

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



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## Background and Objective

Immunostimulants are currently being explored to reduce the complications of radiation/chemotherapy. This double blind randomized trial aims to determine the immunomodulating effects of Arabinoxylan Rice Bran (Biobran) among head and neck cancer patients in addressing radiation treatment complications such as anemia, leukopenia, weight loss and improvement of quality of life.

## Methods

65 patients were enrolled and given either Arabinoxylan Rice Bran (Biobran) or placebo, 2 weeks prior, during radiation/chemoradiotherapy, and 2 months after.

Complete Blood Count (CBC), Body Mass Index (BMI), percent weight loss and EORTC Quality of Life questionnaires QLQ H&N35 were used to assess the degree of anemia, weight loss and quality of life.

### Inclusion Criteria

1. Biopsy proven malignancy of the head and neck, stage I-IVB
2. Early and advance head and neck cancer patients treated with concurrent chemo-radiotherapy
3. Early stage head and neck cancer patients treated with radiation therapy alone

### Exclusion Criteria

1. Local recurrence
2. Metastatic disease during CT planning
3. Elevated hepatic and renal enzymes at the start of treatment.
4. Active cancer in another part of the body

Jose R. Reyes Memorial Medical Center Head and Neck Cancer patients

November 2016- February 2018 (N= 65)

Head & Neck Cancer Patients N= 65

R A N D O M I Z E D

3 grams of Biobran (RBAC) N= 32

Placebo N=33

<b>Hematologic Profile</b>	<b>Nutritional Status</b>	<b>Quality of Life(QOL) and Treatment Related Side Effects</b>
• Complete Blood Count	• Percent weight loss • Body Mass Index (BMI)	• EORTC Quality of Life Questionnaires for Head and Neck Cancer Patients QLQ H&N35 • RTOG grading system

Figure 1. Methodology

## Results and Discussion

Overall CBC results revealed higher values on all parameters in Biobran arm. Upon completion of radiochemotherapy, Biobran arm showed significantly higher mean hemoglobin by 1.30 g/dL ( $p=0.010$ ), hematocrit ( $p=0.001$ ), RBC ( $p=0.001$ ) and platelets ( $p=0.017$ ). Also, higher overall BMI (22.69 versus 21.52) and a lower percent weight loss (6.10% versus 6.91%) for Biobran compared to placebo were noted with a p-values of 0.199 and 0.571, respectively. Treatment related toxicity using the RTOG grading showed lower severity scores on all parameters (p-values:  $>0.05$ ) and better QoL scores for patients taking Biobran (p-value: 0.019).

DEMOGRAPHIC PROFILE	Placebo	Biobran (RBAC)
Median Age	49	54.5
<b>GENDER</b>		
Male	29	24
Female	4	8
<b>RT dose</b>		
70 Gy	29	27
66 Gy	3	1
60 Gy	1	4
<b>Histology</b>		
SCCA	31	31
Adenoid Cystic Carcinoma	1	1
Malignant Ameloblastoma	1	0
<b>Differentiation</b>		
Undifferentiated	12	6
Well differentiated	1	2
Moderately Differentiated	1	2
Poorly Differentiated	6	3

DEMOGRAPHIC PROFILE	Placebo	Biobran (RBAC)
<b>Anatomic Site</b>		
Nasopharyngeal	22	16
Laryngeal	5	6
Maxillary	3	2
Oropharyngeal	1	1
Salivary Gland	1	0
Oral Cavity	1	7
<b>CHEMO given</b>		
Yes	32	28
No	1	4
<b>Stage</b>		
I	0	0
II	5	5
III	8	7
IVA	15	16
IVB	5	4

Table 1. Demographic Profile

## Conclusions

Results from this study showed better clinical outcomes for patients taking Arabinoxylan Rice Bran (Biobran). These have led to fewer blood transfusions, treatment delays and hospital admissions, avoidance of treatment mortalities and morbidities and improved quality of life among head and neck cancer patients undergoing chemoradiotherapy.

Parameters	Group	Pre RT		RT		Post RT	
		Mean ± SD	p-value	Mean ± SD	p-value	Mean ± SD	p-value
Hb (g/dL)	Placebo	14.06 ± 1.72	0.854	12.55 ± 1.29	0.537	10.59 ± 1.53	0.010
	Biobran	14.14 ± 1.56		12.74 ± 1.21		11.89 ± 1.73	
Hct (%)	Placebo	0.42 ± 0.05	0.551	0.37 ± 0.04	0.446	0.31 ± 0.05	0.001
	Biobran	0.41 ± 0.05		0.38 ± 0.04		0.35 ± 0.05	
RBC (x 10 <sup>9</sup> /uL)	Placebo	4.86 ± 0.51	0.330	4.29 ± 0.43	0.196	3.47 ± 0.53	0.004
	Biobran	4.71 ± 0.66		4.46 ± 0.61		4.2 ± 0.93	
WBC (x 10 <sup>9</sup> /uL)	Placebo	9.57 ± 3.67	0.951	9.18 ± 5.25	0.124	6.15 ± 2.23	0.374
	Biobran	9.51 ± 4.3		7.56 ± 2.44		6.72 ± 2.19	
Platelets (x 10 <sup>9</sup> /uL)	Placebo	326.43 ± 90.58	0.404	271.37 ± 60.26	0.739	215.96 ± 78.11	0.017
	Biobran	305.01 ± 104.3		276.96 ± 71.79		271.43 ± 73.36	

Table 2. Hematologic Profile

	ALL	Placebo	Biobran	p-value
BMI (kg/m <sup>2</sup> )	22.10 ± 3.58	21.52 ± 3.62	22.69 ± 3.50	0.199
% Weight Loss	6.51 ± 5.63	6.91 ± 5.61	6.10 ± 5.72	0.571

Table 3. Body Mass Index and Percent Weight Loss

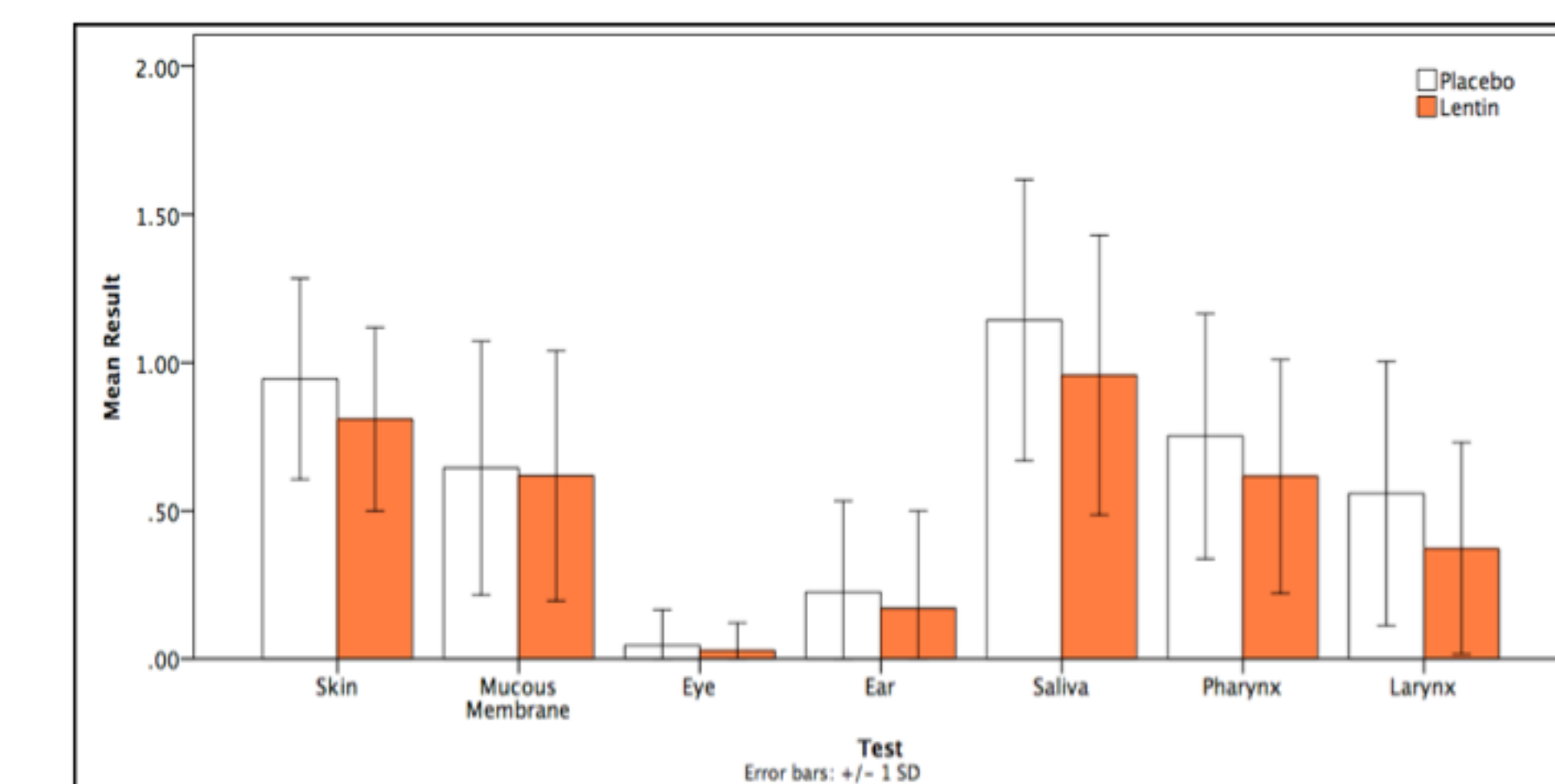


Figure 2. RTOG Grading of Severity of Treatment-Related Toxicities

Group	QOL Scores	p-value
Placebo	1.72 ± 0.33	0.019
Biobran	1.53 ± 0.24	

Table 3. Quality of Life Scores

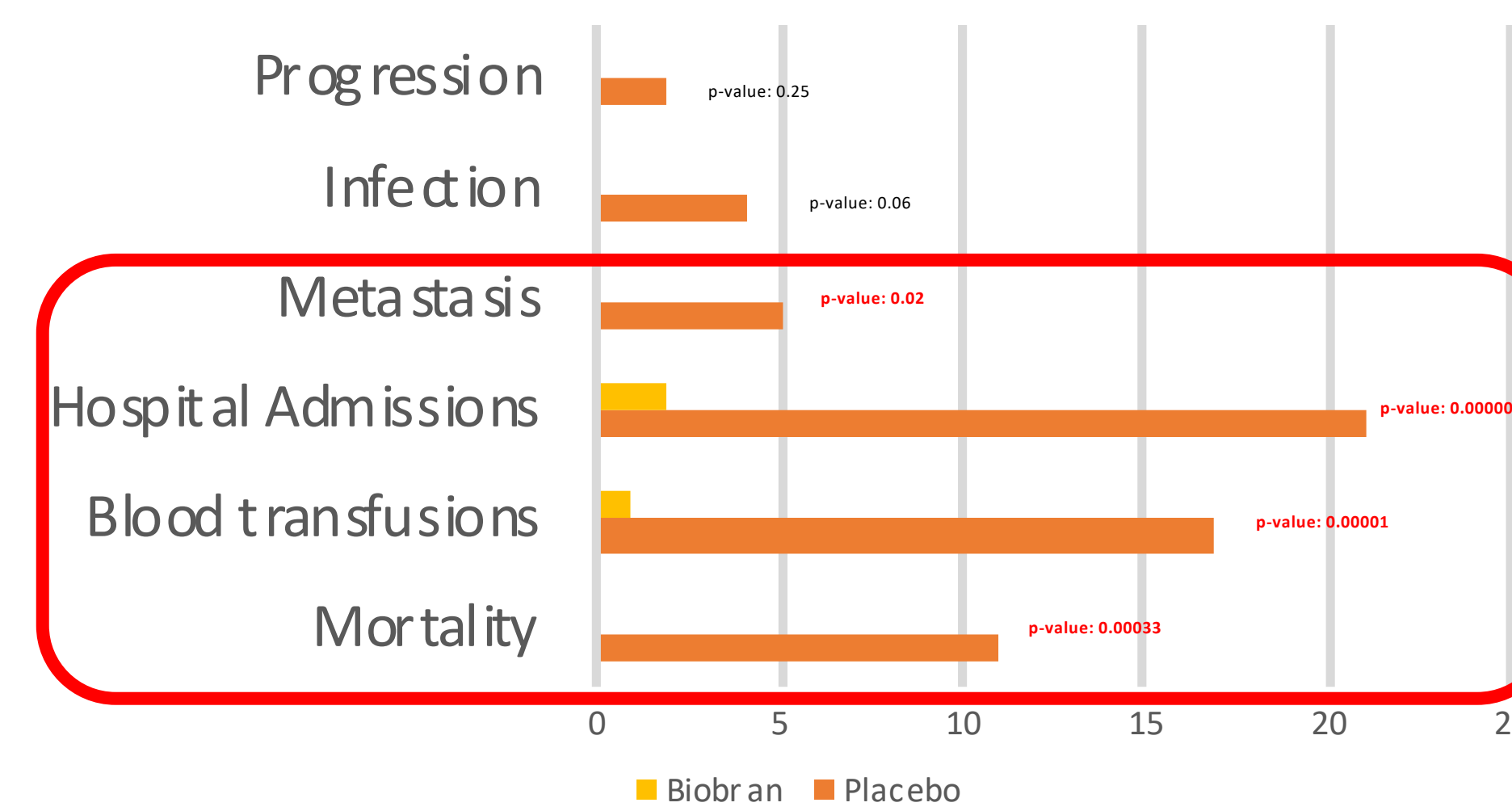


Figure 3. Clinical Outcomes

## References

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2. Masood AI, Sheikh R, Anwer RA. Effect of "Biobran MGN-3" in reducing side effects of chemotherapy in breast cancer patients. Professional Med J Feb 2013;20(1):013-016.