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Response Of Radiation Therapy Between 30 Gy In 10 Fractions Versus 20 Gy In 5 Fractions In The Management Of Bony Metastasis

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Abstract

Background: *Bone metastases are a common complication of advanced-stage cancers, particularly affecting patients with lung, breast, and prostate cancers. Palliative radiotherapy is a primary modality used to alleviate pain and improve quality of life. This study aimed to compare the efficacy and toxicity of two radiotherapy fractionation schedules—20 Gy in 5 fractions versus 30 Gy in 10 fractions—in managing bone metastases in a resource-limited setting.*

Methods: *This prospective, quasi-experimental study was conducted at the National Institute of Cancer Research and Hospital in Dhaka, Bangladesh, from July 2014 to December 2014. A total of 60 patients were divided into two arms: Arm A received 20 Gy in 5 fractions, and Arm B received 30 Gy in 10 fractions. Radiological and laboratory investigations were conducted pre- and post-treatment, and toxicity was monitored. Patient responses were assessed using RECIST version 2.0 criteria.*

Results: *Complete response was achieved in 60.00% of Arm A patients and 66.67% of Arm B patients. Partial responses were observed in 36.67% of patients in Arm A and 33.33% in Arm B. Genitourinary toxicity was significantly higher in Arm A ($p = 0.003$), while skin toxicity resolved in all patients after 3 months. SGPT levels were significantly higher in Arm B both after 1 month ($p = 0.001$) and 3 months ($p = 0.001$).*

Conclusion: *Both fractionation schedules were effective in managing bone metastases, with comparable pain relief and response rates. However, toxicity profiles differed, highlighting the importance of individualized treatment planning, especially in resource-limited settings.*

Keywords: *Bone metastasis, radiotherapy, fractionation schedules, palliative care, toxicity*

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I. Introduction

Bone metastasis is a common and serious complication in advanced-stage cancers, particularly those originating in the lungs, prostate, and breasts. Statistically, bone metastases affect nearly 70% of cancer patients at some point during their disease progression, with lung cancer having the highest prevalence of bone metastases at 18.05%, followed by breast and prostate cancers. These metastases are not only common but significantly affect the prognosis and survival rates of patients, particularly those with advanced prostate cancer, where bone metastases substantially increase mortality risk (1,2). The incidence of bone metastasis in breast cancer, for instance, is alarmingly high, with up to 69% of patients developing bone lesions that substantially reduce their quality of life and functional capacity (3). Bone metastases create unique clinical challenges, primarily through severe pain, pathological fractures, and spinal cord compression, which affect the quality of life and mobility of patients. Pain is the most frequent and debilitating symptom, impacting approximately 90% of cancer patients with skeletal metastases. The metastatic lesions compromise bone structure, leading to pathological fractures and vertebral body collapse, which in turn causes spinal cord compression in 5-20% of cases (4). These complications can result in immediate loss of function, extreme discomfort, and even paralysis, further compounding the challenge of managing these patients. In addition to the clinical burden, the healthcare costs associated with skeletal-related events (SREs), including fractures and the need for surgical interventions or re-treatment, impose a significant economic burden, particularly in resource-constrained settings like Bangladesh, where access to high-quality palliative care and radiotherapy facilities can be limited (5,6).

Radiation therapy (RT) remains one of the most effective and widely used treatment modalities for palliation of bone metastases. The primary goal of RT in this context is pain relief, preservation of function, and maintenance of quality of life by reducing tumor burden and stabilizing weakened bones. Various radiation regimens have been explored, with fractionation being a key component of therapy. Fractionation refers to dividing the total radiation dose into smaller doses delivered over multiple sessions, which helps balance efficacy and toxicity (7,8). Two commonly used regimens for the treatment of painful bone metastases are 30 Gy in 10 fractions and 20 Gy in 5 fractions. These schedules have been shown to achieve similar outcomes in terms of pain relief and quality of life, but they differ in the number of hospital visits required, toxicity profiles, and the potential need for re-treatment (9). The choice between these two fractionation schedules largely depends on clinical objectives, patient preference, and logistical constraints. For instance, studies comparing 20 Gy in 5 fractions with 30 Gy in 10 fractions have found both regimens to provide comparable rates of pain relief, with 89.6% and 87.3% overall response rates, respectively (9). However, 30 Gy in 10 fractions was associated with better complete response rates in some trials, with fewer re-treatment rates but higher incidences of acute toxicity, including nausea, vomiting, and fatigue (10,11). Similarly, a randomized clinical trial comparing 30 Gy in 10 fractions with 8 Gy in a single fraction found that while both schedules provided significant pain relief, the 30 Gy regimen had a better complete pain response rate but also higher acute toxicity, particularly in patients with poor performance status (12). In low-resource settings like Bangladesh, the balance between cost-effectiveness and treatment efficacy becomes a critical consideration. A study comparing these fractionation schedules found that 20 Gy in 5 fractions is often preferred due to fewer hospital visits, which reduces the economic burden on patients and healthcare systems (13). This schedule is particularly advantageous in centers with overburdened radiotherapy facilities, where high patient volume limits the ability to provide longer, more fractionated regimens. Despite the higher acute toxicity in the 30 Gy in 10 fractions schedule, the reduction in re-treatment rates makes it a favorable choice for patients who can tolerate the associated side effects, as this regimen significantly reduces the likelihood of requiring additional radiation sessions within a year (10). Given the high prevalence of bone metastases and the logistical and financial constraints in countries like Bangladesh, the 20 Gy in 5 fractions regimen offers a viable and cost-effective alternative without compromising the quality of pain relief. However, understanding the full implications of each regimen's toxicity and its impact on overall survival and patient quality of life remains essential for clinicians. Therefore, this study aims to compare the outcomes of 30 Gy in 10 fractions and 20 Gy in 5 fractions in terms of pain relief, toxicity, and overall impact on patient well-being in a Bangladeshi cancer care setting. This research will address the gap in region-specific data on the comparative efficacy of these two regimens, offering insights into optimizing bone metastasis management in resource-constrained healthcare systems.

II. Methods

This prospective quasi-experimental study was conducted at the National Institute of Cancer Research and Hospital, Mohakhali, Dhaka, from July 2014 to December 2014. The study population comprised patients diagnosed with metastatic bone tumors, confirmed through histopathology. Patients were selected from the Radiotherapy Outpatient Department, following specific inclusion and exclusion criteria. Inclusion criteria required patients to be below 70 years of age, diagnosed with metastatic bone tumors, with a performance status (P/S) above 40 on the Karnofsky scale, no other visceral metastases, and meeting minimum laboratory standards, including hemoglobin levels greater than 10 g/dL and a total white blood cell count exceeding 4000/cu mm. Exclusion criteria included patients with visceral metastasis, a P/S below 40, pregnancy, uncontrolled diabetes mellitus or hypertension, or those receiving bisphosphonate therapy. Participants were selected using a purposive sampling method, with only those providing informed written consent included in the study. Data collection involved a semi-structured, pre-tested questionnaire and detailed interviews, lasting approximately one hour, alongside a review of medical reports and hospital records. The study adhered to ethical standards, with approval from the ethical committee of the National Institute of Cancer Research and Hospital. Patients were informed about the study's objectives, procedures, risks, benefits, and alternatives in their native language, and confidentiality was maintained throughout the process. The treatment plan involved two arms, each with 30 cases. In Arm A, patients received hypofractionated radiotherapy, delivering 20 Gy in 5 fractions (4 Gy per fraction over one week). In Arm B, patients received conventional radiotherapy, delivering 30 Gy in 10 fractions (2 Gy per fraction over two weeks). Treatment responses were evaluated based on the RECIST version 2.0 criteria for tumor response, while toxicity was assessed according to the CTCAE version 4.0 and the WHO recommendations for grading acute and sub-acute toxicity (14,15). Patients were symptomatically managed with antibiotics, analgesics, steroids, antihistamines, anti-emetics, vitamins, IV fluids, and blood transfusion as needed. Patients were monitored weekly during treatment and up to three months post-treatment through complete blood count (CBC), platelet count, and serum creatinine levels. Data were analyzed using SPSS for Windows (version 17.0). Continuous variables were presented as mean ±

standard deviation (SD) and analyzed using the Student's t-test, while categorical data were expressed as numbers and percentages and compared using the Chi-squared test and Fisher's exact test. A p-value of less than 0.05 was considered statistically significant.

III. Results

Table 1: Distribution of baseline characteristics among the participants (N=60)

Baseline Characteristics	Arm-A (n=30)		Arm-B (n=30)	
	n	%	n	%
Age				
≤40	0	0.00%	2	6.67%
41-50	4	13.33%	8	26.67%
>50	26	86.67%	20	66.67%
Mean±SD	61.1±10.42		55.7±11.08	
Sex				
Male	14	46.67%	12	40.00%
Female	16	53.33%	18	60.00%
Occupation				
Farmer	2	6.67%	3	10.00%
Service	11	36.67%	9	30.00%
Business	2	6.67%	1	3.33%
Housewife	11	36.67%	17	56.67%
Others	4	13.33%	0	0.00%
Education				
Illiterate	10	33.33%	10	33.33%
Up to SSC	4	13.33%	10	33.33%
HSC	7	23.33%	2	6.67%
Graduate& above	9	30.00%	8	26.67%
History of Smoking				
Yes	5	16.67%	6	20.00%
No	25	83.33%	24	80.00%
Final Diagnosis				
Ca lung	11	36.67%	10	33.33%
Ca breast	9	30.00%	8	26.67%
Ca prostate	5	16.67%	6	20.00%
Ca kidney	2	6.67%	2	6.67%
Ca thyroid	0	0.00%	3	10.00%
Ca cervix	0	0.00%	1	3.33%
Unknown primary	3	10.00%	0	0.00%
Morphological types of cancer				
Adenocarcinoma	13	43.33%	13	43.33%
Duct Cell	9	30.00%	8	26.67%
Squamous Cell	5	16.67%	4	13.33%
Renal Cell	2	6.67%	2	6.67%
Others	1	3.33%	3	10.00%
Chief Complaints				
Severe pain	30	100.00%	30	100.00%
Paraplegia	12	40.00%	9	30.00%
Muscle weakness	9	30.00%	13	43.33%
H/O fracture	8	26.67%	0	0.00%
Comorbidities				
Diabetes	14	46.67%	15	50.00%

Hypertension	8	26.67%	6	20.00%
Cardiac problem	6	20.00%	7	23.33%
Karnofsky Performance Status				
KPS80	0	0.00%	1	3.33%
KPS70	4	13.33%	8	26.67%
KPS60	18	60.00%	17	56.67%
KPS50	8	26.67%	4	13.33%

The baseline characteristics of the study participants, which included 60 patients equally divided into Arm A and Arm B, were compared. The mean age in Arm A was slightly higher at 61.1 ± 10.42 years compared to 55.7 ± 11.08 years in Arm B. Most participants in both arms were above 50 years of age, with 86.67% in Arm A and 66.67% in Arm B. There were slightly more female participants in both groups, with 53.33% in Arm A and 60.00% in Arm B. In terms of occupation, the majority of participants were housewives in Arm B (56.67%) compared to 36.67% in Arm A. Service workers also constituted a significant portion of both groups, with 36.67% in Arm A and 30.00% in Arm B. Regarding education, both groups had a similar proportion of illiterate participants (33.33%), while a higher percentage of participants in Arm A had education up to HSC (23.33%) compared to Arm B (6.67%). For smoking history, the majority of participants in both arms were non-smokers (83.33% in Arm A and 80.00% in Arm B). The most common primary cancer diagnosis in both arms was lung cancer, affecting 36.67% of patients in Arm A and 33.33% in Arm B. Breast cancer was also prevalent, with 30.00% in Arm A and 26.67% in Arm B. In terms of morphological types, adenocarcinoma was the most common type, present in 43.33% of patients in both groups. The chief complaints of all patients were dominated by severe pain, reported by 100% of participants in both arms. Additionally, paraplegia was more prevalent in Arm A (40.00%) compared to Arm B (30.00%), while muscle weakness was more commonly reported in Arm B (43.33% compared to 30.00% in Arm A). A history of fractures was noted in 26.67% of patients in Arm A, while no fractures were reported in Arm B. In terms of comorbidities, diabetes was slightly more common in Arm B (50.00%) compared to Arm A (46.67%), while hypertension and cardiac problems were relatively similar across both arms. Finally, when assessing Karnofsky Performance Status (KPS), the majority of patients in both arms had a KPS of 60 (60.00% in Arm A and 56.67% in Arm B), while KPS 50 was more common in Arm A (26.67%) compared to Arm B (13.33%). Only one patient in Arm B had a KPS of 80.

Table 2: Distribution of the patients by general examination findings (N=60)

General Examination Findings	**Arm-A (n=30)**		**Arm-B (n=30)**		**p-value**
	n	**%**	**n**	**%**	
Body build					
Average	18	60.00%	23	76.67%	0.165
Below average	12	40.00%	7	23.33%	
Anemia (+)	0	0.00%	3	10.00%	
Jaundice (mild)	0	0.00%	1	3.33%	
Dehydration					
Mild	11	36.67%	9	30.00%	0.549
Moderate	1	3.33%	3	10.00%	
Absent	18	60.00%	18	60.00%	
Lymph Node					
Palpable	10	33.33%	11	36.67%	0.592
Not palpable	20	66.67%	19	63.33%	
Nutritional status					
Obese	4	13.33%	1	3.33%	**0.009**
Thin	17	56.67%	10	33.33%	
Average	9	30.00%	19	63.33%	

The general examination findings of the patients in both Arm A and Arm B showed some differences, although most were not statistically significant. Regarding body build, the majority of participants in both arms had an average build, with 60.00% in Arm A and 76.67% in Arm B, though this difference was not statistically significant ($p = 0.165$). In terms of anemia, no patients in Arm A had anemia, while 10.00% of patients in Arm B showed signs of mild anemia. Similarly, mild jaundice was present in 3.33% of patients in Arm B, with no cases observed in Arm A. For dehydration, 36.67% of patients in Arm A and 30.00% in Arm B exhibited mild

dehydration, with a few cases of moderate dehydration in Arm B (10.00%) compared to only 3.33% in Arm A. However, the majority of patients in both groups had no signs of dehydration (60.00% in both arms), and the differences were not statistically significant (p = 0.549). In terms of lymph node palpability, 33.33% of patients in Arm A had palpable lymph nodes compared to 36.67% in Arm B, with no significant difference between the two groups (p = 0.592). Nutritional status showed a statistically significant difference (p = 0.009) between the two arms. In Arm A, 56.67% of patients were classified as thin, compared to 33.33% in Arm B, while 63.33% of patients in Arm B were considered to have an average nutritional status, compared to only 30.00% in Arm A. Additionally, 13.33% of patients in Arm A were classified as obese, compared to only 3.33% in Arm B.

Table 3: Distribution of the patients by radiological findings (pretreatment) (N=60)

Radiological Examination Findings	Arm-A (n=30)		Arm-B (n=30)		p-value
	n	%	n	%	
X-Ray					
Normal	11	36.67%	13	43.33%	0.812
Consolidation	11	36.67%	10	33.33%	
Pleural effusion	8	26.67%	7	23.33%	
USG					
Normal	23	76.67%	20	66.67%	0.599
Abnormal	7	23.33%	10	33.33%	
Bone Scan					
Metastasis to Humerus	4	13.33%	5	16.67%	0.141
Metastasis to Femur	3	10.00%	4	13.33%	
Metastasis to Rib	7	23.33%	6	20.00%	
Metastasis to Pelvic Bone	12	40.00%	8	26.67%	
Dorsal vertebrae	17	56.67%	19	63.33%	
Lumber vertebrae	13	43.33%	11	36.67%	
Sacral vertebrae	9	30.00%	5	16.67%	

The radiological findings of the patients, as assessed through X-ray, ultrasonography (USG), and bone scans, did not show statistically significant differences between Arm A and Arm B. On X-ray examination, 36.67% of patients in Arm A and 43.33% in Arm B had normal findings, while consolidation was observed in 36.67% of patients in Arm A and 33.33% in Arm B. Pleural effusion was detected in 26.67% of patients in Arm A and 23.33% in Arm B, with no statistically significant difference between the groups (p = 0.812). In the USG findings, 76.67% of patients in Arm A and 66.67% in Arm B had normal results, while abnormal findings were more frequent in Arm B (33.33%) compared to Arm A (23.33%), although the difference was not statistically significant (p = 0.599). Bone scan results indicated multiple sites of metastasis. Metastasis to the dorsal vertebrae was the most common finding, affecting 56.67% of patients in Arm A and 63.33% in Arm B. Pelvic bone metastasis was more prevalent in Arm A (40.00%) compared to Arm B (26.67%), but this difference was not statistically significant. Similarly, metastasis to the humerus, femur, rib, lumbar vertebrae, and sacral vertebrae occurred at varying rates between the groups, with no statistically significant differences noted (p = 0.141). Overall, the radiological findings demonstrated comparable distribution of metastatic sites in both treatment arms.

Table 4: Distribution of the patients by different grades of toxicity (N=60)

Toxicity		Arm-A (n=30)		Arm-B (n=30)		p-value
		n	%	n	%	
Before Radiotherapy						
Skin Toxicity	Grade 0	26	86.67%	23	76.67%	0.187
	Grade 1	3	10.00%	7	23.33%	
	Grade 2	1	3.33%	0	0.00%	
Lower GIT/pelvis toxicity	Grade 0	3	10.00%	7	23.33%	0.127
	Grade 1	22	73.33%	14	46.67%	
	Grade 2	5	16.67%	7	23.33%	
	Grade 3	0	0.00%	2	6.67%	
Lung toxicity	Grade 0	17	56.67%	21	70.00%	0.514

	Grade 1	6	20.00%	5	16.67%	
	Grade 2	7	23.33%	4	13.33%	
Genitourinary toxicity	Grade 0	1	3.33%	8	26.67%	0.003
	Grade 1	21	70.00%	9	30.00%	
	Grade 2	8	26.67%	13	43.33%	
Haemopoietic toxicity	Grade 0	9	30.00%	3	10.00%	0.045
	Grade 1	21	70.00%	24	80.00%	
	Grade 2	0	0.00%	3	10.00%	
After 4 Weeks of Radiotherapy						
Skin Toxicity	Grade 0	8	26.67%	8	26.67%	0.152
	Grade 1	22	73.33%	22	73.33%	
	Grade 2	0	0.00%	0	0.00%	
Lower GIT/pelvis toxicity	Grade 0	7	23.33%	16	53.33%	0.33
	Grade 1	22	73.33%	12	40.00%	
	Grade 2	1	3.33%	2	6.67%	
	Grade 3	0	0.00%	0	0.00%	
Lung toxicity	Grade 0	18	60.00%	24	80.00%	0.091
	Grade 1	12	40.00%	6	20.00%	
	Grade 2	0	0.00%	0	0.00%	
Genitourinary toxicity	Grade 0	8	26.67%	11	36.67%	0.405
	Grade 1	22	73.33%	19	63.33%	
	Grade 2	0	0.00%	0	0.00%	
Haemopoietic toxicity	Grade 0	25	83.33%	23	76.67%	0.519
	Grade 1	5	16.67%	7	23.33%	
	Grade 2	0	0.00%	0	0.00%	
After 3 Months of Radiotherapy						
Skin Toxicity	Grade 0	30	100.00%	30	100.00%	1
lower GIT/pelvis toxicity	Grade 0	27	90.00%	28	93.33%	0.64
	Grade 1	3	10.00%	2	6.67%	
Lung toxicity	Grade 0	30	100.00%	27	90.00%	0.237
	Grade 1	0	0.00%	3	10.00%	
Genitourinary toxicity	Grade 0	28	93.33%	29	96.67%	0.968
	Grade 1	2	6.67%	1	3.33%	
Haemopoietic toxicity	Grade 0	29	96.67%	29	96.67%	1
	Grade 1	1	3.33%	1	3.33%	

The toxicity outcomes in both Arm A and Arm B were assessed before, 4 weeks after, and 3 months after radiotherapy. Before radiotherapy, the majority of patients in both arms had minimal skin toxicity, with Grade 0 observed in 86.67% of patients in Arm A and 76.67% in Arm B, though Grade 1 toxicity was more common in Arm B (23.33%) compared to Arm A (10.00%). The difference was not statistically significant ($p = 0.187$). Lower gastrointestinal/pelvic toxicity was slightly more prevalent in Arm B, where 23.33% had Grade 0 toxicity, compared to only 10.00% in Arm A, although Arm A had more cases of Grade 1 toxicity (73.33% versus 46.67% in Arm B). However, the differences were not statistically significant ($p = 0.127$). Genitourinary toxicity showed a statistically significant difference ($p = 0.003$), with more Grade 0 cases in Arm B (26.67%) compared to only 3.33% in Arm A. Similarly, haemopoietic toxicity was more prevalent in Arm A, with 30.00% showing Grade 0 toxicity, compared to only 10.00% in Arm B ($p = 0.045$). After 4 weeks of radiotherapy, both arms exhibited skin toxicity primarily at Grade 1, with 73.33% in both Arm A and Arm B, and no cases of Grade 2 toxicity. Lower gastrointestinal/pelvic toxicity was more frequent in Arm A, where 73.33% of patients had Grade 1 toxicity compared to 40.00% in Arm B, though this difference was not statistically significant ($p = 0.33$). Lung toxicity showed Grade 0 in 60.00% of patients in Arm A and 80.00% in Arm B, though the difference was not statistically significant ($p = 0.091$). After 3 months of radiotherapy, skin toxicity had fully resolved, with 100% of patients in both arms exhibiting Grade 0 toxicity. Lower gastrointestinal/pelvic toxicity had improved significantly in both groups, with 90.00% of patients in Arm A and 93.33% in Arm B showing Grade 0 toxicity, and the difference was not statistically significant ($p = 0.64$). Lung toxicity was absent in all patients in Arm A and persisted at a low level (Grade 1) in 10.00% of patients in Arm B, though this was not statistically significant ($p = 0.237$). Genitourinary and haemopoietic toxicities had largely resolved in both groups, with Grade 0 toxicity observed in nearly all patients, and no significant differences between the groups.

Table 5: Distribution of the patients by radiological findings (N=60)

Radiological Findings		Arm-A (n=30)		Arm-B (n=30)		p-value
		n	%	n	%	
After 4 weeks						
X-ray Findings	Improved	16	53.33%	23	76.67%	0.06
	Not Improved	14	46.67%	7	23.33%	
Bone Scan Findings	Improved	0	0.00%	3	10.00%	0.237
	Not Improved	30	100.00%	27	90.00%	
USG Findings	Improved	18	60.00%	10	33.33%	0.035
	Not Improved	12	40.00%	20	66.67%	
After 3 Months						
X-ray Findings	Improved	20	66.67%	24	80.00%	0.24
	Not Improved	10	33.33%	6	20.00%	
Bone Scan Findings	Improved	0	0.00%	1	3.33%	0.927
	Not Improved	30	100.00%	29	96.67%	
USG Findings	Improved	27	90.00%	22	73.33%	0.095
	Not Improved	3	10.00%	8	26.67%	

The radiological findings after treatment demonstrated varying levels of improvement between Arm A and Arm B at both the 4-week and 3-month follow-ups. After 4 weeks, X-ray findings showed improvement in 53.33% of patients in Arm A compared to 76.67% in Arm B, though this difference was not statistically significant ($p = 0.06$). Bone scan findings indicated no improvement in Arm A, while 10.00% of patients in Arm B showed improvement, but the difference was not statistically significant ($p = 0.237$). However, USG findings showed significantly better improvement in Arm A (60.00%) compared to Arm B (33.33%), with a p-value of 0.035, indicating a statistically significant difference. After 3 months, X-ray findings improved in 66.67% of patients in Arm A and 80.00% in Arm B, though the difference was not statistically significant ($p = 0.24$). In contrast, bone scan findings showed minimal improvement in both arms, with no improvement in Arm A and only 3.33% improvement in Arm B ($p = 0.927$). USG findings continued to show better improvement in Arm A, with 90.00% of patients demonstrating improvement compared to 73.33% in Arm B, though this difference was not statistically significant ($p = 0.095$). Overall, Arm B exhibited more frequent improvement on X-ray and bone scan, while Arm A showed significantly better improvement on USG at the 4-week follow-up.

Table 6: Distribution of the patients by laboratory investigations (N=60)

Parameters	Arm-A (n=30)		Arm-B (n=30)		p-value
	Mean	±SD	Mean	±SD	
After 1 Month					
Hb% (gm/dl)	12.107	0.759	11.1433	3.104	0.104
ESR (mm in 1st hour)	121.03	23.36	116.83	43.594	0.216
TC of WBC	7025.9	948.17	6987.1	173.11	0.325
Platelet count	322000	12300	317000	11120	0.303
S.Bilirubin	2	0.035	0.03	0.052	0.303
SGPT	26.87	7.785	38.97	16.951	0.001
S. Calcium	8.1	0.196	7.56	2.579	0.258
Alkaline phosphatase	343.47	36.675	212.6	81.434	0.001
Blood urea (mq/dl)	25.7	7.747	34.667	7.458	0.013
S. Creatinine	1.2667	0.351	0.9907	0.44	0.009
After 3 Months					
Hb% (gm/dl)	12.16	2.408	11.3327	3.168	0.259
ESR (mm in 1st hour)	11833	18.488	121.4	43.804	0.125
TC of WBC	6435.2	791.23	6721.6	86.54	0.321
Platelet count	315000	10540	312000	9780	0.311
S.Bilirubin	0.03	0.037	1.31	0.11	0.311
SGPT	27.4	8.19	39.83	18.564	0.001
S. Calcium	8.227	0.214	9.04	2.496	0.354
Alkaline phosphatase	32333	43.624	190.97	79.026	0.103

Blood urea (mq/dl)	26.933	8.382	33.61	8.8458	0.081
S. Creatinine	1.1437	0.409	1.0427	0.47	0.377

The laboratory investigations conducted after 1 and 3 months of treatment revealed several significant differences between Arm A and Arm B. After 1 month, the mean hemoglobin (Hb) levels were slightly higher in Arm A (12.107 ± 0.759 g/dL) compared to Arm B (11.143 ± 3.104 g/dL), though the difference was not statistically significant ($p = 0.104$). Erythrocyte sedimentation rate (ESR) and total WBC count (TC) were similar between the two arms, with no significant differences ($p = 0.216$ and $p = 0.325$, respectively). Both arms also showed comparable platelet counts and serum bilirubin levels, with no significant differences. However, SGPT levels were significantly higher in Arm B (38.97 ± 16.951 IU/L) compared to Arm A (26.87 ± 7.785 IU/L), with a statistically significant p-value of 0.001. Similarly, alkaline phosphatase levels were notably higher in Arm A (343.47 ± 36.675 IU/L) compared to Arm B (212.6 ± 81.434 IU/L), also with a p-value of 0.001. Blood urea and serum creatinine levels were higher in Arm B, with significant differences in blood urea ($p = 0.013$) and serum creatinine ($p = 0.009$), indicating possible variations in renal function between the two arms. After 3 months, hemoglobin levels remained higher in Arm A (12.16 ± 2.408 g/dL) compared to Arm B (11.3327 ± 3.168 g/dL), though the difference remained statistically insignificant ($p = 0.259$). ESR, WBC count, platelet count, and serum bilirubin levels continued to show no significant differences between the two arms. SGPT levels remained significantly higher in Arm B (39.83 ± 18.564 IU/L) compared to Arm A (27.4 ± 8.19 IU/L) with a p-value of 0.001. Other parameters, including alkaline phosphatase, blood urea, and serum creatinine, showed no significant differences between the two arms after 3 months of treatment.

Table 7: Distribution of the patients by status at last follow-up (N=60)

Status at last follow-up	**Arm-A (n=30)**		**Arm-B (n=30)**		**p-value**
	n	**%**	**n**	**%**	
Complete Response	18	60.00%	20	66.67%	0.562
Partial Response	11	36.67%	10	33.33%	
No Response	1	3.33%	0	0.00%	

At the last follow-up, the treatment response of patients in both Arm A and Arm B showed comparable outcomes. In Arm A, 60.00% of patients achieved a complete response, while in Arm B, 66.67% of patients showed a complete response. The difference between the two arms was not statistically significant ($p = 0.562$). A partial response was observed in 36.67% of patients in Arm A and 33.33% in Arm B, with no significant difference. Additionally, 1 patient (3.33%) in Arm A showed no response, while no patients in Arm B fell into this category. Overall, both arms demonstrated similar levels of treatment efficacy, with a slight, non-significant edge in complete response for patients in Arm B.

IV. Discussion

This study was designed to compare the efficacy, toxicity, and outcomes of two fractionation schedules, 20 Gy in 5 fractions versus 30 Gy in 10 fractions, for the management of bone metastases in a resource-constrained setting. The mean age of the patients in both treatment arms indicates a predominantly older patient population, which is consistent with other studies evaluating radiotherapy for bone metastases, where older age groups are generally more affected by bone metastasis due to the increased incidence of cancer in these demographics. A study on Iranian patients receiving radiotherapy for bone metastases also found a similar mean age range, highlighting that radiotherapy for bone metastases is largely a treatment for older adults (16). Additionally, the gender distribution in our study, where slightly more females were represented, is in line with several other studies, such as the study by Foro Arnalot et al., which also found a comparable distribution between men and women in radiotherapy trials for bone metastases (9). The general examination findings in our study revealed that Arm A patients had a higher prevalence of obesity compared to Arm B, which may influence treatment outcomes. Obesity has been linked to poorer prognosis and more challenging radiological assessments, as noted in studies investigating body composition and radiotherapy outcomes in cancer patients (17). In terms of dehydration and lymph node palpability, both arms showed similar distributions, suggesting that these factors were not major differentiating factors between the two treatment regimens. The radiological findings in our study demonstrated notable improvements in both arms, particularly in X-ray and USG findings. After 4 weeks, X-ray improvement was seen in 53.33% of Arm A patients compared to 76.67% in Arm B, which, while not statistically significant, indicates a trend favoring the 30 Gy regimen. Similar findings were reported by Nakata et al., who found that radiological improvement following radiotherapy was achieved more frequently in patients receiving higher doses (18). Furthermore, the USG findings in our study showed a

statistically significant improvement in Arm A after 4 weeks, suggesting that, while the 30 Gy regimen may offer more immediate X-ray benefits, the 20 Gy regimen also provides substantial improvement in other imaging modalities. These results align with observations from other studies, which report varying radiological responses depending on the treatment regimen used (19). Toxicity findings are essential when evaluating the efficacy and safety of different fractionation schedules. In our study, both arms experienced manageable levels of toxicity, though Arm A had a higher prevalence of genitourinary toxicity (70.00%) compared to Arm B (30.00%), a statistically significant difference. This aligns with the findings of Aluwini et al., who reported that higher genitourinary toxicities are associated with more aggressive fractionation schedules (20). Despite these differences, both regimens demonstrated complete resolution of skin toxicity by 3 months, which is consistent with previous studies that have shown that most acute radiotherapy-related toxicities are transient and tend to resolve over time (21). In terms of laboratory findings, Arm B patients exhibited significantly higher SGPT levels after 1 and 3 months of treatment, while Arm A patients had higher alkaline phosphatase and serum creatinine levels. Elevated SGPT levels in radiotherapy patients, as observed in our study, have also been documented in the literature, with Chauhan et al. noting that SGPT levels can be a marker of liver stress and may indicate underlying treatment-related hepatic toxicity (22). Conversely, the higher levels of alkaline phosphatase and serum creatinine in Arm A suggest that bone turnover and renal function were more affected in this group, a finding supported by studies examining the relationship between radiotherapy, bone metastasis, and biochemical markers (23). At the last follow-up, the response rates between the two arms were comparable, with a complete response achieved in 60.00% of Arm A patients and 66.67% of Arm B patients. This result mirrors those of other trials that compared different fractionation schedules, such as the study by van der Velden et al., which reported similar overall response rates for patients receiving radiotherapy for bone metastases (24). Interestingly, the study by Foro Arnalot et al. also found that different fractionation schedules resulted in comparable pain relief and response rates, supporting our findings that both 20 Gy in 5 fractions and 30 Gy in 10 fractions are effective for managing bone metastasis, with no significant difference in overall outcomes (9). In conclusion, our study contributes to the growing body of evidence suggesting that both hypofractionated and conventionally fractionated radiotherapy regimens are effective for palliating bone metastases, with comparable efficacy in terms of pain relief and radiological response. However, slight variations in toxicity and biochemical parameters may guide the selection of treatment regimens, particularly in resource-constrained settings like Bangladesh, where minimizing hospital visits and managing toxicity are critical considerations. Given the similarities in response rates and the manageable toxicity profiles of both regimens, either treatment option can be considered depending on patient characteristics and clinical objectives. Further studies, particularly those evaluating long-term outcomes and cost-effectiveness, are warranted to refine treatment protocols for bone metastases in diverse clinical settings.

Limitations of The Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

V. Conclusion

This study compared two radiotherapy regimens—20 Gy in 5 fractions versus 30 Gy in 10 fractions—for the management of bone metastases in a resource-limited setting. Both regimens demonstrated comparable efficacy in terms of pain relief, radiological improvement, and overall patient response, with similar rates of complete and partial responses. The study also highlighted differences in toxicity profiles, particularly in genitourinary toxicity, which was higher in the hypofractionated group (Arm A). While both regimens proved to be effective, considerations such as toxicity, patient tolerance, and healthcare resources should guide treatment decisions, especially in resource-constrained settings like Bangladesh. Further research is necessary to optimize treatment protocols for bone metastases and evaluate long-term outcomes and cost-effectiveness in diverse clinical environments.

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