



## A PILOT STUDY ON THE EFFICACY OF AN INDIGENOUS ANTICANCER FORMULATION (AC COMPOUND) IN PATIENTS OF CANCER

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### ABSTRACT:

Cancer is second to coronary artery disease as being the commonest cause of death in the western world. In India, as many as 2,500 persons die every day due to tobacco-related diseases. One woman dies of cervical cancer every 8 minutes in India. In Modern medicine, the available treatment modalities viz chemotherapy and radiotherapy cause decrease in immunity, decreased Quality of life, poor tolerance to surgery and altered efficacy of Chemotherapy and Radiotherapy. Ancient Ayurveda classics have described about tumours as 'Arbuda'. Ayurveda can be helpful in the management of cancer in many ways- as prophylactic, palliative, curative or supportive therapy. No doubt, it helps to improve quality of life (QOL) as adjuvant or as co therapy along with chemotherapy or radio therapy & Post surgery care. Ayurvedic drugs also minimize the side effects of Chemo/radio and other therapies. So, the current pilot study was done with the motive to evaluate the effect of a hypothetical compound (AC Compound) in the patients of Cancer. A significant improvement in some of subjective parameters like general well being, pain, indigestion, constipation and headache was seen in patients as a result of therapy. The results obtained from trial encourage more exploration and extended clinical trials in this field.

**Keywords:** Immunity, Chemotherapy, Radiotherapy, *Arbuda*, AC compound

### INTRODUCTION

Cancer is second to coronary artery disease as being the commonest cause of death in the western world. An estimated 7.4 million males were diagnosed with cancer worldwide in 2012. Lung cancer was the most common, accounting for almost a fifth (17%) of all cases diagnosed as cancer. Prostate cancer being the second most common cancer diagnosed in males worldwide (15%). Bowel, stomach and liver cancers are the remaining of the five most common cancers in males in the world, accounting for 10%, 9% and 7% of the male total, respectively<sup>1</sup>. An estimated 6.7 million females were diagnosed with cancer worldwide in 2012. Breast cancer being the most common, accounting for a quarter (25%) of all cases diagnosed. Bowel cancer was as the second most common cancer diagnosed in females worldwide (9%). Lung, cervical and stomach cancers are the remaining of the five most common cancers in females worldwide, accounting for 9%, 8% and 5% of the female total, respectively<sup>2</sup>. One woman dies of cervical cancer every 8 minutes in India<sup>3</sup>. As many as 2,500 persons die every day due to tobacco-related diseases in India<sup>4</sup>. In Modern medicine, the available treatment modalities viz chemotherapy and radiotherapy cause serious side

effects, decrease in immunity, decreased Quality of life, poor tolerance to surgery and altered efficacy of Chemotherapy and Radiotherapy.

Ancient Ayurveda classics have described about tumours as *arbuda*. *Doshas* vitiated in any part of the body and afflicting the *Mamsa dhatu* produce a swelling, which is circular, fixed, slightly painful, big in size, broad based, slowly growing and does not suppurate<sup>5</sup>. *Acharya Charkha* has described *Arbuda* as a complication of *Vata – Rakta*. *Acharya Madhava* while describing the definition of *Arbuda* opines that the vitiated *Doshas* afflict the *Mamsa* and *Rakta dhatu* to produce a swelling i.e. *Arbuda*<sup>6</sup>. The clinical manifestation of oncological entities or cancer is similar to pathology and clinical presentation of diseases *Shotha*, *Granthi*, *Arbuda*, *Apachi*, *Gulma Dushta vrana* and *Vidraddhi*. Moreover many cancers like lukaemias are described under *Pandu roga*. The disease begins in the form of *Shotha* (swelling) and with the span of time gets converted to *Arbuda*<sup>7</sup>. The ayurvedic principles of management comprise of using *Tridoshashamaka*, , *Srotoshodhaka*, *Shothahara*, *Granthihara*, *Lekhana*, *Vayasthapana*, *Balya* and *Rasayana* drugs along with *nidana parivarjana* (dietary and lifestyle modifications).

Ayurveda can offer support and comfort for the cancer patients. Ayurveda can be helpful in the management of cancer in many ways, as prophylactic, palliative, curative & supportive and no doubt it helps to improve quality of life (QOL) as adjuvant or co therapy along with chemotherapy / radio therapy or as Post surgery care to minimize the side effects of these therapies. Ayurveda helps in many ways to patients of cancer as mentioned above or to slower the progress of the cancer or when Chemo/ Radiotherapy or Surgery is contraindicated or for patients have no other choice for many reasons.

**Need of Study** - The problem of Cancer has been chosen for the study as many factors demand attention and research in this field. There is increase in incidence globally and therapies available till the date are not much satisfactory and have serious adverse effects. Extensive research has been done in this field not only in modern medicine. Indigenous and many other healing methods are being explored. Ayurveda can offer a very good support and comfort to the cancer patients. Ayurvedic treatment can be helpful in the management of cancer in many ways, as prophylactic, palliative, curative & supportive and no doubt may help to improve quality of life (QOL). The Ayurvedic therapeutic principles and drugs can be used as primary or adjuvant or co therapy along with chemotherapy or radio therapy or Post surgery care to minimize the side effects of other therapies.

#### Aims & Objectives:

- To design the Aetiopathogenesis of Cancer in Ayurvedic perspective.
- To study the efficacy of Trial drug 'AC compound' in cancer patients.
- To study the efficacy of trial drug in reducing the toxic effects of radiotherapy and chemotherapy in patients of Cancer.
- To study the efficacy of AC compound in improving the overall quality of life in patients of cancer.
- To provide an safe and cost effective therapy to the patients of Cancer

#### Material & Methods:

**Source and Selection of cases:** 20 well diagnosed and confirmed Patients of cancer visiting Cancer research unit & Opd of University college of Ayurveda attached Hospital, Jodhpur were selected and registered randomly for trial. Patients were subjected to the detailed clinical history and physical examination on the basis of specially prepared research Performa. Patients consent will be taken in prescribed Performa before trial.

**Study design:** Open randomized trial.

**Inclusion criteria:**

- All well diagnosed & histopathologically confirmed cases of cancer.
- Patient with all stages of cancer
- Patients with both Primary, Secondary (metastatic) stages
- Patients of Age group 16-70 years.
- Patients of both sexes
- Patients of cancer on radiotherapy or chemotherapy
- Patients of cancer in which surgery/ chemo or radiotherapy was not recommended or indicated.

#### Exclusion criteria:

Cancer patients with any other serious, Acute or toxic condition were excluded from study.

**Discontinuation Criteria:** Following patients were discontinued from trial -

- Patients not willing to continue the treatment.
- If any severe adverse effects appear during the treatment.
- If some other serious illness occurs during trial which require any emergency intervention.

**Table 1: Trial Drug:** The trial drug was a polyherbal formulation with following ingredients –

S.N	Name of Drug	Botanical name	Part Used	Quantity (in Parts)
1	Madhuyashti	<i>Glycerrhiza glabra</i>	Root	1
2	Giloya	<i>Tinospora cordifolia</i>	Root	1
3	Bala	<i>Sida cordifolia</i>	Root	1
4	Ashwagandha	<i>Curcuma longa</i>	Root	1
5	Rasna	<i>Pluchea lanceolata</i>	Leaves	1
6	Haritaki	<i>Terminalia chebula</i>	Fruit	1
7	Amalaki	<i>Embellica officinalis</i>	Fruit	1
8	Haridra	<i>Curcuma longa</i>	Rhizome	1
9	Daruharidra	<i>Barberis aristata</i>	Rhizome	1
10	Shalparni	<i>Desmodium gangeticum</i>	Leaves	1
11	Shigru	<i>Moringa oliefera</i>	Bark	1
12	Manjishtha	<i>Rubia cordifolia</i>	Root	1
13	Punarnava	<i>Boerhavia diffusa</i>	Root	1
14	Tulsi	<i>Osimum sanctum</i>	Leaves	1
15	Kutki	<i>Picrothiza curroa</i>	Root	1/2
16	Kanchnara	<i>Bauhinia variegata</i>	Bark	1
17	Sadabahar	<i>Lochnera rosea</i>	Leaves	1
18	Gugglu	<i>Commiphora mukul</i>	Resin	Q.S
19	Gomutra	Cow Urine	Urine	Q.S

**Method of preparation of trial drug:** The decoction of ingredients from 1 -17 was prepared by classical method by boiling in four time water and reducing to one fourth part of total quantity. Then obtained decoction was then boiled on medium flame till semisolid form *Ghana* is obtained which was then mixed with *Gomutrabhawita Gugglu*. Pills (*Ghanavati*) were prepared and air dried.

#### Dosage and Duration of trial:

Trial drug was given in dose of 500mg (2 tablets of 250 mg each), three times a day (1.5 gm /day) with *Gomutra Arka* (distilled Cow urine) as *Anupana* for 2 months.

**Follow up** – At every 15 days during the trial and 1 month after completion of trial.

**Criteria of assessment:** All the patients registered for the present clinical trial were screened for their demographic profile like age, sex, religion, marital status, socioeconomic status, occupation, addiction, *Prakriti*, *Ahara* etc. During the trial and follow-up study the patients were assessed on the basis of subjective and objective parameters. All patients registered for the trial were specifically asked for any changes in their clinical manifestations. The clinical features were rated on rating scale designed for the current trial from 0 to 4.

**Observations:**

A total of 20 patients were registered from the O.P.D. and I.P.D., Department of *Kayachikitsa*, Dr. SR RAU, Jodhpur, Rajasthan. 6 Patients did not return for further follow up treatment. One registered patient died during course of treatment. The study was completed in 13 cases. Among selected patients, 5% patients belonged to the age group 16 – 30 yrs, 15% belonged to the age group 31 - 40 yrs, 35% belonged to the age group 41-50 yrs, 15% belonged to the age group 51 - 60 yrs and 20% belonged to the age group 61-70 yrs of age. Among

registered patient 55% patients were male and 45% patients were female. 25% patients had head and cancer, 5% patients were of lung cancer, 25% patients were having liver and gall bladder cancer, 5% patients had Uterus/cervix/ovary cancer and 5% patients had breast cancer. 20% patients had history of HTN and 5% were having past history of DM+HTN both. 5% patients were from lower middle, 85% were from middle and 10% , belonged to upper middle class. Among registered patients, 10% patients had addiction of smoking, 10% patients had h/o addiction to gutkha (tobacco), 5% were addicted to alcohol whereas 50% patients were having addiction of tea only. Among the registered patients, 15% patients were of *Vata Pitta* dominant *Prakriti*, 20% of them had *Pitta kapha*, whereas 65% were of *Vata Kapha prakrati*. 100% patients had *Rajasika* mindsetup. 55% patients were of *Madhyam Satva*, , where as 45% had *Avara Satwa*. 30 % patients had *Madhyam jaran shakti* whereas 70% were *avara jaran shakti*. The effect on various subjective and objective parameters have been shown in tables below-

**Table 1:** Effect of therapy on subjective parameters

Subjective Parameter	n	Mean			% relief	S.D	S.E	“p”	Results
		BT	AT	X					
General well being	13	1.813	0.8750	0.9375	51.71%	0.6801	0.170	0.001	VS
Pain	9	1.500	0.8750	0.6250	41.67%	0.8062	0.2016	0.017	S
Loss of appetite	8	1.000	0.3125	0.6875	68.75%	0.7932	0.1980	0.001	VS
Indigestion	8	0.7500	0.3750	0.3750	50%	0.6191	0.1548	0.054	NS
Constipation	3	0.3750	0.0625	0.3125	83.33%	0.6021	0.1505	0.125	NS
Nausea& Vomiting	1	0.2500	0.1875	0.0625	25%	0.2500	0.0625	0.999	NS
Diarrhoea	2	0.4375	0.4375	0.000	0%	0.3651	0.0912	0.999	NS
Dysphagia	2	0.4375	0.4375	0.000	0%	0.3651	0.0912	0.999	NS
Dyspnoea	4	0.5625	0.375	0.1875	10.54%	0.5439	0.1361	0.3125	NS
Cough	2	0.4375	0.4375	0.000	0%	0.3650	0.0912	0.999	NS
Heamorrhagic tendencies	1	0.7500	0.125	0.625	83.33%	0.8062	0.2016	0.0156	S
Leg cramps	7	0.7500	0.1235	0.4375	58.33%	0.5123	0.1281	0.00156	S
Burning sensation	4	0.5000	0.2500	0.2500	50%	0.4472	0.1118	0.1025	NS
Vertigo	2	0.1875	0.0625	0.1250	66.67%	0.3416	0.08539	0.5000	NS
Insomnia	3	0.4375	0.2500	0.1875	42.86%	0.4031	0.10080	0.2500	NS
Headache	7	0.6250	0.1875	0.4375		0.5123	0.1281	0.0156	S
Pruritus	4	0.4375	0.1875	0.2500	57.14%	0.8563	0.2141	0.3750	NS
Excessive thirst	6	0.5625	0.1250	0.4375	77.78%	0.6292	0.1573	0.0313	S
Weight loss	3	0.1250	0.4375	0.3125	%	0.6021	0.1505	0.1250	NS
Lymphadenopathy	1	0.6250	0.6875	0.0625	10%	0.2500	0.06250	0.9999	NS
Hair loss	1	0.1250	0.0625	0.0625	50%	0.2500	0.06250	0.999	NS

**Table 2:** Effect if therapy on Objective parameters

Biochemical Profile	n	Mean			% change	SD	SE	t	p	Results
		BT	AT	X						
Hbgm%	5	10.740	10.940	0.2000	-0.0186%	1.681	0.7517	0.2661	0.8033	NS
TLC	5	66868	70564	3696	-0.0552%	17500	7826.1	0.4723	0.6613	NS
PLT	5	105300	190280	84980	-0.8070%	103253	46176	1.8404	0.1390	NS
Blood Urea	2	23.55	21.03	2.515	0.10699%	0.181	5.785	0.4347	0.7389	NS
Serum creatinine	2	0.9600	0.7900	0.1700	0.1770%	0.3250	0.2300	0.7391	0.5948	NS
Alkalinephosphatase	5	393.06	275.58	117.48	0.2988%	314.25	140.54	0.8359	0.4502	NS
SerumBilirubin total	4	5.045	6.853	1.808	-0.3583%	3.665	1.832	0.9864	0.3967	NS
SGOT	5	136.57	47.744	88.956	0.6507%	148.91	66.595	1.336	0.2526	NS
SGPT	5	133.80	43.492	90.310	0.6749%	138.3	61.850	1.460	0.218	NS
Serum cholesterol	2	165.60	163.55	2.050	0.01237%	22.69	16.050	0.1277	0.9191	NS
Serum triglycerides	2	159.35	159.00	0.3500	0.0021%	19.304	13.650	0.0256	0.9837	NS
RBS	2	101.20	96.550	4.650	0.0459%	0.91920	0.6500	7.7540	0.0884	NS

**Discussion:**

The incidence and mortality of Cancer is increasing very rapidly. No satisfactory therapy has been found so far though vast research is ongoing in this field. The current research study was designed with the aim of providing some contribution to medical science for the welfare of society specifically to the patients of Cancer. As per ayurveda principles, *Doshas* afflict the *Mamsa* and *Rakta dhatu* to produce a swelling i.e *Arbuda*. The clinical manifestation of oncological entities or cancer is similar to pathology and clinical presentation of diseases described in Ayurveda under nomenclature of *Shotha*, *Granthi*, *Arbuda*, *Apachi*, *Gulma* *Dushta vrana* and *Vidradhi*. Cancers like lukaemias are described under *Panduroga*. The disease usually begins in the form of *Shotha* (swelling) and may get converted into *Arbuda* (tumour).

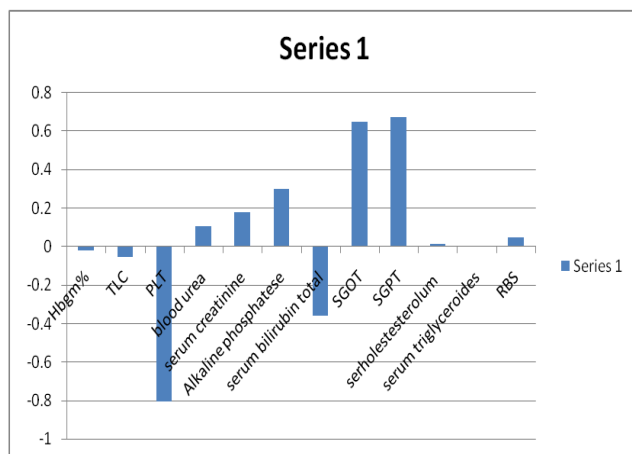
In current trial, most patients were male with age group 31- 45 years with history of addiction to tobacco/gutakha and Tea. Most patients were of liver& gall bladder cancer and cancer of Head and neck. Most patients had *Vata pitta* dominant and *rajasika Prakriti* showing role of *Prakriti* in pathogenesis of cancer. The trial drug showed stastically significant improvement in symptoms of feeling of general wellbeing, loss of appetite, pain, hemorrhagic tendencies, leg cramps, excessive thirst and headache. Though the Ac compound also showed significant improvement in LFT profile in 2 registered patients and also decrease in cancer markers in one patient but stastically the results were insignificant. The trial drug used on the therapeutic principles with multiple systemic actions on *Srotas*, *Agni*, *dosha*, *dhatu*s and *Oja* in body viz. *Tridoshashamaka*, *Raktashodhaka*, *Srotoshodhaka*, *Agnideepana*, *Rasayana*, *Vayasthapan*, antioxidant, antitumour and antimetastatic actions of the ingredients used in formulation of trial drug. Drugs like

*Aswagandha*, *Bala*, *Madhuyashti* & *Punarnava* are having immunomodulator, *dhatubalaya* and *rasayan* properties. Drugs like *Haritaki*, *Amalaki* and *Shigru* has *Amapachaka* (alleviates toxins) and antiinflammatory effects. Drugs like *Giloya*, *Tulsi* have *Agnideepana*, antioxidant and immunebooster actions. *Haridra*, *daruharidra*, *Katuki* and *manjishtha* have anti-inflammatory, antioxidant and *raktashodhaka* effects. *Kanchnara* and *Sadabahaar* have anticancerous properties. *Gugglu* has antiinflammatory, *Shothhara* and *Tridosahara* effects. Cow urine has been found to possess anticancerous effects in various studies. Though, this is a small pilot study to see primary results of trial drug but it can be extended with modifications in drug, dosage and specifically with more sample size.

**Conclusions:**

From the current pilot study following conclusions have been withdrawn-

1. Cancer is really a dreadful condition leads to decrease in span and quality of life of patients
  2. In ayurveda, the condition can be understood as severe *doshik* imbalance, deranged *Agni*, *Dhatupaka* and *Dhatukshya* for which drugs with *Srotoshodhaka*, *Vatakaphashamka*, *Agnideepana*, *Balya*, *Rasayana* properties must be used.
  3. Trial drug showed good results in various subjective parameters though no much changes in laboratory parameters.
  4. The trial drug was free from any adverse effect rather there was reduction in many toxic symptoms in patients taking allopathic treatment so we can conclude that the trial drug is also effective as co therapy and improves quality of life of cancer patients.
- For more authentic results and conclusions, the study should be extended /conducted on specific group of cancers with large sample size.



**Graph showing Effect if therapy on objective parameters**

**References:**

1. WHO, Global health observatory data repository, 2011. <http://apps.who.int/gho/data/node.main.2>

2. Report on causes of deaths in India 2001-2003. office of registrar general of India, Govt. of India, 2010.
3. Nandakumar A, National cancer registry programme, ICMR, consolidated report of the population based cancer registries 1990-96, n. Delhi 2009
4. Reddy KS, Gupta PC, Report on tobacco control in India, Ministry of health & family welfare, N. Delhi,
5. *Thakral kewal krishan, Sushruta samhita, Nidana sthana*, 11/13-14, p-828, Chaukhamba orientalia publication, 2014
6. *Shastri kashinath, Vidyotini commentary, Charak samhita, Uttarardha, Chikitsa sthana*, 29/34, P. N-824, Chaukhamba bharti Academy, 2018.
7. *Shastri sudarshan, Madhukosha Commentary, Madhava nidana* 11/ 18-22, p. n. 88-90, Chaukhamba Prakashan, 2014.