

## A Pilot Study of Cancero-Static Effects of Ayurvedic Herbo-Mineral Formulation (LAS01) in Cases of Cancer of Gall-Bladder

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### Abstract

A retrospective pilot clinical study was carried out for evaluation of canbero-static effects of LAS01- an Ayurvedic herbo-mineral compound in human subjects Guidelines as prescribed by W.H.O., ICMR and Ayurvedic Pharmacopoeia of India (A.P.I.) were followed for this study. Patients suffering from Cancer (CA) of Gall bladder were selected from the OPD of Lavanya hospital. The formulation LAS01 was prepared containing many metallic and minerals substances like Gold, Silver, and Copper; Sulphur, Mica, Arsenic and large number of drugs of vegetable origin. These ingredients were subjected to various processes viz *Sanskaras* for removing toxic effects of these substances by following procedures as laid down in ancient Ayurvedic texts and Ayurvedic Pharmacopoeia of India (A.P.I.). Patients were given the drug one gram twice daily orally after meals however doses were regulated according to the severity of the disease, if required. A feeling of well-being was observed in a short span of two weeks after treatment with LAS01 while biochemical and radiological parameters did not show any significant changes after 30 days or more time period after treatment with LAS01. It was also observed that the growths of the cancer as well as metastasis were checked besides the amelioration of adverse effects of the modern chemotherapy which also subsided gradually.

**Key words:** Ayurvedic texts; Cancer Gall bladder; Cancero-static; Herbo-mineral.

### Introduction

Cancer is a generic term used for a large group of diseases that can affect any part of the body. Other terms used are malignant tumors and neoplasms. One defining feature of cancer is the rapid creation of abnormal cells that grow beyond their usual boundaries and which can then invade adjoining parts of the body and spread to other organs. This process is referred to as metastasis. Metastasis are the major cause of death from cancer.<sup>1, 2, 3</sup> Among billiary tract disorders, Cancer of Gall bladder is a disease of a distinct clinical entity. India has the highest international rate of gall

bladder cancer between 8.8 to 21.2 per 100.000 person years.<sup>4</sup> Gall bladder is one of the vital organs of human body which is like a small pear (7.6-10.29 and 29 cms.) which stores bile and concentrates it. The bile is a digestive liquid continually secreted by the liver which emulsifies the fats and neutralizes acids in partly digested food. A muscular valve in the common bile duct is opened to get the bile flow from the gall bladder into the cystic duct, along the common bile duct and into the duodenum. Some of the substances of the bile crystallize in the gall bladder forming gall stone which are precursor of Gall bladder cancer and are commonly found after the age of 40 years. It is most common in women and native Americans. It is manifested with symptoms of jaundice, pain above the stomach, fever, nausea and vomiting, bloating and lump in the abdomen. It is hard to diagnose gall stone cancer in its early stage. Sometimes it is found when Gall bladder is removed for another reason. But people having gall stone are more prone to have Gall bladder Cancer. It may well

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be understood that any pathology in it may hamper the normal life to a great extent. The Cancerous stage of the gall bladder is frequently found in India possibly due to various aggravating etiological factors including chronic gall stones and as a result of metastasis in the liver from other primary cancers. Junk food stuff and processed food prepared with the admixture of certain chemical substances also affect normal functioning of the organ. Regular stimuli on the gall bladder cause changes in the cell including tendency of uncontrolled multiplication of cell. Often the metastasis is also seen after the Cancer of liver to other organs including Gall bladder.<sup>5</sup>

An increased incidence of Cancer of Gall bladder also occurs in hereditary syndromes including Gardner syndrome, neuro-fibromatosis type I and hereditary non-polyposis colon cancer.<sup>6</sup> The role of various onco-genic mutations in gall bladder cancer is an area of active research. For example, a small study of gall bladder cancer from Japan reported an excess risk associated with polymorphism of the cytochrome P450 1A1 gene (CYP1A1) which encodes a protein involved in catalyzing the synthesis of cholesterol and other lipids.<sup>7</sup> Another study looked at polymorphisms within the apolipoprotein B gene.<sup>6,7,8</sup>

Abnormal anatomy such as congenital defects with anomalous pancreatico-biliary duct junctions and choledochal cysts increase the risk of Gall bladder cancer. The tumor is usually located in the fundus of the Gall bladder. Local spread through the Gall bladder wall can lead to direct liver invasion or in the opposite directions which leads to trans-peritoneal spread (20% of patients at presentation in the liver, bowel, and in the pelvis). -2-

Tumor may also directly invade other adjacent organs such as the stomach, duodenum, colon, pancreas and extra-hepatic bile duct. At diagnosis, the Gall bladder is often replaced or destroyed by the cancer, and approximately 50% of patients have regional lymph node metastasis.<sup>5</sup>

In the light of aforesaid facts it is of great importance to find out a suitable Cancero-cidal or Cancero-static treatment because the existing Chemo-therapeutic and Radio-therapeutic agents are not providing satisfactory and fruitful results. As the incidence of Cancer Gall Bladder is very commonly met in the society and adequate management by modern system of medicine and other therapies is not satisfactorily available so it is hard to treat the Cancer of Gall bladder. As such a ray of hope is observed from the ancient system of medicine (Ayurveda). *Karkatarbuda* term which is used for any type of Cancer denotes that disease which grabs the affected organ like that of a crab and results in the death after a short span of illness.<sup>9,10</sup> (*Su.Sa.Nidan*,11/13-15). It results in dysfunction, necrosis and unwanted changes in the constitutions of cell resulting in Cancerous stage of Gall Bladder. Large number of references are found in Ayurvedic texts to treat *Karkatarbud* (Cancer) by administering various metallic, mineral and vegetable drugs. A formulation LAS01 of such substances was prepared strictly adhering to textual references for their collection, identification, processing, purification and formulating into a finished product. The novel coded drug named LAS01 was given to cases suffering from Cancer of Gall Bladder so as to find a suitable remedy for nullifying the uncontrolled multiplication of the cells. Therefore, the present study was conducted to find out the affectivity and safety of LAS01 in cases of Cancer of Gall bladder.

## Material & Methods

Two hundred sixty five subjects were selected from the Out-Patients-Department (OPD) of Lavanya Ayurvedic Hospital & Cancer Research Centre, Dhawa Estate, Lucknow during 1<sup>st</sup> Jan. 2010 to 30<sup>th</sup> June, 2011. These cases were pre diagnosed as the cases of Cancer Gall bladder either on radiological parameters viz. Ultrasound, CT scan/ MRI / PET or through Cancer markers (CA 19.9 or CEA). They were also subjected

for their proper diagnosis on Ayurvedic parameters with the help of Health Monitoring System<sup>11</sup> as well as by pathological and biochemical investigations. Most of cases were pre-treated at various reputed hospitals of the country and have already undergone either Chemotherapy and Radiation or the Surgery and such refractory and advanced staged Cancer patients have come to Lavanya Hospital as a last resort for Ayurvedic treatment. Patients suffering from Cancer of Gall bladder were given the drug LAS01 one gram twice daily (30 mg./kg.) orally after meals after obtaining their written consent and ethical clearance from IEC of the hospital as per W.H.O. and ICMR guidelines.

The trial drug (LAS01) was prepared with a combination of various metals viz Gold, Silver, Copper, Iron and Mercury etc, minerals like Sulphur, Arsenic, Mica (Abhrak) and large number of raw drugs of vegetable origin as per Ayurvedic Pharmacopoeia of India (API).<sup>12, 13, 14</sup> Purified Mercury (*Parad*) was also added after its purification by eight stages as attributed by classical Ayurvedic texts. These metals and minerals were also subjected for various purificatory processes to remove their toxic effects and make them fit for human consumption. For this purposes procedures as laid down in ancient Ayurvedic texts were strictly followed. Physico-chemical data to comply with pharmacopoeial standards of finished product LAS01 were also recorded by R & D Laboratory of Lavanya Ayurveda (presently functioning at Biotech Park, Govt. of India, Lucknow). Clinical Report Form (CRF) were filled as per usual norms and analyzed accordingly.<sup>15, 23</sup> Statistical analyses of the results was done on the basis of scoring and its conversion into percentage to calculate the mean along with SD (*Prisms Graphpad Software*).

### Observations and Result

Two hundred sixty five cases aged 31-71 years of either sex suffering from CA. Gall bladder associated with metastasis in liver,

pancreas or other organs were treated with Ayurvedic herbo-minerals formulation (LAS01) during January 2010 to June 2011.<sup>15</sup> They were critically analyzed and classified according to their sex (Male 100: 31-40 yrs. 06, 41-50 yrs. 28, 51-60 yrs. 32, 61-70 yrs. 22, 71 and above 12, Female 165: up to 30 yrs. 13, 31- 40 yrs. 21, 41-50 yrs. 53, 51-60 yrs 45, 61-70 yrs 28 and 71 and above 05), occupation (House work 188, agricultural work 28, Office/desk work 29 and other work 20), marital status (Unmarried 02, Married 256 and Widow 07), literacy scale (Up to primary 168, Up to 10<sup>th</sup> class 80 and Graduate 17) and socio-economic status (Lower 170, Middle 92 and Upper 02) and duration of treatment. Only 20 cases used the medicine LAS01 for more than 30 days and rest 245 cases could not continue the medicine due to various reasons. Therefore, analysis of the data of 20 cases is presented herewith in this study. Subjective assessment was done for the tenderness, billiary colic, nausea and vomiting, queasiness, belching, jaundice, fever, pain attack, lump in abdomen and other symptoms like ascitis, edema etc. which were found to be significantly reduced after treatment with LAS01 (Table I A & B).

Similarly objective assessment was carried out for haemogram (Hb %, TLC, DLC, ESR, Platelet count and GBP) before and after treatment (Table II). The objective assessment for biochemical parameters like Serum bilirubin, SGOT, SGPT, Serum alkaline phosphatase, Serum creatinine, Serum uric acid, Blood urea, Total protein, Serum albumin and AG Ratio were also carried out. The mean values were calculated along with standard deviation and P value to find out the statistical significance of the results on different parameters. Perusal of the table shows that none of the parameters showed any significant alterations except SGOT where as Serum billirubin was not reduced significantly (Table II A & B, Table III).

The radiological investigations before and after treatment along with Tumor Markers (CA 19.9 and CEA) and FNAC or Biopsy were taken into account for assessment of the results

of the treatment. It was observed that patients got symptomatic relief in a period of two weeks while the size of the Cancerous part was reduced in a period of 30-45 days in 3 cases (Table IV).

Out of these 20 cases only nine cases got their radiological investigations completed

before and after a treatment. After the treatment with LAS01, six cases showed evidence for the stoppage of further growth of the Cancer associated with Marked symptomatic relief in 67% however in three cases there was a decrease in size being Moderate symptomatic relief of 33% cases.

**Table I (A): Subjective Assessment of Various Signs & Symptoms in 20 cases of GB Cancer**

Subjective Parameters	Mean values and $\pm$ SD Before treatment with LAS01 and after modern Chemotherapeutic and Radiation therapy	Mean values $\pm$ SD After treatment with LAS01	P value
Tenderness	45.00 $\pm$ 19.72	17.50 $\pm$ 20.58	0.0177
Biliary Colic	55.00 $\pm$ 32.60	5.00 $\pm$ 11.18	0.1250
Nausea/Vomiting	33.33 $\pm$ 21.65	13.89 $\pm$ 18.60	0.1058
Queasiness	43.75 $\pm$ 17.68	15.63 $\pm$ 18.60	0.0568
Belching	39.58 $\pm$ 12.87	12.50 $\pm$ 16.86	0.0074
Jaundice	64.29 $\pm$ 19.67	25.00 $\pm$ 25.00	0.0199
Fever	37.50 $\pm$ 14.43	12.50 $\pm$ 14.43	0.1736
Pain Attack	43.18 $\pm$ 22.61	18.18 $\pm$ 22.61	0.0335
Lump in Abdomen	39.29 $\pm$ 24.40	14.29 $\pm$ 19.67	0.1676
Other Specify	50.00 $\pm$ 15.81	20.31 $\pm$ 22.76	0.0020

## Discussion

Cancer of the Gall Bladder is one of the commonest malignancies all over the world<sup>1</sup> with a fatal outcome especially if is not removed in early stages<sup>12</sup>. In the present study, 265 subjects of Gall bladder cancer who were critically ill and were in terminal stages showing metastasis sought admission in the hope of getting an extension of their lives or for getting symptomatic relief as a last resort. Unfortunately, out of 265 subjects admitted during the period from Jan., 2010 to June, 2011, only 20 patients could afford the treatment for 30 days or more duration and rest left out the hospital due to various reasons. The LAS01, an Ayurvedic preparation prepared on the basis of our ancient Ayurvedic literature and Ayurvedic Pharmacopoeia of India (API) did show a symptomatic improvement in all cases without any change in hematological and biochemical parameters. However, radiologically in eight out of 20 cases where such investigation could be done,

significant improvement cannot be claimed due to irreversible damage in the terminal stages with metastasis. In cases some reduction of tumor size seems to be there due to decrease in edema and inflammation around the Cancerous growth by treatment with LAS01. Such an effect seems to be an effect like that dexamethazone in such cases. However in remaining cases the progression of the growth was stopped and there was no increase in metastasis. It proves that the drug has a Cancero-static effect and if it would have been given in early stage it could have been much more efficacious and safe in comparison to modern chemotherapeutic agents. Our observations on anti proliferative and pro-apoptotic activities on Cancer cell lines *in-vitro*<sup>16-21</sup> do support above observations in clinical setting. It appears that a drug under test stops the proliferation at G<sub>0</sub> phase of the cell cycle where the work is still in progress<sup>17-18</sup>. Such molecular targeted Ayurvedic drugs are needed.<sup>3, 25</sup> However the drug could not vanish the existing tumor which perhaps



**Table I (B): Subjective Assessment**

S. No. & Name	TENDERNESS		BILIARY COLIC		NAUSEA/ VOMITING		QUEASINESS		BELCHING		JAUNDICE		FEVER		PAIN ATTACK		LUMPIN ABDOMEN		OTHER SPECIFY	
	BT*	AT*	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
01. A. P. Singh	++	+	+	-	-	-	-	-	+	-	+++	-	-	-	-	-	-	-	++	-
02. Meena Tripathi	-	-	-	-	+	+	-	-	+	+	-	-	-	-	-	-	+	++	++	++
03. Subhadra Devi	-	-	+++	-	+	-	-	-	++	-	-	-	-	-	++	-	+	-	++	-
04. K. Kumari	+	-	-	-	+	-	-	-	-	-	-	-	-	-	++	++	-	-	+	-
05. Annapurna	+	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
06. Ram Mohini	++	++	+	+	-	-	+	-	++	-	-	-	-	-	+	+	-	-	++	+
07. S. Amadya	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	+	-
08. S. S. Yadav	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
09. A. Gupta	+	+	-	-	+	+	+	+	-	-	-	-	++	+	-	-	+	+	++	+
10. R. Devi	+++	-	-	-	++	-	++	-	++	-	++	-	-	-	-	-	+++	-	++	-
11. M. Singh	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	++	-
12. N. Kumari	++	++	-	-	-	+	++	+	++	+	+++	++	-	-	-	-	+	+	-	-
13. Reeta Devi	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14. D. M. Devi	-	-	-	-	++	++	++	++	++	+	+++	++	-	-	+	+	-	-	+++	++
15. Md. Zabir	-	-	-	-	-	-	-	-	+	+	-	-	-	-	++	++	-	-	++	++
16. S. Devi	-	-	-	-	-	-	+	+	+	-	-	-	-	-	+	-	-	-	-	-
17. G. Srivastava	-	-	-	-	-	-	++	-	++	++	-	-	-	-	++	++	-	-	++	++
18. I Beg	++	+	++	-	-	-	-	-	++	-	+++	+	-	-	++	-	+	-	+++	+
19. P. Dikshit	-	-	-	-	-	-	-	-	-	-	+++	++	+	+	-	-	-	-	++	++
20. J. Narayan	+++	-	++++	-	+++	-	+++	-	++	-	+	-	++	-	++++	-	+++	-	+++	-
Mean values and $\pm$ SD before treatment with LAS01 and after modern Chemotherapeutic and Radiation therapy and After treatment with LAS01	45.00 $\pm$ 19.72	17.50 $\pm$ 2058	55.00 $\pm$ 32.60	5.00 $\pm$ 11.18	33.33 $\pm$ 21.65	13.89 $\pm$ 18.60	43.75 $\pm$ 17.68	15.63 $\pm$ 18.60	39.58 $\pm$ 12.87	12.50 $\pm$ 16.86	64.29 $\pm$ 19.67	25.00 $\pm$ 25.00	37.50 $\pm$ 14.43	12.50 $\pm$ 14.43	43.18 $\pm$ 22.61	18.18 $\pm$ 22.61	39.29 $\pm$ 24.40	14.29 $\pm$ 19.67	50.00 $\pm$ 15.81	20.31 $\pm$ 22.76
P value	0.0177		0.1250		0.1058		0.0568		0.0074		0.0199		0.1736		0.0335		0.1676		0.0020	
* BT = Before Treatment																				
*AT= After Treatment																				

**Table II (A): Mean Haematological and Biochemical values before and after treatment with LAS01**

Objective Parameters	Mean values $\pm$ SD before treatment with LAS01 and after modern Chemotherapeutic and Radiation therapy	Mean values $\pm$ SD after treatment with LAS01	P val
Serum Billirubin	4.162 $\pm$ 6.905	2.937 $\pm$ 4.562	0.769
S,G.O.T.	38.31 $\pm$ 18.94	141.9 $\pm$ 161.8	0.032
S.G.P.T.	58.72 $\pm$ 44.52	137.2 $\pm$ 148.5	0.278
S. Alkaline Phosphatase	510.1 $\pm$ 669.1	628.5 $\pm$ 499.7	0.240
S. Creatinine	0.9875 $\pm$ 0.2295	1.015 $\pm$ 0.3331	1.000
S. Uric Acid	4.980 $\pm$ 0.6535	5.180 $\pm$ 1.394	0.437
Blood Urea	27.33 $\pm$ 4.457	32.97 $\pm$ 8.748	0.218
Total Protein	7.200 $\pm$ 0.5916	3.322 $\pm$ 0.6629	0.623
Serum Albumin	3.322 $\pm$ 0.6629	3.444 $\pm$ 0.2698	0.778
AG Ratio	0.6963 $\pm$ 0.3044	0.8938 $\pm$ 0.1882	0.262
Total Leucocyte Count	11711 $\pm$ 4708	10674 $\pm$ 3215	0.213
Platelet Count	249333 $\pm$ 98049	249444 $\pm$ 70320	0.233
Haemoglobin	9.744 $\pm$ 1.527	9.767 $\pm$ 1.967	0.905

**Table II (B): Objective Assessment (Haematological Data)**

S. No. & Name	HB%		TLC		DLC P		DLC L		DLCE		DLC M		DLC B		ESR		Pl. Count	
	BT*	AT*	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
01. A. P. Singh	9.8	-	10400	-	82	-	10	-	1.5	-	5.8	-	0.1	-	-	-	5.41	-
02. Meena Tripathi	8.0	8.6	1,23,00	8,900	79	72	14	24	5	2	2	2	0	0	-	-	1,90,000	2,40,000
03. Subhadra Devi	9	6.00	12,100	14,900	77	87	20	10	1	3	2	0	0	0	-	-	1,95,000	1,86,000
04. K. Kumari	11.6	-	11400	-	62	-	28	-	2	-	8	-	-	-	-	-	312000	-
05. Annapurna	8.8	-	8300	-	70	-	25	-	3	-	2	-	0	0	30	-	160000	-
06. Ram Mohini	10	11.6	6700	8300	34	59	60	37	4	2	2	2	0	0	30	-	280000	290000.0
07. S. Amadya	-	-	5800	-	62	-	34	-	2	-	2	-	0	0	15	-	264000	-
08. S. S. Yadav	9.4	12.9	10600	10200	90	80	6	20	2	0	2	0	0	0	35	20	60000	160000.0
09. A. Gupta	85.0	9.8	24300	13800	94	91	6	8	0	1	0	0	0	0	60	0	190000	200000.0
10. R. Devi	9.5	-	14300	-	90	-	10	-	0	0	0	0	0	0	40	-	280000	-
11. M. Singh	9.5	9	16400	14800	91	80	9	20	0	0	0	0	0	0	35	36	170000	190000.0
12. N. Kumari	13.3	10.8	15800	10200	45	78	55	19	0	1	0	2	0	0	-	38	514000	208000.0
13. Reeta Devi	11.70	-	13000	-	76	-	21	-	1	-	2	-	0	0	-	-	399000	-
14. D. M. Devi	9.5	10.1	14600	12100	76	72	15	24	2	2	2	2	0	0	-	-	274000	415000.0
15. Md. Zabir	10.5	9.1	9400	9900	68	73	22	20	8	5	2	2	0	0	-	-	290000	290000.0
16. S. Devi	11.2	-	6800	-	63	-	31	-	4	-	2	-	0	0	-	-	220000	-
17. G. Srivastava	11.1	-	7400	-	66	-	29	-	3	-	2	-	0	0	-	-	240000	-
18. I Beg	11.2	-	5200	-	51	-	46	-	2	-	1	-	0	0	34	-	-	-
19. P. Dilshat	12.1	-	11800	-	83	-	12	-	3	-	2	-	0	0	46	-	210000	-
20. J. Narayan	11.8	-	16300	-	86	-	10	-	2	-	2	-	-	-	-	-	240000	-
Mean values and ± SD before treatment with LAS01 and after modern Chemotherapeutic and Radiation therapy and After treatment with LAS01	18.24 ± 25.08	9.767 ± 1.967	11711 ± 4708	10674 ± 3215	-	-	-	-	-	-	-	-	-	-	-	-	249333 ± 98049	249444 ± 70320
P value	0.6353		0.2131		-	-	-	-	-	-	-	-	-	-	-	-	0.2324	
* BT = Before Treatment																		
* AT= After Treatment																		

becomes non viable and so continues to produce the obstructive signs and symptoms. In such cases where stent was put or obstruction was removed and channels were opened, signs and symptoms disappeared rapidly without any recurrence. However in such critical cases, resection was not possible. 5 years survival is correlated with effect from the onset of disease. Only 10-20% of patients presented with localized disease. The remainder present with regional or distant metastasis. According to the SEER registry on gall bladder cancer, the 5 year survival rates for localized, regional, and distant disease are approximately 40%, 15% and less than 10%, respectively in such cases.

The median survival for advanced disease is short (2-4 months). Therefore, use of LAS01 in early cases soon after detection of Cancer and/or after resection of existing mass may be of much greater value in stopping the progression of the disease as well as metastasis

without exhibiting toxic side effects. The follow up cases is of utmost importance at least for five years to establish its efficacy in such cases.<sup>22, 24, 26</sup> As such its large scale clinical study is warranted in view of its Cancero-static activity and safety.

### Conclusion

The herbo-mineral formulation (LAS01) was given in 265 patients suffering from Cancer of Gall bladder. In majority of cases metastasis or recurrence was also observed. All the cases were pre-treated at reputed Cancer hospitals. Out of those 265 cases, 20 cases continued the medicine LAS01 for more than 30 days. Rest of the cases either dropped out due to their personal reasons or could not continue the medicine due to their poor financial conditions. Thus the remaining 20 cases were critically analyzed for observing

Table III: Objective Assessment (Biochemical Data)

S. No. & Name	Sr.Bil.		S.G.O.T		S.G.P.T		ALK. PHOS.		Sr.Cre.		Sr. Ur. Ac.		Bl. Urea		To. Pro.		Sr. Alb.		AG Ratio	
	BT*	AT*	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
01. A. P. Singh	10.77	1.86	3.42	48	178	52	331	759	1	-	4.1	-	27	-	8.1	7.3	3.7	3.6	-	0.9
02. Meena Tripathi	1.70	1.16	61	290	72	336	178	458	1.1	1.8	5.6	5.9	31.3	46.3	7.6	7.5	3.7	3.5	0.9	0.87
03. Subhadra Devi	0.7	0.7	29	84	36	50	1222	1350	0.9	1	4.9	7	21.6	40	7.5	5.9	3.6	3.3	0.9	1.27
04. K. Kumari	2.4	-	70	-	69	-	1862	-	-	-	-	-	-	-	-	-	-	-	-	-
05. Annapurna	0.71	-	31	-	35	-	146	-	0.9	-	4.9	-	31.3	-	7.5	-	3.8	-	1	-
06. Ram Mohini	0.44	0.82	31	50	15	58	80	315	0.8	0.8	-	5.1	23.0	26.2	-	7.6	-	3.7	-	0.9
07. S. Amadya	0.92	-	48	-	39	-	153	-	0.72	-	4.9	-	26	-	7.1	-	3.6	-	1.0	-
08. S. S. Yadav	0.72	0.79	47	33	59	29	126	165	0.9	1.00	5.2	5.4	26.5	32.5	7.5	7.4	3.7	3.7	0.1	1
09. A. Gupta	0.69	0.90	30	39	37	33	854	55.1	0.8	0.9	5.3	3.6	28.9	23	7.6	6.7	3.2	3	0.7	0.62
10. R. Devi	8.27	-	148	-	159	-	892	-	1.0	-	5.2	-	32.3	-	5.8	-	2.2	-	0.61	-
11. M. Singh	0.9	1.98	48	68	52	81	2198	1432	1.0	0.9	3.9	4.0	32.7	29.8	6.8	7.0	3	3.1	0.7	0.79
12. N. Kumari	23.6	17.4	36	506	27.9	440	285	1012	0.9	0.72	-	5.9	38	-	-	7.76	-	2.27	-	0.41
13. Reeta Devi	1.06	-	67	-	85	-	104	-	-	-	-	-	-	-	7.40	-	3.60	-	0.95	-
14. D. M. Devi	13.26	1.99	75	36	87	42	153	180	-	0.8	-	5.2	-	25.2	6.4	7.6	1.7	3.4	0.4	0.8
15. Md. Zabir	0.72	1.32	29	62	34	78	87	211	1.5	1	5.4	-	34.6	-	7.5	7.8	3.5	3.8	0.87	0.9
16. S. Devi	12	-	97	-	126	-	245	-	1.2	-	4.7	-	31.4	-	7.3	-	3.5	-	0.9	-
17. G. Srivastava	0.76	5.96	32	345	48	310	97	976	1.0	-	4.9	-	26.8	-	7.6	7.6	3.8	3.6	1.0	0.9
18. I Beg	11.44	-	229.5	-	159	-	1394.5	-	3	-	-	-	92	-	-	-	-	-	-	-
19. P. Dikshit	36.9	-	120	-	155	-	654	-	0.6	-	5.4	-	22.4	-	6.9	-	3.2	-	0.86	-
20. J. Narayan	1.87	-	75	-	91	-	808	-	1.2	-	5.9	-	34.5	-	8.1	-	4	-	0.9	-
Mean values and $\pm$ SD before treatment with LAS01 and after modern Chemotherapeutic and Radiation therapy and After treatment with LAS01	$4.162 \pm 6.905$	$2.937 \pm 4.562$	$38.31 \pm 18.94$	$141.9 \pm 161.8$	$58.72 \pm 44.52$	$137.2 \pm 148.5$	$510.1 \pm 669.1$	$628.5 \pm 499.7$	$0.9875 \pm 0.2295$	$1.015 \pm 0.3331$	$4.980 \pm 0.6535$	$5.180 \pm 1.394$	$27.33 \pm 4.457$	$32.37 \pm 8.748$	$7.200 \pm 0.5916$	$3.322 \pm 0.6629$	$3.322 \pm 0.6629$	$3.444 \pm 0.2698$	$0.6963 \pm 0.3044$	$0.8938 \pm 1.1882$
P value	0.7695		0.0322		0.2783		0.2402		1.0000		0.4375		0.2188		0.6236		0.7781		0.262	
* BT = Before Treatment																				
*AT= After Treatment																				

the effect of the medicine. The size of the Cancer or the metastasis was checked which reflects the Cancero-static effect of the medicine (LAS01) and safety on biochemical and hematological parameters. In cases where blockade in the bile duct is removed, the response was remarkable in terms of no recurrence and complications.

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### References

1. Singh, R.H., An assessment of the ayurvedic concept of cancer and a new paradigm of

anticancer treatment in Ayurveda. *J Altern Complement Med* 2002; 8: 609-614.

- Aggarwal, B.B., Ichikawa, H., Garodia, P. *et al*, From traditional Ayurvedic medicine to modern medicine: identification of therapeutic targets for suppression of Inflammation and Cancer, expert Opin. *Ther Targets* 2006; 10(1): 87-118.
- Saxena, R.C., Molecular targeting of Cancer cells by natural herbal remedies, National Seminar: Brain Storming Session on Integrated. *Therapeutic Approach in the Management of Cancer* 2011; 2.
- Aggarwal, B.B., Kumar, A., Bharti, A.C., Anticancer potential of Curcumin: preclinical and clinical studies. *Anti-Cancer Res* 2003; 23: 363-398.
- Balkwill, F., Mantovani, A., Inflammation and Cancer: Back to virchow. *Lancet* 2001; 357: 539-545.
- Takada, Y., Murakami, A., Aggarwal, B.B., Zerumbone abolishes NF-kappa B and Ikappa B alpha kinase activation leading to suppression of antipoptotic and metastatic gene expression:

- upregulation of apoptosis and down regulation of invasion. *Oncogene* 2005; 24: 6957-6969.
7. Kim, D. M., Koo, S.Y., Jeon, K., *et al*, Rapid induction of apoptosis by combination of flavopiridol and tumor necrosis factor (TNF), alpha or TNF-related apoptosis-inducing ligand in human cancer cell lines. *Cancer Res* 2003; 63: 621-626.
  8. Arguello, F., Alexander, M., Sterry, J. A., *et al*, Flavopiridol induces apoptosis of normal lymphoid cells, causes immunosuppression and has potent antitumor activity. *In vivo against human leukemia and lymphoma xenografts Blood* 1998; 91: 2482-2490.
  9. Charaka. *Charaka samhita*. Varanasi; Chaukhamba Orientalia, 700 BC.
  10. Susruta. *Susruta samhita*. Varanasi; Chaukhamba Surbharati Publications, 700 BC.
  11. Srivastava A, Tripathi S. *A few tips on online diagnostic tool*. An International Ayurvedic Workshop: Brief Overview of the Current Status of Ayurveda in the East & West 2009; 119-132.
  12. Tripathi RK, Tripathi S, Srivastava A. *Lavanya's holistic approach in the treatment of Cancer*. National Seminar: Brain Storming Session Integrated Therapeutic Approach in the Management of Cancer, 2011; 19.
  13. Smit, H.F., Woerdenbag, HJ., Singh, R.H. *et al*, Ayurvedic herbal drugs with possible cytostatic activity. *J Ethnopharmacol* 1995; 47: 75-84.
  14. Kapoor LD. *Handbook of ayurvedic medicinal plants*. Florida; CRC Press, 1990.
  15. Trivedi VP, Tripathi, Rajesh *et al*. *Proceedings of National Seminar on the Management of Cancer through Ayurveda*, Clinical evaluation of cancerostatic effects of Ayurvedic formulation Las 01 in cases of Cancer of gall bladder, 2012; 258-263.
  16. Shoba, G., Joy, D., Joseph, T. *et al*, Influence of piperine on the pharmacokinetics of Curcumin in animals and human volunteers. *Planta Med* 1998; 64: 353-356.
  17. Sheikh S, Srivastava A *et al*. *Proceedings of National Seminar on the Management of Cancer through Ayurveda*. Anti-cancerous Activity of a Novel herbo-mineral Preparation Las01 and its safety profile in human and animals, 2012; 136-143.
  18. Sheikh S, Srivastava A *et al*. *Proceedings of National Seminar on the Management of Cancer through Ayurveda*. In vitro Cancerous activity of Las01 a novel herbo-mineral Ayurvedic drug which inhibits proliferation and increase the apoptosis in MCF-7 and Hela cervical cancer cell-lines, 2012; 144-150.
  19. Fulda, S., Debatin, K.M., Sensitization for tumor necrosis factor-related apoptosis inducing ligand-induced apoptosis by the chemo preventive agent resveratrol. *Cancer Res* 2004; 64: 337-346.
  20. Sheikh S, Trivedi, VP, Singh US. *LAS01: An Ayurvedic Herbomineral Compound inhibits cell proliferation of human adenocarcinoma MCF-7 cell Line*. National Seminar: Brain Storming Session on Integrated Therapeutic Approach in the Management of Cancer, 2011; 17.
  21. Kasibhatata, S., Tseng, B., Why target apoptosis in Cancer treatment? *J Molecular Cancer therapeutics* 2003; 2: 573-580.
  22. Sharma A, Tripathi R, Trivedi VP. *Psychological management in cases of cancer*. National Seminar: Brain Storming Session on Integrated Therapeutic Approach in the Management of Cancer, 2011; 38.
  23. *WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance system*. World Health Organization, 2004.
  24. Balachandran, P., Govindarajan. R., Cancer-an Ayurvedic perspective. *Pharmacol Rec* 2005; 51: 19-30.
  25. Huang mt, M.T., Badmaev, V., Ding, Y., *et al*, Anti-tumor and anti-carcinogenic activities of triterpenoid, beta-boswellic acid. *Biofactors* 2000; 13: 225-230.
  26. Steinmetz, K.A., Potter, J.D., Vegetables, fruit and cancer prevention: A review. *J Am Diet Assoc* 1996; 96: 1027-1039.