

with the majority of patients having grade 1 or 2 toxicity. No treatment-related death was reported.

Conclusion: The SECOX regime demonstrates highly significant clinical activity and good tolerability in advanced HCC patients. Our data support a randomized trial comparing SECOX versus Sorafenib alone for treatment of advanced HCC.

48LBA LATE BREAKING ABSTRACT Algorithmic classifiers to diagnose bladder cancer

K. Williamson¹, F. Abogunrin¹, M. Stevenson², J. O'Sullivan¹, B. Duggan³, N. Anderson⁴, D. O'Rourke⁴, H. O'Kane³, M. Ruddock⁵, J. Lamont⁶.
¹Queen's University of Belfast, Centre for Cancer Research and Cell Biology, Belfast, United Kingdom; ²Queen's University of Belfast, Centre for Public Health, Belfast, United Kingdom; ³Belfast Health and Social Care Trust, Urology, Belfast, United Kingdom; ⁴Belfast Health and Social Care Trust, Pathology, Belfast, United Kingdom; ⁵Randox Laboratories Ltd, Molecular Biology, Crumlin, United Kingdom; ⁶Randox Laboratories Ltd, Research and Development, Crumlin, United Kingdom

Background: Algorithmic classifiers with high diagnostic accuracy have the potential to reduce expensive diagnostic and monitoring investigations in bladder cancer.

Methods and Patients: A case control trial sponsored by Randox Laboratories Ltd, Northern Ireland, recruited 161 patients aged between 19 and 84, with a history of haematuria who had undergone cystoscopy. Seventy-seven (55 males; 22 females) had negative urethroscopy and/or pathology and 84 (69 males; 15 females) had pathologically proven bladder cancer (\leq pT1G2, n=53; \geq pT1G3, n=31). Our objective was to establish proof of concept that multivariate diagnostic algorithms could achieve more accuracy to diagnose bladder cancer, than single biomarkers. Following consent, 10 ml of blood and \geq 100 ml of urine were collected. Urine analyses included nuclear matrix protein 22 (NMP22), cytology, protein creatinine and osmolality. Carcinoembryonic antigen (CEA) and free Prostate Specific Antigen (FPSA) and total PSA (TPSA) were assessed on serum. Detailed demographics, medical histories and investigation results were recorded.

Results: Bladder cancer patients smoked more and for longer and had significantly higher urinary protein levels than controls. Bladder Tumour Antigen (BTA), CEA, D-Dimer, Epidermal Growth factor (EGF), Fas, FPSA, interleukin (IL)-1 α , IL-2, IL-6, IL-8, Matrix Metalloproteinase-9 (MMP-9), MMP-9/Neutrophil-associated Gelatinase Lipocalin (NGAL) and Vascular Endothelial Growth factor (VEGF) levels were significantly higher in bladder cancer patients and C-Reactive protein (CRP) and EGF were significantly higher in controls (p<0.05; t-test). The sensitivities and specificities of individual markers ranged from 33 to 68% and 52 to 95%, respectively. NMP22 and cytology had sensitivities of 58% and 33% and specificities of 87% and 95%, respectively. Nine algorithmic classifiers created using logistic regression analyses, included CEA, D-Dimer, EGF, IL-2, monocyte chemoattractant protein-1 (MCP-1), Neuron Specific Enolase (NSE), NMP22, Thrombomodulin (TM), VEGF and von Willebrand factor together with smoking years and whether or not patients were taking anti-hypertensive medication. Sensitivities of these algorithms ranged from 73 to 88% and specificities from 72 to 81%.

Conclusions: These findings have established proof of concept of multivariate algorithmic classifiers for bladder cancer. This is the first time that anti-hypertensive medication has been associated with diagnosis of bladder cancer.

49LBA LATE BREAKING ABSTRACT Final results of a Phase II randomised study of cediranib (RECENTIN™) in patients with advanced renal cell carcinoma (RCC)

P. Mulders¹, R. Hawkins², P. Nathan³, I. de Jong⁴, S. Osanto⁵, E. Porfiri⁶, A. Protheroe⁷, B. Mookerjee⁸, L. Pike⁹, M.E. Gore¹⁰.

¹University Medical Center St Radboud, Department of Urology, Nijmegen, The Netherlands; ²Christie Hospital NHS Trust, Department of Medical Oncology, Manchester, United Kingdom; ³Mount Vernon Hospital, Northwood, Middlesex, United Kingdom; ⁴Groningen University Medical Center, Department of Urology, Groningen, The Netherlands; ⁵Leids Universitair Medisch Centrum, Department of Clinical Oncology, Leiden, The Netherlands; ⁶Institute for Cancer Studies, University of Birmingham, Birmingham, United Kingdom; ⁷Cancer Research UK Medical Oncology Unit, Churchill Hospital, Oxford, United Kingdom; ⁸AstraZeneca, Wilmington, Delaware, USA; ⁹AstraZeneca, Alderley Park, Macclesfield, United Kingdom; ¹⁰Royal Marsden Hospital, Department of Medicine, London, United Kingdom

Background: Cediranib is a highly potent VEGF signalling inhibitor of all three VEGFRs suitable for once-daily oral dosing. This Phase II,

randomised, double-blind, parallel-group study (study code 2171IL030) compared the efficacy of cediranib with placebo (P) in patients with metastatic or recurrent RCC.

Materials and Methods: Patients were randomised 3:1 to cediranib 45 mg/day or P. The primary objective was to determine the efficacy of cediranib by comparing changes in tumour size after 12 weeks of therapy. Secondary objectives included assessments of response rate and duration (RECIST), progression-free survival (PFS), and safety/tolerability. After 12 weeks (or upon progression if earlier), treatment was unblinded and patients on P were given the option of receiving cediranib.

Results: Seventy-one patients were randomised (cediranib, 53; P, 18). After 12 weeks, there was a highly significant difference in mean % change from baseline in tumour size between cediranib (-20%) and P (+19%; P<0.0001); 14/18 P patients went on to receive cediranib. At data cut-off, the mean best change in tumour size was -31% for cediranib; 10/14 P patients who later received cediranib had a subsequent reduction in tumour size. In the cediranib arm, 18 patients (34%) achieved a partial response (PR); 12/18 still had a PR at data cut-off, 9 for \geq 1 year), and 25 patients (47%) experienced stable disease (disease control rate, 81%). The cediranib arm showed a significant prolongation in PFS vs the P arm, which included P patients who later received cediranib (hazard ratio [HR] = 0.45 [90% CI 0.26, 0.78]; P = 0.017); median PFS was 12.1 and 2.7 months for the cediranib and P arms, respectively. If all patients who received a different cancer therapy to their randomised treatment were censored at the time of switching therapy, the HR was 0.14 (90% CI 0.06, 0.30; P<0.001). The most common adverse events (AEs) with cediranib were diarrhoea (59; 88%), fatigue (44; 66%), dysphonia (42; 63%) and hypertension (41; 61%). The most frequent CTCAEs grade \geq 3 were fatigue (13; 19%), hypertension (13; 19%) and diarrhoea (9; 13%). A total of 58 patients (87%) receiving cediranib had a dose reduction or pause, with a median time to first reduction or pause of 29 days; the mean dose was ~30 mg/day.

Conclusions: In this study of patients with advanced RCC, cediranib monotherapy showed significant evidence of clinical benefit with an AE profile that was generally consistent with previous studies with cediranib 45 mg.

50LBA LATE BREAKING ABSTRACT Radical hysterectomy for small cervical cancer: role of robot assisted laparoscopy

L. Bresson¹, F. Narducci¹, E. Lambaudie², V. Samouelian¹, L. Boulanger¹, E. Leblanc¹. ¹Oscar Lambret Center, Surgery, Lille cedex, France; ²Paoli Calmettes Institute, Surgery, Marseille cedex, France

Objective: The aim of this study is to demonstrate the feasibility and the interest of robotic-assisted laparoscopic radical hysterectomy with pelvic lymphadenectomy in early cervical cancer – tumor size less than four centimeter – in comparison to a series of patients managed by conventional laparoscopy in our 2 institutions.

Study design: We compared our series of 14 first patients with prospective data collection operated on by experimented laparoscopic surgeons with the Da Vinci surgical system with 14 patients with previous or contemporary laparoscopic surgery. We studied surgical time, estimated blood loss, length of stay, lymph node yields, residual cervical tumor, parametrial invasion and complications.

Results: There was no statistically difference between the 2 groups in term of body mass index, age, FIGO stage and previous brachytherapy.

Compared with laparoscopic surgery, robotic surgery had a longer operative time (263 vs 200 minutes, p<0.005) and a shorter length of stay (3.7 vs 5.6 days, p<0.005).

There was a tendency to less post operative complications in the robotic group compared in the laparoscopic group (7.1 vs 57.1%, NS) with less urinary complications (0% vs 28.6%, NS). No difference was found in regards to estimated blood loss (57 vs 89 mL, NS) and parametrial invasion and lymph node yields (16.8 vs 19.9, NS).

Conclusion: Robotic-assisted laparoscopy is feasible in case of small cervical cancer. This new surgical approach is comparable to laparoscopy and is an other offer of minimally invasive surgery.