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Efficiency of strontium-89 for the palliation of painful bone metastases in prostate cancer

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Background. To evaluate the efficiency of strontium-89 chloride for prostate cancer patients with multiple bone metastases, to determine factors that would allow predicting the sensitivity to the strontium-89 therapy.

Materials and methods. We retrospectively studied the data on all the patients referred to the Department of Radiotherapy of the Institute of Oncology, Vilnius University between 1999 and 2006 years with a histologically confirmed diagnosis of prostate cancer with multiple bone metastases. 113 patients received Sr-89, 91 patients were included in our study.

Results. During the years 1999–2006 deaths of 68 patients were recorded (74.7%).

The median survival time (MST) of patients with bone metastases was 32 months.

Arm A: MST 25 months. Gleason score 7.6 ± 1.0; PSA 75.7 ± 40.6 ng/ml; Hb 106.6 ± 13.8 g/l, ALP 1695 ± 1194.0; VAS pain score 8.5 ± 0.8; the number of lesions detected by bone scintigraphy 14.4 ± 3.0; days from the beginning of treatment 828.5 ± 756.7; days after the treatment 108.3 ± 75.9; ECOG performance status 3.

Arm B: MST 42 months. Gleason score 7.1 ± 1.1; PSA 59.5 ± 40.0 ng/ml; Hb 123.6 ± 16.4 g/l, ALP 548 ± 442.0; VAS pain score 8.2 ± 0.7; the number of lesions detected by bone scintigraphy 8.2 ± 2.4; days from the beginning of treatment 1076.8.5 ± 1166.8; days after the treatment 537.0.3 ± 428.4; ECOG performance status 2.

Conclusion. Sr-89 appears to be effective in palliating bone pain from metastatic prostate cancer in 69.2% patients. Average pain improvement was in 36.2% cases, whereas 33.0 % cases were pain-free. Duration of response ranged from 3.2 to 6.7 months. While selecting patients for Sr-89 treatment it is important to pay attention to the fact whether they meet the following criteria: ECOG performance status < 2; HB > 120 g/l; ALP < 500 U/l; the number of lesions detected by bone scintigraphy < 8; the treatment starts as early as possible after the bone metastases are detected.

Key words: strontium chloride-89, prostate cancer, bone metastases, pain

INTRODUCTION

Prostate cancer is one of the most common malignancies accounting for 2005 cases in 2005 (1). Metastases spread to bones in approximately 85% of patients with prostate cancer (2, 3). Patients with prostate cancer typically survive for 2 years after bone metastases are diagnosed. Bone metastases cause pain, which can be severe and reduces the quality of life (QoL) (2, 4, 5). Bone pain is a common symptom and may be difficult to control with analgesic medication alone. Systemic agents such as hormone therapy, chemotherapy, external beam radiation in the form of hemibody or focal bone irradiation are used to control metastatic bone pain. Long-term pain management is still problematic. Radiopharmaceutical strontium-89 represents an attractive and cost-effective alternative. Advantages of strontium-89 include the ease of administration and the ability to treat multiple sites of metastatic disease (6–8).

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Radiopharmaceuticals are preferentially incorporated into bone at sites of increased osteogenesis and give off radiation. Efficiency depends on the doses of radiopharmaceuticals, cancer cell sensitivity to radiation and directly to beta emission. Strontium-89 is the most commonly used radionuclide in the palliative management of bone pain in cancer involving the skeleton. After neutron irradiation by strontium-88, it is converted into strontium-89, a radioactive isotope. Strontium-89 is a pure beta emitter, half time decay T1/2 is 50. 5 days. The maximum beta energy is 1.46 MeV. The maximum range of β- from strontium-89 in tissue is approximately 6, 7 mm. Strontium-89 behaves like calcium analogue, selectively localizing in bone mineral (compare Sr-89 to calcium 10:1). Uptake of strontium by bone occurs preferentially in sites of active osteogenesis; thus primary bone tumours and areas of metastatic involvement (blastic lesions) can accumulate significantly greater concentrations of strontium than the surrounding normal bone (9–12). Following intravenous injection of strontium-89 chloride 150 MBq (4 mCi), one half selectively localizes in bone mineral, the other half is excreted by urine. Strontium-89 kinetics and retaining in bone metastases has been examined in several studies

(12–15). Strontium-89 chloride accumulates in metastatic bone lesions evenly and reaches peak in 10 days. The recommended dose for pain relief is 6–61 cGy/MBq (14), 21–231 cGy/MBq (14).

The work of Firusian et al. (1976) suggested that strontium-89 would be useful for relief of pain secondary to osseous metastases, thus 10 patients were treated with 0.01–0.015 mCi/kg of Sr-89, and 8 of them felt a significant pain relief (16).

Robinson and others further treated 622 patients with bone metastases, and 450 of them were patients with prostate cancer. The administered dose was 40–55 μCi/kg resulting in 80% of patients with improvement in pain relief, while 15% of cases were pain-free (17).

A review by A. T Porter was performed on all the patients (126) who received strontium-89 chloride for prostate cancer metastatic to bone (18). There were patients treated with strontium-89 and external beam irradiation. In another group of patients, the effect of the radionuclide on pain could not be assessed because they received external beam radiotherapy concomitant with a therapeutic radionuclide. The median time to progression for all the patients was 3 months. The present study confirms the fact that following administration of a therapeutic radionuclide, a high proportion of patients experienced improvement of pain, but the time to progression is not long, so that the overall degree of benefit is modest.

In the study reported by Quilty et al., patients were stratified according to suitability for local or hemibody radiotherapy (157 patients), then randomized to that form of treatment or Sr-89, the administered dose was 5.4 mCi (148 patients). No statistically significant differences were reported, pain relief was similar in all the four treatment groups (19).

Kasalicky et al. examined patients with metastatic lung cancer, prostate cancer and breast cancer. This study included 118 patients. The overall pain relief response after considering all the tumour types was significant (20).

Schmeler et al. conclude that patients with a pre-treatment KPS of 50 or less should not be treated with Sr-89, and patients with a pre-treatment KPS of 70 represent the most reasonable treatment option for palliation of their bone pain; pain relief was demonstrated in 75% patients (21).

Having considered the results in the literature (6, 16–29) we have concluded that Sr-89 is effective in pain improvement for 60–85% of patients; pain-free rate is 15–35%. Relief generally begins within 14 to 21 days; duration of response is 3–6 months. Repeated administrations are available.

The aim of this study was to evaluate the efficiency of strontium-89 chloride for prostate cancer patients with multiple bone metastases; to determine factors that would allow predicting the sensitivity to the strontium-89 therapy.

METHODS AND MATERIALS

We retrospectively studied the data on all the patients referred to the Department of Radiotherapy of the Institute of Oncology, Vilnius University, between 1999 and 2006 with a histologically confirmed diagnosis of prostate cancer with multiple bone metastases. 113 patients received Sr-89, and 91 patients were included in our study.

Inclusion criteria were as follows:

- Multifocal, painful osteoblastic or mixed bone metastases confirmed on radiographic or scintigraphic examination.
- Platelet count greater than 100×10^9/l, leukocyte count greater than 3×10^{12}/l.
- 6 weeks after external beam irradiation or chemotherapy.
- Repeated administration of Sr-89 at interval more than 90 days.

Exclusion criteria included:

- Renal insufficiency, creatinine >150 mmol/l.
- Spinal cord compression in patients with skeletal metastases.
- External urinary drainage.

After haematological (Hb, erythrocyte, leukocyte, platelet count), biochemical (bilirubin level, ALP, ALT, AST ratio, creatinine level, PSA), radiographic and scintigraphic examination, we determined indications for Sr-89 treatment, patients received intravenous injection of strontium-89 chloride at a dose 150 MBq with a follow-up once a month. To asses the performance status and VAS pain score, duration of the pain-free period and efficacy of the repeated administration of Sr-89 the patients were divided into three groups: no improvement, average improvement, significant improvement.

Statistical analysis: all the data were entered into the Microsoft Excel database and analysed using Microsoft Excel Statistica program. Descriptive statistics was used to summarize and describe the collection of data. Basic examples include the mean and standard deviations.

RESULTS

A total of 91 eligible patients were studied with a histologically confirmed diagnosis of prostate cancer with multiple bone metastases (mean age 63.7, range 48–79 years). From 1999 to 2006 68 patients (74.7%) advanced cancer died. The median survival time (MST) of patients with bone metastases was 32 months.

Arm A (non-responders): this group consisted of 28 patients (30.8%) with no significant bone pain relief after Sr-89 treatment, MST was 25 months.

Arm B (responders): 63 patients (69.2%) who received Sr-89 with bone pain relief. Average pain improvement was in 33 cases (36.2%), while 30 cases (33.0%) were pain-free. Duration of response ranged from 3.2 to 6.7 months. Of the 24 patients (26.4%) who were retreated with Sr-89, three received Sr-89 for four times, MST in this group was 42 months.

Arm A, pre-therapy assessment: Gleason score 7.6 ± 1.0; PSA 75.7 ± 40.6 ng/ml; Hb 106.6 ± 13.8 g/l, ALP 1695 ± 1194.0; VAS pain score 8.5 ± 0.8; the number of lesions detected by bone scintigraphy 14.4 ± 3.0; days from the beginning of treatment 828.5 ± 756.7; days after the treatment till death 108.3 ± 75.9; KPS less 50; ECOG performance status 3, MST was 25 months.

Arm B, pre-therapy assessment: Gleason score 7.1 ± 1.1; PSA 59.5 ± 40.0 ng/ml; Hb 123.6 ± 16.4 g/l, ALP 548 ± 442.0; VAS pain score 8.2 ± 0.7; the number of lesions detected by bone scintigraphy 8.2 ± 2.4; days from the beginning of treatment 1076.8 ± 1166.8; days after the treatment till death

537.0 ± 428.4; KPS < 70; ECOG performance status 2, MST was 42 months (Table 1).

Statistical evaluation of Gleason score and PSA score data confirmed no significant differences between arms A (Gleason score 7.6 ± 1.0) and B (Gleason score 7.1 ± 1.1), $p < 0.20$, arm A (PSA 75.7 ± 40.6 ng/ml) and arm B (PSA 59.5 ± 40.0 ng/ml), $p < 0.19$. Similar assessment of VAS pain score between arm A (VAS pain score 8.5 ± 0.8) and B (VAS pain score 8.2 ± 0.7), $p < 0.08$ and time from the diagnosis of bone metastases to the beginning of treatment, $p < 0.40$ were determined. Meanwhile the evaluation of haemoglobin level arm A (Hb 106.6 ± 13.8 g/l) arm B (Hb 123.6 ± 16.4 g/), $p < 0.001$; alkaline phosphatase arm A (ALP 1695 ± 1194.0) and arm B (ALP 548 ± 442.0), $p < 0.001$; the number of lesions detected by bone scintigraphy arm A (14.4 ± 3.0) and arm B (8.2 ± 2.4), $p < 0.001$; days after treatment till death arm A (108.3 ± 75.9) and arm B (537.0.3 ± 428.4), $p < 0.0002$, were statistically significant (Table 2).

DISCUSSION

Patients with prostate cancer typically survive for 2 years after bone metastases are diagnosed. Bone metastases cause pain, which can be severe and reduces the quality of life (QoL) (2, 4, 5). In the present study we confirm that the mean survival time for patients, who received Sr-89 for palliation of painful bone metastases in prostate cancer, was 32 months (arm A – 25 months, arm B – 42 months). Having considered the results in the literature (6, 16–29) we have concluded that Sr-89 is effective in pain improvement for 60–85% of patients, whereas 15–35% patients had complete response (pain-free). Relief generally begins within 14 to 21 days, and duration of response is 3–6 months. Repeated administrations are available. In our study we have assessed that the total number of patients 63 (69.2%), who received Sr-89, had bone pain relief. Mean pain improvement was in 33 cases (36.2%), while pain-free state was determined

Table 1. **Baseline characteristics of the whole group, both responders and non-responders**

Group	Label	N	Mean	Std dev	Minimum	Maximum
Arm A	Gleason	28	7.6	1.0	6.0	9.0
	PSA	28	75.8	40.6	1.0	150.0
	Hb	28	106.6	13.8	8.0	127.0
	ALP	28	1695.1	1194.0	279.0	4625.0
	VAS	28	8.5	0.8	7.0	10.0
	MTS	28	14.4	3.0	10.0	20.0
	Till treatment	28	828.5	756.7	71.0	3103.0
	After treatment	28	108.3	75.9	18.0	285.0
Arm B	Gleason	63	7.1	1.1	6.0	10.0
	PSA	63	59.5	40.0	1.0	150.0
	Hb	63	123.6	16.4	87.0	163.0
	ALP	63	548.1	442.0	106.0	1972.0
	VAS	63	8.2	0.7	6.0	10.0
	MTS	63	8.2	2.4	2.0	15.0
	Till treatment	63	1076.8	1166.8	33.0	8715.0
	After treatment	63	537.0	428.4	51.0	2336.0

Table 2. **Univariate prognostic factor analysis of response and non-response to the treatment by strontium-89 for the whole group**

Group	Label	N	Mean	Std dev	Minimum	Maximum	p
Arm A	Gleason	28	7.6	1.0	6.0	9.0	<0.20
Arm B		63	7.1	1.1	6.0	10.0	
Arm A	PSA	28	75.8	40.6	1.0	150.0	<0.19
Arm B		63	59.5	40.0	1.0	150.0	
Arm A	Hb	28	106.6	13.8	8.0	127.0	<0.001
Arm B		63	123.6	16.4	87.0	163.0	
Arm A	ALP	28	1695.1	1194.0	279.0	4625.0	< .001
Arm B		63	584.1	442.0	106.0	1972.0	
Arm A	VAS	28	8.5	0.8	7.0	10.0	<0.08
Arm B		63	8.2	0.7	6.0	10.0	
Arm A	MTS	28	14.4	3.0	10.0	20.0	<0.001
Arm B		63	8.2	2.4	2.0	15.0	
Arm A	Till treatment	28	828.5	756.7	71.0	3103.0	<0.40
Arm B		63	1076.8	1166.8	33.0	8715.0	
Arm A	After treatment	28	108.3	75.9	18.0	285.0	<0.0002
Arm B		63	537.0	428.4	51.0	2336.0	

in 30 cases (33.0%). Duration of response ranged from 3.2 to 6.7 months. Of the 24 patients (26.4%) who were retreated with Sr-89, three received Sr-89 for the fourth time. Our study results are similar to those of other trials.

We tried to select patients for Sr-89 therapy and have concluded that patients with a pre-treatment ECOG performance status 3 had no clinical response to the treatment with Sr-89, whereas the patients with a pre-treatment ECOG performance status <2 represent the most reasonable treatment option for palliation of their bone pain; 69.2% of patients experienced pain relief. Similar results are concluded by Schmeler, Bastin et al. in their study (20). Pre-treatment Gleason score and PSA score in evaluating VAS pain score were also significant. Similar results are concluded by Zyskowsky et al. in their study (31). Meanwhile haemoglobin > 123.1 ± 16.4 g/l, ALP < 548.1 ± 442.0, the number of lesions detected by bone scintigraphy < 8 ± 2.4, the number of days after ending the treatment > 537.0 ± 428.4 are important for patients' selection to treatment, as reviewed by McEwan et al., Oosterhof et al., Windsor et al., Van der Poel et al. (10, 28–30). These criteria can be used to propose the methodology for the selection of prostate cancer patients with multiple painful bone metastases for the strontium-89 treatment.

CONCLUSION

• Sr-89 appears to be effective in palliating bone pain for 69.2% patients with metastatic prostate cancer; average pain improvement was in 36.2% cases, 33.0% cases were pain-free. Duration of response ranged from 3.2 to 6.7 months.

• Repeated administrations are available.

• Patients were eligible for Sr-89 treatment if they met the following criteria: ECOG performance status < 2; HB > 120 g/l; ALP < 500 U/l; the number of lesions detected by bone scintigraphy < 8; treatment starts as early as possible after multiple painful bone metastases are detected.

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STRONCIO-89 VEIKSMINGUMO SLOPINANT SKAUSMĄ ĮVERTINIMAS, ESANT PRIEŠINĖS LIAUKOS VĖŽIO METASTAZĖMS KAULUOSE

S a n t r a u k a

Šio straipsnio **tikslas:** įvertinti stroncio-89 chlorido efektyvumą, slopinant skausmą ligonių, sergančių priešinės liaukos vėžiu ir turinčių dauginių metastazių kauluose, ir nustatyti veiksnius, kurie leistų iš anksto numatyti jautrumą stroncio-89 terapijai.

Medžiaga ir metodai. Vilniaus universiteto Onkologijos instituto Onkologinės radioterapijos skyriuje 1999–2006 m. stronciu-89 buvo gydyta 113 ligonių, sergančių priešinės liaukos vėžiu, kuriems nustatytos dauginės metastazės kauluose. Į tyrimą įtrauktas 91 ligonis. Atlikus klinikinius ir biocheminius, taip pat kaulinės sistemos radiologinį bei scintigrafinį tyrimus ir nustačius indikaciją gydyti strociu-89, ligoniui sutikus, į/v suleidžiama 150 MBq stroncio-89 chlorido.

Visi stronciu-89 gydyti ligoniai buvo apžiūrimi kas mėnesį. Kiekvieno vizito metu atliekami klinikiniai tyrimai, pagal ECOG skalę įvertinama bendra būklė, pagal 10 balų VAS skalę – skausmo sidromas.

Rezultatai. Per 1999–2006 m. stebėjimo laikotarpį 68 (74,7%) ligoniai mirė vėžiui progresavus.

Nustačius metastases kauluose, pacientai vidutiniškai išgyvendavo 32 mėnesius. Pagal nuskausminantį stroncio-89 poveikio efektą jie buvo suskirsti į dvi grupes.

A grupės pacientai, kuriems nuskausminantis stroncio-89 poveikio efektas buvo neigiamas, vidutiniškai išgyveno 25 mėnesius. Šių pacientų parametrų vidurkiai: priešinės liaukos vėžio diferenciacijos laipsnis pagal Gleasoną – 7,6 ± 1,0; PSA – 75,8 ± 40,6 ng/ml; hemoglobinas – 106,6 ± 13,8 g/l; šarminės fosfatazės kiekis kraujyje – 1695,1 ± 1194,0; skausmo intesyvumas pagal VAS skalę – 8,5 ± 0,8; kaulų metastazių, kurios nustatytos scitigrafiškai, skaičius – 14,4 ± 3,0; laikotarpis dienomis, kada pradėtas gydymas stronciu-89, – 828,5 ± 756,7, ir laikotarpis dienomis po gydymo stronciu-89, – 108,3 ± 75,9. Šios grupės ligonių bendra būklė prieš gydymą stronciu-89 pagal ECOG buvo didesnė nei 3.

B grupės pacientai, kuriems nuskausminantis stroncio-89 poveikio efektas buvo teigiamas, vidutiniškai išgyveno 42 mėnesius. Nustatyti tokie jų parametrų vidurkiai: priešinės liaukos vėžio diferenciacijos laipsnis pagal Gleasoną – 7,1 ± 1,1; PSA – 59,5 ± 40,0 ng/ml; hemoglobinas – 123,1 ± 16,4 g/l; šarminės fosfatazės kiekis kraujyje – 548,1 ± 442,0; skausmo intesyvumas pagal VAS skalę – 8,2 ± 0,7; kaulų metastazių, kurios nustatytos scitigrafiškai, skaičius – 8,2 ± 2,4; laikotarpis dienomis, kada pradėtas gydymas stronciu-89, – 1076,8 ± 1166,8; laikotarpis dienomis po gydymo stronciu-89 – 537,0 ± 428,4. Šios grupės pacientų bendra būklė prieš gydymą stronciu-89 pagal ECOG buvo lygi 2.

Statistiškai apdorojus gautus tyrimo duomenis nustatyta, kad naviko diferenciacijos laipsnio pagal Gleason, PSA, skausmo intesyvumo pagal 10 balų VAS skalę parametrų vidurkių skirtumai tarp A ir B grupių nebuvo reikšmingi; tuo tarpu hemoglobino kiekio kraujyje, šarminės fosfatazės kiekio kraujyje, kaulų metastazių skaičiaus skelete bei trukmės dienomis iki mirties datos po gydymo stronciu-89 parametrų vidurkių skirtumai tarp A ir B grupių buvo statistiškai reikšmingi.

Išvados. Analgetinis stroncio-89 poveikis pasireiškė 69,2% pacientų, sergančių priešinės liaukos vėžiu ir jau turinčių skausmigų metastazių kauluose; 36,2% ligonių skausmas sumažėjo vidutiniškai, 33,0% ligonių skausmai kauluose šnyko visiškai. Vidutins beskausmis laiktorpis tęsėsi nuo 3,2 iki 6,7 mėnesio. Galimi pakartotini strocio-89 gydymo kursai.

Atrenkant ligonius, kuriems bus skiriamas stroncis-89, svarbu, kad ECOG būtų mažesnis nei 2, hemoglobinas – didesnis nei 120 g/l, šarminė fosfatazės kiekis – mažesnis nei 500 U/l, scitigrafiškai nustatytų kaulų metastazių – mažiau nei 8 metastazės. Nustačius daugines skausmingas metastzes, gydymas stronciu-89 turi būti pradėtas kuo anksčiau.

Raktažodžiai: stroncio-89 chloridas, priešinės liaukos vėžys, metastazės kauluose, skausmo sindromas