



Effectiveness of
Maharishi Amrit Kalash
an Ayurvedic Herbal Compound
in ameliorating the toxicity
of chemotherapy in Breast
Cancer Patients :
A Randomized Trial

Creating a Disease free Society

Effectiveness of Maharishi Amrit Kalash (MAK) an Ayurvedic Herbal Compound in ameliorating the toxicity of Chemotherapy in Breast Cancer Patients : A Randomized Trial

Authors : A. Srivastava, A. Samaiya, V. Taranikanti, P. Kachroo, O.H. Coshic, R. Parshad, V. Seenu, S. Chumber, & M. C. Misra.

Settings : Breast Cancer Clinic, Dept. of Surgery, A.I.I.M.S., New Delhi.

Published : Federation of American Societies for Experimental Biology Journal, Vol. 14, No. 4, p.A720, 2000.

Patients randomized in MAK Group : 60 (MAK + Chemotherapy)

Patients randomized in Control Group : 68 (only Chemotherapy)

RESULTS	
Appetite	Improved in all 6 Cycles
Karnofsky Performance Score	Significant Improvement
Vomiting	Significantly Reduced
General Health	Well Maintained in MAK Group
Body Weight	Improved in MAK Group

RESEARCH HIGHLIGHTS

MAK-4 & MAK-5 supplemented diets were effective in reducing chemotherapy toxicity in breast cancer patients receiving chemotherapy and effectively supported weight maintenance. **It was also found that MAK does not impede the anti-cancer effects of chemotherapy.**

Introduction

- Chemotherapy is associated with many distressing side effects like anorexia, stomatitis, weight loss, diarrhoea, leukopenia and alopecia.
- Chemotherapy is delayed due to major side effects resulting in poor response. Reduction of these side effects would result in better compliance and improved quality of life.
- Various drugs have been tried to prevent or control toxicity e.g. Amifostine, G-M CSF, but all of these drugs have either limited utility for one particular side effect and / or associated with their own toxicity.
- Maharishi Amrit Kalash (MAK-4 & MAK-5) are herbal formulations from Maharishi Ayurveda which have been shown to protect against chemotherapy related toxicity. They are a rich source of Antioxidants.

Aim

To investigate the effectiveness of Maharishi Amrit Kalash (MAK) in reducing the side effects of chemotherapy in patients with breast cancer.

Setting

Breast Cancer Clinic, Dept. of Surgery, A. I. I. M. S., New Delhi.

Study Design

Open Randomized trial with concealed randomization using sealed numbered envelopes.

Materials and Methods

We entered 129 patients with breast cancer after an informed consent. Sixty one patients received chemotherapy with MAK protection and 68 received chemotherapy alone. Patients were evaluated for 17 side effects namely, poor general well being, anorexia, weight loss, leukopenia, stomatitis, vomiting, diarrhoea, hematuria, cardiac toxicity, pulmonary toxicity, Karnofsky score, alopecia, cutaneous allergy, neurotoxicity, fever and constipation. MAK is given as MAK-4 paste, 1 teaspoonful B. D. with milk and MAK-5 tablets, 1 B. D. with water.

Toxicity Parameters Measured

T-Stage	0=TX, 1=T1, 2=T2, 3=T3, 4=T4A, 5=T4B, 6=T4C, 7=T4D
N-Stage	0=NX, 1=N0, 2=N1, 3=N2
M-Stage	0=MX, 1=M0, 2=M1
General well being	1=Normal, 2=Fair, 3=Poor
Appetite	1=Good, 2=Fair, 3=Poor
Karnofsky Scale	6=Able to care for most needs but requires occasional assistance.; 7=Able to care for self but unable to work or carry on other normal activity.; 8=Normal activity but requiring effort.; 9=Able to carry on normal activity but with minor signs or symptoms of Disease present.; 10=Normal, with no complaints or evidence of Disease
Stomatitis	0=None, 1=Soreness Erythema, 2=Ulcer, 3=Ulcer, Can take liquid diet, 4=Can't take orally

Nausea / Vomiting	0=None, 1=Nausea, 2=Transient Vomiting, 3=Requiring Therapy, 4=Intractable
Diarrhoea	0=None, 1=Transient<=2 days, 2=>2 days, 3=Intolerable, 4=Haemorrhagic and Dehydration
Constipation	0=None, 1=Mild, 2=Moderate, 3=Severe
Allergy	0=None, 1=Oedema, 2=Bronchospasm
Alopecia	0=None, 1=Minimal, 2=Partial, 3=Complete
Infection	0=None, 1=Minor, 2=Moderate 3=major, 4=With low BP
Fever	0=None, 1=<38, 2=38-40, 3=>40, 4=with low BP
Neurotoxicity	0=None, 1=Mild, 2=Moderate, 3=Severe
Cardiotoxicity	0=None, 1, 2, 3, 4=Symptomatic
Tumor Response	1=Complete, 2=Partial, 3=None, 0=Lost to follow-up
Pulmonary toxicity	0=None, 1=Mild, 2=External Dyspnoea, 3=Dyspnoea at rest
Giddiness	0=None, 1=Mild, 2=Moderate, 3=Severe

RESULTS

5 male, 124 female patients

Cyclophosphamide Adriamycin 5FU (CAF)

Cyclophosphamide Methotrexate 5 FU (CMF)

	CAF	CMF	TOTAL
MAK	33	28	61
Control	32	36	68
Total	65	64	129

AGE

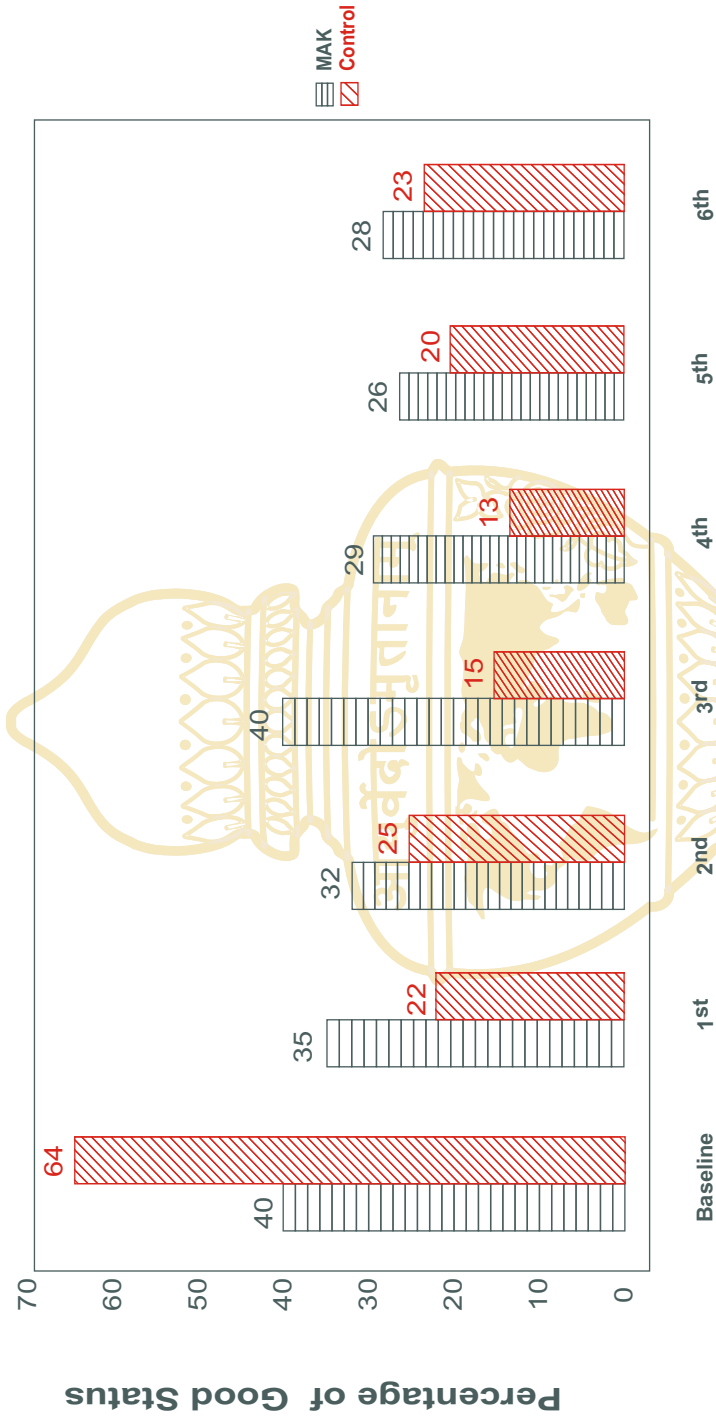
	Mean	SD
MAK	43.47	10.73
Control	45.88	9.84

BODY WEIGHT

	Mean	95%CI
Weight Gain in MAK	0.43Kg	-1.03,1.90
Weight Loss in Control	-1.12Kg	-2.18,-0.069

Paired t test: p = 0.55 (MAK) : p=0.03(Control)

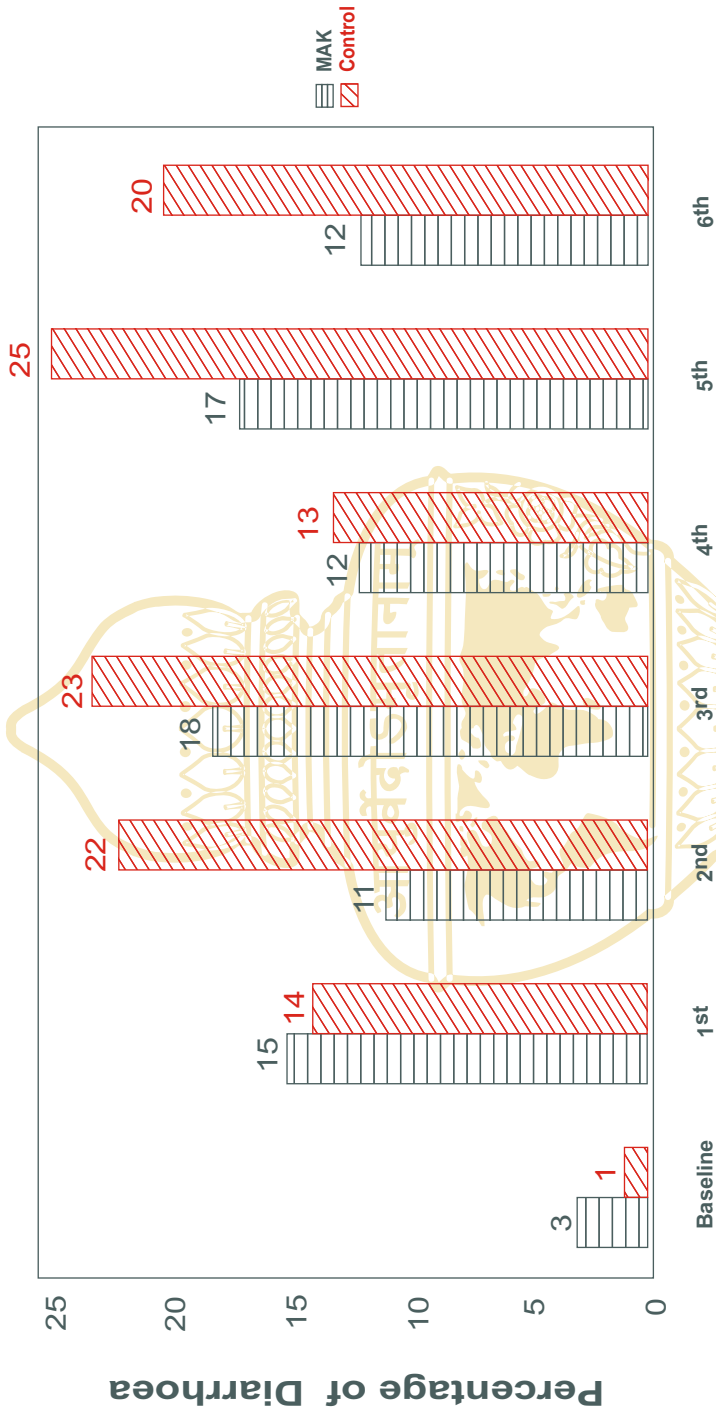
General Well Being



3rd Cycle
 Relative Risk =2.6
 Fishers Exact p=0.004
 Prevented Fraction=62%

Cycles of Chemotherapy

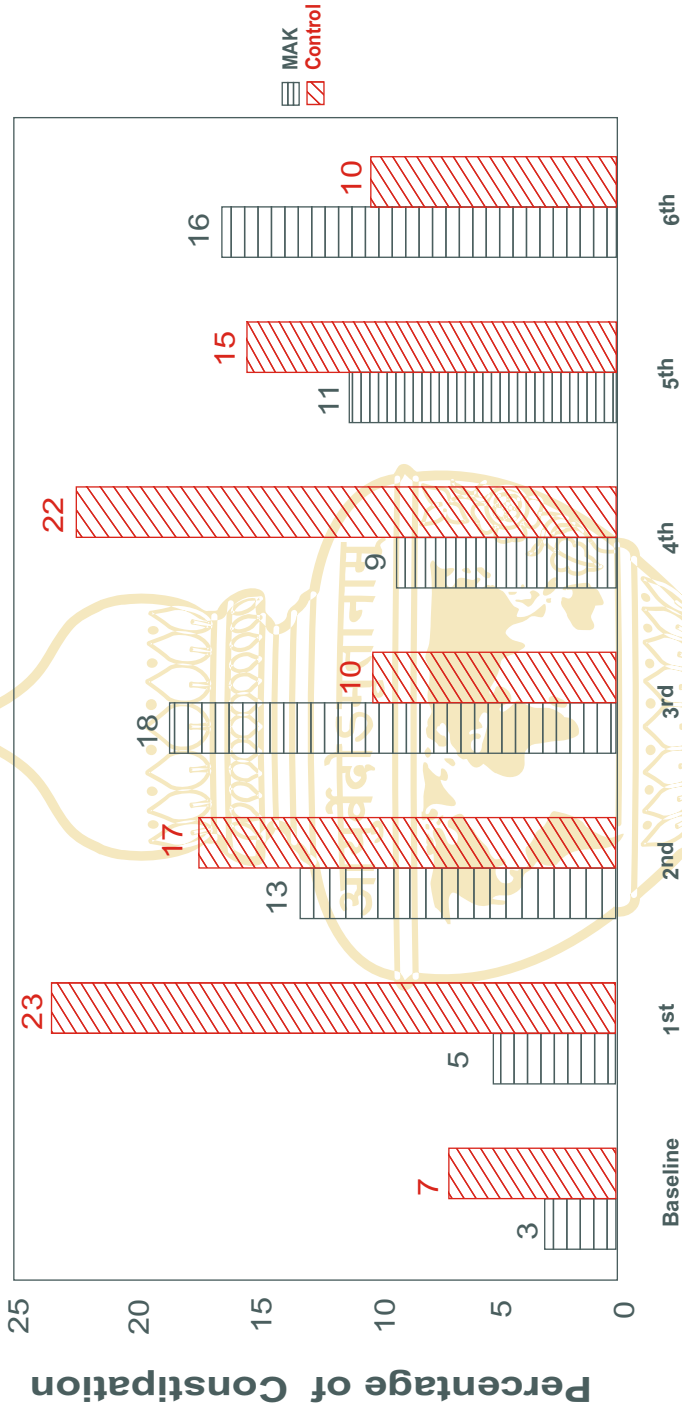
Diarrhoea



2nd Cycle
 Relative Risk =0.5
 Fishers Exact p=0.01
 Prevented Fraction=47%

Cycles of Chemotherapy

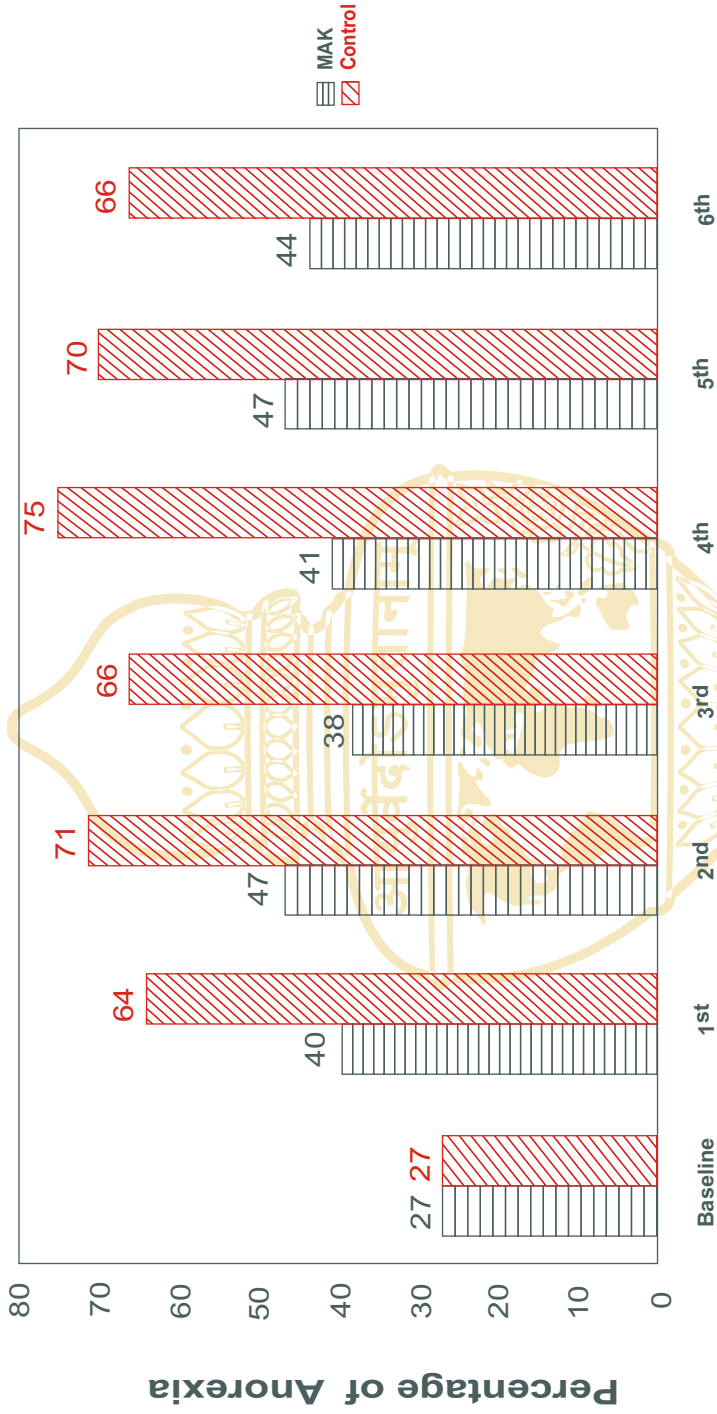
Constipation



1st Cycle
 Relative Risk =0.2
 Fishers Exact p=0.004
 Prevented Fraction=78%

Cycles of Chemotherapy

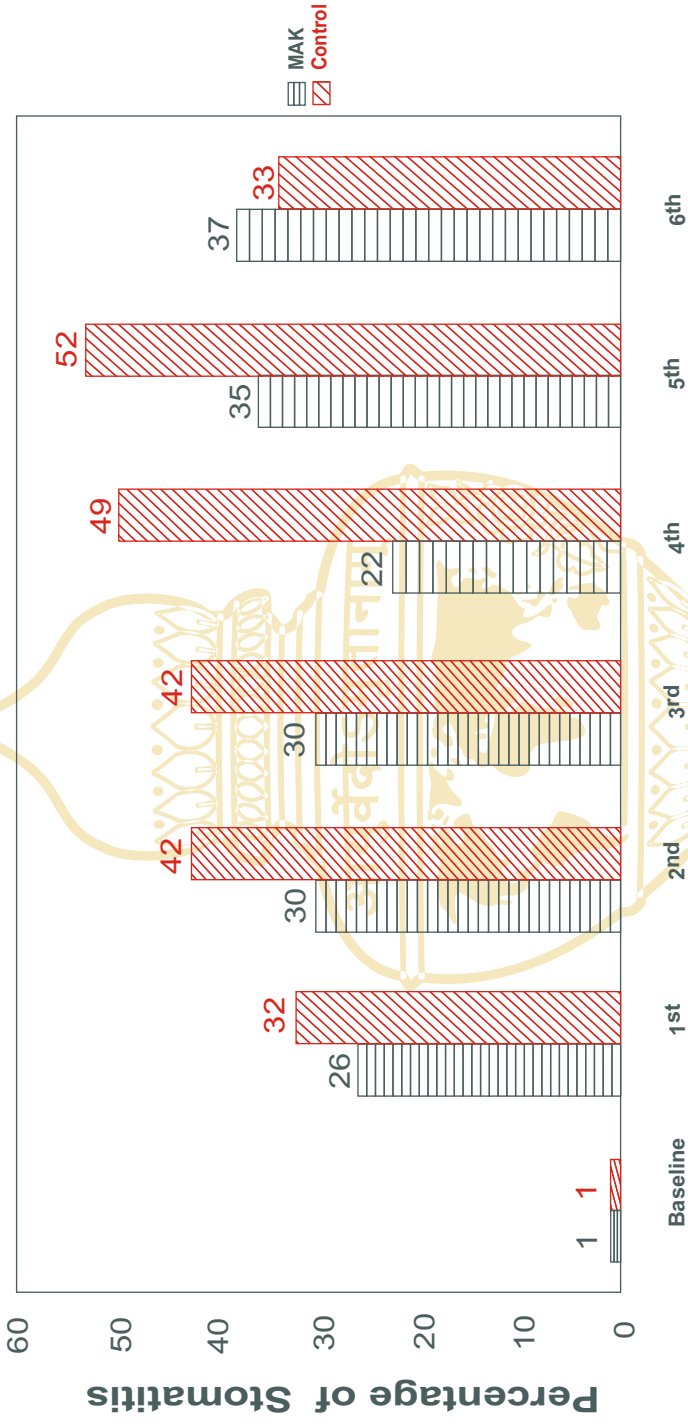
Anorexia



4th Cycle
Relative Risk =0.5
Fishers Exact p=0.001
Prevented Fraction=45%

Cycles of Chemotherapy

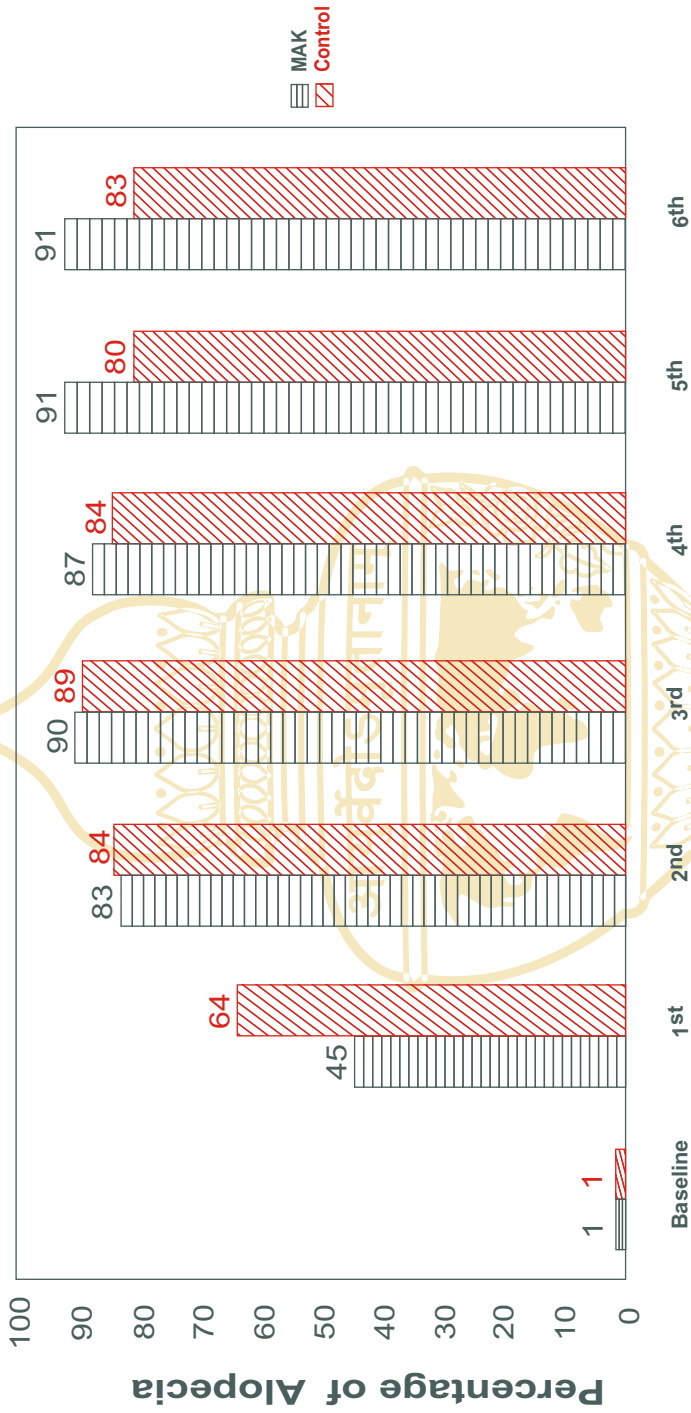
Stomatitis



4th Cycle
Relative Risk =0.4
Fishers Exact p=0.01
Prevented Fraction=55%

Cycles of Chemotherapy

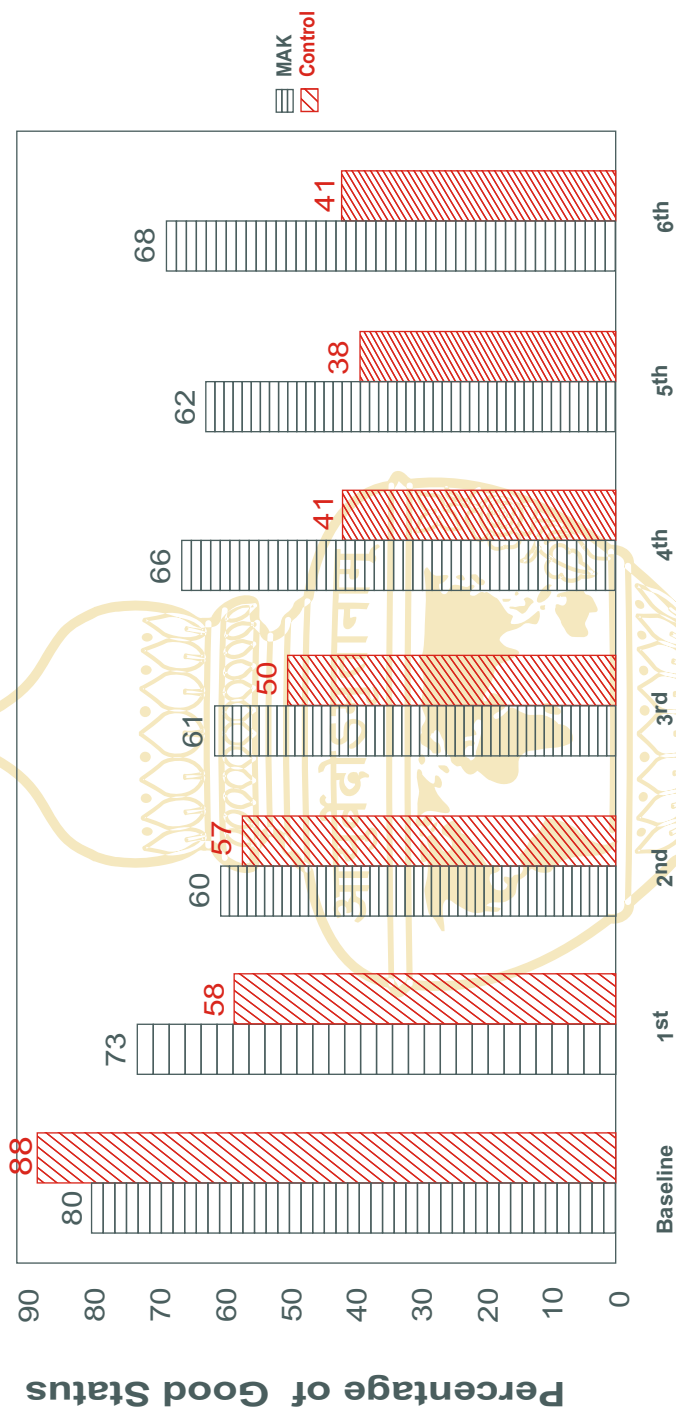
Alopecia



1st Cycle
 Relative Risk =0.7
 Fishers Exact p=0.04
 Prevented Fraction=30%

Cycles of Chemotherapy

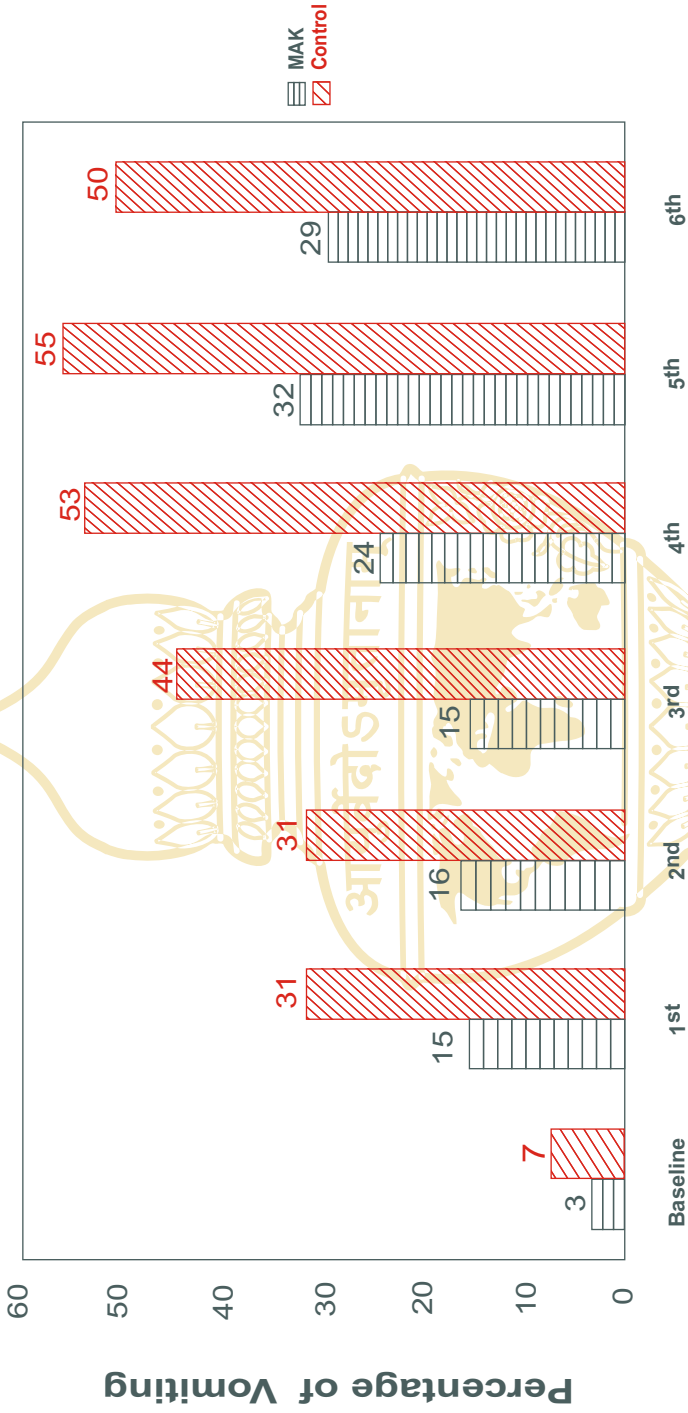
Karnofsky Performance Status



4th Cycle
 Relative Risk = 1.61
 Fishers Exact p=0.02
 Prevented Fraction=37.9%

Cycles of Chemotherapy

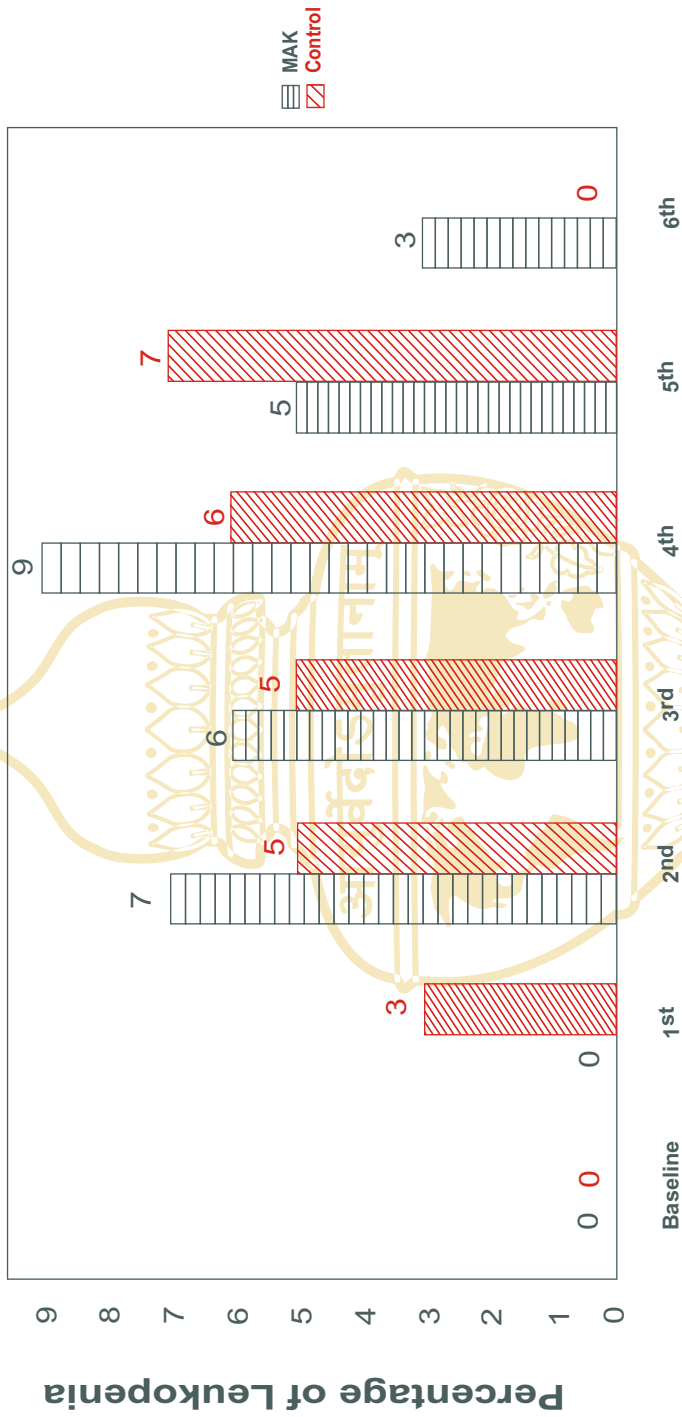
Vomiting



3rd Cycle
Relative Risk = 0.34
Fishers Exact p=0.0009
Prevented Fraction=65.7%

Cycles of Chemotherapy

Leukopenia



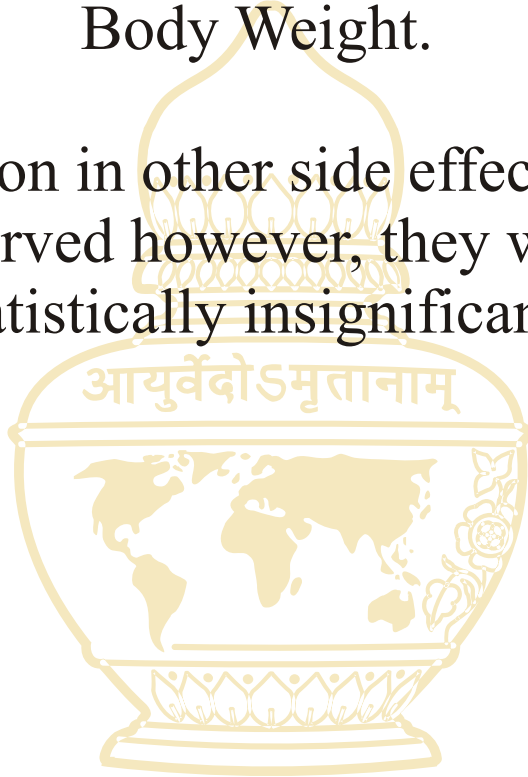
4th Cycle
Relative Risk = 0.5
Fishers Exact p=0.001
Prevented Fraction=45%

Cycles of Chemotherapy

Conclusions

MAK helped in maintaining General Health, Karnofsky Status, Appetite & Body Weight.

Reduction in other side effects were observed however, they were statistically insignificant.



Maharishi Ayurveda Products Pvt. Ltd.

A - 14, Mohan Co-operative Industrial Estate, Mathura Road, New Delhi - 110044, Ph. : 26959827 / 833
E-Mail : map@maharishiyurvedaindia.com, Website : www.maharishiyurvedaindia.com