Professor Shukui Qin: patient reported outcomes in study of axitinib or sorafenib in Asian patients with metastatic renal cell carcinoma

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Prof. Shukui Qin is the deputy director of People's Liberation Army (PLA) 81 Hospital (Nanjing, China), director of Cancer Center of Chinese PLA, and director of National Drug Clinical Trial Agency of PLA 81 Hospital. He serves as the executive member of the *Asian Clinical Oncology Society* (*ACOS*), chair of *Chinese Society of Clinical Oncology* (*CSCO*), council member of PLA Medical Science Commission (and the executive member of its oncology society), member of the Oncology Branch of Chinese Medical Association.

After decades of clinical practice and scientific research, Prof. Qin has accumulated rich experiences in the medical treatment of gastrointestinal cancers and their bone metastases. Prof. Qin has published over 400 articles in peer-reviewed journals and 44 scientific books. He has been granted numbers of professional awards at the ministerial and provincial levels (including four first-class prizes, two second-class prizes, seven third-class prizes, and two fourth-class prizes). Currently he is the editor-in-chief of two highly rated journals (*Journal of Clinical Oncology* and *Clinical Oncology Tribune*) in China (*Figure 1*).

The 16th Annual Meeting of *Chinese Society of Clinical Oncology* (*CSCO*) was held at Xiamen International Conference Center from Sep. 25 to 29, 2013. Prof. Shukui Qin shared his professional patient reported outcomes in study of axitinib or sorafenib in Asian Patients with metastatic renal cell carcinoma (mRCC) with us.

Figure 1 Professor Shukui Qin, MD, PhD.

CCO: Could you please introduce the main results of the phase III AXIS trial and patients-reported outcomes in axitinib study?

Prof. Qin: This randomized controlled phase III clinical research comparing axitinib *vs.* sorafenib as second-line treatment for mRCC (AXIS trial) has shown that the progression-free survival (PFS) superiority of axitinib over sorafenib mainly existed in patients who had failed to respond to prior cytokine therapy (12.1 months with axitinib *vs.* 6.5 months with sorafenib). The PFS in patients who had failed to respond to prior sunitinib was 4.8 months with axitinib *vs.* 3.4 months with sorafenib. Data from the Asian group have demonstrated the PFS on axitinib arm were consistent with data from global arm.

Axitinib is a potent and selective inhibitor of vascular endothelial growth factor (VEGF) receptor tyrosine kinases 1, 2, and 3. Many nations have approved axitinib for use in patients with advanced RCC that had failed to respond to a prior systemic treatment, based on the results of the phase III AXIS trial (comparing axitinib and sorafenib as the second-line treatment).

An old Chinese saying goes, "He who drank it knows whether the water was cold or warm." We can evaluate the efficacy of a drug with objective indicators such as the tumor size and degree of disease progression, while patients have their own standard to evaluate the effect of tumor treatment. So we have been paying close attention to PROS in recent years (Patients' self-evaluation of tumor diagnosis). This is where the significance of my report on outcomes of patients with axitinib treatment.

This is a clinical trial registered in China. Patients

with mRCC which showed resistence to treatment with a cytokine-based regimen or a single treatment with sunitinib were recruited. Investigators randomly assigned (2:1) patients (n=204) to receive axitinib (n=135) 5 mg BID or sorafenib (n=69) 400 mg BID, based on their ECOG PS and prior received treatment. The primary endpoint was PFS with axitinib or sorafenib as second-line treatment assessed by an independent review committee and patient-reported outcomes were secondary endpoints.

Through evaluating the time-to-deterioration (TTD) composite endpoints (time to death, tumor progression, or meaningful worsening in quality of life), we can put patients reported outcomes with clinical outcomes together and our clinical scheme can strive for more time for patients' survival.

CCO: Do you have any special findings in this Asian patients based trial? What are the differences and similarities between Asian patients arm and global patients arm?

Prof. Qin: The study population is mainly composed of Chinese patients as well as a few of Indian and southeast Asian patients. Although it is an Asia-Pacific trial, it was designed for registering in China. The evaluation indexes include the Functional Assessment of Cancer Therapy (FACT), the Functional Assessment of Cancer Therapy-Kidney Sympton Index-15 (FKSI-15), the FKSI-Disease-Related Symptons (FKS-DRS) and so on.

We evaluated the PFS of Asian participators and the result showed patients who were treated with axitinib had a PFS of 4.7 *vs.* 2.8 months with sorafenib (P=0.04). The data had statistical significance and were consistent with global arm.

In terms of completion rates for FKSI-15 and FKS-DRS, completion rates in both arms were high (>97%) at baseline. In the following duration, >90% patients in both arms completed all programs of FKSI-15 and FKS-DRS.

We finally came to the conclusion that in Asian patients (especially Chinese patients) with mRCC, PROs are similar and remained relatively high while on treatment with axitinib or sorafenib as second-line treatment, but they worsened at EOT. Since median PFS was numerically longer with axitinib compared with sorafenib, time to symptom worsening at progression may have been delayed longer with axitinib. Similarly, median TTD was numerically longer with axitinib compared with sorafenib, reflecting that longer PFS was not offset by worsening symptom or toxicity. These results were similar to findings in the global phase III AXIS trial.

CCO: What are the problems which still remain in the targeted therapy of advanced kidney cancer?

Prof. Qin: As more targeted drugs reached clinical trials and approved by many national drug administrations, doctors have more options in the treatment. But the targeted therapy of advanced kidney cancer is still facing many challenges.

At present the complete response rate of targeted drugs is low (only 1-3%) in the treatment of advanced kidney cancer, so we has yet to find safer and more efficient targeted therapy mode; secondly, advanced kidney cancer scheme is given priority to with monotherapy, so we should explore the safety and efficacy of combination therapy; thirdly, attention must be paid to the targeted drug resistance and molecular markers used to guide individualized treatment in kidney cancer which are difficult problems to be broken through; finally, targeted drugs such as sorafenib, sunitinib, everolimus do not be accepted into the Chinese medical insurance. It leads to higher medical expenditure, which brings a lot of barriers to treatment options.

CCO: Thank you very much!

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