

## ***RASAYANA EFFECT OF ASWAGANDHADI GRANULES IN PATIENTS OF ORAL CARCINOMA- A RANDOMISED CONTROLLED CLINICAL TRIAL***

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### ABSTRACT

Oral Cancer, a type of Head and Neck Cancer is any cancerous tissue growth located in the Oral cavity. Due to the different interventions like surgery, radiotherapy and chemotherapy, the quality of life of oral cancer patients decreases and the patient become weak day by day. This signifies the importance of some measures which improve the quality of life of oral cancer patients. In recent time, we can find people opt for more safe and effective alternative treatment. Hence *Ayurveda* has a major role here. Considering all the above facts and the rate of occurrence of the disease, the study has been selected and a sincere effort has been made to evaluate the *Rasayana* effect of *Aswagandhadi granules* in improving the quality of life of patients suffering from Oral Carcinoma (Mugharbuda).

**Keywords:** *Mugharbuda, Aswagandhadi Granules.*

### INTRODUCTION

Oral cancer is one of the ten most common cancers in the world.<sup>1</sup> According to study by WHO, oral cancer diagnoses around the world have steadily been rising. Global cancer deaths are expected to reach 7.9 million. Annually 1.3lakh people succumb to oral cancer in India which translates into approximately 14 deaths per hour.<sup>2</sup>

Poor nutritional status, weight loss, malnutrition are the common challenges being faced by patients with cancer. These entities lead to

decreased quality of life. Nutritional challenges contribute significantly to increased morbidity and mortality rate. Awareness and timely action is the key to fight against this deadly disease.<sup>3</sup>

This clinical study is a small effort to observe changes in the nutritional status and overall wellbeing of patients suffering from Oral Carcinoma. *Ayurveda* put forth a unique branch called "*Rasayana*"<sup>4</sup> which focuses on the *Poshana* of *Rasadi Sapta Dhatus*, thereby contri-

buting to *Dehendriya Bala Vruddhi* which in turn shows its impact on the *Ayurarogy* of the person. Here *Naimittika Rasayana*<sup>5</sup> is selected as it is 'Vyadhinimittaja'.

The formulation selected for this study is *Aswagandhadi granules* having the property of *Rasayana*. The ingredients in the formulation are a cluster of *Tridosha Shamaka*, *Agni Deepaka* and *Balavardhaka Aushadha*.

*Aswagandha*, the first drug in this formulation is proved to have anti cancerous and anti stress actions.<sup>6,7,8,9,10</sup> Besides, ingredients in this formulation have *Keshya*, *Vatanashaka* effect and overall it helps in the nourishment of *Rasadi dhatus*.

Hence, a study was focused on assessing the Rasayana effect of *Aswagandhadi Lehya* in oral carcinoma patients receiving conventional anti cancerous therapy against the control group, where only conventional oral carcinoma treatment carried out.

## MATERIALS AND METHODS:

### Study design

Randomized control clinical trial was adopted. In this clinical trial, 40 patients fulfilling the diagnostic and inclusion criteria were selected and randomly assigned into 2 groups- Group A and Group B.

Method of sampling: Lottery Method

Total number of patients for the study was 47.

In that 2 patients were not registered.

So total 45 patients were registered for the study. In that 40 patients completed the clinical trial. Number of dropouts in group A was 5. There were no drop outs in group B.

### Inclusion criteria

- Any type of oral carcinoma on tongue, lip or other mouth areas.
- First 3 stages of oral carcinoma.

- Patients in the age group of 20-60 years.
- Patients who will agree to participate in the clinical trial and who will give their written consent.

### Exclusion criteria

- Last stage of oral carcinoma patients
- People suffering from other diseases which would interfere the present study like chronic liver failure, diabetes mellitus.
- Vulnerable group of patients

### Intervention

The patients in Group A were treated with *Aswagandhadi granules* with a dose of 25 gm, twice a day before food, with 100ml *ksheera* as *anupana*. The patients in Group B were treated as control Group with 100ml *ksheera*. The duration of study was 30 days. 15 days after the treatment schedule follow up was done.

### Investigations

Hemoglobin in gram %, TC, DC, ESR

## ASSESSMENT CRITERIA

The oral cancer patients who were diagnosed with histopathological examination or other investigations were selected for the study. Response of the treatment will be assessed using a detailed performa which will be done with 3 levels of assessment criteria.

The details of the assessment criteria are as follows:

### 1) Clinical parameters

#### a) Subjective clinical parameters

- *Abhyavarana Shakti*.
- *Jarana Shakti*
- *Deha Upachaya*
- *Shareera Bala*.

#### b) Objective clinical parameters

- Weight.
- BMI

## 2) Laboratory parameters

- Hemoglobin in gram %, TC.

## 3) Overall assessment

EORTC SCALE

### Statistical analysis

**Summary of statistics:** Mean, Standard Deviation, Standard Error, Percentages.

**Descriptive Statistical Data:** t-value, and P-value were calculated for all the variables.

**Pre- post comparison:** paired 't' test.

**Comparison between the groups:** unpaired 't' test.

**Test of significance:** value of < 0.05 is considered as the statistical significance level for obtaining absolute result.

**Table 1:** EFFECT OF ASHWAGANDHADI LEHYA BASED ON ASSESSMENT PARAMETERS AFTER 30 DAYS OF TREATMENT. (GROUP A)

CRITERIA	MEAN BT	MEAN AT	M.D	%	S.D	S.E	't' VALUE	P VALUE
<i>Abhyavarana shakti</i>	2.85	3.75	0.9	31.57%	0.96	0.21	6.28	<0.001
<i>Jarana shakti</i>	2.85	3.45	0.6	21.05%	1.05	0.23	3.26	0.004
<i>Deha Upachaya</i>	1	1.6	0.6	60%	0.59	0.13	4.48	< 0.001
<i>Sareera bala</i>	3.4	2.45	0.95	27.94%	0.75	0.17	5.14	<0.001
Wt	50.5	51.32	0.82	1.62%	7.29	1.63	3.71	0.001
BMI	19.67	20.03	0.35	1.80	2.36	0.52	1.36	0.188
Hb	10.43	10.69	0.25	2.44%	1.09	0.24	1.85	0.07
EORTC	111.4	106.95	4.45	3.99%	8.58	1.91	2.32	0.031

**Table 2:** EVALUATION OF ASSESSMENT PARAMETERS AFTER 30 DAYS WITHOUT GIVING ANY MEDICINE. (GROUP B)

CRITERIA	MEAN BT	MEAN AT	M.D	%	S.D	S.E	't' VALUE	P VALUE
<i>Abhyavarana shakti</i>	2.6	2	0.6	23.07%	0.64	0.14	3.94	<0.001
<i>Jarana shakti</i>	2.8	2.15	0.65	23.21%	0.933	0.20	4.33	<0.001
<i>Deha Upachaya</i>	1	1.2	0.2	20.0%	0.41	0.09	2.17	0.042
<i>Sareera bala</i>	3.3	3.7	0.4	12.12%	1.03	0.23	2.17	0.042
Wt	51.7	50.87	0.88	1.70%	9.87	2.20	2.62	0.017
BMI	20.05	19.5	0.49	2.44	2.31	0.51	3.93	<0.001
Hb	10.45	10.15	0.3	2.87%	1.18	0.26	4.59	<0.001
EORTC	111	115.1	4.1	3.69%	12.59	2.81	4.52	<0.001

## COMPARATIVE EFFECTS OF GROUP 'A' AND GROUP 'B'

The assessment criteria of Group A and Group B are compared and analysed by unpaired t test. Comparison is done between the results obtained after 30 days of treatment in both the groups.

CRITERIA	MEAN		M.D	SD		SE		t	p
	A	B		A	B	A	B		
Abhyavarana shakthi	-0.900	0.600	-1.50	0.64	0.68	0.14	0.15	-7.17	= < 0.001
Jarana shakthi	0.600	0.650	-1.25	0.82	0.67	0.18	0.15	-5.27	= < 0.001
Deha upachaya	-0.600	-0.200	-0.40	0.59	0.41	0.13	0.09	-2.46	= 0.018
Shareera bala	0.950	-4.00	5.18	0.82	0.82	0.18	0.18	5.18	= < 0.001
Weight	-0.820	0.880	-1.70	0.98	1.49	0.22	0.33	-4.23	= < 0.001
BMI	-0.355	.488	-0.84	1.16	0.55	0.26	0.12	-2.92	= 0.006
Hemoglobin	-0.255	0.295	-0.55	0.61	0.28	0.13	0.06	-3.63	= < 0.001
EORTC scale	4.450	-4.100	8.55	8.56	4.05	1.91	0.90	4.03	= < 0.001

### OVERALL ASSESSMENT OF THE TREATMENT:

	GROUP A		GROUP B		TOTAL	
	NO	%	NO	%	NO	%
No relief (0%)	3	15	8	40	11	27.5
Minimal relief (0.1-24%)	13	65	9	45	22	55
Mild relief (24-49%)	3	15	3	15	6	15
Moderate Relief (50-74%)	1	5	0	0	1	2.5
Marked relief (75-99%)	0	0	0	0	0	0
Complete relief (100%)	0	0	0	0	0	0

### DISCUSSION

#### Discussion on follow up:

There was recurrence of symptoms in few patients after stopping the treatment. So we can assume that the effect is not retaining after follow up without taking medicine. Exact assessment after follow up could not be done in all the patients as the time period was less.

#### Discussion on dropouts:

There were 5 Dropouts from Group A. Group B had no drop outs.

Reasons for drop out-

02 patients reported nausea on taking the test

medicine.

03 patients had their anticancer treatment schedules during the study period and had to stop the trial drug. Hence they were excluded from the study.

#### Discussion on probable mode of action of Drugs:

In *Mugharbuda*, as it is a *mamsavaha srotovyadhi*, *guru* and *pichila guna* will be predominant, this in turn vitiates *kaphadosha*. As it is spreading in nature, there will be involvement of *vata* also. So here, we need to adopt *Kaphavatahara chikitsa*. *Rasayana* with

Kaphahara properties should be given to improve the quality of life. Here Aswagandha Lehya plays a major role.

In this formulation, Aswagandha<sup>11</sup> is having Tikta kashaya Rasa, Laghu guna, Ushna virya, and Madhura vipaka. So, it acts as vata-kapha-hara rasayana and Balya.

In the oral cancer patients, as the quality of life of patients decreased, Agnibala will be less. Likewise, Abhyavaranasakti and jarana sakti got hampered. So, some drugs which improve Agnibala are needed. Tila<sup>12</sup> is having Ushna virya and Katu vipaka, so it is pitta agni vardhaka. So, here tila fulfils the criteria.

Weight loss is a major problem in oral cancer patients after conventional therapy. So in order to improve weight, some of the drugs needed. Masha<sup>13</sup> is having Guru guna, Ushnavirya, and Madhura vipaka. So, it acts as Bala and pushti vardhaka.

Pippali<sup>14</sup> having Ushnasita virya, katu rasa, and Madhura vipaka. So act as kaphavata nasaksa, deepana, pachan, triptighna and kaphavatanulomana.

Guda is having Madhura rasa, it is ruchya, balya and pushtikara.

Srapi<sup>15</sup> is having Madhurarasa, sita virya and madhura vipaka. So it is agnikrita, oja teja vivardhaka, vayasthapaka, balya, ayushyaand rasa vardhaka.

Aswagandha possess active ingredients like withaferin a, 5-dehydroxy withanolider. So it has anti-stress effect, Adaptogenic effect, Immunomodulatory effect Ashwagandha can neutralize the negative effects of stress on physiology and restore homeostasis Inhibited cell growth and prevent cell attachment.<sup>16</sup> So act as sinergizer in therapies.<sup>17</sup>

Pippali possess active ingredients like piperine, Piplartine. So it increases the WBC count, Improves dig-power.<sup>18</sup>

All these contributing to improve in quality of life of oral cancer patients. So we got results like improve in Abhyavarana Shakti, jarana-sakthi, Deha upachaya, shareera Bala, weight, BMI, and even in the overall assessment EORTC scale.

## CONCLUSION

After completion of the study the following conclusions were drawn:

ASWAGANDHADI LEHYA showed clinical and statistically significant effect on Abhyavaranana Shakti, Jarana Shakti, Shareera upachaya, Deha Bala, weight, BMI, Hb, and overall assessment EORTC.

On comparison between the two groups, statistically significant difference was found in the outcome variables.

To calculate the overall effect, the Mean difference and percentage were calculated which was better in group A

Thus null hypothesis was rejected and alternate hypothesis (H<sub>1</sub>) is accepted, there is a significant effect of Aswagandhadi lehya on improving quality of life in oral cancer patients.

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