

ORGANIC POLY HERBAL INTERVENTION IN TREATMENT OF ORAL CANCER: A CLINICAL STUDY

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ABSTRACT

Oral cancer is presently becoming an epidemic particularly in younger generation due to the habit of tobacco chewing and changing life style which includes frequent use of alcohol. The incidence of oral cancer is also at increased rate in poor population due to unhygienic condition of teeth and mouth. The complete eradication of oral cancer is a big challenge before clinician since the current standard approach of modern system of medicine do not provide permanent cure but also destroy the immune system making the body prone to opportunistic infections, reduce strength and vitality. Organic medicinal herbs being used since ancient time for the treatment of various ailments can play an important role in prevention and treatment of oral cancer. In order to develop effective therapeutics based on medicinal herbs for prevention and treatment of oral cancer, the organic poly-herbal combination consisting of Ashwagandha (*Withania somnifera*), Tulsi (*Ocimum sanctum*), Wheat Grass (*Triticum aestivum*) and Neem (*Azadirachta indica*), organically grown and free from toxic chemicals, pesticides, herbicides and weedicides, was evaluated to see its beneficial effects in treatment of oral cancer. This herbal formulation showed beneficial effect in patients of oral cancer when treatment was continued over a period of about one year thereby suggesting its long term use as complimentary or alternative therapy in prevention and treatment of the oral cancer.

KEY WORDS

Oral cancer, *Ocimum sanctum*, *Triticum aestivum*, *Withania somnifera*, *Azadirachta indica*

INTRODUCTION

Cancer is one of the major threats to public health in the developed world and increasingly in the developing world. In developed countries cancer is the second most common cause of death. According to the World Health Report 2004 [1], oral squamous cell carcinomas are among the 10th most common cancers worldwide and the 6th most common in males. The incidence rates for oral cancer in India for both males and females are $\geq 6.9/100,000$ population according to global data. Data obtained from studies conducted in the US indicate oropharyngeal cancers to account for 3% of all diagnosed malignancies [2-4]. The chief risk factors for oral squamous cell carcinoma are smoking (especially > 2 packs/day) and alcohol use. Risk

increases dramatically when alcohol use exceeds 6 oz of distilled liquor, 6 oz of wine, or 12 oz of beer/day. The combination of heavy smoking and alcohol abuse is estimated to raise the risk 100-fold in women and 38-fold in men. Squamous cell carcinoma of the tongue may also result from any chronic irritation, such as dental caries, overuse of mouthwash, chewing tobacco, or the use of betel quid. Oral human papillomavirus (HPV), typically acquired via oral-genital contact, may have a role in etiology. Although modern treatments like radiation therapy, chemotherapy and surgery have been developed to treat the patients with oral cancer, but these have not been able to cure the patients completely. These modern treatments make the life of the patients more miserable by producing

undesirable adverse reactions and disturb the immune system thereby making the body immunologically deficient. This system of medicine for treatment of cancer consists of an attempt to eradicate cancer affected cells with combined treatment such as surgery, chemotherapy and radiation. In this treatment, surgical operation for removing cancer affected cells is taken up as usual and remaining cells are given radiation by Cobalt rays or X-rays and it is tried to destroy cancerous cells. Simultaneously, chemotherapy is also given to check the multiplication of cancerous cells. In chemotherapy, some chemical substances are used to stop the multiplication of cancerous cells while these chemical substances are not compatible to human body. The side effects of these two therapies are seen in form of spread of cancer on the other site in the body. In case, even one cell is left untreated/ burnt by radiation, it again multiplies and on the other hand normal cells are also burnt. In the same manner, by chemotherapy, not only the growth of cancerous cells is hampered, it also checks the growth of normal or healthy cells. As a sequel the cancer re-begins in fresh organs. Meaning there by the relief provided by these both the therapies is not only incomplete but also temporary and timely. Even one untreated cell may result in a fresh disease. As such the treatment based on the theory of "Killing of Cells" viz. Surgical Aids. Thus, chemotherapy and the radiation do not provide a complete relief from the cancer and a doubt of recurrence of the disease is always remains alive. In many cases it makes human life miserable and usually reduces the span of life. The patient remains sick due to toxic effect of radio and chemotherapies as these do not kill only cancerous cell but normal cell also and produced low hematological picture and low immune syndromes taking the patients prone to opportunistic infections, reduce strength and vitality. In this scenario, medicinal herbs/ plants being used since ancient time for the treatment of various ailments can play an important role in prevention and treatment of oral cancer. Medicinal herbs/plants having anti-stress / adaptogenic, immunomodulatory and anti- viral properties may be used in the management of such conditions. Therefore a clinical study was conducted to evaluate the efficacy of organic medicinal herbs in the treatment of oral cancer. In the present study the

medicinal herbs namely Ashwagandha (*Withania somnifera*), Tulsi (*Ocimum sanctum*), Katuki (*Picrorrhiza kurroa*), Wheat Grass (*Triticum aestivum*) and *Azadirachta indica* (Neem) were used as these medicinal herbs have been found to exhibit multifactorial therapeutic properties.

Withania somnifera (WS) is well known for its biological activities like adaptogenic/anti-stress, immuno-modulatory, anti-ageing, anti-fatigue, antioxidant, anti-parkinsonism, anti-ulcerogenic, anti-tumors/adenomas, support healthy thyroid function. WS and its chemical ingredients are effective in prevention and treatment of different kinds of cancer like colon cancer, lung cancer, blood cancer, skin cancer, breast cancer, renal cancer, fibrosarcoma, prostate cancer and pancreatic cancer [5-6]. *Ocimum sanctum* (OS) is well known for its other biological activities like bronchial asthma, antioxidant activities in bronchitis, hypertension, protection against viral encephalitis, anti-ulcer, anti-stress/ adaptogenic activity, improvement in NIDDM (non-insulin-dependent diabetes mellitus), protection against mouth and dental infection, fatigue syndrome, protection against tropical pulmonary eosinophilia in children, antimicrobial activity against mycobacterium tuberculosis, hepatoprotective activity. *Ocimum sanctum* and its phytochemicals are beneficial in prevention and treatment of different kind of cancer [7]. *Triticum aestivum* Linn. (Wheat grass) with a large number of biologically active constituents such as chlorophyll, amino acids, minerals, vitamins and enzymes has been found to provide health benefits ranging from supplementation nutrition to unique curative properties [8]. Katuki has been found to possess hepato and renoprotective [9], Immunomodulatory [10], antiviral [11] and adaptogenic/antistress [12] properties. *Azadirachta indica* has been found as natural antibiotic [13-14], Strong Immunomodulator [14-15], anti-inflammatory [16-17], antipyretic [18], antifungal [14], antibacterial [14], antiviral [13-14, 19], antiparasitic [20], anti-hyperglycemic [14], anti candidiasis [14, 21].

The multifactorial therapeutic actions present in these medicinal herbs prompted us to conduct a clinical study in order to evaluate the efficacy of combination of organic medicinal herbs Ashwagandha (*Withania somnifera*), Immunity: Vana Tulsi (*Ocimum*

gratissimum) + Krishna Tulsi (*Ocimum sanctum*) + Katuki (*Picrorrhiza kurroa*), Wheat Grass (*Triticum aestivum*), Neem (*Azadirachta indica*) in the treatment of oral cancer. The results of this clinical study are presented in the present research paper.

MATERIALS AND METHODS

Clinical studies are conducted in the treatment of various types of cancers including oral cancer, usually 3rd and 4th stage of cancer cases reporting at the International Institute of Herbal Medicine (IIHM) clinic for treatment. The patients are those who have been refused treatment due to advance stage of disease or who have not responded to surgery, chemotherapy and radiotherapy. Seventeen patients clinically and histopathologically diagnosed for oral cancer attending the clinic of International Institute of Herbal Medicine (IIHM), Lucknow were included in the present study after taking their informed written consent. The data were collected from patient record in predesigned data sheet which included presenting clinical symptoms, results of histopathological and hematological / laboratory findings. Collected data were analyzed and expressed in multiple tables. These patients enrolled at IIHM clinic were given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg) : combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg) + Katuki (*Picrorrhiza kurroa*, 165mg) twice daily + Neem (*Azadirachta indica*, 325 mg) twice daily within meals, as main agents for treating the cancer. Wheatgrass (350mg) twice daily within meals was also included in the treatment for the better nourishment of health. The above medicinal herbs/plants used in the study were organically grown and free from toxic chemicals, herbicides, weedicides and pesticides. This poly herbal treatment was continued for a period of one and half year. A regular follow up of

disease condition and health profile of each patient was carried out at the end of the each month. The clinical profile of patients including pathological and histo-pathological examination was given in different tables as mentioned below. This clinical study at International Institute of Herbal Medicine (IIHM), Lucknow was carried out under the supervision of a duly formed Ethical Committee of the institute and the study was approved by Ethical committee of the institute. Each patient served as his own control in this study since it may not be possible to take group of patients as control due to ethical consideration.

RESULTS

The clinical symptoms, health status and hematological parameters including hemoglobin levels and blood platelets counts of patients, before the start of herbal treatment and after herbal treatment at the interval of three months were given in different tables as mentioned below. The case wise description of the results showing the beneficial action of polyherbal combination in improvement of oral cancer patients was mention as under. **Table 1** represents kinds of oral cancer in patients as confirmed by histopathological findings.

The clinical symptoms of oral cancer cases included in the study before the start of herbal treatment and after herbal treatment at interval of three months were summarized in **Table 2 and Table 3**. As is evident from **Table 2 and Table 3**, a gradual decrease in symptoms of oral cancer such as fever, swelling, weight loss, pain with ulcer in mouth, difficulty to swallowing up water and taking food, fatty tissue collection, insomnia, bleeding from mouth, headache, restlessness, hyperacidity, breathlessness were observed at intervals of 3 months, 6 months and 9 months in patients taking continuous poly herbal combination as compared to those in patients before the start of herbal treatment.

Case. No.	Histopathological Findings
Case 1	carcinoma of right buccal mucosa
Case 2	invasive squamous cell carcinoma (moderately differentiated esophagus)
Case 3	invasive adenocarcinoma of throat
Case 4	invasive adenocarcinoma of throat
Case 5	squamous cell carcinoma of right upper cheek
Case 6	Tumor In Lower Chin
Case 7	adenocarcinoma mandible left and right
Case 8	squamous cell carcinoma of esophagus
Case 9	squamous cell carcinoma of esophagus, secondaries on lung with fibrosis
Case 10	squamous cell carcinoma of mouth palates
Case 11	postoperative squamous cell carcinoma of tongue
Case 12	postoperative oral squamous cell carcinoma (tobacco induced)
Case 13	invasive squamous cell carcinoma large cell keratinizing type
Case 14	invasive squamous cell carcinoma cheek
Case 15	invasive squamous cell carcinoma tongue
Case 16	oesophageal squamous cell carcinoma tongue
Case 17	oesophageal squamous cell carcinoma tongue

Table 1: Histopathological Findings of Patients of Oral Carcinoma

Symptoms	Frequency	Percentage (%)
FEVER	8	47.05
SWELLING	7	41.17
WEIGHT LOSS	5	29.41
PAIN WITH ULCER IN MOUTH	6	35.29
DIFICULTY TO SWALLOWING UP/ WATER AND FOOD INTAKE	10	58.82
FATTY TISSUE COLLECTION	3	17.64
INSOMNIA	4	23.52
BLEEDING FROM MOUTH	3	17.64
HEADACHE	6	35.29
RESTLESSNESS	7	41.17
HYPERACIDITY	5	29.41
BREATHLESSNESS	4	23.52

Table 2: Clinical Systems of Oral Carcinoma before the Treatment

Symptoms	Frequency at interval			Percentage (%)		
	3 months	6 months	9 months	3 months	6 months	9 months
FEVER	1	0	0	05.8	0.00	0.00
SWELLING	2	1	0	11.76	05.8	0.00
WEIGHT LOSS	1	1	0	05.8	11.76	0.00
PAIN WITH ULCER IN MOUTH	3	2	1	17.6	17.6	05.8
DIFICULTY TO SWALLOWING UP/ WATER AND FOOD INTAKE	4	3	1	23.52	05.8	05.8
FATTY TISSUE COLLECTION	2	1	0	11.76	05.8	0.00
INSOMNIA	3	1	0	17.6	05.8	0.00
BLEEDING FROM MOUTH	1	0	0	05.8	0.00	0.00
HEADACHE	2	0	0	11.76	0.00	0.00
RESTLESSNESS	3	1	0	17.6	05.8	0.00
HYPERACIDITY	0	0	0	0.00	0.00	0.00
BREATHLESSNESS	0	0	0	0.00	0.00	0.00

Table 3: Clinical symptoms of Oral carcinoma after the Treatment

The laboratory findings reflected in table 4 and table 5 indicated that hemoglobin level and platelets counts were significantly increased in patients when herbal treatment was continued over the period of nine months.

CASE NO.	HEMOGLOBIN (g/dl)	PLATELETS
Case 1	8.0	189
Case 2	10.8	262
Case 3	9.8	297
Case 4	9.7	197
Case 5	11.7	306
Case 6	10.0	220
Case 7	9.7	275
Case 8	11.0	295
Case 9	8.3	417
Case 10	8.2	287
Case 11	9.2	321
Case 12	11.0	187
Case 13	10.2	245
Case 14	9.9	197
Case 15	10.5	254
Case 16	12.0	197
Case 17	8.8	256
Normal Range in Adult		150-450

Table 4: Laboratory Finding in Patients with carcinoma cancer before the start of Herbal treatment

CASE NO.	HEMOGLOBIN at Months Interval (g/dl)			PLATELETS at Months Interval		
	3 months	6 months	9 months	3 months	6 months	9 months
Case 1	10	10.5	11.2	200	232	250
Case 2	11	11.8	11.5	265	262	259
Case 3	10.6	11.2	12.2	300	302	312
Case 4	11.0	11.5	12.5	205	220	236
Case 5	11.8	12.2	12.5	300	305	330
Case 6	10.8	10.9	11.9	256	289	300
Case 7	9.9	10.5	11.0	284	295	315
Case 8	10.9	11.7	11.9	300	302	319
Case 9	9.3	10.4	11.0	415	417	420
Case 10	9.0	10.9	11.9	290	298	312
Case 11	10.2	10.9	11.0	329	347	350
Case 12	11.5	11.8	11.9	212	230	248
Case 13	10.9	11.0	12.2	274	300	315
Case 14	10.5	10.8	11.9	214	220	284
Case 15	11.2	11.9	12.3	300	302	315
Case 16	12.2	12.5	12.9	212	234	295
Case 17	10.0	10.9	11.8	274	288	316
Normal Range in Adult	150-450					

Table 5: Laboratory findings in patients with oral cancer after herbal treatment at fixed interval

CASE WISE DESCRIPTION

Case 1:

A 36 year old male histo-pathologically diagnosed as carcinoma of right buccal mucosa attended the clinic of International Institute of Herbal Medicine (IIHM) on 04.05.2012 with history of weight loss and difficulty to swallowing up. The patient had subjected to the treatment with chemotherapy. The patient was given

herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg): combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg)+ Katuki (*Picrorrhiza kurroa*, 165mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one

capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of nine months and the patient got improvement in his health as per his clinical condition and hematological examination. As is evident from table 2 and table 3, gradual improvements in clinical conditions including fever, swelling, weight loss, pain with ulcer in mouth, difficulty to swallowing up water and taking food, fatty tissue collection, insomnia, bleeding from mouth, headache, restlessness, hyperacidity, breathlessness were observed. The health profiles of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (table 4 and table 5) at the interval of 3 months, 6 months and 9 months. For other health benefits, some common medicines like monotox-OD 200 mg twice daily, Flagyl 400 mg 1 tab twice daily were also given. The patient is still continued on the above treatment and is showing better recovery in his health.

CASE 2:

A 85 year old male diagnosed as invasive squamous cell carcinoma (moderately differentiated esophagus) attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 04.05.2011 with history of weight loss, difficulty in swallowing food and drinking water. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg) : combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg)+ Katuki(Picrorrhiza kurroa, 165mg) one capsule twice daily within meals, as main agents for treating the cancer. Liver Kidney care capsule (325mg) : combination of Bhumiamalaki (Phyllanthus niruri, 125 mg) + Punarnava (Boerhaavia diffusa, 100 mg)+ Katuki(Picrorrhiza kurroa, 100 mg) one capsule twice daily within meals, Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven months and the patient got improvement in his health as per his clinical condition and hematological examination. As evident from table 2 and table 3,

gradual improvements in clinical health condition including increase in weight, improvement in drinking water and swallowing food and other health profile of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were also observed (**Table 4 and Table 5**).

Case 3:

A 56 year old male diagnosed as invasive adenocarcinoma of throat attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 10.08.2010 with history of weight loss, difficulty in drinking water and swallowing food since last 6-7 month from date of registration at the clinic. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, *Ocimum sanctum* (275 mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven month and the patient got improvement in his health as per his clinical condition and hematological examination. As is evident from tables 2 and table 3, gradual improvements in weight loss, difficulty in drinking water and swallowing food and other health profile of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 4:

A 40 year old male diagnosed as invasive adenocarcinoma of throat attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 16.08.2010 with history of weight loss, difficulty in swallowing food and pain with ulcer. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, *Azadirachta indica* (325mg) one capsule twice daily, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the

better nourishment of health. This herbal treatment was continued for a period of eleven months and the patient got improvement in his health as per his clinical condition and hematological examination. As is evident from table 2 and table 3, gradual improvements in weight gain, improvement in drinking water and swallowing food, decreasing pain due to ulcer and other health profile of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 5:

A 71 year old male diagnosed as squamous cell carcinoma of right upper cheek attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 07.03.2012 with history of weight loss, difficulty in swallowing food and drinking water. The patient had been subjected to surgery and radiation also. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg) : combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg)+ Katuki (*Picrorrhiza kurroa*, 165mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health and liver disorder. In addition to above herbal treatment, Bramhi (*Centella asiatica*, 350 mg), which is the main revitalizing herb for cell neurons and their nerve fibers, and is said to increase intelligence, longevity, and memory while preventing senility and aging was also given to the patient. This herbal treatment was continued for a period of nine months and the patient got improvement in his health as per his clinical condition and hematological examination. As is evident from table 2 and table 3, gradual improvements in weight gain, improvement in drinking water and swallowing food and improvements in health profile of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 6:

A 35 year old female diagnosed as tumor in lower chin attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 20.05.2011 with history of fatty tissue collection since last 6 years from date of registration. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg) : combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg)+ Katuki (*Picrorrhiza kurroa*, 165mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven month and the patient got improvement in her health as per her clinical condition and hematological examination. As is evident from **Table 2 and Table 3**, gradual improvements in weight gain, depletion in fatty tissue collection and improvements in other health profile of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 7:

A 63 year old male diagnosed as adenocarcinoma mandible left and right attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 23.03. 2010 with history of post operated case of oral squamous cell carcinoma. The patients had also been subjected to radiotherapy before attending the clinic. The patient was given herbal treatment with the combination of Ashwagandha (I), two capsules (each capsule containing 400 mg) twice daily within meals, *Ocimum sanctum* (275 mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. The above herbal treatment was continued for a period of eleven months and the patient got improvement in his health as per his clinical condition and hematological examination. As is evident from table 2 and table 3, gradual improvements in health profile including

improvement in swallowing food and weakness of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were also observed (**Table 4 and Table 5**).

Case 8:

A 68 year old female diagnosed as squamous cell carcinoma of esophagus attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 09.09.2011 with history of esophagus squamous cell carcinoma including weight loss, difficulty in swallowing food, insomnia. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg): combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg)+ Katuki (*Picrorrhiza kurroa*, 165mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven months and the patient got improvement in his health as per her clinical condition and hematological examination. As is evident from **Tables 2 and Table 3**, gradual improvements in weight gain, improvement in swallowing food, reduction in insomnia and other health profile of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were also observed (**Table 4 and Table 5**).

Case 9:

A 44 year old female diagnosed as squamous cell carcinoma of esophagus, secondaries on lung with fibrosis attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 10.09.2011 with history of weight loss, difficulty in swallowing food and bleeding from mouth. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg): combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg)+ Katuki (*Picrorrhiza kurroa*, 165mg) one capsule

twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven months and the patient got improvement in her health as per her clinical condition and hematological examination. As is evident from **Table 2 and Table 3**, gradual improvements in weight gain, improvement in drinking water and swallowing food, bleeding from mouth and other health profile of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 10:

A 55 year old female diagnosed as squamous cell carcinoma of mouth palates attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 02.08.2010 with history of difficulty in swallowing food and headache. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, *Ocimum sanctum* (275 mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven months and the patient got improvement in her health as per her clinical condition and hematological examination. As is evident from **Table 2 and Table 3**, gradual improvements in weight gain, reducing headache and other health profile of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 11:

A 58 year old male diagnosed as postoperative squamous cell carcinoma of tongue attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 20.02.2011 with history of difficulty in swallowing food, weight loss and restlessness. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*),

two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg): combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg)+ Katuki (*Picrorrhiza kurroa*, 165mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven months and the patient got improvement in his health as per his clinical condition and hematological examination. As is evident from **Table 2 and Table 3**, gradual improvements in weight gain, improvement in drinking water and swallowing food, other health conditions and reduction in restlessness of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 12:

A 43 year old male diagnosed as postoperative oral squamous cell carcinoma (tobacco induced) attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 27.09.2011 with history of difficulty in swallowing food, pain and ulcer in mouth. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg) : combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg)+ Katuki(*Picrorrhiza kurroa*, 165mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven months and the patient got improvement in his health as per his clinical condition and hematological examination. As is evident from **Table 2 and Table 3** gradual improvements in weight gain, improvement in drinking water and swallowing food and other health profile including reduction in pain due to ulcer were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood

platelets count of the patient were observed (**Table 4 and Table 5**).

Case 13:

A 65 year old male diagnosed as invasive squamous cell carcinoma large cell keratinizing type attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 29.11.2011 with history of weight loss and typhoid. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg) : combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg)+ Katuki(*Picrorrhiza kurroa*, 165mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven months and the patient got improvement in his health as per his clinical condition and hematological examination. As is evident from **Table 2 and Table 3**, gradual improvements in weight gain and other health profile of the patient were recorded at the interval of 3months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 14:

A 65 year old male diagnosed as invasive squamous cell carcinoma cheek attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 22.03.2012 with history of weight loss and diabetes mellitus type-II. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg) : combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg)+ Katuki (*Picrorrhiza kurroa*, 165mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven months and the patient got improvement in his health as per his clinical condition and hematological

examination. As is evident from **Table 2 and Table 3**, gradual improvements in weight gain and other health conditions of the patient were recorded at the interval of 3 months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 15:

A 64 year old male diagnosed as invasive squamous cell carcinoma tongue attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 08.09.2011 with history of weight loss and mouth bleeding. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, Immunity (275 mg) : combination of Vana Tulsi (*Ocimum gratissimum*, 55 mg) + Krishna Tulsi (*Ocimum sanctum*, 55 mg) + Katuki (*Picrorrhiza kurroa*, 165 mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. This herbal treatment was continued for a period of eleven months and the patient got improvement in his health as per his clinical condition and hematological examination. As is evident from **Table 2 and Table 3**, gradual improvements in weight gain and other health conditions including reduction in bleeding from mouth of the patient were recorded at the interval of 3 months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 16:

A 70 year old female diagnosed as esophageal squamous cell carcinoma of tongue attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 09.04.2012 with history of difficulty in swallowing food and water, hyperacidity and breathlessness. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, *Ocimum sanctum* (275 mg) one capsule twice daily within meals, as main agents for treating the cancer. Bowelcare (375 mg): combination of Bel, chandrashoor

and isabgol) one capsule twice daily and Wheatgrass (350 mg) one capsule twice daily within meals were also included in the treatment for the better nourishment of health and constipation. Turmeric powder was also given for local inflammatory response. This herbal treatment was continued for a period of eleven months and the patient got improvement in her health as per her clinical condition and hematological examination. As is evident from **Table 2 and Table 3**, there is gradual improvements in weight gain and other health conditions including reduction in hyper acidity, reduction in breathlessness and improvement in drinking water and swallowing food of the patient were recorded at the interval of 3 months, 6 months and 9 months. Similarly, the marked improvements in hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

Case 17:

A 76 year old male diagnosed as oesophageal squamous cell carcinoma tongue attended the clinic of International Institute of Herbal Medicine (IIHM), Lucknow on 09.04.2012 with history of weight loss, difficulty in swallowing food and water and throat ulcer. The patient was given herbal treatment with the combination of Ashwagandha (*Withania somnifera*), two capsules (each capsule containing 400 mg) twice daily within meals, *Ocimum sanctum* (275 mg) one capsule twice daily within meals, as main agents for treating the cancer. Wheatgrass (350 mg) one capsule twice daily within meals was also included in the treatment for the better nourishment of health. In addition, Bramhi (*Centella asiatica*, 350 mg) which is the main revitalizing herb for our cell neurons and their nerve fibers, and is said to increase intelligence, longevity, and memory while preventing senility and aging is also included in above herbal combination. This herbal treatment was continued for a period of eleven months and the patient got improvement in his health as per his clinical condition and hematological examination. As is evident from **Table 2 and Table 3**, gradual improvements in weight gain, improvement in drinking water and swallowing food and reduction in hyper acidity and throat ulcer of the patient were recorded at the interval of 3 months, 6 months and 9 months. Similarly, the marked improvements in

hemoglobin level and blood platelets count of the patient were observed (**Table 4 and Table 5**).

The above results clearly demonstrated that the regular treatment of the patients with the poly-herbal combination increased the hemoglobin level and platelets counts as compared to those of untreated oral cancer patients. Similarly, gradual improvements in health status and clinical symptoms of patients were recorded during the treatment over the period of one year at the interval of three month, six month and nine month.

DISCUSSION

Cancer can affect any part of the oral cavity, including the lips, tongue, mouth, and throat, can be life threatening if not diagnosed and treated early. There are two kinds of oral cancer (i) Oral cavity cancer (ii) Oropharyngeal cancer. Oral cancer appears as a growth or sore in the mouth that does not go away. Since, surgery, chemotherapy and radiation have miserably failed to treat and control the oral cancer, medicinal herbs can be used in treatment of oral cancer. The poly herbal formulation consisting of medicinally active organic herbs viz. Ashwagandha (*Withania somnifera*), Tulsi (*Ocimum sanctum*), Wheat grass (*Triticum aestivum*) with diverse varieties of biological and health boosting actions on human systems and animal models was used to study its beneficial properties in prevention and treatment of oral cancer cases. They are proven to be effective in experimental cancer in vivo and as well as in vitro. *Withania somnifera* (Ashwagandha) has been found effective on Chinese Hamster Ovary (CHO) cells carcinoma [22]. It has also been shown to possess tumor preventing activity against urethane induced lung adenomas in adult male albino mice [23]. Recent research in mice indicates that withaferin A has anti-metastatic activity [24-28]. Tulsi has been found to decrease the incidence of benzo (a)pyrene-induced neoplasia (squamous cell carcinoma) in stomach of mice and 3-methyldimethylaminobenzene induced hepatomas in rats [29]. The ethanolic Tulsi leave extract has been found to produce significant reduction in values of tumor values of tumor incidence (papillomas) in the skin of albino mice [30, 31]. Tulsi leaves have also been shown to induce carcinogen

detoxifying enzyme glutathione-S-transferase in Swiss mice [32]. Tulsi extract has also been found to give a higher stem cell survival rate with radiotherapy suggesting likely good results with human clinical use [33, 34]. Wheatgrass, a powerful energy booster, bearing anticancer properties also [7] has been used to maintain good health during treatment. We are conducting clinical studies under the supervision of Ethical Committee of IIHM to evaluate the efficacy of large number of medicinal herbs in cancer patients and beneficial results have been observed.

We conducted the clinical studies to evaluate the therapeutic potential of above poly herbal combination in treatment of oral cancer patients and the results of the study conducted in seventeen cases of clinically diagnosed oral cancer revealed that all patients got beneficial response as reflected by their clinical condition and hematological examination when treatment of poly herbal combination was continued over a period of about one year. The gradual increase in hemoglobin level and blood platelets counts and significant reduction in disease symptoms such as fever, swelling, weight loss, pain with ulcer in mouth, difficulty to swallowing up/ water and food, fatty tissue collection, insomnia, bleeding from mouth, headache, restlessness, hyperacidity, breathlessness in patients after poly-herbal treatment at the interval of three month, six month and nine month clearly demonstrated the therapeutic potential of poly herbal formulation in prevention and treatment of oral cancer patients. All seventeen oral cancer patients included in the study got benefitted by above poly herbal treatment which suggests that long term treatment of the patients with above polyherbal combination might prove to be a better therapeutics in prevention and treatment of oral cancer which is becoming as a epidemic disaster in the present day where a large number of population including youths are becoming habitual of tobacco chewing. In above poly-herbal formulation, the medicinal herbs *Withania somnifera*, *Triticum aestivum* and *Ocimum sanctum* are present and they are good immunomodulators, antistress/adaptogens and antioxidants. The multi factorial biological actions of above medicinal herbs and a large number of biological compounds present in them might be playing an important role to make the poly-herbal combination more active in oral cancer

prevention and making the complex human system more strong to fight against the disease. The building of a strong immune system helps to bring about a faster therapeutic response, a larger survival and improved chances of complete remission of the tumor. Thus, the above poly-herbal combination may be used as complimentary or alternative therapy in prevention and treatment of the oral cancer.

CONCLUSION

The present clinical studies concluded that organic poly herbal combination consisting of *Withania somnifera*, *Ocimum sanctum* and *Triticum aestivum* used in the treatment of oral cancer produced beneficial effect in the overall health condition of patients which suggests that this poly-herbal combination may be used as complimentary or alternative therapy in prevention and treatment of the oral cancer. Since the incidence of oral cancer is becoming as epidemic in population especially in youths due to tobacco chewing and smoking habits and faulty life style, this clinical study appears to be of great clinical significance in treatment of oral cancer. The clinical study on large size of oral cancer patients may generate more clinical data which might be useful for long term use of above poly herbal combination in prevention and treatment of the disease.

ACKNOWLEDGEMENT

Authors are grateful to Dr. Narendra Singh, M.D. Director, International Institute of Herbal Medicine (IIHM) and President, International Society for Herbal Medicine (ISHM), Lucknow (U. P.) India, who expired on July 31st, 2012, for his help and guidance in conducting the present clinical study.

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