therapies. Current strategies include imaging techniques and serum markers such as alpha-fetoprotein (AFP). Recently, we discribed the value of GOLPH2, a Golgi-phosphoprotein associated with development and progression of HCC (1).
Using tissue microarrays and immunohistochemistry we semiquantitatively analysed GOLPH2 protein expression in patients with HCC (n = 170), benign liver tumours (n = 22) BDC (n = 114) and normal liver tissue (n = 105). The newly designed sandwich ELISA was used to analyse GOLPH2 levels in the sera of patients with HCC (n = 18), HCV (n = 10), BDC (n = 5) and healthy control persons (n = 12).
GOLPH2 protein is highly expressed in HCC. Significant serum GOLPH2 levels are detectable and quantifiable in the sera of patients by our novel ELISA. In Hepatitis C genotype 1b, serial ELISA measurements in the course of the disease appear to be a promising complementary serum marker in the surveillance of HCC. Meanwhile by expanding our analysis we and others find AFP and sGOLPH2 to be at least equally discriminative in detecting early HCCs and conclude that the complementary use of both markers improves the detection and surveillance of HCCs.

6656 POSTER

Evaluation of sE-Selectin and circulating Vascular Endothelial Growth Factor (VEGF) in patients with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma treated with cetuximab in combination with cisplatin and docetaxel (Italian phase II DOCETUX Study)

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Background: The Vascular Endothelial growth factor (VEGF) and the adhesion molecule E-selectin expressed on activated endothelial cells are reported to play an important role in tumour angiogenesis. The aim of this study was to evaluate the predictive significance of sE-Selectin and circulating VEGF modifications in advanced gastric or GEJ cancer pts treated with cetuximab in combination with cisplatin and docetaxel as first-line therapy (DOCETUX STUDY).
Materials and Methods: Pts received cetuximab 400 mg/m^2 *iv* followed by 250 mg/m^2 *iv* weekly, cisplatin 75 mg/m^2 *iv* and docetaxel 75 mg/m^2 *iv* d1 every 3 weeks, for a maximum of 6 cycles; cetuximab alone was continued in pts with CR/PR/SD. Anti-tumor activity was assessed by CT-scan every 6 weeks. sE-Selectin and VEGF serum and plasma levels were determined on day 1 (baseline) and on days 4, 8, 22, 43 during treatment. Biomarkers levels were assessed using commercial quantitative sandwich enzyme immunoassays (Quantikine Human VEGF Immunoassay, R&D Systems; Human sE-selectin ELISA, Bender MedSystems) according to the manufacturer's instructions.
Results: Forty-five out of 72 pts (72.6%) enrolled in the DOCETUX Study were evaluated. Pt characteristics were: 33 (73.3%) males, 12 (26.7%) females; primary site: 37 (82.2%) stomach, 8 GEJ (17.8%). Forty-two (93.3%) pts were evaluable for response. The objective responses (RECIST) were: 1 complete response, 16 partial response, 16 stable disease (33 pts with disease control) and 9 disease progression. The median time to progression (TTP) was 4 months. The median basal values of biomarkers were: serum sE-selectin = 30.2 ng/ml; serum VEGF = 461.6 pg/ml; plasma VEGF = 64.3 pg/ml. On the day 22 after start of therapy pts who will have disease control presented higher levels of both biomarkers as compared with those who will present disease progression; mean increase of sE-Selectin +21.0% (p = 0.010), VEGF +44.8% (p = 0.014). The biomarker increase was also significantly correlated with TTP $\geqslant$ 4 months: sE-selectin +16.3% (p = 0.041), and VEGF +50.4% (p = 0.003).
Conclusions: These data suggest that cetuximab in combination with cisplatin/docetaxel chemotherapy regimen may induce a modulation in sE-selectin and VEGF circulating levels. An increase in these biomarkers levels would seem to correlate with treatment activity.

Genitourinary malignancies − Prostate cancer

Oral presentations (Mon, 21 Sep, 11:00−13:00)
Genitourinary malignancies − Prostate cancer

7000 ORAL

A multi-institutional analysis comparing adjuvant and salvage postoperative radiation therapy for prostate cancer patients with undetectable PSA and high-risk features in the prostatectomy specimen

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Background: Two prospective RCT showed that adjuvant radiotherapy (ART) to the prostatic fossa after radical prostatectomy (RP) improves all clinical endpoints compared to an observational policy in patients with extracapsular extension (ECE), seminal vesicle invasion or positive surgical margins (SM). It is unclear whether early salvage radiotherapy (SRT) upon PSA relapse might offer the same ultimate benefit as ART in patients with negative SM. This study aims at comparing ART with early SRT after biochemical failure.
Materials and Methods: Using a multi-institutional database, 233 patients receiving ART or early SRT were identified. None of them received hormonal therapy (neo)adjuvantly and all had an undetectable PSA after RP. In total, 93 patients had early SRT and 140 ART (see table for patient characteristics). The patient group was tested for heterogeneity of patient age and tumour parameters (preoperative PSA, Gleason score, T-stage, ECE, SM, capsular, lymphatic and vascular invasion) and then divided into four homogeneous subgroups based on the status (+/−) of lymphatic invasion (LI) and SM to permit a comparison of ART and SRT. There existed marked heterogeneities in one patient group (SM−/LI−) in favour of SRT (lower T-stages, less ECE and less capsular invasion). bDFS was calculated from the date of surgery and from the end of RT for every subgroup.

	ART (n = 140)	Early SRT (n = 93)
Median PSA preRP (ng/mL)	9.7	8.7
SM +	89 (63.6%)	40 (43.0%)
ECE +	99 (70.7%)	58 (62.4%)
Gleason score > 7	10 (7.1%)	13 (14%)
pT		
pT2	37 (26.4%)	32 (34.4%)
pT3a	90 (64.3%)	49 (52.7%)
pT3b	13 (9.3%)	11 (11.8%)
pT4	0 (0%)	1 (1.1%)
Median PSA preRT (ng/mL)	0	0.3
Median FUP (months)		
From RP	105	122
From end of RT	101	79

Results: In one patient group (SM−/LI+), there were no significant predictors of bDFS, probably due to the small patient number in this group. In the three other patient groups, SRT was a significant predictor of a decreased bDFS from the date of surgery and from the end of RT on Cox regression analysis. This was most striking in the SM−/LI− cohort, despite the more favourable prognostic factors in the SRT group. The only other significant predictor in multivariate analysis was Gleason score >7 (in SM−/LI− and SM+/LI− group).
Conclusions: Immediate ART for prostate cancer with high risk features in the prostatectomy specimen significantly reduces the risk of long-term biochemical progression after RP compared with SRT. Gleason score > 7 was the only other factor on multivariate analysis associated with decreased bDFS.