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Sequential Use of Targeted Therapies (TT) in Metastatic Renal Cell Cancer (mRCC): Overall Results of a Large Experience

E. Verzoni[1], R. Buzzoni[1], F. Agustoni[1], I. Testa[1], P. Biondani[1], M. Catanzaro[2], T. Torelli[2], G. Procopio[1]. [1]*Fondazione IRCCS Istituto Nazionale Tumori, Medical Oncology, Milan, Italy;* [2]*Fondazione IRCCS Istituto Nazionale Tumori, Urology Unit, Milan, Italy*

Background: Targeted therapies (TT) are recognized as the standard treatment for mRCC. The optimal sequence of the available drugs is still unclear.

Methods: Baseline characteristics and outcomes of 310 consecutive patients affected by mRCC receiving TT were collected from the database of Istituto Nazionale Tumori of Milan, Italy. The main characteristics of patients were: ECOG PS 0/1/2 168 (54%)/123 (40%)/19 (6%); sex M/F 229 (74%)/81 (26%); clear-cell histology 268 (86%); non clear-cell 42 (14%); previous nephrectomy 273 (88%); Fuhrman grade 1/2/3/4 15 (6%)/93 (34%)/118 (44%)/43 (16%). The Furhman grade was unspecified in 41 (13%) patients. Overall, 163 (53%) patients received only one TT while 113 (36%), 30 (10%) and 4 (1%) received 2, 3 and 4 TT, respectively. Altogether, 233 (75%) patients received sorafenib, 172 (55%) sunitinib, 32 (10%) a bevacizumab regimen and 20 (7%) other TT. The uni- and multivariate analyses for OS were carried out by means of Cox proportional hazard regression analysis.

Results: After a median follow-up of 37 months, 179 patients (57%) had died. The median overall survival (OS) was 22 months and the 5-year OS was 23.4% (95% CI: 16.7–30.0) without any statistical difference as regards the sequence used (Su/So vs So/Su) (HR 0.70; 95% CI: 0.40–1.23; p = 0.388 in the multivariate analysis). In patients receiving a bevacizumab regimen or m-Tor inhibitor as first line no differences in OS were reported in comparison with Su and/or So used sequentially (HR 0.85; 95% CI: 0.55–1.30; p = 0.675 in the multivariate analysis). These results were confirmed in the univariate analysis (Su/So vs So/Su) (HR 0.69; 95% CI: 0.41–1.16; p = 0.212 and bevacizumab or m-Tor inhibitors vs Su and/or So (HR 0.77; 95% CI: 0.51–1.17; p = 0.212).

Conclusions: These efficacy data suggest the absence of cross resistance between targeted therapies and support the emerging use of sequential antiangiogenic agents in mRCC. Overall no statistical difference in OS was reported using different sequences of TT.

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Prognostic Factors and Overall Survival in Metastatic Renal Cell Carcinoma (mRCC) Treated With Anti-angiogenic Therapies − Results of a Large Experience From a Single Institution

G. Procopio[1], E. Verzoni[1], R. Iacovelli[2], F. Mattana[1], V. Guadalupi[1], F. Gelsomino[1], S. Stagni[3], R. Salvioni[3], R. Buzzoni[1]. [1]*Fondazione IRCCS Istituto Nazionale Tumori, Medical Oncology, Milan, Italy;* [2]*"Sapienza" University of Rome, Medical Oncology, Rome, Italy;* [3]*Fondazione IRCCS Istituto Nazionale Tumori, Urology Unit, Milan, Italy*

Background: While the most important prognostic factors for mRCC have been evaluated in the cytokine era, less evidences are available to validate the role of prognostic factors when using targeted therapies (TT). This study was performed to assess the role of prognostic factors in mRCC treated with TT.

Methods: Baseline characteristics and outcomes of 310 patients affected by mRCC receiving TT were collected from the database of Istituto Nazionale Tumori of Milan, Italy.

According to Motzer criteria 100 cases (32%) had low risk, 146 (47%) had intermediate risk and 64 (21%) had poor prognosis. One hundred sixty-three (53%) patients received only one TT, while 113 (36%), 30 (10%) and 4 (1%) received 2, 3 and 4 TT, respectively. The uni- and multi-variate analyses were undertaken by means of Cox proportional hazard regression analysis.

Results: After a median follow-up of 37 months, 179 patients (57%) had died. The median overall survival (OS) was 22 months and the 5-year OS was 23.4% (95% CI: 16.7–30.0). The Motzer criteria were validated as prognostic factors in the uni- and multi-variate analysis (p < 0.001).

The median and 5-year OS was 43 months and 42.8% in low risk patients, 21 months and 15.9% in the intermediate risk, and 8 months in poor risk. In the univariate analysis nephrectomy, ECOG PS, number of sites of disease and Fuhrman grade were independent predictive factors of outcome (p < 0.001) (Table 1).

Conclusions: The Motzer criteria were validated in patients with mRCC receiving TT.

ECOG PS, nephrectomy, Fuhrman grade and number of sites of disease were independent prognostic factors of outcome. The overall survival in this consecutive patient population with mRCC was better in comparison with the historical control receiving cytokines.

Univariate Overall Survival Analysis

	HR (95% IC)	p-value
Age 10-year increasing	0.98 (0.86; 1.11)	0.735
Sex M *vs* F	1.09 (0.77; 1.55)	0.635
ECOG 1 *vs* 0	1.69 (1.25; 2.29)	**<0.001**
2 *vs* 0	2.62 (1.39; 4.95)	
Cytokine Yes vs No	1.28 (0.95; 1.72)	0.101
Histology Papillary *vs* clear cell	1.39 (0.85; 2.27)	0.247
Others *vs* clear cell	1.47 (0.75; 2.89)	
Nephrectomy Yes *vs* No	0.41 (0.26; 0.65)	**<0.001**
Motzer Intermediate *vs* Low risk	2.30 (1.57; 3.35)	**<0.001**
High *vs* Low risk	7.90 (5.07; 12.31)	

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PREDICT (Patient Characteristics in REnal Cell Carcinoma and Daily PractICe Treatment With Sorafenib) Non-interventional Study − Final Report

D. Jäger[1], J. Ma[2], E. Korbenfeld[3], M. Zemanova[4], N. Leonhartsberger[5], K. Stauch[6], A. Boeckenhoff[7], J. Yu[8], J. Mardiak[9], B. Escudier[10]. [1]*Universitätsklinikum Heidelberg, Medizinische Onkologie, Heidelberg, Germany;* [2]*Peking Union Medical College, Department of Urology, Beijing, China;* [3]*Hospital Británico de Buenos Aires, Oncology, Buenos Aires, Argentina;* [4]*Charles University, First Faculty of Medicine, Prague, Czech Republic;* [5]*Medical University Innsbruck, Department of Urology, Innsbruck, Austria;* [6]*Bayer Healthcare, Global Operations & Coordination, Leverkusen, Germany;* [7]*Bayer Healthcare, Global Integrated Analysis, Wuppertal, Germany;* [8]*Bayer Healthcare, Global Medical Affairs, Montville NJ, USA;* [9]*Narodny Onkologicky Ustav, Interne Oddelenie D, Bratislava, Slovak Republic;* [10]*Institut Gustave Roussy, Department of Immunotherapy, Villejuif, France*

Background: To gain insights into the treatment of advanced renal cell carcinoma (RCC) patients with sorafenib (Nexavar®) under standard practice settings, we enrolled patients in a large prospective, open-label, non-interventional, non-controlled study (NCT00895674) and monitored safety and patient outcomes.

Methods: Investigators from 592 sites in 18 countries in Europe, Asia/Pacific and Latin America participated in this study. Patient characteristics and tumour status were assessed at baseline and during routine follow-up therapy for up to 12 months.

Results: A total of 2855 patients were enrolled; 2599 patients evaluable for safety and 2311 for efficacy. Based on the efficacy population, 71% were male, 84% had prior nephrectomy, and 83% were clear cell histology. Patient subsets represented to a larger degree than in previous sorafenib RCC studies, included Asian patients (40%) and patients with ECOG performance status (PS) $\geqslant$ 2 (29%). Sizeable numbers of patients were $\geqslant$70 years old (23%), had pre-existing hypertension (29%) or diabetes (10%), had not received prior systemic anticancer therapy (37%), or had brain metastases (5%). The median sorafenib treatment duration was 7.3 months (222 days, range 2–1480), with 25% of patients treated 12 months or longer. Treatment duration was lower in several subsets of patients, including non-nephrectomized (6.3 months), 2 or more metastatic sites (6.2 months), $\geqslant$70 years (6.1 months), non-clear cell histology (4.8 months) or ECOG PS3 (4.6 momonths). Interestingly, 60−78% of patients with ECOG PS 1−4 had either an improvement or no change in PS during treatment. Treatment was well tolerated, with 91% of patients receiving full dose (400 mg bid) and of these 83% without dose reduction. The most common drug-related adverse events (AEs) were hand-foot skin reaction (20%), diarrhea (17%), rash (9%), alopecia (6%), hypertension (4%) and fatigue (3%). Serious drug-related AEs were documented in <5% of patients.

Conclusions: Patients enrolled into the PREDICT study were quite diverse and included subsets of patients (e.g. brain metastases) previously excluded from registration trials. Nonetheless, the large majority of patients received full dose sorafenib over the full study period, with a quarter of patients treated for 12 months or longer. These results support the widespread safety and tolerability of sorafenib in the treatment of advanced RCC regardless of baseline clinical characteristics and/or prior cancer treatment.