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Original Research Article

Comparison of two palliative regimens of radiation on the quality of life in metastatic non small cell lung cancer

Tarun J. Singh[1]*, Gurpreet K. Taggar[2], Vikas Fotedar[3], Manish Gupta[3], Siddharth Vats[3]

[1]Department of Radiotherapy and Oncology, Dr. Y. S. Parmar Medical College, Nahan, Sirmour, Himachal Pradesh, India
[2]Department of Immunohematology and Blood Transfusion, [3]Department of Radiotherapy and Oncology, Indira Gandhi Medical College and Hospital, Shimla, Himachal Pradesh, India

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***Correspondence:**
Dr. Tarun J. Singh,
E-mail: tarunjotkhalsa@yahoo.com

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ABSTRACT

Background: Lung cancer is one of the most common cancers in males worldwide and its number is increasing every year. Of these cases 75-80% case are of non-small cell type.
Methods: This study was conducted on 30 patients of stage IV non-small cell lung cancer in the department of radiation oncology at tertiary care center, Shimla, Himachal Pradesh India from 1st Jun 2019 to 30th Jun 2020 by dividing them into study and control arm for assessing quality of life (QOL) with EORTC QLQ-C30 version3.0.
Results: We observed significant improvement in Global health scale of control arm (p=0.005) but it got worse in study arm (p=0.743). All the parameters of Functional scale i.e. Physical (p=0.584; 0.170), Role (p=0.213; 0.016), Emotional (p=0.239; 0.002), Cognitive (p=0.793; 0.247) and Social functioning (p=0.030; 0.231) got worse in study arm while they improved in control arm. As far as Symptom scale is concerned, in the study arm; dyspnea (p=0.724), appetite (p=0.836), constipation (0.192), diarrhea (p=0.341) improved but other symptoms like fatigue (p=0.566), nausea (p=0.347), pain (p=0.305), insomnia (p=0.025), financial difficulties (p=0.082) got worse while in control arm; fatigue (p=0.003), pain (p=0.000), dyspnea (p=0.022), insomnia (p=0.336), appetite (p=0.028), constipation (0.019), diarrhea (p=0.336), financial difficulties (p=0.336) improved and nausea (p=0.120) got worse.
Conclusion: QOL assessment by the physician before commencement of the treatment and later on at every visit seems to be beneficial for symptom relief and to allay the anxiety of both patient and their attendants.

Keywords: Lung cancer, Stage IV NSCLC, Quality of life, EORTC-QLQ C30, Locally advanced lung cancer, Metastatic lung cancer

INTRODUCTION

Lung cancer constitutes 13% of all cancers worldwide. It is the most common cancer in the world with 20,938,676 new cases and 1,761,007 deaths. In males, the incidence of lung cancer is the highest amongst all cancers constituting 16.7% of all cancers and mortality is 23.6% of all cancer deaths. In females, incidence rates are generally lower. In India, incidence in male has increased and it is now the most common cancer along with oral cancers (11.3% of all cancer cases) and causes 13.7% of cancer deaths in Indian males. In Indian females' incidence is 3.1% of all cancers.[1] In Regional Cancer Centre, Shimla, lung cancer is the single most common malignancy registered in males. Non-small cell lung cancer is the most common histological subtype constituting about 75-80% of lung cancer.[2] It Includes squamous cell cancer, adeno-carcinoma and large cell carcinoma. These are grouped as non-small cell lung

cancer (NSCLC) because of similarities in presentation, natural history and treatment. In patients with NSCLC, the most important prognostic factor is tumor stage. More than two thirds of patients will present with stage III or IV disease. A majority of these patients will have symptoms from primary tumor, including dyspnea, cough and hemoptysis. Thoracic radiotherapy is an effective treatment modality in relieving such symptoms.[3-5] According to the world health organization health has been defined as absence of disease along with physical, social and mental wellbeing. This led to alternative approaches to measure health like the analysis of the patient's quality of life (QOL) particularly who has been diagnosed with cancer.[6] This is an emerging science of particular relevance to clinical cancer research as it includes physical health and symptoms, functional status and activities of daily living, mental wellbeing and social health including social role functioning.[7] It is an important outcome of the disease and its treatment as well.[8, 9]

Experts have developed standard questionnaires for a more accurate evaluation of the wellbeing of individuals or groups of patients and of the benefits and side-effects that may result from medical intervention.[10] It also helps the physician plan appropriate treatment strategies and set practical therapeutic goals.[11] Even when palliative chemotherapy does not prolong survival in these patients, it can significantly ameliorate symptoms leading to improvements in QOL.[12] Both chemotherapy and radiation have an important role in the palliative treatment of advanced NSCLC patients. Among the instruments for measuring QOL, there are some specifically developed for lung cancer, such as functional assessment of cancer therapy-lung questionnaire, the lung cancer symptom Scale and the European Organization for Research and Treatment of Cancer lung cancer module-30 (EORTC-QLQ C30 version3).0questionnaire.

The feasibility, reliability and validity of the EORTC questionnaire have been shown in studies of patients with lung cancer.[13-15] In Metastatic, and advanced NSCLC higher radiation doses administered with conventional fractionation achieve better results in terms of local control and survival. The rate of palliation of local symptoms is high, being 60-80% for chest pain and hemoptysis, while breathlessness and cough are controlled at a somewhat lower rate (50-70%). General symptoms (fatigue, anorexia, and depression) are affected in a minority of patients. Tertiary cancer care center, IGMC Shimla is one of the best centers in the whole state for diagnosis and treatment of cancer. Majority of the patients are poor and belong to rural areas, so the cost of traveling and staying in the city is both unbearable and uncomfortable for them. Considering these facts and poor survival of patients, our department proposed a study in the patients of metastatic NSCLC with following objectives; to assess QOL before and after two different regimens of palliative radiation therapy and to check survival benefits separately after two different regimens of palliative radiation therapy.

METHODS

This prospective study was conducted in the department of radiation oncology, tertiary cancer care centre, Indira Gandhi medical college and hospital, Shimla, Himachal Pradesh, India from 1 July 2019 to 30 June 2020.

Study design

After approval by the institutional ethical committee study was conducted on 30 patients of both genders in the age group ≥ 18 years with confirmed diagnosis of Stage IV NSCLC (AJCC 8th edition) having less than 6 Metastasis sites and Karnofsky performance status (KPS) ≥70. We excluded patients with records of previous radiotherapy received to thorax, brain metastasis and SVC syndrome. We divided 30 patients equally into control and study arm (15 patients each) using computer-generated random number written on sealed opaque envelopes in two groups for comparison. Chemotherapy (CCT): Injection Paclitaxel-175 mg/m2+Injection Carboplatin (AUC 5) every 21 day. In case of progressive disease, chemotherapy regimens were changed accordingly. External beam radiation therapy (RT) was delivered by teletherapy theratron 780e and Equinox Cobalt-60 machines while immobilizing using vacculoc or custom-made thermoplastic cast.

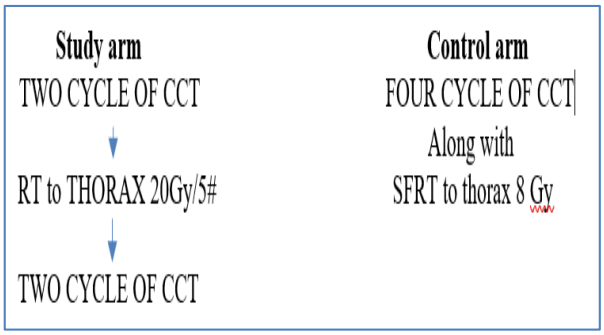

Figure 1: Study design.

Duration of treatment

Planned duration was 12 to 16 weeks for both arms. Treatment was withheld/delayed for 1 week if the patient had a total leukocyte count less than 4000/mm^3 and/or any other unmanageable toxicity.

Assessment of disease status and toxicity

CECT chest was done before commencement of treatment and at first follow up (6 weeks) post treatment. Disease response was assessed with chest radiographs every 3 weeks. Performance status was evaluated using the Karnofsky scale. QOL was evaluated using European Organization for Research and Treatment of Cancer QLQ C30 version.

Statistical analysis

QOL and survival were the primary end points for analysis. The data obtained was analyzed using the student "t" test and Chi-square test, p value of <0.05 was considered significant.

RESULTS

In our study, majority of patients was in the age group of 60-70 years. In the control arm, there were 2 females and 13 males; while in study arm, all patients were male. Only one patient in the study arm was non-smoker rest all patients in both arms were smokers. There was no other type of addiction found in our patients. When we compared prognostic factors in both the arm they seem to be balanced as shown in (Table 1).

Table 1: Comparison of prognostic factors in the two arms.

Prognostic Factors	Control Arm	Study Arm
Mean age (Overall=61 years)	60.77±7.243 (range 48-71 years)	60.20±8.312 (range 46-76 years)
Males:females	13:2	15:0
Smokers:non smokers	14:1	15:0
SCC:Adenocarcinoma	10:5	11:4
KPS	≥70	≥70

The distribution across the arms with regard to histology was homogenous as shown in (Table 2).

Table 2: Histology wise distribution of patients between the two arms.

Parameters		Group				Total	P value
		Study	%age	Control	% age		
ADENO CA	Adeno CA	4	44.4	5	55.5	9	
SCC	M/D Sq cell CA	7	77.8	2	22.2	9	0.067 (NS)
	P/D Sq cell CA	2	50	2	50	4	
	W/D Sq cell CA	2	25	6	75	8	

Table 3: Results of global health status in study arm.

GHS	Paired differences					T value	df	P value	Result
	Mean	SD	SEM	95% CI					
				Lower	Upper				
	3.000	29.492	8.892	16.813	22.813	0.337	10	0.743	Not significant

Table 4: Results of functional scale in study arm.

Parameters	Paired differences					T value	df	P value	Result
	Mean	SD	SEM	95% CI					
				Lower	Upper				
PF2	4.182	24.515	7.391	-12.287	20.651	0.566	10	0.584	NS
RF2	7.455	18.592	5.606	-5.036	19.945	1.330	10	0.213	NS
EF	7.636	20.225	6.098	-5.951	21.224	1.252	10	0.239	NS
CF	2.182	26.791	8.078	-15.817	20.180	0.270	10	0.793	NS
SF	25.909	33.872	10.213	3.154	48.664	2.537	10	0.030	Significant

In the control arm; out of 15 patients, there were 10 patients (2, 2, 6 moderately, poorly, well differentiated respectively) of squamous histology, 5 patients had adenocarcinoma histology. In the study arm, out of 15 patients there were 11 (7, 2, 2 moderately, poorly, well differentiated respectively) had squamous and 4 had adenocarcinoma histology.

Disease response

In patients with squamous cell carcinoma- No one had complete response in control arm as well as study arm; partial response in 7 patients in control arm and 6 in study arm; stable disease in 2 patients in control arm and one in study; 1 patient each in study and control arm had progressive disease.cIn patients with adeno-carcinoma histology- No one had complete response in study arm but it was observed in one patient in control arm; partial response was seen in 3 patients in control arm and 2 in study arm; stable disease in none of the patient in control arm and one in study arm; no patient shown progressive disease in either study or control arm in this subset. Overall disease response (complete+partial) rates when compare between study and control arm results were significant

with p value of 0.04. Survival benefit: Four patients (26.7%) in the study arm died during the treatment while mortality rate in the control arm was 6.67% with the death of only one patient. Results were insignificant with p value 0.33. Study arm Global health status (GHS): Mean of GHS was 3.00 while the p value came out to be 0.743 which means there was no significant improvement in the general health status of the patient post treatment in the study arm shown in (Table 3).

Table 5: Results of symptom scale in study arm.

Parameters	Paired differences					T value	df	P value	Result
	Mean	SD	SEM	95% CI					
				Lower	Upper				
FA	-6.727	37.556	11.323	-31.957	18.503	-0.594	10	0.566	NS
NV	-13.818	46.465	14.010	-45.034	17.397	-0.986	10	0.347	NS
PA	-12.091	37.109	11.189	-37.021	12.839	-1.081	10	0.305	NS
DY	3.000	27.430	8.270	-15.428	21.428	0.363	10	0.724	NS
SL	-18.000	22.689	6.841	-33.243	-2.757	-2.631	10	0.025	NS
AP	2.909	45.531	13.728	-27.679	33.497	0.212	10	0.836	NS
CO	9.000	21.340	6.434	-5.336	23.336	1.399	10	0.192	NS
DI	3.000	9.950	3.000	-3.684	9.684	1.000	10	0.341	NS
FI	-9.000	15.414	4.648	-19.355	1.355	-1.936	10	0.082	NS

FA-Fatigue, NV-Nausea and Vomiting, PA-Pain, DY-Dyspnoea, SL-Insomnia, AP-Appetite loss, CO-Constipation, DI-Diarrhoea, FI-Financial difficulties.

Table 6: Results of global health status in control arm.

GHS	Paired differences					T value	df	P value	Result
	Mean	SD	SEM	95% CI					
				Lower	Upper				
	-17.071	19.044	5.090	-28.067	-6.076	-3.354	13	0.005	HS

Table 7: Results of functional scale in control arm.

Parameters	Paired differences					T value	df	P value	Result
	Mean	SD	SEM	95% CI					
				Lower	Upper				
PF2	-10.786	27.752	7.417	-26.809	5.238	-1.454	13	0.170	NS
RF2	-19.929	26.817	7.167	-35.412	-4.445	-2.781	13	0.016	Significant
EF	-17.786	17.546	4.689	-27.917	-7.655	-3.793	13	0.002	HS
CF	-5.571	17.203	4.598	-15.504	4.362	-1.212	13	0.247	NS
SF	-6.143	18.296	4.890	-16.707	4.421	-1.256	13	0.231	NS

PF-Physical Functioning, RF-Role Functioning, EF-Emotional Functioning, CF-Cognitive Functioning, SF-Social Functioning, HS-highly significant.

Functional scale

We found that only social functioning scale showed significant results (p=0.030) which means patient experienced improvement in their overall health during treatment. Other parameters of functional scales i.e., physical, role, emotional, cognitive functioning did not show any significant result showing that patient felt anxious/depressed, encountered difficulties doing their normal day to day activities which in turn interfered with family and social life. (Table 4).

Symptom scale

All the symptoms on symptom scale got worse as the treatment progressed except that patients were able to sleep better at night (p value=0.025) (Table 5).

Control arm global health status

Mean of GHS was -17.071 with the p value of 0.005 which shows significant improvement in the general quality of the patient post treatment in the control arm (Table 6).

Table 8: Results of symptom scale in control arm.

Parameters	Paired differences					T value	df	P value	Result
	Mean	SD	SEM	95% CI					
				Lower	Upper				
FA	15.071	15.395	4.114	6.183	23.960	3.663	13	0.003	HS
NV	-8.071	18.142	4.849	-18.547	2.404	-1.665	13	0.120	NS
PA	27.429	15.336	4.099	18.574	36.283	6.692	13	0.000	HS
DY	21.214	30.650	8.192	3.518	38.911	2.590	13	0.022	Significant
SL	7.071	26.459	7.071	-8.205	22.348	1.000	13	0.336	NS
AP	14.143	21.325	5.699	1.830	26.455	2.482	13	0.028	Significant
CO	11.786	16.409	4.386	2.311	21.260	2.687	13	0.019	Significant
DI	2.357	8.820	2.357	-2.735	7.449	1.000	13	0.336	NS
FI	4.714	17.639	4.714	-5.470	14.899	1.000	13	0.336	NS

FA-Fatigue, NV-Nausea & Vomiting, PA-Pain, DY-Dyspnoea, SL-Insomnia, AP-Appetite loss, CO-Constipation, DI- Diarrhoea, FI-Financial difficulties.

Functional scale

Role functioning and emotional functioning of the patient improved post treatment showing significant results (p value=0.016 and .002 respectively) which means patients felt that the present situation no longer hampered their work and that they were able to pursue their hobbies or other leisure activities comfortably. Other parameters of functional scales i.e., physical, cognitive and social functioning did not show any significant result showing that patient had a hard time concentrating as well as remembering things, encountered difficulties doing their normal day to day activities which in turn interfered with family and social life (Table 7).

Symptom scale

Few symptoms like fatigue, pain, dyspnea, loss of appetite, constipation improved post treatment showing significant results while others like nausea and vomiting, insomnia, diarrhea, financial difficulties got worse as the treatment progressed. Thus, patient showed symptomatic improvement in the control arm as compared to study arm (Table 8).

DISCUSSION

In the present study, majority of patients were in the age group of 60-70 years similarly reported by a German study. A study by Kirmani et al found it to be highest (33.6%) in 51-60 years of age group and 28.9% between 61-70 years. In a study from UK and study (USA)by Rocha et al the overall mean age was found to be 71(Range 31-95) and 70.1±10.9 years respectively.[16,17] Lung cancer remains predominantly a disease of males in India, with a male to female ratio of 6.7**:**1.5 (from 1958-1985) and 5.7**:**1(from 1986-2001). In another study from Kashmir it was found to be 6.1**:**1.[18] In our study we found that males were predominantly affected (80.2%) giving a ratio of 4**:**1. Present study divided patients into control and study arm while comparing GHS, functional scale, and symptom scale. All the other authors looked-for above-mentioned scales in their study groups without any division of control and study arm. We found significant improvement in Global health scale in control arm (p =0.005) but it got worsened in study arm (p=0.743). All the parameters of Functional scale i.e., Physical (p=0.584; 0.170), Role (p=0.213; 0.016), emotional (p=0.239; 0.002), cognitive (p=0.793; 0.247) and social functioning (p=0.030; 0.231) got worse in study arm while they improved in control arm respectively. Bergman et al found a significant decline in the social functioning and improvement in the emotional functioning.[19] Montazeri et al observed that patients functioning and global quality of life had decreased.[20] A study by Langendijk et al saw a significant decline in physical, role and social functioning.[21] Arraras et al and Mohan et al saw no difference in the global QOL at the end of treatment.[22, 23] Maric D observed a significant better global QOL (p=0.043), social (p=0.001), emotional (p=0.001) and cognitive functioning (p=0.011).[24] Jiancun et al found decreased scores for all functioning scales, except for cognitive functioning, which increased.[25] A study in USA found a significant decline in the physical and emotional role functioning at follow up. On the contrary Aaronson et al found a significant improvement in the global QOL, physical and role functioning. The scores of physical, emotional, role, cognitive and social functioning also did not change significantly at follow up.[26] The reason could be that the patients were on treatment and this may have prevented the worsening in these areas. In our study, in study arm dyspnea (p=0.724), appetite (p=0.836), constipation (0.192), diarrhea (p=0.341) improved over the course of treatment but the results were not statistically significant. Other symptoms fatigue (p=0.566), nausea (p=0.347), pain (p=0.305), insomnia (p=0.025), financial difficulties (p=0.082) got worse over time. In control arm we found out that fatigue (p=0.003), pain (p=0.000), dyspnea (p=0.022), insomnia (p=0.336), appetite (p=0.028), constipation (0.019), diarrhea (p=0.336), financial difficulties (p=0.336) improved during our study period while nausea (p=0.120) got worse over time. Avelino et al in their study compared

symptom scores in each cycle of chemotherapy. There were significant differences in pain scores between the 1st and 2nd cycles of chemotherapy (p=0.027), as well as in the scores for loss of appetite between the 1st and 2nd cycles (p=0.037) and between the 1st and 4th cycles (p=0.026). There was a large change in the scores for constipation between the 1st and 4th cycles of chemotherapy. There were moderate changes in the scores for fatigue, insomnia, and financial difficulties between the 1st and 4th cycles of chemotherapy. These changes suggest an improvement in all of the aforementioned HR, QOL aspects except insomnia, which was reported more frequently in the 4th cycle of chemotherapy.[27] Bergman et al found that fatigue decreased significantly over time.[19] Akin et al found that appetite of the patients had decreased significantly after treatment. These results show that nausea and vomiting, which is the most prominent side effect of chemotherapy, had increased, along with increase in other side effect like appetite and sleep disturbances. On the other hand, there was improvement in symptoms scales of dyspnea which shows the response to chemotherapy.[25,28] Langendijk et al documented excellent palliation of hemoptysis (79%) and good palliation of pain in the arm/ shoulder (52%), chest pain (60%), and cough (48%). Palliation of dyspnea (36%) was less satisfactory. They concluded, conventional thoracic radiotherapy offers palliation of respiratory symptoms and improvement in QOL, in a substantial proportion of patients with locally advanced and metastatic NSCLC.[21] The findings suggest that patient centered variables should receive sufficient consideration in the treatment of lung cancer. The study results clearly indicate that information on quality of life contributes to our understanding of patients' experience of their cancer treatment. In these patients, palliative treatment may have played a stabilizing role. Emotional distress and coping capacity influence QOL and might be targets for intervention in palliative care.

Limitations

Current study is limited in a manner that we had a smaller sample size and also as survival benefit in stage IV NSCLC patients is poor, the follow up measurements of only 25 registered patients could be recorded rest 5 patients could not survive the treatment. Though, it seems that there is still scope for patient to lead a better quality of life even if the cancer in inoperable but lung cancer patients tend to under report their problems which make it challenging to fill up individual EORTC-QLQ-LC30 questionnaire and help them with their symptoms.

CONCLUSION

Since lung cancer patients tend to underreport their problems, the clinician should emphasize on routine assessment of problems related to symptoms in the patients. This should be integrated into clinical practice and further evaluated prospectively. Protocol should be made to assess QOL at the time of presentation and every visit for each individual as it can guide us further in patient's treatment. To address all the challenges involved with the care of stage IV NSCLC patients, a palliative care team can be formed at department level including doctor, nurse, a psychologist, a pain management specialist and a nutritionist.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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