

PATHOLOGY, RADIOLOGY AND BGDO

- P01 -

PROSPECTIVE RANDOMIZED STUDY COMPARING HEPATIC INTRA-ARTERIAL INJECTION OF YTTRIUM-90 RESIN-MICROSPHERES (HAI-Y90) WITH PROTRACTED IV 5FU (5FU CI) VERSUS 5FU CI ALONE FOR PATIENTS WITH LIVER-LIMITED METASTATIC COLORECTAL CANCER (LMCRC) REFRACTORY TO STANDARD CHEMOTHERAPY (CT). A. Hendlisz (1), M. Van den Eynde (2), M. Peeters (3), L. Defreyne (3), G. Maleux (4), J. Vannoote (5), P. Delatte (1), M. Paesmans (1), J.L. Van Laethem (6), P. Flamen (1). (1) Institut Jules Bordet, Brussels, Belgium, (2) UCL Saint-Luc, Brussels, Belgium, (3) UZ, Gent, Belgium, (4) UZ, Leuven, Belgium, (5) KU, Leuven, Belgium, (6) ULB Erasme, Brussels, Belgium.

Introduction : Chemo-refractory colorectal cancer metastatic to the liver only (LMCRC) has a poor prognosis. We hypothesized a significant improvement of the patient's outcome after HAI-Y90 radioembolization of hepatic metastases given along with 5FU CI over 5FU CI alone.

Aim : Primary endpoint was time to liver progression (TTLP). Secondary endpoints were time to progression (TTP), overall survival (OS) and safety.

Methods : This prospective, multicentric, randomized trial compared arm A : 5FU CI (300 mg/m² D1-14 q3weeks) with arm B : HAI-Y90 and 5FU CI (225 mg/m² D1-14 followed by 300 mg/m² D1-14 q3weeks) until disease progression. Eligibility criteria were : chemo-refractory (5FU, oxaliplatin, irinotecan) LMCRC, PSd2, normal direct bilirubin, and no lung shunting. Cross-over (HAI-Y90 monotherapy) was permitted in arm A after disease progression. Analysis was by intention to treat. To detect an increase in median TTLP from 6 to 18 weeks, 35 local progressions were needed (alpha 5%, power 90%). Distribution of time to events variables was modelled through Cox regression (likelihood ratio tests).

Results : Trial randomized 46 patients (pts) of whom 44 were eligible for analysis (23 in arm A and 21 in arm B). Pts' characteristics in the 2 arms were well balanced. Local progression was documented in 41 pts. Median length of follow-up was 108 weeks. Median TTLP were respectively 9 and 24 weeks in arm A and B (Hazard Ratio 0.38 (95% CI : 0.20-0.72, p = 0.003)). Median TTP were respectively 9 and 20 weeks in arm A and B (Hazard Ratio 0.51 (95% CI : 0.28-0.94, p = 0.03)) and Overall Survival were 32 and 43 weeks in arms A and B (Hazard ratio 0.92 (95% CI : 0.47-1.78, p = 0.80)). Treatment was well tolerated with few side effects reported, essentially grade 3 asthenia (5 pts ; 22%) in arm A. Most pts (25/44) received further treatment after local progression, including 10 pts with cross-over to HAI-Y90 in arm A, which may explain apparent lack of difference in overall survival.

Conclusion : HAI-Y90 with CI 5FU significantly improves TTLP and TTP over CI 5FU alone and is a valid salvage therapeutic option for chemo-refractory LMCRC.

- P02 -

EUS PREDICTS LOCAL RESECTION FOR RECTAL CANCER. E. Csmeli (1), K. Geboes (1), P.J. De Munck (1), B. Claerhout (1), W. Ceelen (1), P. Pattyn (1), D. De Looze (1), M. Peeters (2), M. De Vos (1). (1) UZ, Gent, Belgium, (2) UZ, Antwerpen, Belgium.

Introduction : Pre-malignant (T0) and early T1 rectal tumours are treated by local excision techniques. In this study we tried to assess the accuracy of endoscopic ultrasound (EUS) in selecting patients with rectal neoplasia suitable for local resection

Methods : Patients with rectal tumours deemed suitable for local resection by the gastroenterologist were staged using endoscopic ultrasound (EUS). With a radial 10 MHz instrument (Olympus GF-UM160) the depth of invasion in the rectal wall was evaluated. The pre-operative stage predicted by EUS (uT stage) was compared to the definitive histopathology (pT stage)

Results : In 65 consecutive patients 66 rectal lesions were evaluated between march 2005 and july 2009. 4 Patients were excluded from the analysis because they had received neo-adjuvant chemo-radiation therapy (2), incomplete staging (1) or the absence of definitive histopathology (1). In 53 patients histopathology confirmed early rectal disease : pT0 disease in 43 patients and pT1 disease in 10 patients. 9 lesions (in 8 patients) showed a higher T-stage : pT2 (5) and pT3 (4). Endoscopic ultrasound predicted early rectal disease correctly in 49 of the 62 lesions. 4 patients were overstaged by EUS : 1 patient with a very large villous adenoma and 3 patients with a recent endoscopic manipulation. The table below depicts the results for early disease in more detail.

EUS	Sensitivity	Specificity	PPV	NPV	Accuracy
pT 0/1	92,4%	100%	100%	69,2%	93,5%