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Optimization of radiation exposure for staff using e-controlling devices during radiopharmaceuticals' loading and dispensing procedures in F18-PET/CT daily practice

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Abstract – Background: F18-PET/CT technique has been permanently optimized to ensure the best accuracy and to extend its clinical application. Radiation protection remains an omnipresent aspect of daily practice in F18-PET/CT. Introduction: We tried to demonstrate the usefulness of remotely controlled radiopharmaceutical dispensers with smart-phones or tablets in the optimization of staff exposure. Material and methods: We performed a study to evaluate the exposure during loading and dispensing of radiopharmaceuticals working in two different ways: according to the user's manual of the automatic dispenser and, respectively, with an e-controlling application. We calculated the maximal radiation exposure and analyzed the differences related to the annual effective dose. Have been considered 40 loading and 353 dispensing procedures. During the loading, it has been manipulated a total activity of 9348.8 mCi (345905.6 MBq) FDG. A total activity of 2622.5 mCi (97032.5 MBq) FDG has been manipulated during dispensing. Results: The effective dose resulted from the loading procedure measured at the dispenser contact was 445.05 μ Sv. The effective dose measured in the remote control area during the loading procedure was 0.34 μ Sv, having a difference of 444.71 μ Sv. The total effective dose during dispensing procedures measured at the dispenser was 206.6 μ Sv and the total effective dose measured in the controlling room was 2.64 μ Sv, thus a difference of 203.96 μ Sv. The cumulative difference between the effective doses was of 648.67 μ Sv. Discussion: E-controlling the dispenser, we got an exposure saving representing 61.2% from the operator's annual dose. Conclusions: This study demonstrates the effectiveness of e-controlling devices in radiation protection of the staff working in F18-PET/CT.

Keywords: radiation protection / PET/CT / automatic dispenser / staff exposure / e-controlling device

1 Introduction

Since its clinical implementation, at the beginning of the XXI century, F18-PET/CT technique has been permanently optimized to ensure the best diagnostic accuracy and to extend their clinical application (Workman and Coleman, 2006). Many guidelines and publications of prestigious scientific organizations have been published to offer a proper standardization through the multitude of particular aspects regarding this hybrid imaging technique (IAEA, 2008a, 2013, 2014; Boellaard *et al.*, 2014).

Despite all the progress achieved in technology, radiopharmacy, molecular biology, radiation protection remains an omnipresent aspect of daily practice in a PET/CT department.

Governed by three key principles (justification, optimization and limitation), the radiation protection is implemented to protect three categories of individuals: exposed workers, patients and population, by the effects of ionizing radiation (European Parliament, 2014).

In a PET/CT department we confront with already justified practice, according to all international regulations (ICRP, 2007). The most important application of F18-PET/CT remains the oncology, where the method has an important position in diagnostic and follow-up protocols, according to the guidelines (IAEA, 2008a). Staff radiation exposure is limited having established limits for the effective dose, the equivalent dose for eye lens, skin and extremities. As professionals, remain in our responsibility to use all the available methods to optimize the radiation exposure for staff but also for other categories and to comply with the second principle of radiation protection and to minimize the exposure

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as low as reasonably achievable (ALARA) (ICRP, 2007; Boellaard *et al.*, 2014).

The activity in a PET/CT department implies some procedures that lead to staff exposure. As a first step in the implementation of a radiation protection strategy is to identify where it should be applied. There are few steps in the examination procedure where radiation risk may occur to different professional category:

- the radiopharmaceutical performed by technologist or radiopharmacist;
- the dispensing of the activity into syringe where technologists or radiopharmacists could be involved;
- the infusion of the radiopharmaceutical into the patients performed by technologists or physician;
- the positioning of the patient and the scan performing, usually done by technologists;
- the discharging of the patient from the department, after dosimetric measurements, with the involvement of the physicist or technologist.

These aspects may vary from a country to another and from department to department due to the significant differences regarding the local or national regulations and regarding the competencies, skills and knowledge of the staff. No matter what professional category is involved, the procedures with highest risk of irradiation for staff remain: the loading and the dispensing of the radiopharmaceutical.

Having the particular physical aspects involved in PET, it is important to have additional radiation protection methods in comparison to conventional nuclear medicine. The radioisotopes used in F18-PET have particulate beta⁺ emissions which lead after the annihilation process in the matter to high energetic 511 keV photons. These photons have a high penetration, the half value layer (HVL) in lead is 4 mm (Zito *et al.*, 2007), properties that impose the necessity to have strong shielding devices. Another physical aspect is the relatively short half-life which leads to the necessity to manipulate high activities on a regular basis. These aspects became the main reasons to develop automatic loading and dispensing devices in order to optimize the exposure of the staff manipulating the radiopharmaceuticals. These automatic dispensers offer an effective radiation protection for the staff with a reduction of whole body effective dose over 30% and a reduction of the exposure of extremities over 90% in comparison with manual methods (Lecchi *et al.*, 2012). The most used radioisotope in PET is F-18 (fluorine-18) mainly labeling flouro-deoxy-glocose (FDG), the most used radiopharmaceutical in PET.

There is a constant concern for the optimization of exposure for the staff handling PET radiopharmaceuticals and numerous studies reflect this, analyzing different methods to optimize the irradiation during the manipulation of PET radiopharmaceuticals. Most of the studies evaluate the efficiency of new protocols for injection and administration of the radiopharmaceuticals (Lecchi *et al.*, 2012), demonstrate the efficiency of automatic injectors in radiation protection (Schleipman and Gerbaudo, 2012) and even homemade syringe drawing devices (Guillet *et al.*, 2005) and also compare the exposure of staff using these devices with the exposure manually handling the radiopharmaceuticals (Schleipman and Gerbaudo, 2012).

In the light of the second principle of radiation protection, the optimization, stated in all regulatory documents (IAEA, 2002, 2008b, ICRP, 2007; European Parliament, 2014), we tried to optimize, furthermore, the radiation protection of the staff performing radiopharmaceutical loading and dispensing procedures in a PET/CT department. We evaluated and tried to demonstrate the usefulness of e-controlling devices in the optimization of staff exposure for those professional categories involved in radiopharmaceutical loading and dispensing. With this procedure we tried to demonstrate the possibility to reduce the exposure during dispensing and loading the PET radiopharmaceuticals in the respect of ALARA principle.

2 Materials and methods

We performed a prospective study ruled over a period of one year between January and December of 2015 in our PET/CT department and we evaluated the exposure of an experienced technologist during loading and dispensing of FDG working in two different ways: as it is designed, according to the user's manual of the automatic dispenser and, respectively, controlling the dispenser from the distance using an e-controlling software. This software is a free available e-controlling application installed on smart-phone or tablet. We calculated the maximal radiation exposure and analyzed the differences related to the annual effective dose of the technologist and also to the dose limit as stated in the regulations. The study aimed only the loading of radiopharmaceutical into the dispenser and the syringe preparation, no measurement have been performed during the injection phase of the PET/CT procedure, since no remotely controlled devices can be designed for this phase.

2.1 The staff

We used an experienced technologist with 16 years experience in the field of nuclear medicine, being obvious that the loading and dispensing of the radiopharmaceutical requires advanced competencies and specific skills, to minimize the risk of incidents and to ensure the high quality of procedure respecting all the standards and regulations. It has been settled a plan of responsibilities for the staff members qualified to perform loading and dispensing procedures and radiopharmaceutical administration and patient positioning in order to uniformly distribute the radiation exposure caused by these procedures. In respect to this, the responsibilities for loading and dispensing the radiopharmaceutical were attributed to one technologist and the radiopharmaceutical injection and patient handling to another technologist. The technologist involved in this study, received an annual effective dose of 1.06 mSv, measured over the period of the study, wearing termoluminescent dosimeters.

2.2 The workflow

In both ways, it is required the presence of the staff and manual handling of lead pot and syringes to be mounted onto dispenser. Besides that, during the automatic loading or dispensing, the dispenser can be manipulated from its own touch screen as it is designed, or from the distance using the

e-controlling software as we propose. During the study, the technologist only loaded the radiopharmaceutical and the syringes into the dispenser remaining that all the other procedures (radiopharmaceutical data input, loading, syringe presetting, dispensing) to be performed from the distance. The remote controlling computer was located into scanner controlling room for two reasons: because it is closely located to the dispensing room, being in the same place of the controlled area without any inconvenience for the workflow and because it is the space with the lowest dose rate from the controlled area, without any interference with the open sources. The radiopharmaceutical loading and syringe preparation with the automatic dispenser we used to perform the study have predictable, specific procedural steps required by the dispenser's workflow and have no variation regarding the length of the procedure.

2.3 The equipment

For this study, we used an automatic dispenser Karl 100[®] produced by Tema Sinergie, considered to be superior concerning the radiation protection of the staff, since minimal radioactive source manipulation is needed in comparison with a fixed hotcell. The automatic dispenser able to automatically load the radiopharmaceutical from the lead pot and to automatically transfer the requested activity into syringe. The dispenser extracts the radiopharmaceutical from the transport multi-dose vial without being necessary any manual handling except the manual placement of the vial into the designed drawer. From this point, the device automatically manipulate the transport vial and extract the radiopharmaceutical which is deposited into the so-called mother-vial strongly shielded with 50 mm of lead into the dispenser's body offering efficient radiation protection. The device is also capable to automatically load the requested activity into the syringe which is manually inserted into its designed insertion system and efficiently protected by a tungsten shielding. The automatic dispenser is equipped with an incorporated calibrator to measure the activity prepared for each patient and also with an incorporated dosimeter able to measure the dose rate in real time. The dispenser is designed to have the dosimeter's probe placed under the controlling display measuring the H*(10) ambient dose rate. To measure the dose rate in the control room, we used a Radiagem[®] dosimeter able to record H*(10) ambient dose equivalent rate with an accuracy of $\pm 15\%$ within a range of 0.01 $\mu\text{Sv/h}$ to 100 mSv/h, having an energy range for gamma and X-rays of 40 keV to 1.5 MeV (IEC 60846) equipped with a Geiger Mueller energy compensated detector. All the equipment we used respect the regulations, being verified, having updated valid calibration certificates.

2.4 Data registration and calculations

For this study, we measured the maximal dose rates measured by the dispenser's dosimeter and by the dosimeter placed in the remote control area. Knowing the time of the procedure, we calculated the effective dose and we compared the data in relation with annual effective dose of the technologist.

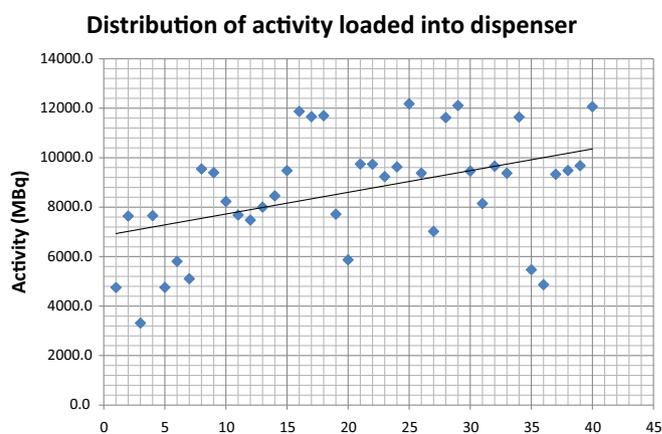


Fig. 1. Activity distribution of loaded radiopharmaceutical.

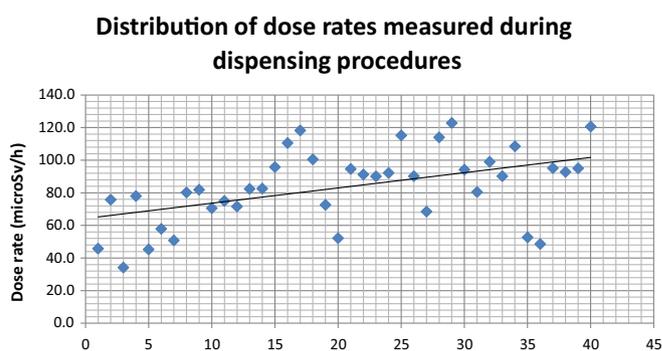


Fig. 2. Distribution of dose rates measured during loading procedures by the dispenser's dosimeter.

We included in the study all the values recorded for all the scheduled working days when the technologist involved in the study performed loading and dispensing procedures. Have been considered 40 valid working days when the technologist involved in the study performed 40 loading procedures (one in each day) and dispensed 353 syringes with radiopharmaceutical to be injected to the scheduled patients. This was the workload for the technologist involved in the study performing loading and dispensing of the radiopharmaceutical, over the entire period of the study, from January to December of 2015.

During the loading procedures it has been manipulated a total activity of 9348.8 mCi (345905.6 MBq). Each loading procedure lasts 8 minutes from the moment when the radiopharmaceutical starts to be loaded from the lead pot into the mother vial of the dispenser.

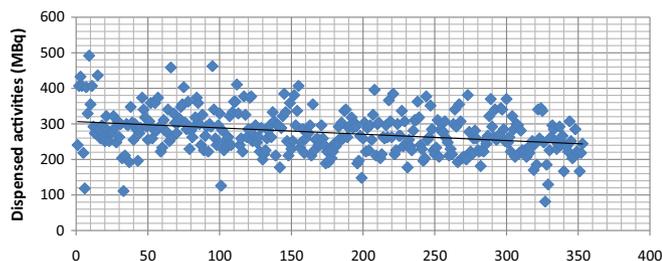
A total activity of 2622.5 mCi (97032.5 MBq) has been manipulated to dispense the radiopharmaceutical into 353 syringes. Each dispensing procedure lasts 4 minutes from the moment when the radiopharmaceutical is extracted from the mother vial, measured into calibrator and then loaded into syringe. Every syringe activity has been calculated based on the body-weight of the patients.

3 Results

The average radioactive activity per loading procedure was 233.7 mCi (8646.9 MBq) with a standard deviation (SD) of ± 63.3 (2342.1). The distribution of the activity was

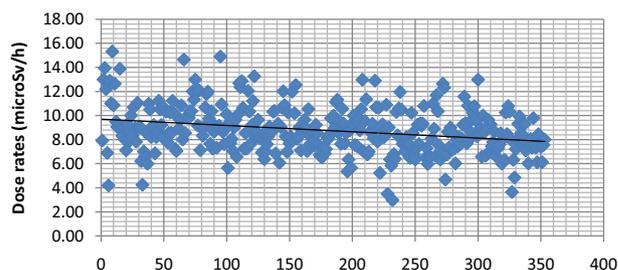
Table 1. Loading procedure – manipulated activities, measurements and effective dose calculation.

Manipulated activity (average) 233.7 mCi (SD \pm 63.3) 8646.9 MBq (SD \pm 2342.1)	Dose rate (average of maximal values during loading) at the dispenser 83.4 μ Sv/h (SD \pm 22.6)	Dose rate (average of maximal values during loading) e-controlled 0.064 μ Sv/h (SD \pm 0.016)
	Total effective dose calculated from the dose rates measured during loading procedures 445.05 μ Sv	Total effective dose calculated from the dose rates measured during loading procedures 0.34 μ Sv
$P < 0.0001$		

Distribution of activities dispensed into syringes**Fig. 3.** Distribution of activities dispensed into syringes.

homogenous (Fig. 1). The maximal dose rates measured by the dispenser's dosimeter had a homogenous distribution (Fig. 2), with an average value of 83.4 μ Sv/h (SD \pm 22.6). The maximal dose rates measured in the control area had an average value of 0.064 μ Sv/h (SD \pm 0.016). The total effective dose resulted from this procedure measured near the dispenser over the period of the study was 445.05 μ Sv. The total effective dose calculated from the dose rates measured at the remote control area during the loading procedure over the entire period of the study was 0.34 μ Sv, having a difference of 444.71 μ Sv between the effective doses resulting from all loading procedures measured near dispenser and in the controlling room. We calculated the P value for the two sets of effective dose values and we found a two-tailed P value less than 0.0001, statistically significant (Tab. 1).

The average radioactive activity of all 353 dispensed syringes was 7.4 mCi (273.8 MBq) with a standard deviation of SD \pm 1.6 (59.2). The maximal dose rates measured by the dispenser's dosimeter and the maximal dose rates in the remote control area had average values of 8.78 μ Sv/h with a standard deviation of 1.93, respectively 0.11 μ Sv/h with a standard deviation of 0.02. We found the distribution of the activities dispensed into syringes and the distribution of dose rates measured during dispensing procedures being homogenous (Figs. 3 and 4). The total effective dose during all dispensing procedures calculated from the dose rates measured near the dispenser had a maximal value of 206.6 μ Sv and the total effective dose calculated from the dose rates measured in the controlling room was 2.64 μ Sv, thus a difference of 203.96 μ Sv. Regarding the statistical significance between the two groups of calculated effective doses, at the dispenser and respectively, in the remote control area, the calculated P value was less than 0.0001, statistically significant (Tab. 2).

Distribution of dose rates measured during dispensing procedure**Fig. 4.** Distribution of dose rates measured during dispensing procedure by the dispenser's dosimeter.

The cumulative difference between the effective doses resulted from loading and dispensing procedures received in these two ways has a value of 648.67 μ Sv representing a reduction of 61.2% from the annual exposure of the technologist, which has been calculated from the monthly dose measurements at the end of the study as 1.06 mSv.

4 Discussion and conclusions

During this study, we evaluated for each procedure the maximal dose rate, in order to calculate the maximal effective dose, considering appropriate to evaluate the maximal risk of irradiation for staff from each procedure and to calculate the maximal effectiveness of the method we propose.

Searching on the available journal databases, we found peculiar data related to e-controlling applications used to optimize radiation protection in nuclear medicine departments, so we considered useful to perform research in this area. According to our knowledge, this is the first study in the literature that is addressed specifically to e-controlled optimization of staff radiation exposure; in present times with an increased availability of smart devices, this was a really opportunity to study how these might be useful in radioprotection. The added value of the method we propose for loading and dispensing the PET radiopharmaceuticals is that, despite other published methods, it improves the exposure of an already optimized procedure demonstrating that always we should be concerned by the optimization of radiation protection. This study gives a quantification of the efficiency of radiation protection of the described method not only in comparison with a manual method, but with an already optimized automatic procedure.

Table 2. Dispensing procedure –manipulated activities, measurements and effective dose calculation.

	Dose rate (average of maximal values during dispensing) at the dispenser	Dose rate (average of maximal values during dispensing) e-controlled
Manipulated activity (average) 7.4 mCi (SD +/- 1.6) 273.8 MBq (SD +/- 59.2)	8.78 µSv/h (SD +/- 1.93)	0.11 µSv/h (SD +/- 0.02)
	Total effective dose calculated from the dose rates measured during dispensing procedures 206.6 µSv	Total effective dose calculated from the dose rates measured during dispensing procedures 2.64 µSv
$P < 0.0001$		

Considering the fast developing field of hybrid nuclear imaging, the extension of the clinical application for F18-PET/CT and its increased availability all over the world, it is in the light of the optimization principle of the radiation protection to optimize all the procedures in order to have a radiation risk as low as reasonably achievable (ALARA). Any ALARA oriented procedure available should be used to minimize the irradiation of staff working in a PET/CT department, in order to cope the increased risk of irradiation induced by the tremendous development of the PET/CT techniques.

The dose limit for the exposed workers according to all European and International regulations is 20 mSv per year. In special circumstances, a higher dose of max 50 mSv per year may be authorized, if the average dose in any five consecutive years will not exceed 20 mSv per year.

Without any additional costs, using only a free e-controlling application available on any smart-phone or tablet, remotely controlling the automatic dispenser we got a reduction of the exposure representing 61.2% from the received annual dose. With this major advantage, it is feasible to optimize and change working protocols to remotely control the automatic dispenser. It is in the benefit of the staff to learn and adopt new working conditions using e-controlling devices like tablets or smart-phones to manipulate from the distance the automatic dispenser in order to optimize their irradiation risk during loading and dispensing the radiopharmaceutical.

No evaluation of the extremity doses has been ruled during the study because those procedures involving manual handling of the radioactive sources or near the radioactive sources (*e.g.*, lead pot handling, empty syringe mounting into dispenser) are mandatory performed without any difference in the respect of how the dispenser is controlled.

Having fixed and predictable procedural steps during loading and dispensing the radiopharmaceutical using this type of dispenser, the procedure is very standardized. Only one technologist was involved in the study without being necessary to evaluate the differences in irradiation savings upon the working habits. During the radiopharmaceutical loading and dispensing procedures, which are very standardized, the differences in irradiation risk might be recorded based on the differences between different workflows and workloads. This

paper represents a starting point for a multicentre study where further analysis should be performed in different working conditions.

To conclude, based on the results and having the discussion above, this study demonstrates the effectiveness of e-controlling devices in radiation protection of the staff working in PET/CT departments and performing radiopharmaceutical loading and dispensing procedures. Even in the case of some very well optimized, automatic and validated procedures, the radiation exposure can be furthermore optimized.

As an additional outcome from the registered data, having a homogenous distribution of the manipulated activities and measured dose rates we can also conclude that rotation between staff members can be scheduled without any impairment and with a homogenous distribution of radiation exposure of the individuals.

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