andrew Kunzmann and Ethna McFerran

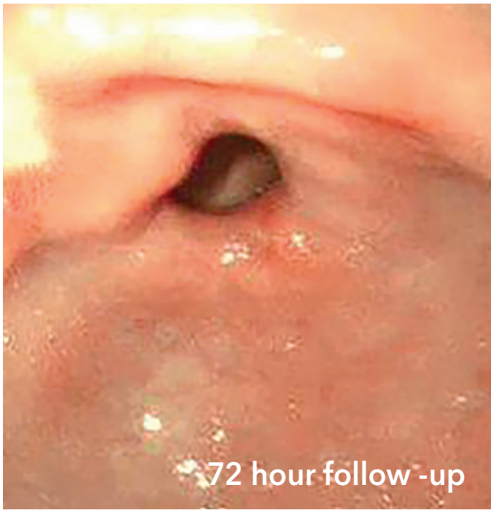
Mark Ellis and Hayley Welch Amgen with Peter Watson

Peter Watson and William Richards Northern Hospital Supplies

A different approach to hemostasis.







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Peptic ulcer bleed images courtesy of Prof. Joseph Sung, Chinese University of Hong Kong, Hong Kong, China.

Spring Meeting 2019

Audience View

Conor Braniff-Speaker

Shivaram Bhat and Tim McAdam officers of USG

Alistair Harvey HSL with Heather Logan and Allison Lloyd

Irish Society of Gastroenterology/ Irish Society of Coloproctology

Summer Meeting

Kilashee Hotel
14-15 May 2020

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Because ulcerative colitis is a life-long condition, you need mesalazine MR tablet options that best suit your patients' varying needs. The NHS needs treatments that consistently offer good value.

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Octasa® offers:[1-3]

- High-dose options up to 4.8g/day*
- Once-daily dosing up to 2.4g/day‡
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There are no clinical comparisons of Octasa® vs Asacol®. SmPCs may differ; consult individual SmPCs before prescribing.
*For the induction of remission in patients with moderate UC. ‡Doses above 2.4g/day must be administered in divided doses.

OCTASA 400mg Modified Release Tablets (mesalazine) and OCTASA 800mg Modified Release Tablets (mesalazine) - Prescribing Information
Presentation: Modified Release tablets containing 400mg mesalazine or 800mg mesalazine. **Indications:** *Ulcerative Colitis* - Treatment of mild to moderate acute exacerbations. Maintenance of remission. *Crohn's ileocolitis* - Maintenance of remission. **Dosage and administration:** *400mg tablets – Adults:* Mild acute disease: 6 tablets (2.4g) once daily or in divided doses, with concomitant steroid therapy where indicated. Moderate acute disease: 6 to 12 tablets (2.4g – 4.8g) daily. 2.4g may be taken once daily or in divided doses, higher doses should be taken in divided doses. Maintenance therapy: 3 to 6 tablets (1.2g – 2.4g) once daily or in divided doses. *800mg tablets - Adults:* Mild acute disease: 3 tablets (2.4g) once daily or in divided doses with concomitant steroid therapy where indicated. Moderate acute disease: 3 to 6 tablets (2.4g – 4.8g) daily. 2.4g may be taken once daily, higher doses should be taken in divided doses. Maintenance therapy: 2 to 3 tablets (1.6g - 2.4g) once daily or in divided doses. *400mg and 800mg tablets* – No more than 2.4g should be taken at one time. Tablets must be swallowed whole. *Elderly:* Normal adult dose may be used unless liver or renal function is severely impaired. *Children:* Limited documentation of efficacy in children >6 years old. Dose to be determined individually. Generally recommended that half the adult dose may be given to children up to a body weight of 40 kg; and the normal adult dose to those above 40 kg. **Contra-indications:** Hypersensitivity to salicylates, mesalazine or any of the excipients, severe impairment of hepatic or renal function (GFR less than 30 ml/min). **Warnings and Precautions:** Urinary status (dip sticks) should be determined prior to and during treatment, at discretion of treating physician. Caution in patients with raised serum creatinine or proteinuria. Stop treatment immediately if renal impairment is evident. Haematological investigations are recommended prior to and during treatment, at discretion of treating physician. Stop treatment immediately if blood dyscrasias are suspected or evident. Caution in patients with impaired hepatic function. Liver function should be determined prior to and during treatment, at the discretion of the treating physician. Do not use in patients with previous mesalazine-induced cardiac hypersensitivity and use caution in patients with previous myo- or pericarditis of allergic background. Monitor patients with pulmonary disease, in particular asthma, very carefully. In patients with a history of adverse drug reactions to sulphasalazine, discontinue immediately if acute intolerance reactions occur (e.g. abdominal cramps, acute abdominal pain, fever, severe headache and rash). Use with caution in patients with gastric or duodenal ulcers. Intact tablets in the stool may be largely empty shells. If this occurs repeatedly patients should consult their physician. Use with caution in the elderly subject to patients having normal or non-severely impaired renal and liver function. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, should not take this medicine. **Interactions:** No interaction studies have been performed. May decrease the anticoagulant activity of warfarin. May increase the myelosuppressive effects of azathioprine, 6-mercaptopurine or thioguanine. Monitoring of blood cell counts is recommended if these are used concomitantly. **Fertility, pregnancy and lactation:** Only to be used during pregnancy and lactation when the potential benefit outweighs the possible risk. No effects on fertility have been observed. **Adverse reactions:** *Common:* dyspepsia, rash. *Uncommon:* eosinophilia (as part of an allergic reaction), paraesthesia, urticaria, pruritus, pyrexia, chest pain. *Rare:* headache, dizziness, myocarditis, pericarditis, abdominal pain, diarrhoea, flatulence, nausea, vomiting, photosensitivity. *Very rare:* altered blood counts (aplastic anemia, granulocytosis, pancytopenia, neutropenia, leucopenia, thrombocytopenia), hypersensitivity reactions (such as allergic exanthema, drug fever, lupus erythematosus syndrome, pancolitis), peripheral neuropathy, allergic and fibrotic lung reactions (including dyspnoea, cough, bronchospasm, alveolitis, pulmonary eosinophilia, lung infiltration, pneumonitis), interstitial pneumonia, eosinophilic pneumonia, lung disorder, acute pancreatitis, changes in liver function parameters (increase in transaminases and cholestasis parameters), hepatitis, cholestatic hepatitis, alopecia, myalgia, arthralgia, impairment of renal function including acute and chronic interstitial nephritis and renal insufficiency, renal failure which may be reversible on withdrawal, nephrotic syndrome, oligospermia (reversible). *Not known:* pleurisy, lupus-like syndrome with pericarditis and pleuropericarditis as prominent symptoms as well as rash and arthralgia, intolerance to mesalazine with C-reactive protein increased and/or exacerbation of symptoms of underlying disease, blood creatinine increased, weight decreased, creatinine clearance decreased, amylase increased, red blood cell sedimentation rate increased, lipase increased, BUN increased. Consult the Summary of Product Characteristics in relation to other adverse reactions. **Marketing Authorisation Numbers, Package Quantities and basic NHS price:** 400mg - PL36633/0002; packs of 90 tablets (£16.58) and 120 tablets (£22.10). 800mg - PL36633/0001; packs of 90 tablets (£40.38) and 180 tablets (£80.75). **Legal category:** POM. **Marketing Authorisation Holder:** Tillotts Pharma UK Ltd, The Larbourne Suite, The Stables, Wellingore Hall, Wellingore, Lincolnshire, LN5 0HX, UK. Octasa is a trademark. Further Information is available from the Marketing Authorisation Holder. Date of preparation of API: November 2017

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Tillotts Pharma UK Ltd. (address as above) Tel: 01522 813500.

References: 1. Octasa® 400mg Modified Release Tablets – Summary of Product Characteristics. November 2017. 2. Octasa® 800mg Modified Release Tablets – Summary of Product Characteristics. November 2017. 3. Data on file, Tillotts Pharma UK Limited. [Octasa® cost savings 2014–2018 – March 2019].

Date of preparation: March 2019. PU-00241.

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Entyvio® is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or anti-TNFα therapy.

Entyvio® vedolizumab

BEGIN THE CHANGE

Entyvio® (vedolizumab) PRESCRIBING INFORMATION
Refer to the Summary of Product Characteristics (SmPC) before prescribing.
Presentation: 300 mg powder for concentrate for solution for infusion. **Indication:** Adult patients with moderately to severely active ulcerative colitis(UC)/Crohn's disease (CD) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. **Dosage & Administration:** Treatment should be initiated and supervised by a specialist healthcare professional experienced in diagnosis and treatment of ulcerative colitis or Crohn's disease. Patients should be monitored during and after infusion in a setting equipped to manage anaphylaxis. Ulcerative colitis: Recommended dose regimen 300mg administered by intravenous infusion over 30 minutes at 0, 2, 6 weeks and 8 weeks thereafter. Discontinue treatment if no evidence of therapeutic benefit by week 10. If patients experience a decrease in response, they may benefit from increased dosage frequency to 300mg every 4 weeks. Corticosteroids may be reduced/discontinued in patients who respond to treatment with Entyvio. If therapy is interrupted and needs to be restarted, Entyvio dosing every 4 weeks may be considered. Crohn's disease: Recommended dose regimen is 300mg administered by intravenous infusion over 30 minutes at 0, 2, 6 weeks and 8 weeks thereafter. Patients who have not shown evidence of therapeutic benefit may benefit from a dose at week 10. Continue therapy every 8 weeks from week 14 in responding patients. Therapy should be discontinued if no evidence of therapeutic benefit is observed by week 14. If therapy is interrupted and needs to be restarted, Entyvio dosing every 4 weeks may be considered. Paediatric populations: No data available in children aged 0-17 years. Not recommended. Elderly patients: No dosage adjustment required. Renal or hepatic impairment: Entyvio has not been studied in these populations. No dose recommendation can be given. **Contraindications:** Hypersensitivity to Entyvio or any of the excipients. Active infections such as tuberculosis (TB), sepsis, cytomegalovirus, listeriosis and opportunistic infections such as Progressive Multifocal Leukoencephalopathy (PML). **Warnings and Precautions:** Patients should be observed continuously during infusions for signs/symptoms of hypersensitivity reactions. Patients should continue to be observed for two hours following infusion completion for the first two infusions and one hour for subsequent infusions. Infusion-related reactions (IRR): Hypersensitivity reactions have been reported, the majority were of mild to moderate severity. Discontinue treatment if anaphylaxis or other serious allergic reactions occur and institute appropriate treatment. In mild to moderate IRR, slow or interrupt infusion. Consideration for pre-treatment with antihistamine, hydrocortisone and/or paracetamol should be given prior to next infusion, for patients with history of mild/moderate IRR to Entyvio. Infections: Not recommended in patients with active, severe infections until infections are controlled. Consider withholding in patients who develop severe infection while on treatment with Entyvio. Before initiating treatment, patients must be screened for TB. If latent TB is diagnosed, anti-tuberculosis appropriate treatment must be initiated prior to Entyvio treatment. Progressive Multifocal Leukoencephalopathy (PML): John Cunningham (JC) virus infection resulting in PML and death has occurred in patients treated with other integrin receptor antagonists and systemic immunosuppressive agents. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs/symptoms. Malignancy: Underlying increased risk of malignancy in UC and CD. Immunomodulatory products may increase risk. Prior and concurrent use of biological products: No clinical data available for Entyvio use in patients previously treated with natalizumab or rituximab. Patients previously exposed to natalizumab should wait at least 12 weeks prior to initiating Entyvio therapy. Entyvio not recommended for concomitant use with biologic immunosuppressants as no clinical data available. Live and oral vaccines: Patients may continue to receive non-live vaccines. Patients recommended to be up-to-date with all appropriate immunisations prior to initiating Entyvio. Live vaccines may be administered concurrently only if benefit clearly outweighs risk. **Interactions:** No interaction studies performed. Concomitant administration of corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine, and methotrexate) and aminosalicylates did not have a clinically meaningful effect on Entyvio pharmacokinetics. **Fertility, pregnancy and lactation:** Women of child-bearing potential should use adequate contraception and continue for at least 18 weeks after last Entyvio treatment. Preferable to avoid use of Entyvio during pregnancy unless benefits clearly outweigh potential risk to both the mother and foetus. Entyvio has been detected in human milk. The effect on infants is unknown. Use of Entyvio in lactating women should consider the benefit of therapy against potential risks to the infant. **Undesirable Effects:** Very Common (≥1/10): nasopharyngitis, headache, arthralgia. Common (≥1/100, <1/10): bronchitis, gastroenteritis, upper respiratory tract infection, influenza, sinusitis, pharyngitis, paraesthesia, hypertension, oropharyngeal pain, nasal congestion, cough, anal abscess, anal fissure, nausea, dyspepsia, constipation, abdominal distension, flatulence, haemorrhoids, rash, pruritus, eczema, erythema, night sweats, acne, muscle spasm, back pain, muscular weakness, fatigue, pain in extremities, pyrexia. Other serious undesirable effects: respiratory tract infection, pneumonia, anaphylactic reaction, anaphylactic shock. **Refer to the SmPC for details on full side effect profile and interactions. UK Basic NHS Price:** £2,050 for one vial (300mg powder for concentrate for solution for infusion). **Legal Classification:** POM. **Marketing Authorisation:** EU/1/14/923/001 **Additional information is available on request from:** Takeda UK Ltd. Building 3, Glory Park, Glory Park Avenue, Wooburn Green, Buckinghamshire, HP10 0DF. Tel: 01628 537900 Fax: 01628 526617. Takeda Products Ireland Ltd. 3013 Lake Drive, Citywest Business Campus, Dublin 24. Tel: +353 (0)1 642 0021 Fax: +353 (0)1 642 0020. **PI Approval Code:** UK/EYV/1712/0182(3) **Date of revision:** March 2019.

UK: Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Takeda UK Ltd. Tel 01628-537900

Ireland: Adverse Events should be reported to the Pharmacovigilance Unit at the Health Products Regulatory Authority (medsafety@hpra.ie). Information about Adverse Event reporting can be found on the HPRA website (www.hpra.ie). Adverse events should also be reported to Takeda UK Ltd Tel 1800 937 970

References: 1. Dulai P, Meserve J, Hartke J, *et al*. Poster presented at European Crohn's and Colitis Organisation (ECCO); 15–18 February 2017; Barcelona, Spain. Abstract DOP023. **2.** Dulai PS, Singh S, Jiang X, *et al*. Am J Gastroenterol. 2016;111(8):1147–1155. **3.** Loftus EV, Colombel JF, Feagan B, *et al*. Poster presented at the European Crohn's and Colitis Organisation (ECCO); 15–18 February 2017; Barcelona, Spain. Poster P209. **4.** Vermeire S, Loftus EV, Colombel JF, *et al*. Poster presented at Digestive Disease Week (DDW); 6–9 May 2017; Chicago, IL, USA. Poster Su1931. **5.** Takeda UK Data on File UK/DF/1804/0008(1).

UK/EYV/1808/0089(1)
Date of preparation: April 2019.

Takeda