

research funding from Pfizer, Sanofi, Amgen, Roche, Novartis, Celgene, Teva, AstraZeneca, Myriad Genetics, AbbVie, and Vifor Pharma. Charles E. Geyer Jr.: Received research funding from Incyte and Merck.

## Scientific Symposium New Trends in Upper GI

10

### ANALYSIS OF FUNCTIONAL OUTCOMES POST GASTRECTOMY AND OESOPHAGECTOMY

O. Mc Cormack<sup>1</sup>, N. McLaren<sup>1</sup>, V. Mengardo<sup>1</sup>, J. Andreyev<sup>2</sup>, W. Allum<sup>1</sup>. <sup>1</sup>Royal Marsden Hospital, Upper GI Surgery, London, United Kingdom; <sup>2</sup>Royal Marsden Hospital, Gastroenterology, London, United Kingdom

**Background:** Advances in gastric and oesophageal cancer management have led to improved survivorship. Factors affecting quality of life in long-term survivors are now coming to the attention of caregivers. The causes are multifactorial and include structural changes in upper gastrointestinal tract, abnormal gastrointestinal motility, altered pH, bacterial overgrowth, and insufficient bile salt or pancreatic enzyme production. The objective of this study was to analyse the extent of this problem in a gastric and oesophageal cancer population.

**Materials and methods:** A prospectively maintained database identified 174 patients who underwent gastrectomy for gastric cancer and 146 patients who underwent oesophagectomy for oesophageal cancer from 2006–2014. A retrospective analysis was performed to assess those referred to gastroenterology with functional symptoms. Investigations performed and subsequent results were analysed.

**Results:** 45/174 (26%) of patients had significant functional symptoms post gastrectomy and 33/146 (22.6%) of patients had similar problems post oesophagectomy requiring referral to gastroenterology. Concerning symptoms included weight loss, diarrhoea, nausea, and abdominal pain. 27/45 (60%) of gastrectomy patients had undergone a total gastrectomy. 32/33 (97%) of oesophagectomy patients had undergone an Ivor Lewis oesophagectomy. The most common diagnosis was small intestine bacterial overgrowth (SIBO) 40/45 (89%) gastrectomy patients were found to

Putter<sup>5</sup>, H. Boot<sup>6</sup>, A. Cats<sup>6</sup>, K. Sikorska<sup>7</sup>, H. van Tinteren<sup>7</sup>, M. Verheij<sup>3</sup>, C. van de Velde<sup>1</sup>. On behalf of the CRITICS investigators<sup>1</sup> Leiden University Medical Center, Surgery, Leiden, Netherlands; <sup>2</sup>The Netherlands Cancer Institute- Antoni van Leeuwenhoek Hospital, Surgery, Amsterdam, Netherlands; <sup>3</sup>The Netherlands Cancer Institute- Antoni van Leeuwenhoek Hospital, Radiation Oncology, Amsterdam, Netherlands; <sup>4</sup>VU University Medical Center, Department of Pathology, Amsterdam, Netherlands; <sup>5</sup>Leiden University Medical Center, Medical Statistics, Leiden, Netherlands; <sup>6</sup>The Netherlands Cancer Institute- Antoni van Leeuwenhoek Hospital, Gastroenterology and Hepatology, Amsterdam, Netherlands; <sup>7</sup>The Netherlands Cancer Institute- Antoni van Leeuwenhoek Hospital, Biometrics, Amsterdam, Netherlands

**Background:** The American Intergroup 0116 study (Macdonald et al; NEJM; 2001) and the British MAGIC trial (Cunningham et al; NEJM; 2006) changed clinical practice for resectable gastric cancer. It was shown that overall survival after surgery improved with postoperative chemoradiotherapy and perioperative chemotherapy, respectively. Intention-to-treat analysis of the data in the CRITICS trial (chemotherapy versus chemoradiotherapy after surgery and preoperative chemotherapy for resectable gastric cancer; Lancet Oncology; 2018) did not show a survival difference between the two treatment arms. Due to comorbidity, the aging society, treatment related toxicity and major surgery, compliance is a problem in clinical studies. A per protocol analysis was performed acknowledging the limitations of such analysis.

**Material and methods:** The CRITICS trial was an open label phase 3 trial in which 788 patients with stage Ib– IVa resectable gastric or oesophago-gastric adenocarcinoma were included. Patients from the Netherlands, Sweden, and Denmark were randomly assigned to perioperative chemotherapy or preoperative chemotherapy with postoperative chemoradiotherapy. For this analysis, only outcomes of patients who actually started postoperative treatment were analyzed. Since the two treatment arms are not inherently balanced in such per protocol analysis, landmark analysis (adjusting for baseline, preoperative chemotherapy, surgery and pathology variables) and Inverse Probability Weighted (IPW) analysis were used to estimate and compare overall and event-free survival.

**Results:** Median follow-up duration is 6.2 years.

|     | Randomization | Pre-operative CT | Surgery   | Post-operative CT | Post-operative CRT | Completed treatment |
|-----|---------------|------------------|-----------|-------------------|--------------------|---------------------|
| CT  | 393 (100%)    | 334 (85%)        | 310 (79%) | <b>233 (59%)</b>  |                    | 180 (46%)           |
| CRT | 395 (100%)    | 318 (81%)        | 326 (83%) |                   | <b>245 (62%)</b>   | 197 (50%)           |

CT = chemotherapy; CRT = chemoradiotherapy

have SIBO, diagnosed on methane breath test or duodenal aspirate. 26/33 (79%) oesophagectomy patients were diagnosed with SIBO. Organisms isolated included E. Coli, Enterococcus, Klebsiella, Streptococcus, Clostridium and Candida. 8/45 (18%) post gastrectomy and 5/33 (15%) post oesophagectomy had bile salt malabsorption diagnosed on SeHCAT scan. 5/45 (11%) post gastrectomy and 3/33 (9%) post oesophagectomy had pancreatic insufficiency on faecal elastase testing.

**Conclusions:** Improved survival rates post upper gastrointestinal surgery have identified that survivors can develop functional problems months to years after surgery. The most common diagnosis is SIBO. As this is easily treated with antibiotics we would advocate early recognition and investigation of functional symptoms to avoid weight loss and distressing symptoms in this population.

**Conflict of interest:** No conflict of interest.

11

### CHEMOTHERAPY VERSUS CHEMORADIOTHERAPY AFTER SURGERY AND PREOPERATIVE CHEMOTHERAPY FOR RESECTABLE GASTRIC CANCER: PER PROTOCOL ANALYSIS OF THE CRITICS TRIAL

W. de Steur<sup>1</sup>, Y. Claassen<sup>1</sup>, H. Hartgrink<sup>1</sup>, E. Meershoek Klein Kranenbarg<sup>1</sup>, J. van Sandick<sup>2</sup>, J. Braak<sup>1</sup>, E. Jansen<sup>3</sup>, N. van Grieken<sup>4</sup>, H.

**Conclusion:** Actual results of the per protocol analysis as well as updated results of the intention-to-treat analysis will be presented.

**Conflict of interest:** No conflict of interest.

12

### LAPAROSCOPY-ASSISTED VERSUS OPEN D2 DISTAL GASTRECTOMY FOR ADVANCED GASTRIC CANCER: FIVE YEAR OVERALL SURVIVAL AND MORBIDITY RESULTS FROM A RANDOMIZED PHASE II MULTICENTER CLINICAL TRIAL (COACT 1001).

Y.W. Kim<sup>1</sup>, B.H. Nam<sup>2</sup>, Y.J. Lee<sup>3</sup>, Y. Park<sup>4</sup>, S.E. Lee<sup>5</sup>, J. Oh<sup>6</sup>, J.H. Lee<sup>7</sup>, K.Y. Yoon<sup>8</sup>, S.H. Jeong<sup>9</sup>, O.K. Kwon<sup>10</sup>, T. Kim<sup>11</sup>, W. Yu<sup>10</sup>, Y.S. Kim<sup>12</sup>, M. Han<sup>13</sup>, S. Kim<sup>12</sup>, K.W. Ryu<sup>12</sup>. On behalf of COACT<sup>1</sup> National Cancer Center, Surgery, Goyang-si, Gyeonggi-do, Korea; <sup>2</sup>National Cancer Center, Biometric Research Branch- Division of Cancer Epidemiology and Prevention- Research Institute and Hospital-, Goyang, Korea; <sup>3</sup>Cyengsang National University Hospital, Department of surgery, Jinju, Korea; <sup>4</sup>Chonnam National University Hwasun Hospital, Department of surgery, Hwasun, Korea; <sup>5</sup>Konyang University Hospital, Department of surgery, Daejeon, Korea; <sup>6</sup>Chonnam National University Medical School, Department of surgery, Hwasun, Korea; <sup>7</sup>Samsung Medical Center,