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Comparative Study of Hypofractionated Palliative Radiotherapy 17 Gy in 2 Fractions vs. 30 Gy in 10 Fractions in Lethal Locally Advanced Non-small Cell Lung Cancer

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Abstract: *Background*: Lung cancer kills the most people worldwide. Most Bangladeshi patients had regionally advanced surgically inoperable Non-Small Cell Lung Cancer (NSCLC), a deadly disease. Radiotherapy to main tumor and regional lymphatics with chemotherapy is conventional treatment. *Objective*: This study was done to investigate the symptoms relief and treatment related toxicities in hypo fractionated 17 Gy in 2 fractions which is effectively comparable to 30 Gy in 10 fractions. *Methods*: A total 60 patients were divided equally into Arm A and Arm B with locally advanced stage IIIA, and stage IIIB NSCLC patients with the objective to compare palliation of symptoms and to assess the toxicity profile. This Quasi Experimental study was carried out from January 2018 to December 2018 in the department of Radiation oncology, National Institute of Cancer Research and Hospital. Cases of Arm A were treated with 17 Gy radiotherapy in 2 fractions and those of Arm B were treated with 30 Gy radiotherapy in 10 fractions. *Results*: The mean age was 49.3±8.8 and 52.2±8.1 years for the Arm- A and the Arm-B respectively. Most patients in both groups were males, 80% in group A and 90% in group B. Adenocarcinoma (Arm A-70%, Arm B- 66.7%) was the most common pathological subtype in both groups, followed by Squamous cell carcinoma (30%, 33.3% respectively). This study showed that there was a significant palliation of these symptoms following radiotherapy as reported by patients and as assessed clinically with no statistically significant difference between two Arms. Hemoptysis had the highest rate of improvement, 100% in both arms and improvement in chest pain by 83.3% in arm A and 70% in Arm B. Cough was improved in 83.3% and 67.7% and dyspnea was palliated in 80.0% and 70.0% of patients in Arm A and Arm B, respectively as per clinical assessment of the patients. The early toxicities in both arms had no significant difference. Patients with locally advanced inoperable NSCLC have poor prognosis and less survival. The first goal was acceptable symptoms control as cough, dyspnoea, haemoptysis and chest pain. *Conclusion*: The result of this study showed that a significant palliation of symptoms with minimum toxicities improving quality of life following radiotherapy as reported by patients also assessed clinically and radiographically with no statistically significant difference among both arms.

Keywords: Hypofractionated Palliative Radiotherapy, Lung Cancer, Toxicities

1. Introduction

Globally, cancer is the leading cause of mortality. The global cancer burden is expected to increase to 18.1 million new cases and 9.6 million deaths in 2018. Lung cancer is the most common type of cancer, accounting for 2.09 million new cases and 1.76 million cancer-related deaths annually [1].

The two most common kinds of lung cancer are Non-Small Cell Lung Cancer and Small Cell Lung Cancer. NSCLC accounts for 75% to 80% of lung cancer incidences, while small cell lung cancer accounts for 15% of lung cancer instances [2].

The principal varieties of lung cancer include adenocarcinoma, squamous cell carcinoma, large cell carcinoma and small cell carcinoma. Approximately 58 percent of lung cancers were identified in poorer nations. Tobacco use is the most significant lung cancer risk factor. Environmental exposure to radon, asbestos, some metals like chromium, cadmium, and arsenic; certain organic compounds like PAH and nitrosamines; radiation exposure; coal smoke; and indoor pollutants from fuel burning are also significant concerns [3, 4]. As these risk variables are considerably changeable through smoking cessation and clean air programs, population-based preventative interventions ought to be able to reduce their incidence and resulting death [5, 6].

As elsewhere, lung cancer is the most prevalent cancer in Bangladesh [7]. According to a recent population-based cancer registry at the National Institute of Cancer Research and Hospital, 17.9% of all cancer patients treated in 2014 was diagnosed with lung cancer [8].

Greater risk exists for smokers compared to nonsmokers. The relationship between smoking and lung cancer is undeniable. About 85–90% of lung cancer patients are smokers. However, lung cancer can also occur in nonsmokers, showing that environmental tobacco smoke (ETS), environmental and home air pollution, work-related risk factors, radon exposure, and some viruses may influence the prevalence of lung cancer [9].

Additionally, despite the fact that less than 20% of smokers would get lung cancer in their lifetime, hereditary vulnerability may be a significant influence [10]. The lifetime chance of developing lung cancer is around 1 in 13 for males and 1 in 16 for women. These numbers include both smokers and nonsmoker [9].

Important in terms of pharmacological and prognostic consequences is the identification of the disease's stage. Essential to disease staging is determining the location and extent of primary and metastatic tumor involvement. The choice of therapy depends on the disease's stage and a combination of clinical and pathological parameters [3].

The majority of NSCLC patients have either locally advanced or metastatic disease. More than two-thirds of individuals will enter with a stage III or IV disease [3]. Patients at this advanced stage often exhibit dyspnea, chest pain, cough, and hemoptysis as their most noticeable symptoms.

Due to their dismal prognosis and short life expectancy, locally advanced, inoperable cancers with a low performance status are ineligible for curative radiation therapy (RT). Palliation is therefore the key therapy objective and concern for this group of individuals. These characteristics may be met by hypo fractionated RT employing a minimal number of large single fractions. Previous randomized trials favor hypofractionation, however some advice against it due to increased toxicity and/or lower survival.

The 5-year survival rate for the majority of patients with inoperable locally advanced NSCLC ranges from 3 to 7 percent [4]. The optimal treatment for locally advanced, inoperable Non-Small Cell Lung Cancer (NSCLC) depends on a variety of parameters, such as the disease's severity, the patient's age, the presence of concomitant risk factors, the patient's performance status (PS), and weight loss.

Patients with locally advanced, incurable, and poor PS non-small cell lung cancer are candidates for chest radiation therapy to treat pulmonary symptoms. The most common indications for thoracic radiation therapy (TRT) include dyspnea, cough, hemoptysis, and pain. These symptoms result from the tumor's obstruction and irritation of the normal intrathoracic structures [5]. Patients will have a significant decrease in hemoptysis, dyspnea, cough, and chest pain as a result of the success of palliative thoracic RT in lowering symptoms. Numerous studies have determined the optimal thoracic RT protocol for the palliation of locally advanced, inoperable Non-Small Cell Lung Cancer (NSCLC). Ideal treatment would permanently eradicate all symptoms, improve patient survival, and require little treatment time. Clearly, these objectives are not entirely realizable, but efforts should be made to maximize palliation and limit adverse effects. The most often used palliative radiotherapy regimen, 30 Gy in 10 doses over 2 weeks, 5 days per week, is a viable alternative for a patient desiring palliative radiotherapy for thoracic symptoms. A patient with strong PS may be treated with a longer fractionated regimen, while a patient with low PS may benefit from a shorter fractionated treatment, such as 17 Gys in two fractions of 8.5 Gys one week apart (days 1 and 8). This simple protocol will also be suitable for managing the hospital's overwhelming patient population.

This prospective study compares the symptomatic alleviation of dyspnea, cough, hemoptysis, and chest discomfort with the routinely used palliative radiation regimen of 30 Gys in 10 fractions over 2 weeks, 5 days per week versus a shorter regimen of 17 Gys in two fractions, 8.5 Gys each, one week apart (days 1 and 8). All surviving patients will be followed for a minimum of six months.

2. Objective

To investigate the symptoms relief and treatment related toxicities in hypo fractionated 17 Gy in 2 fractions which is effectively comparable to 30 Gy in 10 fractions.

3. Methods and Materials

This Quasi Experimental study was conducted at the

Department of radiation oncology, National institute of cancer research and hospital (NICRH), Mohakhali, Dhaka, Bangladesh from January 2018 to December 2018. A Total of 60 cases were selected. There were two arms (Arm A and Arm B). In each arm there were 30 cases. Patients with clinically, radiologically and histopathologically detected inoperable non-metastatic non-small cell lung cancer who were referred by different local or district level hospitals or general practitioners. Diagnosed and histopathologically proven cases of inoperable non-metastatic non-small cell lung cancer patients were selected randomly from the radiation oncology department of National institute of cancer research and hospital according to the inclusion and exclusion criteria of the study. Patients with clinically, radiologically and histopathologically detected inoperable non-metastatic non-small cell lung cancer who were referred by different local or district level hospitals or general practitioners.

3.1. Inclusion Criteria

1) Histopathologically proved NSCLC.
2) Locally advanced inoperable stage (stage IIIA & IIIB).

3.2. Exclusion Criteria

1) Patient age- below 25 and above 70.
2) UICC performance status score >3 (Please see appendix V).
3) Pregnant women.
4) Recurrent cases.
5) Prior radiotherapy to lung.

3.3. Data Collection and Analysis

Data were collected by face to face interview and review of admission registry, hospital indoor documents. The particulars of the patients and clinical data were recorded in a pre -designed data sheet. After collecting data, it was checked, coded manually and then enter into computer. Data analysis was done according to the objectives of the study by using Microsoft Excel software program. Statistical significance was taken at 0.05 probability level.

4. Results

The study included 60 patients of locally advanced inoperable lung cancer in two arms, 30 patients in each arm (Arm- A and Arm –B). They were divided into 3 age groups. The age distribution of patients is shown in table 1.

Table 1. *Age distribution of the study subjects (N=60).*

Age Group in years	Arm- A (N=30)		Arm- B (N=30)		P value
	N	%	N	%	
35-44	9	30.0	6	20	
45-54	12	40.0	12	40	
55-65	9	30.0	12	40	
Total	30	100.0	30	100.0	0.193ns
Mean ± SD	49.3±8.8		52.2±8.1		

Sex distribution of the studied patients is shown in figure 1. In arm-A, among 30 patients there were 24 (80%) male and 6 (20%) female. In arm-B, among 30 patients there were 27 (90%) male and 3 (10%) female. (Figure 1).

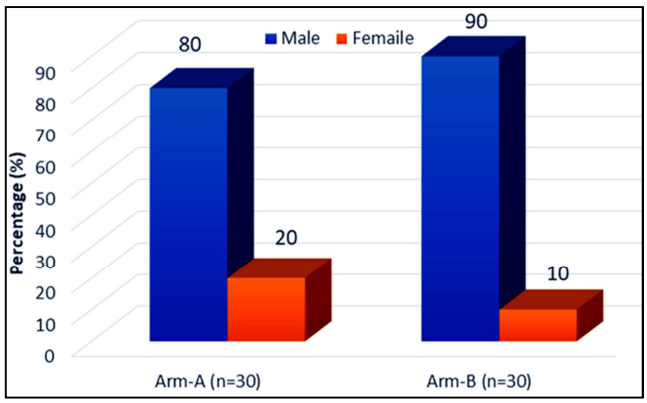

Figure 1. *Bar diagram showing the sex distribution of patients.*

Smoking status of studied patients is shown in table 2. Among the 30 patients in arm-A, 26 (85.00%) were smoker and 4 (15.00%) were non-smoker and in arm-B, among the 30 patients 24 (80.00%) were smoker and 6 (20.00%) were non-smoker with no significant statistical difference. (Table 2)

Table 2. *Association of smoking status between two groups (n=60).*

Smoking status	Arm- A (N=30)		Arm- B (N=30)		P value
	N	%	N	%	
Smoker	26	86.7	24	80.0	
Non-smoker	4	13.3	6	20.0	0.488ns
Total	30	100.0	30	100.0	

Staging status of study patients is shown Table 3. Among the 30 patients Arm A 20 (66.7%) were stage IIIA and 10 (33.3%) were stage IIIB and in Arm B 18 (60.0%) were stage IIIA and 12 (40.0%) were stage IIIB with no significant statistical difference. (Table 3)

Table 3. *Distribution of patients according to stage (n=60).*

Smoking status	Arm- A (N=30)		Arm- B (N=30)		P value
	N	%	N	%	
Stage IIIA	20	66.7	18	60.0	
Stage IIIB	10	33.3	12	40.0	0.592ns
Total	30	100.0	30	100.0	

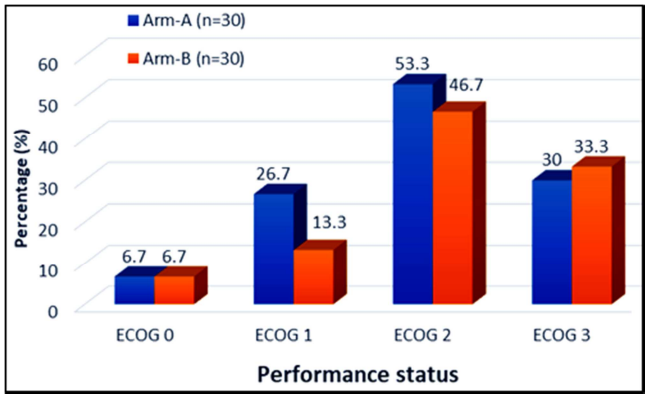

Figure 2. *Distribution of patients according to performance status.*

Performance status of the studied patients is shown in figure 2. Among 30 patients in arm-A, ECOG performance status 0 were 2 (6.7%), 1 were 8 (26.7%), 2 were 16 (53.3%), and 3 were 9 (30.0%). In arm-B, among 30 patients, ECOG performance status 0 were in 2 (6.7%), 1 were in 4 (13.3%), 2 were 14 (46.7%) and 3 were 10 (33.3%). (Figure 2)

Histology of the studied patients is shown in table 4. Among the 30 patients in arm-A, 21 (70.0%) patients had adenocarcinoma and 9 (30.0%) patients had squamous cell carcinoma. Among the 30 patients in arm-B, 20 (66.7%) had adenocarcinoma and 10 (33.3%) had squamous cell carcinoma (Table 4).

Table 4. *Distribution of patients according to histology (n=60).*

Histology	Arm- A (N=30)		Arm- B (N=30)		P value
	N	%	N	%	
Adenocarcinoma	21	70.0	20	66.7	
Squamous cell carcinoma	9	30.0	10	33.3	0.781ns
Total	30	100.0	30	100.0	

Distribution of patients according to presenting symptoms and signs and the responses after radiotherapy and comparison of symptomatic improvement before and after radiotherapy are shown in tables 5, 6 and 7.

Table 5. *Distribution of patients according to presenting symptoms and signs.*

Symptom and signs	Arm- A (N=30)		Arm- B (N=30)		P value
	N	%	N	%	
Cough					
Severe	10	33.3	9	30.0	0.193ns
Moderate	16	53.3	16	53.3	
Mild	4	13.3	5	16.7	
Dyspnea					
Severe	7	23.3	8	26.7	0.804ns
Moderate	16	53.3	17	56.7	
Mild	7	23.3	5	16.7	
Chest pain					
Severe	9	30.00	6	20.00	0.353ns
Moderate	14	46.7	12	40.00	
Mild	7	23.3	12	40.00	
Hemoptysis					
Present	9	30.00	10	33.33	0.804ns
Absent	21	70.00	20	66.67	

Table 6. *Response in after radiotherapy.*

Arms	Cough	Before RT	6 weeks after RT	12 weeks after RT	18 weeks after RT	24 weeks after RT
Arm-A	Severe cough	10 (33.3%)	0 (0%)	0 (0%)	--	--
	Moderate cough	16 (53.3%)	04 (13.3%)	0 (0%)	--	--
	Mild cough	04 (13.3%)	08 (26.7%)	04 (13.3%)	03 (10.0%)	04 (13.3%)
	None	--	18 (60.0%)	24 (80.0%)	25 (83.3%)	20 (66.7%)
Arm-B	Severe cough	09 (30.0%)	0 (0%)	0 (0%)	--	--
	Moderate cough	16 (53.3%)	7 (23.3%)	05 (16.7%)	03 (10%)	07 ((23.3%))
	Mild cough	05 (16.7%)	05 (16.7%)	02 (16.7%)	01 (3.3%)	03 (10%))
	None	--	18 (60.0%)	22 (73.3%)	25 (83.3%)	18 (60.0%)

Arms	Dyspone	Before RT	6 weeks after RT	12 weeks after RT	18 weeks after RT	24 weeks after RT
Arm-A	Severe dyspnoea	07 (23.3%)	0 (0%)	0 (0%)	--	--
	Moderate dyspnoea	16 (53.3%)	10 (33.3%)	0 (0%)	--	--
	Mild dyspnoea	07 (23.3%)	06 (20%)	05 (16.7%)	0 (0%)	05 (16.7%)
	None	--	14 (46.7%)	23 (76.7%)	27 (90.0%)	21 (70.0%)
Arm-B	Severe dyspnoea	08 (26.7%)	0 (0%)	0 (0%)	--	--
	Moderate dyspnoea	17 (56.7%)	15 (50%)	07 (23.3%)	02 (6.7%)	04 ((13.3%)
	Mild dyspnoea	05 (16.7%)	08 (26.7%)	03 (10%)	03 (10.0%)	03 (10.0%)
	None	--	07 (23.3%)	18 (60.0%)	22 (73.3%)	15 (55.0%)

Arms	Chest pain	Before RT	6 weeks after RT	12 weeks after RT	18 weeks after RT	24 weeks after RT
Arm-A	Severe chest pain	09 (30%)	0 (0.0%)	0 (0%)	--	--
	Moderate chest pain	14 (46.7%)	10 (33.3%)	03 (10%)	--	--
	Mild chest pain	07 (23.3%)	06 (20.0%)	05 (16.7%)	02 (6.7%)	05 (16.7%)
	No pain	--	14 (46.7%)	20 (66.7%)	26 (86.7%)	20 (66.7%)

Arms	Chest pain	Before RT	6 weeks after RT	12 weeks after RT	18 weeks after RT	24 weeks after RT
Arm-B	Severe chest pain	08 (26.7%)	0 (0%)	0 (0%)	--	--
	Moderate chest pain	12 (40.0%)	05 (16.7%)	05 (13.3%)	02 (6.7%)	04 ((13.3%)
	Mild chest pain	10 (33.3%)	10 (33.3%)	02 (6.7%)	05 (16.7%)	06 (20.0%)
	No pain	--	15 (50.0%)	16 (53.3%)	18 (60.0%)	16 (53.3%)

Table 7. *Comparison of symptomatic improvement before and after radiotherapy.*

Arms	Haemoptysis	Before RT	6 weeks after RT	12 weeks after RT	18 weeks after RT	24 weeks after RT
Arm-A	Haemoptysis present	09 (30%)	03 (10.0%)	01 (3.3%)	--	--
	Haemoptysis absent	21 (70%)	27 (90.0%)	26 (86.7%)	--	--
Arm-B	Haemoptysis present	10 (33.3%)	02 (6.7%)	0 (0.0%)	--	--
	Haemoptysis absent	20 (66.7%)	27 (90.0%)	26 (86.7%)	--	--

Symptoms and signs	Arm –A Number of patients		Arm-B Number of patients		*p*-value
	Before radiotherapy	After radiotherapy	Before radiotherapy	After radiotherapy	
Cough	30 (100.0%)	25 (83.3%)	30 (100.0%)	23 (76.7%)	
Dyspnoea	30 (100.0%)	24 (80.0%)	30 (100.0%)	21 (70.0%)	0.924^{ns}
Chest pain	30 (100.0%)	25 (83.3%)	30 (100.0%)	21 (70.0%)	
Haemoptysis	09 (30.0%)	30 (100.0%)	10 (33.3%)	30 (100.0%)	

According to RECIST. No significant differences were seen between the arms in regarding histology. Histology of the studied patients is shown in table 8 are compared in relation with treatment response.

Table 8. *Distribution of patients according to histology in relation with response.*

Histology	Arm-A (n=30)		Arm-B (n=30)		*p*-value
	No.	%	No.	%	
Adenocarcinoma	21		20		
Complete response	01	4.8	01	5.0	
Partial response	17	81.0	15	75.0	0.885^{ns}
Progressive disease	03	14.2	04	20.0	
Squamous cell carcinoma	9		10		
Complete response	01	11.1	01	10.0	
Partial response	06	66.7	07	70.0	0.987^{ns}
Progressive disease	02	22.2	02	20.0	

Treatment related hematological and non-hematological early toxicities of the studied patients were described in table 9. Dysphagia, nausea, vomiting, mucositis, anaemia, leucopenia and lethargy were most common early toxicities.

Table 9. *Treatment related hematological and non-hematological early toxicities of the studied patients.*

Toxicities	Arm-A		Arm-B		P value
	No.	%	No.	%	
Dysphagia	15	50.0	8	26.7	0.063^{ns}
Mucositis	7	23.3	5	16.7	0.519^{ns}
Anorexia	26	86.7	24	80.0	0.488^{ns}
Nausea	13	43.3	12	40.0	0.793^{ns}
Vomiting	8	26.7	7	23.3	0.766^{ns}
Lethargy	26	86.7	23	76.7	0.316^{ns}
Anaemia	14	46.7	15	50.0	0.796^{ns}
Leucopenia	12	40.0	11	36.7	0.790^{ns}

5. Discussion

Radiotherapy is the standard treatment for locally or regionally advanced inoperable NSCLC, but induction chemotherapy before radiation significantly improves median survival (4 months) and doubles long-term survival as radiotherapy alone with excellent PS, minimal weight loss, and localized visible disease on radiography [11, 12]. Inoperable locally advanced NSCLC patients with poor PS and short life expectancy benefit from palliative hypofractionated radiation.

Both study groups had similar characteristics. Arm-A and Arm-B had mean ages of 49.3 and 52.2 years. The medical research council (MRC) I study (1991) had a mean age of 65 years, and Sundstrom et al. (2004) had a mean age of 68 years. Group A had 80% male patients and Group B 90% [13, 2]. The only exception is the American study by Cross et al. (2004), which had 61% female participants [14]. All instances had NSCLC histopathology. Adenocarcinoma was the most common pathological subtype in both groups (70% & 66.7%), followed by squamous cell carcinoma (30% &

33.3%). Unlike the MRC I, the Norwegian study by Medical Research Council Lung Cancer Working Party (1991) and the Polish study by Sundstrom et al. (2004) found SCC to be the most common subtype [13, 2]. Maximum individuals exhibited partial response in both arms and histologic type. Adenocarcinoma partial response was 81.0% in Arm A and 75% in Arm B. Squamous cell carcinoma partial response was 66.7% in Arm A and 70% in Arm B. Few patients progressed. Some studies had similar results. 20 patients in Arm A were stage IIIA and 10 were stage IIIB [15, 14]. Arm B included 18 (60%), stage IIIA, and 12 (40%), stage IIIB. Most studies examined stage IIIA and IIIB patients [15, 2]. Cough, dyspnea, chest pain, and hemoptysis were the main symptoms of intra-thoracic illness in this study group, which had a low life expectancy. The study found that patients and clinicians experienced significant symptom relief after radiation, with no statistically significant difference between groups. The MRC Cancer Trials Office's contemporary definition of palliation includes symptom improvement (reduction of moderate or severe symptoms), control (no progression in mild symptoms), and prevention (no symptoms) [16]. Palliative radiation works best for certain symptoms. Hemoptysis and chest pain were the most efficiently treated tumor-related symptoms after radiation, according to multiple studies [14]. Radiotherapy relieved cough and dyspnea in various studies, including this one [13, 2]. Haemoptysis was 100% in both Arms following radiation and during the recommended follow-up period. Patients reported initial improvement in chest pain by 83.3% in arm A and 70% in arm B, but increased mean scores at week 18 after radiation. Arm A improved cough in 83.3% and Arm B in 76.7%. Arm A and Arm B patients had dyspnea alleviated 80% and 70%, respectively. Dyspnea and cough palliation lasted until week 16 after radiation, longer than chest pain. Palliation rates were not statistically different across arms. These results matched the MRC I and II prospective randomized trials by Sundstrøm et al. (2004) and Senkus-Konefka et al (2005) [2, 17]. All these investigations demonstrated that the hypofractionated regimen of 17 Gy in two fractions reduced intra-thoracic symptoms as well as longer regimens. These investigations showed that hemoptysis improved 100%, cough 65–75%, dyspnea 55–70%, and chest discomfort 50–75%. Radiotherapy effectively controls hemostasis. Some research showed that higher radiation doses improved palliation [18, 19, 20]. Different fractionation regimens, endpoints, and evaluation tools may explain these variances [19]. Many research stressed patient self-assessment over physician evaluation. Only a few patients developed dysphagia, the principal toxicity of the therapy, with no significant difference between groups. One week after radiotherapy, 50% of patients in arms A and 26.7% in arm B had grade I dysphagia, which was managed with medication. These patients had dysphagia from primary tumors and/or enlarged mediastinal lymph nodes compressing the esophagus. Patients in both arms reported anorexia, nausea, mucositis, and fatigue during the first week of radiotherapy, which medicine alleviated within days. Without therapy, skin toxicity was mild. No patients in both arms had radiation-induced myelopathy or pneumonitis during follow-up. These results are consistent with some previous randomized trials that reported dysphagia as the main toxicity of treatment with no differences among fractionation schedules, while others reported more dysphagia in the hypo fractionated arm and two trials showed more dysphagia in the more protr [11, 17, 20, 13, 21]. In good-risk patients with surgically unresectable NSCLC, induction chemotherapy followed by radiotherapy was superior to hyper fractionated RT or standard RT alone, yielding a statistically significant short-term survival advantage that challenged our study, which focused on induction chemotherapy and long-course radiotherapy [22]. Hypo fractionated radiation has equal overall survival and progression-free survival rates, effective symptom control, and reduced side effects to conventional RT for inoperable locally advanced (stage IIIA and IIIB) NSCLC patients [15].

6. Conclusion

Radiotherapy can effectively palliate the symptoms of poor PS patients with locally advanced NSCLC disease and in the improvement of the quality of life who have short expected survival time and intolerance to combined chemotherapy and/or curative radiotherapy regimen Considering the cost utility ratio and a huge burden of patients hypo fractionated short course palliative chest RT would be beneficial Which requires short visits to the hospital for RT. Data indicate that hypofractionated thoracic radiotherapy 17Gy in 2 fractions renders similar symptom relief with minimum toxicities compared with 30Gy in 10 fractions in locally advanced inoperable NSCLC.

The short course palliative hypofractionated RT regimen used in this study group proved to be comparable and equally effective in terms of intrathoracic symptom control with minimum toxicities and improvement in quality of life.

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