The Study of the Treatment Efficacy in Prostate Cancer with Low Dose Abiraterone

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Background: Abiraterone acetate (AA) has been approved for treatment metastatic castration-resistant prostate cancer (CRPC) in the standard dose that prescribed with 1,000 mg plus prednisolone 5 mg twice daily, and recommended to administer under fasting condition. Previous observational data in Ramathibodi hospital showed patients who had treated with standard dose of AA ; had PSA response 60% that results in the same direction as pivotal studies. Previous phase 2 studies showed using low dose AA of 250 mg with food had the non-inferior results in CRPC patients. AA was not be reimbursed in Thailand and costly treatment for majority of Thai patients, so the ability to use a highly effective drug at a quarter of the dose, could help in patient accessibility to cancer treatments. We sought to test the hypothesis that administration a low-dose AA with food would have the comparable activity in Thai CRPC patients in both of the pre-Docetaxel and post-Docetaxel groups, and exploring the quality of life (QOL) of these patients.

Methods: An observational cohort enrolled newly diagnosed metastasis CRPC at Ramathibodi hospital from 1st January 2019 to 31st December 2019. Patients were assigned to AA (250 mg) with actual daily life meal. We collected the data of serum PSA and the adverse events every 4 weeks for 4 months. The QOL data was collected with the EuroQoL (EQ-5D) questionnaire which was done at baseline and every 4 weeks. The primary end point was PSA response that defined as PSA decreased > 50% from PSA level at baseline. The secondary end points were the depth of PSA change, QOL and adverse events by using Fisher's exact test and T-test.

Results: 21 CRPC patients were enrolled. At 12 weeks, there were 10 patients (47.61%) achieved 50% PSA response and 6 Patients (28.57%) achieved 90% PSA response. The adverse events occurred 61.90%, and mostly were mild grade. The adverse events were comparable with the historical data in standard dose of AA. Low dose AA has shown the significant improvement in quality of life from baseline ($p<0.001$), and especially in pre-Docetaxel subgroup.

Conclusions: Low-dose AA with food has good efficacy in PSA response; improve QOL and acceptable adverse events. Moreover, low dose AA shows more efficacies especially in pre-Docetaxel mCRPC patients. Low dose AA may be helping in reducing cost of cancer care, enabling in delivering affordable cancer care and increasing value of treatment.