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## <sup>153</sup>Sm-EDTMP radionuclide treatment of bony metastatic disease: a radiation protection evaluation

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**RIASSUNTO.** Con questo lavoro sono state individuate e ottimizzate le prescrizioni di radioprotezione da attuarsi nel caso in cui pazienti ricoverati nei normali reparti di degenza siano sottoposti a terapia radiometabolica palliativa delle metastasi ossee con attività di <sup>153</sup>Sm-EDTMP minori di 3 GBq. L'adeguatezza delle procedure di prevenzione della contaminazione di ambienti e oggetti e di protezione del personale ospedaliero, degli altri pazienti e dei parenti dai rischi da irradiazione esterna e da contaminazione interna è stata valutata mediante l'esecuzione di una serie di misure sia di contaminazione superficiale all'interno della stanza di degenza, sia di dose in vicinanza dei pazienti trattati. I risultati delle misure effettuate mostrano che la contaminazione degli oggetti e degli ambienti venuti in contatto con i pazienti portatori di radioattività è molto contenuta. I maggiori rischi di contaminazione sono associati alla gestione degli escreti fisiologici, che pertanto devono essere accuratamente raccolti e smaltiti come rifiuti radioattivi. Le misure di irradiazione esterna indicano che nelle aree adiacenti alla stanza di degenza non viene superato il limite di dose per le persone del pubblico e che parimenti non viene superato il vincolo di dose di 3 mSv fissato per coloro che volontariamente e consapevolmente assistono il paziente, i quali ricevono una dose inferiore a 20 µSv a paziente. Il rispetto delle procedure radioprotezionistiche proposte garantisce pertanto il contenimento del rischio di esposizione e di contaminazione per il personale ospedaliero impegnato nelle attività della radioterapia metabolica.

**Parole chiave:** Sm-153 EDTMP, Radioprotezione, Radioterapia metabolica palliativa.

**ABSTRACT.** The aims of the study were the identification and optimization of the radiation protection measures for in-patients who underwent palliative radionuclide therapy for bone metastases with <sup>153</sup>Sm-EDTMP activities lower than 3 GBq. The suitability of the preventive procedures from the contamination of places and objects, and for the protection of the hospital staff, other patients and relatives from the danger of external radiation and internal contamination has been evaluated by carrying out a series of measurements both of superficial contamination inside the confinement room and of the dose near the treated patients. The results show that the contamination of the places and the objects close to treated patients is really low. The greatest risk of contamination depended on the management of the physiological waste that, therefore, should be collected and disposed as radioactive one. The measurements of external radiation show that nearby the confinement room the dose limit for public is not exceeded. The same is true for the dose limit of 3 mSv established for relatives who, when taking care treated patients, receive a dose lower than 20 µSv a patient. The fulfilment of the proposed radiation protection measures assures the containment of the risk of exposure and contamination for nursing and medical staff involved in radionuclide-based therapy.

**Key words:** Sm-153 EDTMP, Radiation protection, Palliative radionuclide therapy.

### Introduction

The palliative or symptomatic treatment of skeletal metastasis-related pain is one of the applications of the radiotherapy, which allows an effective pain control with a relatively low dose (2 - 4 Gy) (1).

More recently the metabolic radiotherapy, with radionuclide linked to a bone seeker, has become an alternative method to the external beam radiotherapy for the treatment of patients with multiple skeletal locations (2). This new approach being related to the new radiopharmaceuticals easy to administer and devoid of systemic toxicity.

For therapeutic purpose is now available the ethylenediaminetetramethylenephosphine acid (EDTMP) chelated with <sup>153</sup>Sm (a beta particle-emitting radionuclide) which properly fulfils the "optimal" requirements for the local palliative therapy (3).

The administration of <sup>153</sup>Sm-EDTMP to hospitalised patients involves, however, many problems linked both to the radiation protection of the operators and the public and to the management of the radioactive physiological waste produced by treated patients.

The aim of the present study has been to identify the radiation protection procedures to be used during the treatment with <sup>153</sup>Sm-EDTMP of in-patients in order to reduce the dose for the ward staff and to respect the dose limit suggested in recent European Commission recommendations (4, 5) for people who look after the patient treated with radionuclide therapy and, finally, to manage correctly the radioactive waste produced.

### Materials and methods

Twenty-three consecutive patients with bone metastases from prostatic and breast cancer received 37 MBq/kg i.v. of <sup>153</sup>Sm-EDTMP (Quadramet<sup>TM</sup>, CIS bio international, France). Each patient was taken into a single room with walls and floor covered by washable and non-absorbent material and equipped with an exclusive bathroom. By means of a beta-gamma detector Berthold LB 122, the staff of the Medical Physics Service everyday check the level of contamination for surfaces, objects which were in contact with or were used by the patients

(sheet, armchair, patient's clothes), and for the solid waste produced in the room.

The air kerma rate (with a ionization chamber Victoreen 470 A Panoramic close to the patient and at 50 cm from him, which is the distance where the operator in charge could be) was also measured.

The urine has been completely collected and the whole volume produced recorded. By routine, bladder catheters have been inserted in all patients and the bags have been changed at stated times (every three hours the first day, every six hours the second and the third day and in the morning of the fourth day). A sample of 10 ml has been taken from each collected volume and its activity has been measured by a spectrometric system with NaI scintillator.

For the four initial patients a series of measurements for environmental dosimetry have been carried out using 5 film-badge dosimeters put on the headboard, near the urine container placed in the bathroom, on the dividing wall from the lift, on the dividing wall from the adjacent room and in this room. Apart from the dosimeter put on the headboard, the others were located at a floor height near the position of the urine container and the bag, because of their high concentration of activities mainly during the first hours after administration.

## Results

All the measurements (on the room surfaces, materials close to or used by the patients, solid waste produced) did not show values of contamination greater than  $3.7 \text{ Bq/cm}^2$ , which is the derived limit of radioactive contamination for public areas (6). Actually we found confined and precise contamination of the floor and of the sheet only when little losses of urine accidentally occurred from the bladder catheter.

The mean excreted fraction curve of the 23 treated patients is shown in Figure 1, and the excreted specific activity is presented in Figure 2. The inter-patient variability seems to be related to metastatic tumor burden, which sustains a different uptake of radionuclide (i.e. a greater number of metastatic site is responsible for a lower activity excretion). Overall, the radionuclide excretion is rapid during the first six hours and, by a slow progressive decrease, it reaches a specific activity in the urine lower than  $1 \text{ kBq/ml}$  at three days. The behaviour of the air kerma rate measured close to the patient and at 50 cm far away is shown in Figure 3. The wide variability of the measurements depends on the different anatomical distribution of the skeletal metastases for individual patient and therefore on the different pharmacokinetics of the radioactive compound. For catheterised patients, the presence of the collecting urine bag located beside the bed contributes to the variability of these measurements. Considering the fact that the greatest value of the air kerma rate during the first hours of the administration is lower than  $20 \mu\text{Gy/h/GBq}$  and that this value falls under  $1 \mu\text{Gy/h/GBq}$  at the fifth day, the limit of  $3 \text{ mSv}$  for adults younger than 60 years, who voluntarily and consciously take care or live with patients treated with radioactivity, is widely respected (4, 5).

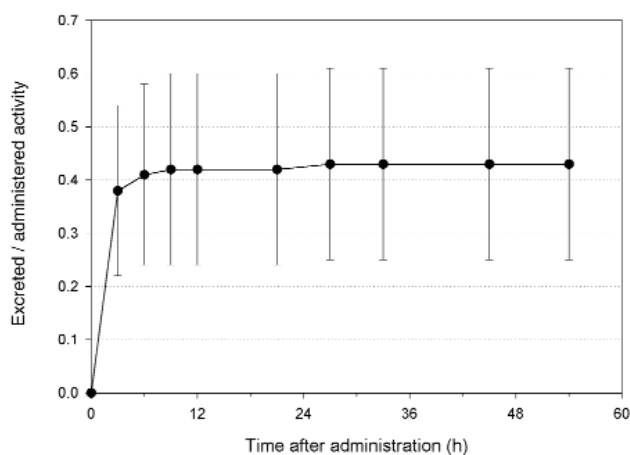


Figure 1. Cumulative excreted fraction of the administered activity

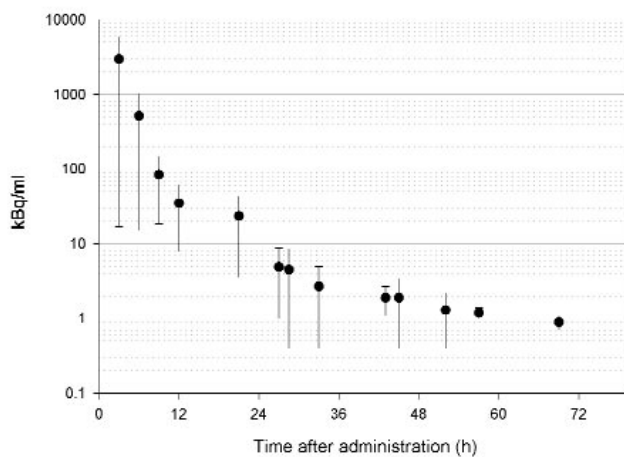


Figure 2. Specific activity of the excreted fraction at various time after administration

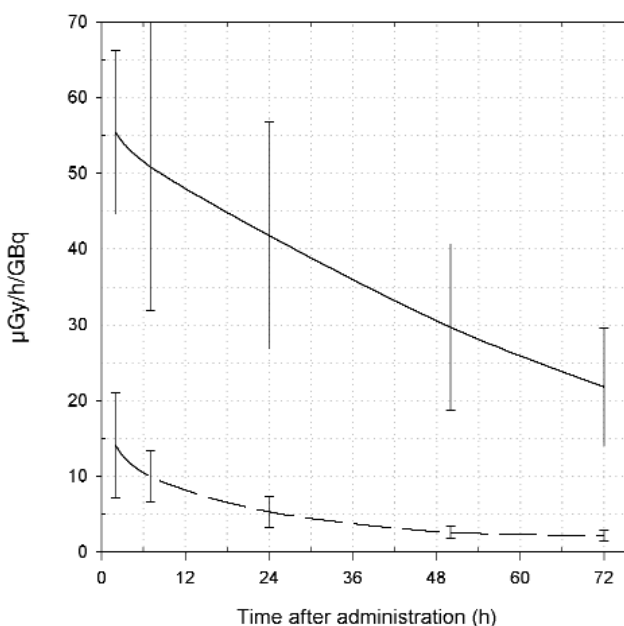


Figure 3. Behaviour of the air kerma rate close (continuous line) and at 50 cm (dotted line) from treated patient

Table I shows an estimate of exposure presuming that 15 operators take care of 50 patients per year (each patient receiving a mean of 3 GBq activity) for 10 min. per hour, during the 72 h after radionuclide administration. This estimate is based on the calculation of the 95<sup>th</sup> percentile of the air kerma, measured 50 cm from the patient.

The results of the environmental measurements are shown in Table II. These dose values are expressed per patient and per unit of administered activity.

**Table I. Dose estimation for the staff**

Situation	μSv
Care of a patient treated with 3 GBq for 10 minutes/hour during the 72 h after administration	246
Care of 50 patients	12300
Dose for operator/year (15 operators per ward)	820

**Table II. Environmental dosimetry results using film-badge**

Film-badge position	Floor height (cm)	μSv/patient	μSv/GBq
Headboard	170	543	192
Urine container	30	130	46
Dividing wall from the lift	50	213	75
Dividing wall from the adjacent room	30	102	36
Adjacent room	30	69	24

### Comment

Our preliminary experience carried out in 23 patients with bony metastatic disease allows the following considerations: a) each individual patient, eligible for <sup>153</sup>Sm-EDTMP therapy, has to be isolated in a single confinement room with an inside bathroom and washable surfaces; - b) due to the lack of contamination risk by saliva and sweat, there is no need of collecting and checking personal belonging of treated patients; - c) it is, however, mandatory for the ward staff to use protective means (aprons, gloves and overshoes) in order to avoid any risk of personal contamination by patient's urine; - d) the yearly dose of external exposure for care-takers in activity for the first 72 hours after radionuclide administration is lower than 1 mSv. The dose which could be absorbed later is negligible, and, however, in the range of the activity usually administered for diagnostic purpose; - e) the

external radiation risk is minimum in areas close to the confinement room (estimated dose values less than 1 mSv/year); - f) an additional source of radiation risk, to be added to the total dose absorbed by the ward staff, is the bag of collected urine. For the purpose a suitable shielding should be at hand for both radiation protection and hygienic safe-guard; - g) in order to comply with recommended dose limit of 0.3 mSv (7) of external radiation for healthy population, the protection procedure can be stopped at the third day from the <sup>153</sup>Sm-EDTMP administration. At this point in time (when the urine specific activity is less than 1 kBq/ml) the urine collection can be stopped, and the patient, who need to continue hospitalisation for other clinical reasons, can be safely transferred in the ward with other patients.

### Conclusions

An optimised radiation protection procedure to be used in a normal confinement ward for patients receiving radionuclide therapy for the treatment of the bone metastases with <sup>153</sup>Sm-EDTMP has been evaluated. Our dosimetric assessment showed this approach as suitable for containing the risk of exposure for both care-takers and relatives as well as for allowing the proper radioactive waste disposal. With proper protection facilities <sup>153</sup>Sm-EDTMP therapy is possible even in a normal confinement ward.

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