

Management of Urinary Bladder Cancer with A Novel Herbomineral Drug

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Abstract

Urinary bladder cancer is fourth most common cancer in men hence it has ever been attracting the attention of medical field for search of a safe and effective treatment for recovery from it. As it induces a poor quality of life (QOL) despite aggressive treatment with radical cystectomy, primary Transitional Cell Carcinoma (TCC) of bladder is relatively common tumor with a risk of its recurrence. As the W.H.O. has been advocating for search of newer modalities for the treatment of TCC, an Ayurvedic coded herbo-mineral formulation (LAS01) was evaluated in such cases so as to find out a safe, effective and indigenous treatment.

Keywords: Urinary bladder cancer; Quality of life, Transitional cell carcinoma, Herbo-mineral treatment.

Introduction

In men, Urinary bladder cancer is the fourth most common cancer after prostate, lungs, colorectal malignancy accounting for 6.2% of all cancer cases. In women it is the eighth most common cancer accounting for 2.5% of all cancer cases. Bladder cancer is the second most common urological malignancy after prostate cancer in males¹. Primary transitional cell carcinoma (TCC) of the bladder is relatively a common tumor with a risk of recurrence² despite aggressive treatment with radical cystectomy and patients have a poor quality of life (QOL)³. Further surgical removal of the entire tumor is rarely possible⁴. As such the need for a newer modality of treatment in such cases of malignancies has been advocated by WHO⁵. Therefore, in the present study, effect

of a novel herbo-mineral (Ras-rasayan) Las01 has been evaluated in cases of cancer of urinary bladder.

Selection of Cases

Eighteen terminal cases of pre-diagnosed Transitional Cell Carcinoma of Urinary bladder of either sex aged 50-70 presented themselves to the OPD of Lavanya Hospital, Lucknow to seek Ayurvedic treatment as a last resort after being rejected by the modern Oncologist and Surgeons during a period of seven months (Between 17.05.10 to 22.01.11). However, only 6 patients could afford to Ayurvedic treatment with LAS01 out of 18 and 12 patients dropped out either due to their financial constraints or their terminal stages or other reasons. Average treatment taken by remaining six cases ranged for 2 months to 5 months and 20 days i.e. for an average period of 3 months. LAS01 (a coded herbo-mineral drug) was prepared as per ancient Ayurvedic literature, Ayurvedic Pharmacopoeia of India (API) which contained various elements viz metallic substances like Gold, Iron, Bronze, Silver, Mercury and Non metallic substances like Arsenic, Sulphur, Mica, Diamond and

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(Received on 18.11.2012, accepted on 12.01.2013)

Pearl in addition to large number of herbs which were used to purify these substances as described in ancient literature. There has been no conflict of interest. After clearance from the Institutional Ethical Committee (I.E.C.) of our hospital, drug was administered to all 6 patients in doses of 20 mg/kg. in two divided doses of 0.5 g. a day for an average period of 3 months.

The efficacy of the drug under test was assessed by the symptomatic relief and radiological improvements whereas its safety was judged by various haematological as well as biochemical parameters.

The results were analyzed statistically by using student's 't' test to find out the statistical significance of the results.

Results

Table one shows the age and the sex distribution of all 18 patients who were examined in OPD which indicates that commonest age of patients was more than 50 years. Maximum number of cases belonged to the group aged between 61 years to 70 years. The Table also shows that Cancer of Urinary bladder is more commonly encountered in male patients as compared to female patients in the ratio of 8:1.

Perusal of table II shows that Urinary bladder Cancer is more common in Socio-economically weaker section of the society viz. in lower and middle income groups of patients belonging to agriculture and service class group having an average education up to 10th class.

Table I: Table showing classification according to Age and Sex

Age group in years	Male	Female	Total
0-50	0	0	0
51-60	6	2	8
61-70	10	0	10
Total	16	2	18

Table II: Classification according to Literacy scale, Socio-economic Condition and Occupation

Literacy scale	Socio-economic	Occupation	Status
Illiterate	2	EWS 00	House wife 02
Up to primary	2	LIG 14	Agriculture 02
Up to 10 th	12	MIG 04	In service 10
Up to 12 th	2	HIG 00	Retired 04
Total	18	18	18

Table III shows the percent reduction scores of the symptoms in remaining 6 cases who continued treatment from average period of 3 months with LAS01. The table indicates significant reduction in microscopic as well as frank haematuria, frequency of micturition, burning and dysuria and associated pain in the lower abdomen. However, appetite and constipation like symptoms were not much affected.

Perusal of table VI shows that all cases were suffering from transitional cell carcinoma on the left side of Urinary bladder (U.B.) with secondaries in case no. 5 and 8 indicating Carcinostatic effect of LAS01 was also seen in case no. 1-4 with post treatment showed that LAS01 as a symptomatic improvement except in case no. 9.

Discussion

The cases belonged to the age group of 50-70 yrs. where maximum incidence of transitional cell carcinoma has been reported with male predominance⁶ and incidence of such cases is 7%³. It is 4th most common cause of malignancy in western European male population⁷.

Such tumors are more prone to develop metastasis and are not diagnosed at an early stage with available diagnostic tools hence chemotherapy is given normally to such cases following cystectomy to improve treatment efficacy⁸ and such transitional cell carcinoma arising from urine proof urothelium⁹ of bladder have an aggressive behavior³ as was

Table III: Shows the percent reduction scores of the symptoms

Subjective Parameters	Mean values of percent scores along with SD on admission treated earlier with modern Chemotherapy and Radiation therapy	Mean values \pm SD after treatment with Las 01
Haematuria	40.00 \pm 13.69	15.00 \pm 13.69*
Blood Traces in Urine	35.00 \pm 12.91	7.500 \pm 12.08*
Urinary Frequency	45.00 \pm 11.18	10.00 \pm 13.69*
Pain in Lower Abdomen	41.67 \pm 14.43	16.67 \pm 14.43*
Burning & Discomfort During Urination	45.83 \pm 10.21	20.83 \pm 18.82*
Loss of Appetite	16.67 \pm 20.41	37.50 \pm 20.92
Constipation	21.43 \pm 17.26	21.43 \pm 26.73

Table IV: Shows no alteration in hematological and biochemical parameters after treatment with LAS01 as compared to the values on admission

Objective Parameters (Biochemical Data)	Mean values \pm SD before treatment with Las01 and after treatment with modern Chemotherapy and Radiation therapy	Mean values \pm SD after treatment with Las 01
Serum Billirubin	1.045 \pm 0.4031	1.035 \pm 0.1626
S,G.O.T.	36.32 \pm 15.48	50.00 \pm 13.11
S.G.P.T.	48.20 \pm 22.94	58.33 \pm 15.63
S. Alkaline Phosphatase	128.0 \pm 26.87	203.5 \pm 18.17
S. Creatinine	1.110 \pm 0.1609	1.100 \pm 0.2828
S. Uric Acid	5.533 \pm 0.4041	5.467 \pm 0.3512
Blood Urea	30.13 \pm 0.9713	29.33 \pm 2.706
Total Protein	7.367 \pm 0.2887	5.600 \pm 3.822

seen in all six cases in the present study on admission in our hospital.

Mean disease free survival rate have been reported to be 69 months³ and despite radical surgical treatment in a follow up period of 32

months, there was recurrence in 40% and 21% died as reported by Antumes *et al*³, however these patients despite recurrence and rejection by modern urologists & radiologists, patients are still surviving after treatment with our

Table V shows no alteration in hematological and biochemical parameters after treatment with LAS01 as compared to the values on admission

Objective Parameters	Mean values \pm SD before treatment with Las01 on admission but after treatment with modern Chemotherapy and Radiation therapy	Mean values \pm SD after treatment with Las01
HAEMATOLOGICAL DATA		
Total Leucocyte Count	9880 \pm 4459	10480 \pm 2737
Platelet Count	255000 \pm 128550	240000 \pm 53385
Haemoglobin	10.57 \pm 3.782	10.20 \pm 3.180
DLC Poly.	72.00 \pm 5.244	74.20 \pm 12.13
DLC Lympho.	23.60 \pm 5.899	22.20 \pm 9.497
DLC Eosino.	2.200 \pm 1.304	2.600 \pm 1.949
DLC Mono	2.333 \pm 0.5774	1.667 \pm 0.5774

novel Herbomineral Las01. Antumes³ has reported 53% recurrence despite Chemotherapy³.

However in our present study radiologically size of the Cancerous mass did not grow further and there was a definite symptomatic relief in all cases improving their Quality of Life (QOL). It appears that actively proliferating cancerous mass is converted to an inactive inert mass. We have also shown in-vitro studies on cell-lines that naturally occurring phenomenon in healthy state is time bound programme cell death i.e. apoptosis, abnormally occurring phenomenon in enhanced with LAS01 whereas which is proliferation of Cancer cells was significantly reduced in a dose dependent manner with anti-cancerous LAS01 coded compound^{15,16}.

Bladder cancer appears to be multifactorial in origin¹⁰ such as environmental factors; occupational hazards cigarette smoking, anatomic congenital abnormalities, urinary tract abnormalities and chronic infections, tryptophan metabolism, pelvic radiations and geographical factors, nitrosamine, metabolite of several chemicals artificial sweeteners like cyclamate and saccharine, anticancer alkylating agents and parasitic infections like schistosomiasis.^{10, 11, 12, 13}. However, in our small

series of cases none of these etiological factors could be correlated but maximum number of cases belonged to lower and middle socioeconomic group of male patients as well as in patient who were more than 50 years of age as compared to females an observation supported by many workers¹⁴. Our preliminary observations in otherwise incurable transitional cell carcinoma of Urinary bladder do indicate carcinostatic activity giving symptomatic relief to the patients with LAS01 without any side effect and without any flare of secondaries. We have also earlier reported its carcino-static effects in cases of Gall bladder¹⁷, Brainstem Glioma¹⁸ as well as in a single case of Cancer of Urinary bladder¹⁹ which warrants further comparative clinical trials with LAS01 vis-a-vis using modern modalities of treatment?

Conclusion

Invasive and metastatic bladder cancer remains a persistent clinical and scientific challenge for urologist. Even in modern system of medicine for bladder cancer, multi drug therapy has been shown to have a greater activity than single agent¹. Thus the test drug

which is a mineral based poly herbo-mineral therapy Las01 chosen for these patients of grade 3 (T3) was employed in this study. Over 60% of patients have one or more recurrence after initial treatment with modern therapy¹⁴ which has actually happened in our cases and also prevention of recurrence is needed in such type of cancer cases. All six cases included in the study not only showed symptomatic improvement in their clinical condition and in their quality of life (QOL) but also exhibited no recurrence of growth radio logically. In view of its Carcinostatic activity and safety of LAS01, large scale clinical trial is warranted with Las01 in such cases suffering from Urinary bladder carcinoma.

Acknowledgement

Authors are highly thankful to Dr. Shalini Tripathi, Dr. Sujeet Jaiswal and Ms. Saba Sheikh for their contribution in analyzing the data and in finalizing the manuscript. Authors are also thankful to a team of doctors, nurses and other paramedical staff for helping in patients' management. Guidance from Members of IEC is also thankfully acknowledged.

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