ROLE OF LOW DOSE CAPECITABINE IN INOPERABLE CANCER GALLBLADDER IN PRESENCE OF JAUNDICE: A PILOT STUDY FROM ENDEMIC WORLD

Abhinav Sonkar1, Jitendra Kushwaha2, Manoj Kumar3, Abhijit Chandra2, Havi Gupta4, Devendra Singh5, Awanish Kumar6, Akshay Agarwal7
1King George’s Medical University, Lucknow, India, 2King George Medical University, Lucknow, India, 3King George Medical University, Lucknow, India, 4King George Medical University, Lucknow, India

Background: Gallbladder cancer (GBC) is an aggressive disease. At the time of presentation the resectability is limited to 25-30%. In western world internal drainage is routinely done for palliation of jaundice, but in our scenario most patients being poor, cannot bear the high cost of the procedure involving stents and repeated visits to hospitals for i.v. chemotherapy. This study has been done to see the effect of low dose capecitabine on overall survival in inoperable cases of GBC especially in presence of jaundice after external drainage.

Methods: Patients (n = 32) who reported in Surgery OPD from Jan 2011 to Feb 2012 with unresectable carcinoma gallbladder with jaundice were enrolled and planned for palliation and chemotherapy. All patients underwent external drainage for palliation of jaundice when ERCP stenting failed. The standard dose of capecitabine is 1250 mg/m2. Post drainage patients with bilirubin 1 to 5 mg/dl received low dose capecitabine 1000mg and between 5 to 10 mg/dl received 500mg PO twice a day on day 1 to 14 of a 3 weekly cycle for 6-8 cycles. To assess the tumor response to chemotherapy, CECT Abdomen or ultrasound abdomen as by defined by WHO criteria was done after 3rd and 6th cycle.

Results: Mean age of presentation was 47.83 ± 11.66 yrs. 21(65.6%) had bilirubin level > 10mg% while rest 11(34.4%) had bilirubin levels < 10mg%. The average pre-drainage bilirubin level was 16.8 mg/dl and post drainage was 7.5 mg/dl after one week. Due to palliative external drainage most of the patients had 20% decrease in their jaundice level within 2 weeks. After external drainage and capecitabine treatments, QOL life improved in most of the patients (95.8%). At the time of admission Karnofsky Performance scale ranged between 50% to 80% with median of 60%. After treatment of 6 week that is after external drainage and starting chemotherapy, scale ranged between 90% and 50% with median of 70%. Most common complication during chemotherapy was nausea and vomiting. 13(40.6%) had abdominal distension and 6(18.7%) developed joint pain/flu like symptoms. 4 (12.5%) patients developed diarrhea and 4 (12.5%) developed rashes, which were the least common complications in descending order. Only 2 patients were able to complete 6 cycles, 8 patients: 5 cycles, 9 patients: 4 cycles, 6 patients: 3 cycles, 5 patients: 2 cycles and 2 patients receiving only 1 cycle. 25 patients (>3cycles) assessed for tumor response showed 17/25(68%) progressive disease and 8/25(32%) stable disease. In 1-year follow up all the patients died, with maximum survival of 6 months and minimum survival of 1 month (median 3 months).

Conclusion: This study shows that low dose of capecitabine can be safely given in GBC in presence of jaundice without any significant toxicity. It also shows that in combination with external drainage procedure, it improves the quality of life. Though it remains to be established whether improved QOL was due to reduced levels of jaundice or chemotherapy regimen. This study sample is too small to comment on effect of capecitabine on overall survival of GBC with jaundice.