

ESOPHAGEAL CANCER SURGERY IN PATIENTS OLDER THAN 75 : LONG TERM RESULTS. C. Honoré, A. De Roover, A. Al-Azzeh, N. Gilson, P. Honoré, M. Meurisse. University of Liège, Liège, Belgium.

Aim : The purpose of this study was to evaluate short and long term results after esophageal resection for cancer in patients older than 75 which are often denied surgery because of a suspected increased morbidity and a lesser life expectancy.

Methods : We retrospectively analyzed the prospective electronic database of esophageal cancer surgically treated in our department between January 2003 and December 2009 to identify patients older than 75. The preoperative (denutrition, ASA score, WHO general status, Charlson Comorbidity Index, histological subtype, neoadjuvant treatment), operative and postoperative characteristics (morbidity, mortality, disease free and overall survival) were analyzed.

Results : Among the 137 patient surgically treated during that period, 23 patients were older than 75. The preoperative characteristics' analysis showed 39% of severe/moderate denutrition, a mean ASA score of 2 (ASA1 : 4%, ASA2 : 87%, ASA3 : 9%), a mean WHO general status of 1 (WHO 0 : 65%, WHO 1 : 13%, WHO 2 : 22%), a mean Charlson Comorbidity Index of 3 (Range : 2-5). 4% of patients received a preoperative chemoradiotherapy, 26% received a preoperative chemotherapy. The histological subtype was adenocarcinoma in 100%. The surgical techniques were a "Lewis-Santy" procedure in 43%, a trans-hiatal resection in 22%, a "Sweet" procedure in 13%, a stripping in 13% and a "McKeown" procedure in 9%. The in-hospital postoperative mortality was 13%. The in-hospital postoperative morbidity (Dindo-Clavien Grade > 2, deceased patients included) was 26%. In univariate analysis, no statistically significant risk factor of morbidity was found. A Charlson Comorbidity Index > 2 was, in univariate analysis, associated to postoperative death ($p = 0.0362$). The mean hospital stay was 22 ± 12 days. The median survival was 24.2 months. The 5-year overall survival was 39% and the 5-year disease free survival was 26%. 57% of long-term deaths were not cancer related.

Conclusion : Esophageal surgery performed in selected patients older than 75 has an acceptable morbidity and mortality. Anyway, when a severe complication occurs, it leads to death in half of the cases, mostly in patients with associated comorbidities. The long term survival after surgery is comparable to a younger population. This study confirmed our attitude of not considering age as a contra-indication for esophageal surgery but rather considering general status, self-reliance and associated comorbidities for the patients' selection.

COMBINATION OF GEMCITABINE AND CETUXIMAB IN PATIENTS WITH ADVANCED CHOLANGIO-CARCINOMA : A PHASE II STUDY. A. Ceratti (1), I. Borbath (1), C. Verslype (2), T. Delaunoit (3), M. Van Den Eynde (1), S. Laurent (4), M. Peeters (4), A. Hendlisz (5), A. Deleporte (5), P. Vergauwe (6), B. Delhougne (7), M. Polus (8), E. Van Cutsem (2), J.L. Van Laethem (9). (1) Cliniques Universitaires Saint-Luc, Brussels, Belgium ; (2) University of Leuven, Leuven, Belgium ; (3) Hôpital de Jolimont, Haine-Saint-Paul, Belgium ; (4) UZ, Gent, Belgium ; (5) Institut Jules Bordet, Brussels, Belgium ; (6) AZ Groeninge, Kortrijk, Belgium ; (7) CHC de la Citadelle, Liège, Belgium ; (8) CHU Liège, Liège, Belgium ; (9) ULB Erasme, Brussels, Belgium.

Introduction : Cholangiocarcinomas (CCK) are uncommon tumors with an increasing incidence and a poor prognosis. Epidermal growth factor receptor (EGFR) expression and activation in CCK have been demonstrated.

Aim : The aim of this trial was to assess the efficacy of combining cetuximab (Ctx) and gemcitabine (Gem) in front line treatment of advanced unresectable CCK. The primary endpoint was to determine the progression-free survival (PFS) rate at 6 months with this regimen. Secondary endpoints were to assess response rate, safety profile and overall survival (OS).

Methods : We conducted a multicenter phase II trial combining Ctx, an anti-EGFR chimerized IgG1 monoclonal antibody, to Gem. Patients with either locally advanced (LA) or metastatic (M) measurable CCK (excluding gallbladder cancer) were included ; no prior systemic therapy was allowed. Ctx was administrated at the initial dose of 400 mg/m² and further injections at 250 mg/m² every 7 days, and Gem was administrated at 1000 mg/m² on day 1, 8 and 15 every 4 weeks. The primary endpoint was the 6 month-PFS rate. A Simon 2-stage design was used. We hypothesized that the combination therapy would improve 6 month-PFS rate from 20% to 40% . We therefore needed 3 patients with PFS > / = 6 months from the first 13 to further include a total of 43 patients.

Results : A total of 44 patients with advanced CCK (41% LA/59%M) was enrolled from September 2008 to January 2010. The median age was 61.5 years (range : 40 to 86 years) and baseline ECOG performance status was 0 for 68% and 1 for 32% of the patients. Forty-three percent of the patients had prior surgery. Forty-six percent of the patients were free from progression at 6 months. Median PFS was 5.8 months (95% CI, 4.4-7.4 months) and median OS was 11.6 months (95% CI, 8.7-14.6 months). Nine patients (20.9%) had partial response with a median duration of 5 months (range, 2-10 months). Disease control rate (PR + SD > 8 weeks) was 81.4%. The most common grades 3/4 related-

toxicities were haematological abnormalities (47.7%), skin rash (13.6%) and fatigue (11.3%). Due to toxicity, 6 patients discontinued study treatment ; 14 patients had a Gem dose reduction and 3 patients had a Ctx dose reduction. Among the nine responders, 8 experienced a skin rash of at least grade 2, suggesting a relationship between skin toxicity and efficacy.

Conclusion : Our study met its endpoint, i.e. a PFS rate of 46% at 6 months, suggesting that Gem-Ctx combination had promising activity with a manageable toxicity profile. Adding Ctx to the new standard of care Gem-cisplatin deserves further investigations in CCK.

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SHORT TERM SIDE EFFECTS AFTER RADIOFREQUENCY ABLATION. ARE WE READY TO ABLATE NON-DYSPLASTIC BARRETT ? Y.N. Choi, H. Willekens, G. Coremans, S. Depeyper, R. Bisschops. UZ Leuven Department of Gastroenterology, Leuven, Belgium.

Introduction : Radiofrequency ablation (RFA) is an effective treatment for Barret's associated dysplasia and eradication of intestinal metaplasia. Due to its efficacy and good safety profile it has been suggested that RFA of non-dysplastic Barrett's might be cost-effective. Although major complications are well studied and limited, little is known on RFA induced symptoms.

Aim : We aimed to assess the short-term side effects after circumferential (HALO 360) or focal (HALO 90) RFA.

Methods : RFA was performed to obtain total eradication of intestinal metaplasia in patients with low grade of high grade dysplasia, after endoscopic resection of any visible lesion. Post RFA, patients who were on pantoprazole 40 mg bid and an evening dose of ranitidine 300 mg, were asked to fill out a 30-day diary in which they had to score for the following 8 symptoms on a 7 point Likert scale (0 = no symptoms to 7 = unbearable, rendering normal daily activity impossible) : retrosternal pain and burning, dysphagia, epigastric pain, decreased appetite, sour throat, nausea and vomiting. A score above or equal to 3 was defined as symptoms that cannot be ignored and were regarded as significant side-effect. Mean scores were calculated for symptomatic patients as well as the time until the mean score dropped below 1.

Results : Data for 13 Halo 360 and 22 Halo 90 procedures were available. Retrosternal pain, retrosternal burning, dysphagia and decreased appetite were the most common symptoms after RFA occurring in 70-92% of the patients. These symptoms did not significantly differ between the Halo 360 and 90 group. Retrosternal pain was a highly prevalent and the most severe symptom with a maximum mean score of 4 and 3.76 and lasting 14 and 13 days in the HALO 360 and HALO 90 group respectively. Dysphagia was the most prevalent symptom but was rather limited in severity. It was present in 92% and 91% of cases but only significant in 23% and 27% of Halo 360 and Halo 90 cases respectively. Decreased appetite occurred in 69% and 63% of HALO 360 and HALO 90 patients respectively, but was only severe in 15% and 14%. Nausea and vomiting was not so prevalent (18-38%) and was only significant in 8-15% of patients. Fever occurred in 31% and 19% after Halo 360 and Halo 90 respectively. No cases of melena were reported. After 16 days the mean score for all symptoms dropped below 1.

Conclusion : The majority of patients report short term side effects after RFA. In more than 25% of patients these symptoms are considered significant to severe and last for about two weeks. These findings are important when consenting patients for RFA and should be taken into account when considering RFA for non-dysplastic Barrett.