A prospective randomized study of oral metronomic chemotherapy versus best supportive care in metastatic/recurrent head and neck cancer

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Background

The angiogenesis is key factor in tumor growth and metastasis, angiogenesis has started to redefine chemotherapy and new protocols have emerged. Various studies proved that Oral metronomic chemotherapy may be safer and more effective in patients with metastatic, relapsed or inoperable HNSCC. We designed a study to compare the efficacy and safety of oral metronomic chemotherapy (MCT) versus best supportive care (BCS) in patients with metastatic/recurrent head and neck cancer.

Material and Methods

A total of 117 randomly selected patients with metastatic or relapsed HNSCC previously treated, were randomized to oral MC (60 patients; daily Celecoxib 200 mg BD and weekly Methotrexate 15 mg/m2) versus only symptomatic treatment (57 patients). Statistical comparison of both arms was performed by using Kaplan Meier method. All statistical calculations were performed using SPSS version 21.

Results

117 patients were enrolled (median age: 53 years, males 74.4%, ECOG performance status 1/2: 67.5% v/s 32.5%).Overall survival was significantly increased in MCT patients compared to BCS arm. Response rate was 18.3% in MCT arm. The median OS at one year in MCT arm was 297 days [95% CI; 265-329] versus median OS in BSC arm 198 days [95% CI; 170-226] p value <0.01. The patients in MCT arm have better control of symptom i.e pain. The patients in MCT arm have higher incidence of mucositis (3.5% vs. 6.6%), fatigue (7.0% vs. 13.3%).

Interpretation

Oral MCT have significantly superior OS than BCS in the palliative setting with cost effective management in metastatic/recurrent head and neck malignancy.

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Conflicts of Interest: Nil
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