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Some results of a simulated test for administration of activity in nuclear medicine

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Abstract

This paper describes the results obtained using a simulated test for administration of activity in nuclear medicine between 2002 and 2004. Measurements in the radionuclide calibrator are made during the different stages of the procedure. The test attempts to obtain supplementary information on the quality of the measurement, with the aim of evaluating in a more complete way the accuracy of the administered activity value compared with the prescribed one. The participants' performance has been assessed by means of a statistical analysis of the reported data. Dependences between several attributes of the simulated administration tests results are discussed. Specifically, the proportion of satisfactory results in the 2003–2004 period was found to be higher than in 2002. It reveals an improvement of the activity administration in the Cuban nuclear medicine departments since 2003.

Keywords: Radionuclide calibrator; Activimeter; Administered activity; Fisher exact test; Activity measurements; Nuclear medicine

1. Introduction

The main instrument for activity measurements in the field of nuclear medicine is the radionuclide calibrator. Several comparisons using this type of instrument, involving hospitals and clinics with the purpose of contributing to the quality improvement of the end-user service, have been reported in the scientific bibliography (Paras et al., 1986; Debertin and Schrader, 1992; Iwahara et al., 2001, 2002; Woods and Baker, 2003; Olšovcová and Dryák, 2003; Joseph et al., 2003; dos Santos et al., 2004). The normal protocol adopted for these reported comparisons is that solutions of a single radionuclide are calibrated for radioactivity content and distributed in containers of the type commonly used in nuclear medicine services, as blind samples to the participants. The participants perform activity measurements exactly as would normally be done in their facility and report the values back to the organizer, usually the national standards laboratory. Therefore, these exercises checked the measurement process, including the measurement performance of the involved personnel. However, other aspects of the procedure for administering radiopharmaceuticals to a patient have not been examined.

During the years 2002–2004, the Radionuclide Metrology Department of the Isotope Center of Cuba (CENTIS-DMR) has performed a test, that tries to simulate the whole administration procedure of a radiopharmaceutical by injection of the a priori planned amount of radioactivity to a patient. This test is an attempt to obtain supplementary information on the quality of measurement, with the aim of evaluating in a more complete way the accuracy of the administered activity value compared with the prescribed one. The outcome of the tests in 2002 was previously published (Oropesa et al., 2003). In this paper, the sum of reported values for all of these tests between 2002 and 2004 is presented. The data treatment included the calculation of the Fisher exact probability p, with the aim of establishing associations between several attributes of the simulated administration tests results. Specifically,

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the proportion of satisfactory results in the 2003–2004 period was found to be higher than in 2002. It reveals an improvement of the activity administration in the Cuban nuclear medicine departments since 2003.

2. Materials and methods

Nuclides of the most widespread use in Cuban nuclear medicine, ^{131}I, ^{201}Tl and ^{99m}Tc were employed. Glass injection vials of size designation 10R or 15R according to ISO 8362-1 (ISO, 2003) were filled with the single nuclide solution. Specifically, the 10R glass vials contained 5 ml of the ^{131}I or the ^{99m}Tc solution, and the 15R vials contained 10 ml of the ^{201}Tl solution. Each participant received a separate vial. The reference activity, X_{ref}, of each individual vial was established with a relative combined standard uncertainty of 1.9%, by means of its measurement in a reference radionuclide calibrator, previously calibrated at CENTIS-DMR for the specific nuclide and sample geometry (Oropesa et al., 2002, 2003; Oropesa and García-Toraño, 2004).

Nine nuclear medicine departments took part in these tests between 2000 and 2004. The participants were requested to simulate the administration to a patient by injection of a prescribed activity applying their established routine procedures for that purpose (Oropesa et al., 2003). Sealed glass vials, containing a non-radioactive solution with a chemical composition similar to the composition of the radioactive samples of each employed nuclide, simulated the patient to whom the activity should be administered. The non-radioactive solution contained in the vials played the role of the blood for carrying out the typical ''washing or ''rinsing'' of the syringe during the injection of the radiopharmaceutical. The participant was required to decide, before the exercise, a planned quantity of activity to be transferred from the vial supplied by CENTIS-DMR to the ''patient''—the vial containing the non-radioactive solution. This a priori planned activity, X_{plan}, had to be taken with a plastic syringe from the calibrated radioactive sample and injected through the rubber stopper to the vial with the non-radioactive solution. Several activity values are measured in the radionuclide calibrator during the different stages of the procedure, namely, the activity of the radioactive sample in the original vial, X_{ini}, the activity in the syringe, X_{syr}, the activity transferred to the sealed glass vial with the non-radioactive solution from the syringe, X_{adm}, the residual activity in the original vial, X_{res}, and the activity in the generated radioactive wastes.

Although these wastes were not in a standard format or geometry so that the calibration factor for the calibrator were not known accurately, their activities were always so low that this inaccuracy was not significant and their contributions were negligible in respect of the activity balance in all samples. This is corroborated by Fig. 1, which summarizes the results of checking for activity losses during the tests, plotted in a histogram form. For each sample, the z-score was calculated as the ratio of $(X_{adm}+X_{res}—X_{ini})$ to the standard uncertainty of X_{ini}. The sampling distribution of the 36 z-scores, which resulted in a mean value of $\hat{z}=-0.20$ (corresponding to 0.4% below the X_{ini} value) and a variance of 0.93, was compared to the normal distribution using a χ^2 test. The calculated χ^2 value, equal to 2.59 for two degrees of freedom, confirmed that these z-values were associated with a normal distribution. Therefore, no significant activity losses were detected during the tests with respect to the combined standard uncertainties of 1.9% of the respective reference activities of ^{99m}Tc, ^{131}I and ^{201}Tl in the samples. Hence these losses were also not significant with respect to the $\pm$10% accuracy limit for the value of the administered activity, as required in Cuban regulations and in the European Pharmacopoeia (Guía, 2002; European Pharmacopoeia, 2001). Moreover, this result is a confirmation that the volume corrections to be applied to the measurements with the vials after emptying were not significant with respect to the combined standard uncertainties of 1.9% of the respective nuclide reference activities in the samples.

2.1. Performance evaluation

The z-score statistics (ISO/IEC, 1997), z_1 and z_2, were calculated to evaluate the performance:

$$z_1=(X_{adm}-X_{plan})/0.033X_{plan}, \quad (1)$$

$$z_2=(X_{real}-X_{plan})/0.033X_{plan}, \quad (2)$$

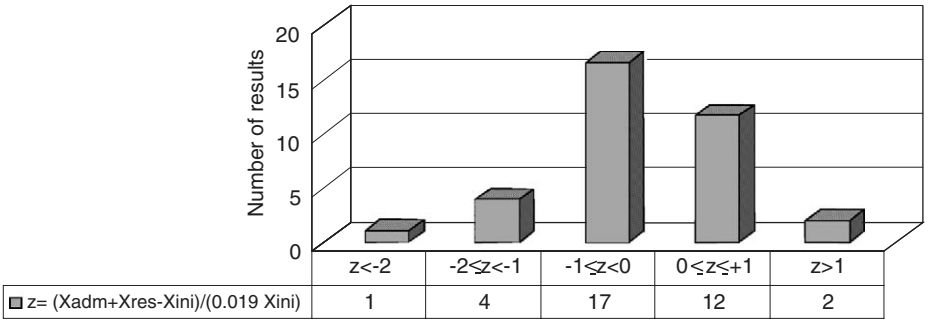

Fig. 1. Results of checking for activity losses during the tests. The z-score expresses the difference between the sum of the X_{adm} plus the residual activity in the original vial, X_{res}, and the X_{ini} value.