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Radiation Therapy in Metastatic Compression of the Spinal Cord: Results of 8 Gy x 2 Fractions

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ABSTRACT

Purpose: Our aim was to evaluate the clinical outcome and toxicity of a short course of radiation therapy in selected patients with metastatic spinal cord compression.

Patients and methods: Between September 1997 and December 1998, 35 patients with metastatic spinal cord compression from low radio-responsive primary tumors (non small cell lung, kidney, bladder and gastrointestinal carcinomas and soft tissue sarcomas), or more radio-responsive ones (breast and prostate carcinomas, myeloma and non-Hodgkin's lymphoma) with paresis, plegia, low performance status (PS ECOG ≥ 3) and/or short life expectancy, underwent short-course of radiation therapy; a single fraction of 8 Gy repeated after 1 week in responders or patients with stable disease for a total of 16 Gy. Out of 35 evaluable patients, 3 (8.6%) underwent simple laminectomy and radiotherapy and the other 32 received radiotherapy alone. Median follow up was 20 months (range, 7-32). Response was assessed according to the severity of back pain and motor function and bladder capacity before and after radiotherapy.

Results: Pain relief was achieved in 82.9% of patients and motor function response rate reached 71.4%. Early diagnosis and therapy were very important in predicting response to radiotherapy. All but 2 (90%) pretreatment walking patients and all but 1 (96.4%) with good bladder function preserved these capacities. On the contrary, when diagnosis was late, only 46.7% of non-ambulatory patients and 42.9% of those with bladder dysfunction improved. Median survival was 6 months, with a 32% probability of survival for 1 year. Length of survival was significantly longer in patients with the ability to walk before and/or after radiotherapy. The survival and duration of response was significantly associated with each other with no evidence of relapse in the irradiated area. Sickness appeared only in a few cases. Slight oesophagitis was more frequent, dysphagia for solid foods was observed in 25% of patients irradiated thoracic vertebrae. Late toxicity was not observed.

Conclusion: The use of a single fraction of 8 Gy repeated after 1 week for a total of 16 Gy gave a clinical outcome comparable with that expected from more protracted regimens with only slight side effects. The use of a few large treatment fractions could be explored considering the associated advantages for the patients and radiation therapy centers often overloaded by long patient waiting lists.

Key Words: *Metastatic compression of spinal cord - Radiotherapy.*

INTRODUCTION

Metastatic compression of the spinal cord is a relatively frequent complication of many cancers **[6,27,33]**. In the majority of reports, the pathology usually associated with metastatic spinal cord compression were lung, prostate and breast tumors **[9,10,13,25]**. Over the last 10 to 15 years, treatment of metastatic compression of the spinal cord has been increasingly oriented to radiation therapy alone, reserving surgery for selected cases **[7,22,26,28,29,31]**. Various studies, comparing radiotherapy alone and radiotherapy plus surgery **[1,4,6,8,22,32]** have given practically the same results but a better quality of life for patients treated with radiotherapy alone. An optimal radiation dose schedule has not yet been established. With the exception of a few protocols, the use of conventional radiotherapy (daily fractions of 2 Gy to a total dose of 30-40 Gy) has been abandoned in favor of radiotherapy regimens requiring a fewer number of fractions **[1,2,9,13,14,21,33]**. This trend, supported by radiobiological findings, is convenient for the patients who can be treated in a few days, avoiding the stress due to prolonged treatment and gives advantages to radiotherapy centers often overloaded by patient waiting lists **[16,23,30]**. In view of these data, we conducted this prospective nonrandomized trial to evaluate the outcome and toxicity of 2 large doses/fraction (8 Gy) of radiotherapy separated by 1 week rest in selected patients with metastatic compression of the spinal cord.

PATIENTS AND METHODS

This study was performed on 35 patients presented to Clinical Oncology Unit, Faculty of Medicine, Zagazig University, from September 1997 to December 1998.

Patient eligibility:

1- Metastatic compression of the spinal cord (MCSC) diagnosed by magnetic resonance imaging (MRI) or computed tomography (CT).

2- No previous radiotherapy to the treated area.

3- Metastases of unfavorable histologies or less radio-responsive primary tumors such as kidney, gastrointestinal, head and neck, melanoma, sarcoma and non small cell lung with or without clinical evidence of neurological deficit.

4- Metastases of favorable histologies or radio-responsive tumors such as breast, prostate, lymphomas and myeloma in patients with neurologicl deficit (plegia or paresis) and/or low performance status (ECOG ≥ 2) [29] and/or short life expectancy.

Radiotherapy:

Eligible patients were treated with telecobalt radiation at 80 cm SSD. The treatment portals consisted of a single posterior field (prescribed to the appropriate depth) or parallel opposed fields (prescribed to midplane dose) were used. The treatment volume included 2 vertebral bodies above and below the involved vertebrae and the entire paravertebral mass according to MRI or CT. The tumor dose was calculated at a depth of 5-7 cm. Patients received one single fraction of 8 Gy, repeated after one week for a total dose of 16 Gy. Parenteral dexamethasone 8 mg twice daily was given from the time of diagnosis to the end of radiation therapy and then tapered over 10 days. All patients with treatment fields covering the upper abdomen received anti-emetics before each fraction. Systemic treatment (chemotherapy and/or hormonal therapy) was given to patients with tumors responsive to systemic treatment.

Treatment evaluation:

Each patient was evaluated on the day of radiotherapy, then weekly for the first 4 weeks. Follow-up continued monthly thereafter. Evaluation of response to radiation therapy was done 1 month after the end of radiotherapy. Eligible patients were evaluated for the following:

1- Back pain before and after radiation therapy, separating patients into 3 groups: (a) no pain (b) pain controllable with minor analgesics (c) pain controllable with narcotics.

2- Ambulatory status before and after radiation therapy graded according to Tomita's classification [29]: Grade I: ability to walk without support; Grade II: ability to walk with support; Grade III: inability to walk; Grade IV: plegia.

3- Bladder function before and after radiotherapy, evaluating the need for catheterization.

4- Post-treatment survival.

5- Duration of response.

6- Acute and late toxicity.

Statistical analysis:

Statistical analysis was done by Kaplan Meier method and comparison between groups by the log-rank test [12]. The level of significance was set at $p \leq 0.05$.

RESULTS

Patient characteristics:

The study included fourteen female and twenty-one male patients. The median age was 50 years (range 36-67 years). The majority of patients were treated with radiation therapy alone (32 patients), the other 3 patients underwent surgery (simple laminectomy) and radiotherapy. The median follow-up period was 20 months (range, 7 to 32 months). In the present study, the dorsal vertebrae were the commonest sites for spinal cord compression (51.4%) followed by the lumbar vertebrae (28.6%). In all patients, metastatic compression of the spinal cord (MCSC) was localized at one level. Lung and GIT cancers were the most common histopathologies causing metastatic compression of the spinal cord in our study (20% for both types), followed by breast and myeloma. Tumors reported as, "others" in table (1) were bladder and soft tissue sarcoma (2 and 1 respectively).

Pain was the most common presenting symptom in 32 patients (91.4%), followed by motor weakness in 30 patients (85.7%). Urinary dysfunction was found in 7 patients (20%). Be-

fore the beginning of radiation therapy there were 3 patients without pain, 12 patients with pain requiring minor analgesics and 20 patients with pain requiring narcotics (Table 2).

Five patients (14.3%) did not present with motor weakness (grade I) at the time of diagnosis of MCSC, 15 patients (42.9%) were able to walk with support (grade II), 10 patients (28.5%) unable to walk (grade III) and 5 patients (14.3%) were paraplegics (grade IV).

Response to radiotherapy:

In 20 patients with pain requiring narcotic analgesics, 10 (50%) patients achieved complete improvement of pain, 4 (20%) had their pain controlled with minor analgesics after radiation therapy. Ten of 12 (83.3%) patients using minor analgesics to control their pain, discontinued the use of analgesics, while in the remaining 2 (16.7%) it did not worsen. Pain control was achieved in 82.9% of patients.

In 15 patients with grade III and IV motor dysfunction before treatment, 7 patients (46.7%) regained their motor ability at the end of radiation therapy. Improvement of motor dysfunction was verified in eleven patients with favorable histopathologies (myeloma, breast, lymphoma and prostate) and in another 7 patients with unfavorable ones (lung, GIT, kidney and bladder). Two patients out of five with paraplegia before radiotherapy regained their ambulation. The total response rate for motor function was 71.4% (Tables 2 & 3).

Sphincter dysfunction was observed in 7 patients (20%) before radiation therapy, 3 with favorable and 4 with unfavorable histopathologies. Three patients (42.9%) with urinary dysfunction recovered function (2 with favorable histologies and 1 with unfavorable one) after radiotherapy. Only 1 of 28 patients (3.6%) with good sphincter control required catheterization after radiation therapy; therefore, 30 of 35 patients (85.7%) maintained or recovered urinary control.

The median survival for all patients was 6 months and probability of surviving 1 year was 32% (Fig. 1). The median survival for walking and non-walking patients before radiotherapy was 8 and 3 months with 1-year probability of survival of 38% versus 12%, respectively ($p < 0.02$) (Fig. 2). After radiation therapy, the difference in median survival was estimated for ambulatory patients and non-ambulatory ones (9 and 2 months, respectively). The probability of surviving 1 year was 38% for walking patients and 0% for non-walking patients ($p < 0.0001$; Fig. 3).

Seven out of thirty-five (20%), patients had metastatic compression of the spinal cord (MCSC) as the only site of metastasis, 16 (45.7%) had bone metastases also and the remaining 12 (34.3%) had other metastatic sites apart from bone. The median survival of the three groups was 7,6 and 3 months, respectively, with no statistical significant differences. Analysis of survival in relation to the type of primary tumor, revealed 8 months in patients with favorable tumors and 3 months for those with unfavorable ones. the difference was not statistically significant ($p = 0.1$).

There was an association between survival and duration of response. The median duration of response in the whole group was 8 months; the ambulatory status and type of the primary tumor did not affect significantly the duration of response.

None of the patients with response had motor or sphincter dysfunction due to in-field progression or relapse of disease. Two patients of 29 with no pain or with pain required minor analgesics developed back pain within 5 to 13 months from radiation therapy, but they were able to walk and maintained their bladder function. Acute and late toxicity was recorded. Fifteen patients treated with fields covering the upper abdomen, control of vomiting was obtained in thirteen of them with antiemetics (86.7%). The remaining 2 (13.3%) experienced 2-3 daily emetic episodes from the day of first radiotherapy fraction until 3-4 days after the second radiotherapy fraction. Neither of the patients exhibiting sickness refused to continue scheduled radiotherapy because of this side effect. The other twenty patients, only two experienced nausea and vomiting with 3-4 events on the same day of treatment. Mild oesophagitis with slight difficulty in swallowing solid foods occurred in 5 of 18 patients treated to the thoracic vertebrae, which spontaneously disappeared in 4 to 7 days. Skin reactions were few. None of the patients had to be hospitalized because of toxicity. Late toxicity was never recorded.

Table (1): Site of epidural metastases according to the site of primary tumor.

1 ry	No.	Cervical	Dorsal	Lumbar	Lumbosacral	Sacral
Myeloma	5	1	3	1	-	-
Prostate	2	-	1	1	-	-
Breast	5	1	3	1	-	-
Kidney	3	-	1	1	-	1
Lung	7	-	3	2	2	-
NHL	3	-	1	-	1	1
GIT	7	-	4	3	-	-
Others	3	-	2	1	-	-
Total	35	2	18	10	3	2

Table (2): Symptoms before and after radiotherapy.

		No. of patients	% of patients
A- *Back pain:*			
1- No analgesics pretreatment		3	8.6
	Treatment outcome		
No pain		3	100
Development of new pain		-	-
2- Minor analgesics pretreatment		12	34.3
	Treatment outcome		
No pain		10	83.3
Stable pain		2	16.7
Worsening of pain		-	-
3- Narcotics pretreatment		20	57.1
	Treatment outcome		
No pain		10	50
Need of minor analgesics		4	20
Stable pain		6	30
Total number of responders		29	82.9
B- *Motor function:*			
1- Walking before treatment		20	57.1
Ambulatory		18	90
Not ambulatory		2	10
2- Not walking before treatment		15	42.9
Ambulation regained		7	46.7
Not ambulatory		8	53.3
Total number of responders		25	71.4
C- *Sphincter control:*			
1- Normal before treatment		28	80
Good sphincter control		27	96.4
Poor sphincter control		1	3.6
2- Abnormal before treatment		7	20
Sphincter control regained		3	42.9
Poor sphincter control		4	57.1
Total number of responders		30	85.7

Table (3): Motor capacity outcome of patients according to Tomita's grading system and primary tumor.

1 ry tumor	No. of patients	Before treatment		No. of patients after treatment			
		Grade	No.	GI	GII	GIII	GIV
Lung	7	I	1	1	-	-	-
		II	3	1	2	-	-
		III	2	-	1	1	-
		IV	1	-	-	-	1
GIT	7	I	2	2	-	-	-
		II	4	2	1	1	-
		III	-	-	-	-	-
		IV	1	-	-	1	-
Myeloma	5	I	-	-	-	-	-
		II	1	1	-	-	-
		III	3	1	2	-	-
		IV	1	-	-	-	1
Breast	5	I	-	-	-	-	-
		II	2	2	-	-	-
		III	2	1	1	-	-
		IV	1	-	-	1	-
Kidney	3	I	-	-	-	-	-
		II	-	-	-	-	-
		III	2	-	1	1	-
		IV	1	-	-	-	1
NHL	3	I	-	-	-	-	-
		II	2	1	1	-	-
		III	1	-	1	-	-
		IV	-	-	-	-	-
Prostate	2	I	1	1	-	-	-
		II	1	1	-	-	-
		III	-	-	-	-	-
		IV	-	-	-	-	-
Others	3	I	1	1	-	-	-
		II	2	1	1	-	-
		III	-	-	-	-	-
		IV	-	-	-	-	-

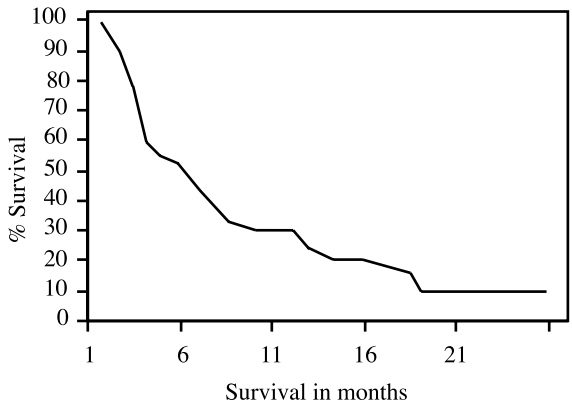

Fig. (1): Actuarial survival curve for all 35 evaluable patients.

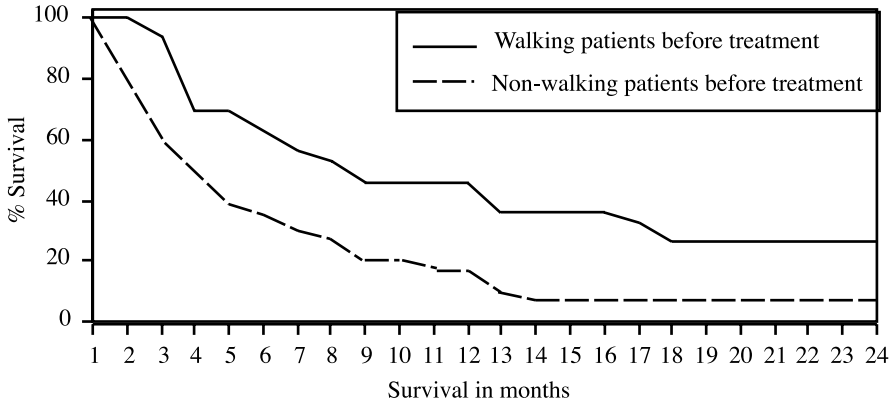

Fig. (2): Comparison of actuarial survival curves.

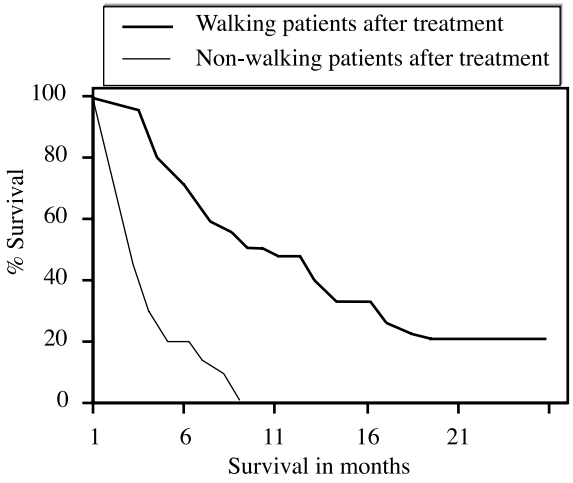

Fig. (3): Comparison of actuarial survival curves in walking and non-walking patients after radiotherapy.

DISCUSSION

An increasing number of studies were published in the last few years suggested that radiation therapy supported by steroids is as effective as the combination of laminectomy and radiotherapy **[7,8,9,15,19,32]**. Ever since Rubin **[24]** provided experimental and clinical evidence that high daily doses do not increase the risk of tumor swelling due to irradiation edema, numerous authors **[8,9,15,32]** apply doses of 4-5 Gy daily for the first 3 days accompanied by steroids. The radiobiological rationale behind this approach is to produce a rapid tumor shrinkage hopefully allowing for a swift regression of neurologic symptoms. Higher daily fractions ranging from 6 to 10 Gy have been explored as well, with good results and tolerance **[1,2,11]**. Studies concerning radiotherapy of patients with bone metastases have proved that low fraction **[1-3,5,30]** regimens and high single doses (3-10 Gy) have a clinical outcome similar to more protracted regimens, also in patients with vertebral metastases **[18,20,23,30]**. Spinal cord compression is usually accompanied by pain, loss of walking ability and sphincter dysfunctions **[14, 21]**. The most common initial complaint in our study, preceeding all other symptoms by weeks to months, was pain. After radiotherapy, 65.7% of our patients no longer had back pain and in 11.4% of cases the pain diminished to the point when only mild analgesics instead of narcotics were necessary. The total response rate to back pain was 82.9%. Maranzano et al., in a prospective analysis reported that back pain responded to radiation therapy in 80% of patients with spinal cord compression **[20]**. Eighteen of twenty patients who were ambulatory at the time of diagnosis, maintained ambulation after treatment. Only 2 patients who were able to walk with support deteriorated. Return to ambulation out of a paraparetic condition was achieved in 50% (5/10) of our patients. Two of five paraplegic patients (40%) improved after treatment. Maranzano et al. **[20]** reported that a large majority of their ambulant patients maintained function (100% of cases walking without support and 87% of those walking with support) and 50% of non-ambulant patients (grade III) regained motor ability, while none of the paraplegics (grade IV) regained the ability to walk.

In pretreatment non-walking patients, there was improvement in the motor ability in 12 patients (85.7%) with more radio-responsive histologies (myeloma, breast, lymphoma and prostate) and in another 8 (47%) with less radioresponsive ones (lung, G.I.T., kidney and bladder) but because of the small number of patients, it is impossible to determine whether his-

tology influenced response or not but the significance of histology as a predictor to treatment outcome has been shown in the majority of reports [15,17,18]. Bladder control was regained in 42.9% of patients with sphincter dysfunction. Only 1 of 28 patients (3.6%) with good bladder function developed bladder dysfunction after radiotherapy. Good bladder function was maintained or recovered in 85.7% of patients. Information on the improvement of sphincter function, however, is sparse and concerns small numbers of patients. Forty-four percent of the patients (4/9) in the study of Maranzano et al. [20] showed recovery of sphincter function after radiotherapy, while urinary capacity was maintained or recovered in 88% of cases. Landmann et al. [14] reported recovery in 33% (2/6) of patients in their series, also Latini [15] describes improvement in sphincter function after irradiation. Young [32] who conducted the only randomized study on treatment of spinal epidural metastases and contrary to the previous results, found sphincter function to recover in 83% of patients after radiotherapy.

Survival and duration of response were analyzed on the bases of pretreatment and post-treatment ambulatory status and primary tumor histologic conditions. The median survival for our group of patients was 6 months and the probability of survival for 1 year was 32% for the entire evaluable group. An observation shared by all authors [14,15,20,32], is the fact that the ability to walk at the time of diagnosis is an important positive prognostic factor. Severe neurological deficit on presentation is associated with a less frequent response to treatment [14]. In ambulant patients, median survival was significantly better than in non-ambulant ones: 8 versus 3 months ($p < 0.02$) in pretreatment walking versus non-walking patients and 9 versus 2 months ($p < 0.0001$) in post treatment walking versus non-walking. Our results are comparable with those reported by most authors [14,15,20,32] even if some have obtained longer survival [11,17]. There is a general agreement that the type of the primary is an important factor concerning response to treatment [14,20]. In our study the best responders were patients with breast cancer, myeloma, lymphoma and prostate who could maintain a good quality of life following treatment without displaying symptoms in the treated site. The median survival was 8 months for patients with favorable histologies versus 3 for those with unfavorable types, but the difference did not reach statistical significance ($p < 0.1$), which could be explained by the limited number of patients. Taking into consideration that survival was not conditioned by the presence of other metastatic sites apart from bone, the only two variables conditioning survival were pre and post-treatment motor capacity of patients. The median duration of improvement was 8 months with agreement between length of survival and duration of response. Two patients developed pain again in the treated site within 5- to 13- month interval from radiation therapy, but they were able to walk and maintain their bladder function. Treatment related toxicity was minimal. Fifteen patients treated with fields covering the upper abdomen received pretreatment antiemitcs. In 13 of 15 patients control of vomiting was achieved. The remaining 2 patients developed episodes of vomiting for 2-3 days following each radiation therapy fraction. None of the patients refused to continue radiotherapy because of vomiting. Only slight oesophagitis with mild dysphagia occurred in about 25% of patients treated at the thoracic vertebrae. No other acute or late toxicities were recorded. In conclusion, the short-course radiotherapy adopted gave a clinical outcome comparable with that resulting from more protracted regimens with only slight side effects. A randomized study, incorporating a greater number of patients, is necessary for drawing any firm conclusions regarding the use of a few large treatment fractions considering the associated advantages for patients and radiotherapy centers often overloaded by long patient waiting lists.

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