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The Immunomodulating Effects of Biobran (Rice Bran Arabinoxylan Compound) on Hematologic Profile, Nutritional Status and Quality of Life among Head and Neck Carcinoma Patients Undergoing Radiation Therapy: A Double Blind Randomized Control Trial

Introduction:
Radiation treatment delays in the management of head and neck malignancies secondary to anemia and poor nutritional status had greatly affected local control and survival. Immunostimulants in the form of soluble fibers have been explored to reduce the complications of radiation and chemotherapy to allow patients to tolerate treatment better in the hope of improving treatment outcomes and quality of life. This study aims to determine the immunomodulating effects of Biobran (RBAC) as a supplement among head and neck cancer patients in addressing radiation treatment complications such as anemia, leukopenia, weight loss and improvement of quality of life.

Methodology:
A total of 65 patients were enrolled in a double blind randomized study either to placebo or the Biobran (RBAC). Patients were given 3 grams of either placebo or Biobran (RBAC) per day, starting two weeks before the start of treatment, during radiation/chemoradiotherapy, and for two months after radiotherapy or radio-chemotherapy.

Complete Blood Count (CBC), Body Mass Index (BMI), percent weight loss and EORTC Quality of Life questionnaires for Head and Neck Cancer Patients QLQ H&N35 were used to assess the degree of anemia, weight loss and evaluate quality of life. These parameters were obtained weekly starting 2 weeks prior to start of treatment, weekly during the course of radiotherapy/radio-chemotherapy and; at 1 month and 2 months after treatment completion.

Results:
65 patients were enrolled in the study from November 2016 to February 2018. The median age were 52 years old, and majority were male. Most of the patients'malignancies were nasopharyngeal type with squamous cell carcinoma histology that are undifferentiated. Most of the patients had locally advanced stage and were given concurrent chemoradiotherapy. Majority of the total radiation dose prescribed was 70 Gy.

Based on overall complete blood count results, there were higher counts on all hematologic parameters in Biobran (RBAC) arm. Pre-treatment (2 weeks) CBC values showed higher hemoglobin, hematocrit, red blood cell (RBC), neutrophilic, lymphocytic, eosinophilic and basophilic counts in Biobran (RBAC) arm compared to placebo. During radiotherapy/chemoradiotherapy, patients given Biobran (RBAC) have favorable results in all CBC parameters except in WBC and neutrophilic counts. While on post-treatment hematologic assessment (2 months), Biobran (RBAC) patients have better results in all parameters except in eosinophilic and basophilic counts. These outcomes resulted to more blood transfusions, significant treatment delays and increased hospital admissions (secondary to blood transfusion and infections) in placebo compared to Biobran (RBAC).

On the nutritional status, recorded weight and BMI on follow-ups showed higher overall BMI for Biobran/RBAC (22.69) compared to placebo (21.52) and a lower percent weight loss on Biobran/RBAC (6.10%) versus placebo (6.91%).

Treatment related toxicity RTOG grading showed lower severity scores on all parameters in Biobran (RBAC) compared to placebo. Quality of Life (QOL) scores using EORTC H&N35 are worst in placebo compared to Biobran/RBAC. Deaths during the course of treatment were significantly higher in placebo (11) compared with Biobran (RBAC) with no recorded treatment related mortality.

Conclusion:
Results from this study showed better clinical outcomes based on hematologic parameters, nutritional status, treatment-related toxicities and quality of life in Biobran (RBAC) compared to placebo. These have led to fewer blood transfusions, less treatment delays and hospital admissions, avoidance of treatment mortalities and morbidities and improved quality of life among head and neck cancer patients undergoing radiotherapy/chemoradiotherapy given with Biobran (RBAC).

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