SAFETY OF CAPECITABINE IN TREATMENT OF PATIENTS WITH METASTATIC COLORECTAL CANCER – INTERIM ANALYSIS FROM “AXIOM” TRIAL

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Background: Capecitabine as oral prodrug of 5-FU has shown as more convenient therapy for patients in treatment of metastatic colorectal cancer (mCRC) with similar efficacy and better safety profile than IV 5-FU. In clinical practice, dosing of capecitabine can be modified in order to control frequency and severity of adverse events. This is interim analysis of clinical trial AXIOM, where we investigated safety profile of capecitabine in treatment of mCRC, both as a monotherapy or in combined regiments.

Methods: AXIOM is prospective, multicentric non-interventional clinical trial to follow-up patients receiving capecitabine in treatment of mCRC in real life clinical practice. The patients are followed-up until disease progression. Frequency and severity of adverse events was monitored and recorded on every patient’s visit to the hospital, approximately every three weeks. Data presented in this analysis were collected until 31st of December 2012, and were analyzed by methods of descriptive statistics.

Results: This interim analysis was performed on 233 patients (age = 65.6 ± 10.18 years; male:female ratio = 1.4, baseline ECOG PS 0 (70%), 1 (68%) and 2 (0.9%) who were receiving capecitabine in first and further treatment lines in rates of 45.9% (107 patients) and 53.7% (125 patients), respectively. Data on therapy is missing for one patient. Capecitabine has been applied as monotherapy or in combined regimens (irinotecan, oxaliplatin, oxaliplatin + cetuximab, irinotecan + cetuximab and mitomycin C) in 47% and 43% of patients, respectively. For 23 patients (10%) there is no data available on treatment regimen. Initial capecitabine dose was average 2,735 ± 664.2 mg daily. Capecitabine therapy was well tolerated, the dose has not been modified in 182 patients (86.64%), 47.14% (99 patients) receiving capecitabine as monotherapy and in 39.5% (83 patients) receiving combined regiments. The most common reported adverse events were hand-foot syndrome 37.14% (78 patients), nausea 29.52% (62 patients), stomatitis 17.61% (37 patients), diarrhea 19.04% (40 patients), vomiting 11.42% (24 patients) and other 11.90% (25 patients). There were four serious adverse events reported: thrombophlebitis of right leg grade 3/4, deep vein thrombosis, death and gastrointestinal disorders grade 3/4. Capecitabine treatment was discontinued after average 5.38 ± 2.054 cycles. Average time spent on therapy was 4 months. The reasons for discontinuation were attributed to disease progression (76.19%), complete response (2.85%), serious adverse event (1.42%), patient’s decision (3.8%), loss of follow-up (7.61%), stable disease (2.38%), surgery (0.95%) and other reasons (0.47%).

Conclusion: This interim analysis from AXIOM trial data demonstrated favorable safety profile of capecitabine used as monotherapy and combined in chemotherapy regiments. Adverse events reported were in line with known safety profile of capecitabine and no new safety signals were observed.