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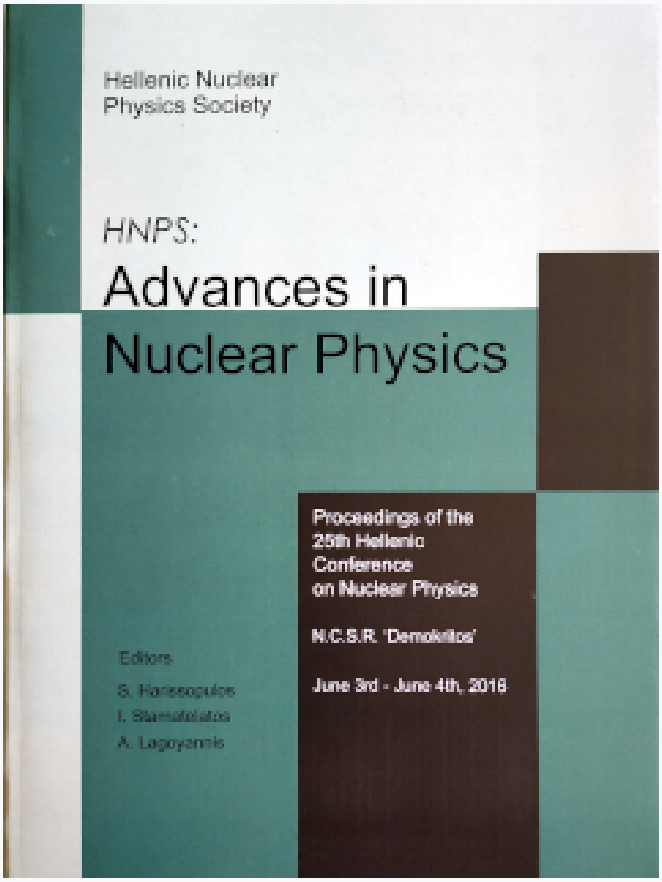

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Design and operation of a therapeutic unit with unsealed radioactive sources

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Abstract

A radioisotope therapeutic unit (RTU) for the treatment of patients with radiopharmaceuticals was designed and set in operation by the Ioannina University Hospital Medical Physics and Nuclear Medicine Departments. A number of parameters and procedures have been taken into account during the design stage to combine high quality medical services with minimum unjustified radiation exposures. Two pre-existing wards were modified to therapy / isolation wards by the addition of structural shielding made of concrete or/and iron and lead plates. Similar modifications were carried out in some of the remaining rooms of the RTU, such as the corresponding hot-lab and the storage-to-decay rooms. A network of GM detectors was installed for continuous monitoring of radiation levels at various locations. Among the first one hundred patients treated at the Unit, 80 had differentiated cancer and 14 had hyperthyroidism and were treated with ^{131}I of activity ranging between 0.74 and 7.4 GBq. The maximum H*(10) rate at 1.0 m distance from the patient's body was one of the criteria for patient release and was set on patient-specific terms. The adequacy of the RTU design and the employed operational policies were verified in practice. In conclusion, the RTU meets successfully the predicted needs.

Keywords ^{131}I, radionuclide therapy, radiation safety, shielding, cancer, hyperthyroidism

1. INTRODUCTION

Nuclear medicine therapy procedures have been introduced since the first half of the 20th century. The use of radioiodine-131 (^{131}I) to treat thyroid disorders was one of the first therapeutic uses of radionuclides [1, 2]. The large experience by such treatments led to the development and therapeutic use of a number of radiopharmaceuticals for a variety of diseases. A radioisotope therapeutic unit (RTU) for treatment and hospitalization of patients from a wide geographical area was designed and set in operation by the Ioannina University Hospital (IUH) Medical Physics and Nuclear Medicine Departments, aiming to combine high quality medical services with low financial and radiological cost. RTU consists of two double-bed treatment / isolation wards and auxiliary facilities for treatments with β^- or/ and α-emitters. This study aims to present the design requirements and the operational strategy of a new RTU and the experience gained by treating its first 100 patients in it.

2. UNIT DESIGN AND DESCRIPTION

2.1 Introduction: World-wide, the vast majority of the therapies with radiopharmaceuticals are treatments of well differentiated papillary and follicular thyroid carcinomas that synthesize thyroglobulin and some benign thyroid diseases, carried out by administration of NaI^{131} containing capsules. These treatments are based on the avidity of the thyroid gland for

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iodine ions [3-5]. ^{131}I decays with a half-life of 192.5 h though β^-emission to excited levels of ^{131}Xe, the isomeric ^{131m}Xe included ($T_{1/2}$=286 h, 1.18% abundance). ^{131}I liberates on the average per decay, 191.8 keV as electron kinetic energy (mean electron range in soft tissue ~400 μm) and 383 keV as photon energy (principle γ-emission at 364.5 keV (81.2%)). Beside ^{131}I, ^{177}Lu-DOTA-Tyr[3] and ^{153}Sm-EDTMP are also administered at IUH/RTU to treat metastatic neuroendocrine tumors and for pain reduction in patients with multiple bone metastases, respectively. Treatments of bone metastasis in patients with castration-resistant prostate cancer with the α-emitting $^{223}RaCl_2$ are to be initiated at the near future.

2.2 Radiation shielding: Two pre-existing rooms and the corresponding WCs were modified to treat under isolation "hot" patients by the addition of structural shielding made of concrete and plates made either by iron or lead. Structural modifications were also carried out in the auxiliary rooms of the Unit, when required, such as at the adjacent hot-lab and the rooms used for decay-in-storage of solid short-live radioactive items (e.g. linen, toilet papers, food residues, forks, plates) in dedicated freezers, if appropriate, to the time their activity drops below the corresponding clearance levels. Narrow windows that do not overlook occupied areas were constructed. Mobile shields made of lead were positioned close to each patient's bed to protect personnel in case a patient could need assistance. All the items used at the Unit, such as furniture, cloth cabinet, WC items, waste baskets, electric equipment, and work-benches, were chosen in a way that reduces the probability of radioactive contamination and allows easy decontamination. Among other things, special lining was used in the entire Unit to reduce the spread of contamination and allow the easy cleanup, if needed.

2.3 Gaseous and liquid discharges: A local system was installed for contineous release to the atmosphere of the gases generated in the unit, such as the exhaled ^{131}I and ^{131m}Xe, few meters above the roof of the building. A large fraction of the administered ^{131}I is excreted before decay during the first few days, mainly by urine. Thus, an independent drainage network from the RTU to the IUH biological waste management unit (BWMU) was build to ensure the safe transport and in-situ treatment of the biological excretions. A detailed study carried out by the Medical Physics Department modeled the transport of the biological excretions from the wards via the IUH/BWMU, to the BWMU of the town of Ioannina, the Kalama's river and then to the final receiver, the Ionian sea, at a distance of about 80 km from their origin (a fraction of the track is through "Natura 2000" regions). The study showed that there is no need of waste holding tanks for in-situ decay of the stored urine, according to the currently employed regulations on radiological protection.

2.4 Equipment: A CSP-COM network of eight STTC GM detectors, by Canberra Ind, was installed and continuously monitor the H*(10)-rate. More specifically, a detector is located at ~!1.3 m above each bed, one over the heavily shielded entrance door of each isolation room, one at the hot-lab and at the nurse station opposite to the isolation wards. The Unit is also equipped with a Veenstra 404 dose calibrator located at a biosafety cabinet, a Como 170 surface contamination meter, a Fluke 451 P DE-SI-RYR survey meter, two EPD Mk2(+) pocket dosimeters by Thermo, as well as with a number of accessories for radiation protection. When needed, additional equipment is available from either other IUH units or from the University of Ioannina Medical Physics Laboratory, such as an IdentiFinder survey meter by by Target with spectroscopic capabilities, a RAM Ion survey meter by Rotem with a thin entrance window and a multi-detector whole-body counter.

Two cameras are in use at each isolation room for remote optical surveillance of the patients 24 h per day. In addition, the Unit is equipped with facilities that ease the safe patient’s hospitalization, such as a refrigerator, a TV set and a DVD player per room and a local Wi-Fi network. A fire detection and extinction system was installed and is use at the hot-lab. Emergency plans were prepared and IUH personnel was instructed how to act in case of medical or non-medical emergencies (e.g. respiratory or cardiac arrest, incontinence, vomiting, earthquake, fire).

3. INITIAL EXPERIENCE FROM THE OPERATION OF THE UNIT

3.1 ^{131}I treatment procedures: Among the patients treated during the first 16 months of RTU operation, 94 received ^{131}I treatments. Their age was 18 y to 81 y (mean 50.0 y). About 20% were male and 80% female (pregnant and breast feeding women were excluded). Fourteen patients were treated for hyperthyroidism (7 for Graves' disease, 6 for toxic adenoma and 1 for adenoma Hurthie) and the remaining 80 for differentiated cancer (69 for post-operative ablation of remnants, 5 for relapsed disease and 6 for impairment of large operation residue). According to local protocol, each referred patient was initially informed about the treatment procedures with emphasis on radiation protection issues both during hospitalization and after it. Some points were reminded to them just before drug administration. The postoperative thyroid remnant and serum thyrotropin (TSH) were measured a week before treatment. On the admission day a complete course of blood analyses was performed (TSH, thyroid hormones, thyroglobulin, autoantibodies etc.) combined with pregnancy test, if applicable.

The mean administered ^{131}I dose in cancer patients was 3.44 GBq (93.0 mCi, range 30 to 200 mCi) and 0.884 GBq (23.9 mCi, range 15 to 30 mCi) in hyperthyroidic patients. The nominal total activity of the administrated ^{131}I during the study period corresponded to ~ 20% of the maximum annual activity that the RTU was licensed, resulting to an annual collective dose less than 2 man·mSv due to the released radioactivity, according to our modeling.

During the study period, 77% of the treated patients stayed at the isolation rooms about 48 h post-administration and the remaining about 24 h. One of the criteria for the patient release from the Unit was the maximum H*(10)-rate at 1.0 m distance from his body. This was set on individual basis considering several factors, such as his health status and whishes, the duration and type of patient’s transportation from the Unit to his residence, the local conditions in it, his anticipated activities and the degree of the anticipated compliance to the instructions that he got both orally and in written form and signed before administration.

The median H*(10)-rate upon release was 21 μSv/h (range 4.5 to 39 μSv/h) Note that the mean rate in cancer patients, 21 μSv/h, was lower than that hyperthyroidic ones, 25 μS/h and that the maximum value corresponded to a patient with papillary carcinoma and 1.4% 24-h uptake, given 3.7 GBq ^{131}I 50 h earlier. Combining the initial measurements on 27 cancer patients with small post-surgical residue with measurements 8 d post-administration indicated that the H*(10)-rate data could be fitted with two exponential components of median $T_{1/2,eff}$ 12 and 28 h, respectively, i.e. times compatible with those in the literature. Therefore, the

biological elimination rate was about an order of magnitude faster than the decay rate.
3.2 Other treatments: Four 740 MBq ^{177}Lu-DOTA-Tyr^3 sessions were given in two patients. Each session required a 7 to 8 h-long hospitalization. About 2 h before and 2 h after the drug administration that lasted 40 to 50 min, amino acids were administered to protect his kidneys. Although, ^{153}Sm-EDTMP treatments usually do not require hospitalization, some patients remained at the Unit, over few hours after administration. In both treatment schemes, a whole-body scan was carried out, for verification purposes during each session. IUH is also licensed to administer the recently developed and approved α-emitting bone seeker $^{223}RaCl_2$ that targets heavily the bone metastatic sites (the short range of the α-particles restricts the radiation damage in highly localized volumes).
3.3 Radioactive waste: The solid radioactive waste produced at the wards is measured by a medical physicist (usually 1 day after the patient's release), and kept in the storage-to-decay rooms of the Unit, in exclusive freezers, if required. The β-γ emitting short-lived waste is removed from the RTU, only if the maximunm H*(10)-rate at 10 cm distance from the surface of the packages is < 5μSv/h under the current Radiation Protection Regulation [6].
3.4 Other issues of radiological protection: During its initial period of UIH/RTU operation about 100 patients received treatment, including cases with specific management needs (paraplegics, non-native Greek speakers, etc.). Neither accidents nor incidents of radiological importance took place during the study period. Periodic H*(10)-rate measurements around RTU and at IUH BWMU proved the adequacy of the design and the compliance with the posed requirements. In addition, individual personnel monitoring indicated non-reportable doses to personnel exclusively exposed at RTU, and no increase to the remaining personnel that offers services to the entire Nuclear Medicine Department.

4. CONCLUSION

An up-to-date RTU was designed, constructed and operates at IUH. The Unit provides a variety of therapeutic schemes and meets successfully the medical needs of a wide geographical area (Epirus, Ionian Islands, Aetolia-Acarnania, Western Macedonia and a part of South Albania). Its operation is under ISO-9001:2008 quality system, as the remaining activities of the IUH Nuclear Medicine and Medical Physics Departments. The employed protocols provide high quality health services and adherence to the regulations of both the Greek and the European Union Authorities [3-7]. For the future we are ambitious to implement novel treatment protocols in the more personalized fashion of modern targeted radiotherapy.

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