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Towards personalized patient 3D Monte Carlo dosimetry for Lu-177-psma prostate treatments

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ABSTRACT

Prostate-Specific Membrane Antigen (PSMA)-labeled Lu-177 therapy is a novel nuclear medicine therapy for metastatic prostate cancer, increasingly adopted worldwide due to the benefits observed in different patient studies. Administered in several cycles, each with a single injection and with a standard activity, the therapy requires customized dosimetry to evaluate efficacy and toxicity. The uptake of Lu-177-PSMA-617 in different organs strongly depends on the patient's anatomy, metastasis distribution, and the activity injected, underscoring the need for personalized dosimetry. This study aims to conduct dosimetry research on patients after several cycles of Lu-177-PSMA administration by Monte Carlo simulation using MCNP6.2. In order to make this study as realistic as possible, a high-resolution anthropomorphic computational phantom is used, the "Mesh-type Reference Computational Phantom" (MRCP) described in ICRP publication 145. This methodology is applied to different distributions of metastatic tissue, based on SPECT images where activity distribution within the patient's body is localized. Since Lu-177-PSMA-617 is deposited in those regions where prostate cancer metastasis has occurred, in Monte Carlo simulations these organs are considered as a source of irradiation with different emission activities probabilities depending on the patient. Once the organ activity distribution is determined, the simulation is performed in MCNP6.2 and the 3D dose distribution in the phantom is evaluated. Based on Monte Carlo results, doses at organs at risk are evaluated, estimating the total absorbed doses until the complete disintegration of Lu-177.

Simulation results enable personalized adjustment of injected Lu-177 according to the needs of the clinical case. This approach has proven to be a valuable tool for assessing individual patient doses, treatment effectiveness, and healthy organ irradiation levels.

1. Introduction

After lung cancer, prostate cancer is the second most frequent primary tumor affecting men worldwide (Delker et al., 2016). Despite therapeutic improvements introduced in recent decades, over time, prostate cancer tends to become very aggressive in most patients and ultimately causes the death of more than 250,000 men per year around the world (Mydlo & Godec, 2003).

Recently, on March 23, 2022, the FDA approved Pluvicto® (also known as Lu-177-PSMA-617) for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC). The recommended Lu-177-PSMA-617 dose is 7.4 GBq (200 mCi) intravenously every 6 weeks for up to six cycles, or until disease progression or unacceptable toxicity (Fallah et al., 2023).

Lu-177-PSMA-617-based treatments are non-invasive and highly effective, designed to precisely target malignant cells without affecting surrounding healthy tissues. Numerous studies have analyzed the radiation doses administered to organs of patients undergoing Lu-177-PSMA-617 treatment, revealing that the doses fall within acceptable ranges. However, considerable variability in doses exists across different organs, influenced by the patient's unique anatomy and the location of metastases. Consequently, a tailored dosimetry assessment becomes imperative (Kabasakal et al., 2017).

In prostate cancer therapy with Lu-177-PSMA dosimetry plays a crucial role in effective treatment planning. The main objective is to maximize the dose absorbed by malignant structures and minimize the dose absorbed by healthy Organs At Risk (OAR). There are several

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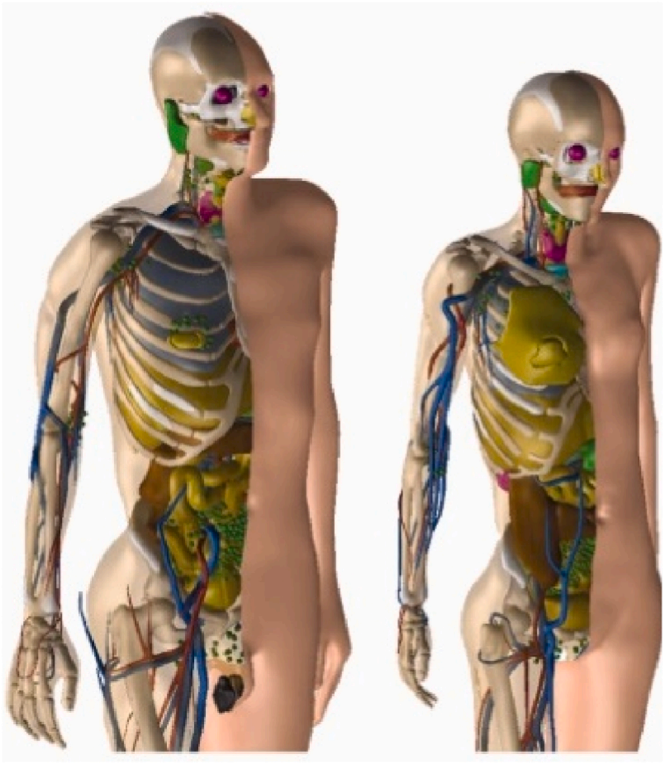

Fig. 1. ICRP 145 MRCP representing male (left) and female (right) anatomy (Kim et al., 2020).

strategies for assessing absorbed doses to tissues, each of which is distinguished by the level of patient-specific information considered and by the use of a 3D absorbed dose model or absorbed dose factors (S-values) (Gosewisch et al., 2019).

Monte Carlo (MC) techniques present a comprehensive approach to simulate all interactions of radioactive particles moving within the surrounding material in a very accurate manner. Moreover, MC simulations are considered the gold standard to predict the radiation interactions through matter and thus, permitting the study of its effects on patients (Rogers, 2006; Andreo, 2018). Various MC codes are available for applications in nuclear medicine, allowing for the incorporation of patient-specific 3D activity and anatomical characteristics by integrating SPECT, PET, and CT data into the simulation process (Botta et al., 2013). Consequently, 3D-absorbed dose distributions can be generated, offering resolution and accuracy dependent on the quality of the input image data (Gosewisch et al., 2019). In this work, data on how the Lu-177 radioisotope is distributed during different treatment cycles were collected from various SPECT scans in the literature. These data were then applied to a detailed computational model of a human body, known as Mesh-type Reference Computational Phantom (MRCP), according to the International Commission on Radiological Protection (ICRP) Publication 145 (Kim et al., 2020), for analysis. This phantom represents the patient's anatomy and has been completed with Lu-177 activity distribution sources and included in MC simulations, using the MCNP6.2 code (Los Alamos Scientific Laboratory Group, 1979; Los Alamos National Laboratory, 2017), to calculate the dose distribution at the whole phantom geometry after Lu-177-PSMA-617 treatment.

In Lu-177-PSMA prostate therapy, numerous OAR come into consideration, particularly in patients with advanced metastasis who frequently exhibit a substantial bone and liver tumor burden and potential hematological function impairment. Employing MC simulations holds the promise of enhancing estimates for absorbed doses in metastasis and at OAR. This is attributed to the capability of MC simulations to comprehensively incorporate patient-specific 3D disease characteristics,

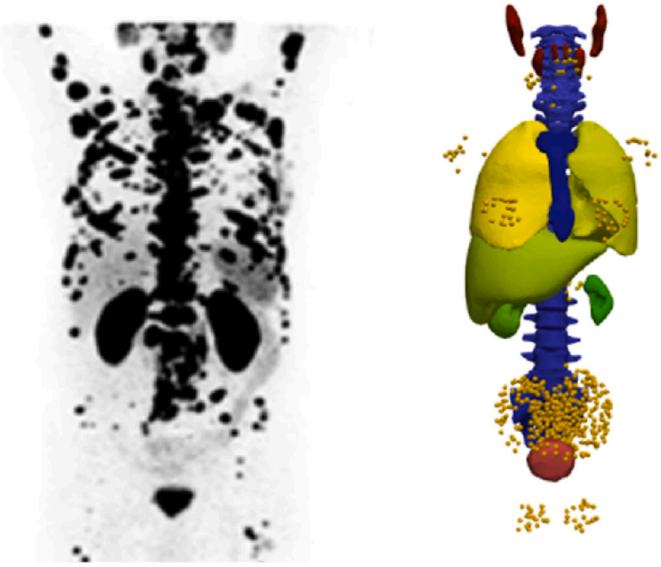

Fig. 2. SPECT test showing disease dissemination in a patient with mCRPC (Gosewisch et al., 2019) (left) and the organs of the MCRP considered as source in Paraview (Paraview,) (right).

offering an accurate representation of the treatment scenario.

Considering that Lu-177-PSMA-617 is reasonably novel technique, there are not many articles that perform dosimetry with MC for this treatment modality. However, there are some remarkable studies about this treatment such as Jackson et al. (2020), the authors have developed a methodology for radiation dosimetry in Lu-177-PSMA-617 therapy using a single post-treatment SPECT/CT scan. Similarly, the study of Gosewisch et al. (2019) have focused on calculating the absorbed dose in bone marrow using MC simulations. The study presented below stands out for its focus on treatment personalization, which not only optimizes efficacy but also minimizes toxicity by adjusting the injected activity according to the specific anatomical and clinical characteristics of each patient. The use of the MC techniques using the MCNP code, together with the integration of the state-of-the-art ICRP 145 phantom, adds a level of detail and accuracy not found in the other studies.

2. Material and methods

2.1. MRCP phantom model

To make the study as realistic as possible, phantoms made according to ICRP standards and guidelines are used. Specifically, the MRCP male phantom presented in ICRP 145 (Kim et al., 2020). These mesh-type phantoms (Fig. 1), represented by Polygonal Mesh (PM) or Tetrahedral Mesh (TM) formats as required, provide high resolution and detail, reaching the micrometer scale (Kim C. H. et al., 2018). Moreover, they are now considered as an advanced type of computational phantom that can be directly implemented in many MC codes.

ICRP phantom mesh model can be read directly in TM format by MCNP6.2 code. In the context of this prostate cancer study, the MRCP-AM model is used, which is adapted to represent the male anatomy. The computational phantom measures 176 cm, weighs 73 kg and is composed of 8.2 million tetrahedra.

It is important to note that, although it is possible to directly transfer anatomical information and data on Lu-177 activity distribution from a patient's SPECT to the model, we have chosen to first use standard values of activity in different organs, based on previous scientific data, and then integrate them into the three-dimensional model. In future works, the methodology will be evaluated based on the SPECT of a personalized case, which will ensure that the simulations are fully adapted to the individual anatomy of the patients, thus improving the

Table 1
Lu-177-PSMA-617 activity administered in each cycle (Ricaurte Fajardo, Osborne and Sawoszczyk, 2023).

Cycle	^{177}Lu-PSMA-617
1	203 mCi (7.5 GBq)
2	160 mCi (5.92 GBq)
3	193.5 mCi (7.1 GBq)
4	160.6 mCi (5.94 GBq)

Table 2
Relevant organs for the study of dosimetry in Lu-177-PSMA-617 treatment and their corresponding activity during cycle 1.

Organ	Activity (Bq/ Injected Bq)	Cell in MCRP	Volume (cm ^{3})
Spine	0.398	4700, 4900, 5100, 5300	54.592, 152.017, 98.764, 57.941
Sternum	0.104	5500	5.247
Kidneys (right, left)	0.102, 0.102	9000, 9300	36.429, 37.381
Liver	0.040	9500	2226.415
Salivary glands (right, left)	0.066, 0.066	12000, 12100	42.721, 42.721
Bladder	0.118	13800	192.308
Lungs	0	9700, 9900	1315.366, 1573.160
Lymph nodes	0	10100, 10300	15.454, 126.166

accuracy of the results obtained.

2.2. Image processing

After each injection of Lu-177-PSMA-617, typically 24 h later, a SPECT scan is performed to check the progression of the disease and the effectiveness of the treatment (Fig. 2 left). These images can be processed to see what portion of Lu-177-PSMA-617 of the total amount administered is absorbed by each organ in each cycle. For this purpose, the ImageJ program (MIJ Running ImageJ and Fiji with Matlab. , n.d.) is used: from the grayscale of the image, the probabilities of accumulation of the radiotracer in each organ are obtained (since a higher black level means a higher amount of substance and higher probability of emission).

2.3. Monte Carlo simulation

MC simulations have become the gold standard for many applications in the field of medical physics (Fahey et al., 2018; Liu et al., 2019; Verhaegen and Seco, 2022). MCNP6, standing for Monte Carlo N-Particle, version 6, is a particle transport Monte Carlo simulation code (Los Alamos National Laboratory, 2017) widely employed in various applications, including nuclear medicine. It plays a crucial role by allowing detailed modeling of radiation interactions with biological materials and medical devices. In this work, MCNP6 version 2 code is used, which allows the incorporation of meshed geometries, which confers a high precision to the results.

Simulations were performed on a cluster using 9 CPUs of an AMD EPYC 7282 16 Core Processor. "MODE PE" has been used to track both photons (P) and electrons (E) during the particle transport simulations, with a stipulated cut-off energy of 10 keV for electrons and 1 keV for photons in all materials. Type An uncertainties lower than 5% ($k = 1$) were achieved in the organs of interest, that is those shown in Table 2, to allow this uncertainty in the different scoring organs, 10^7 particles were simulated for each simulation study.

2.3.1. Source definition

Choosing the right location and type of source is crucial for the simulation to making sure it accurately represents the problem being addressed. In this case, Lu-177 disintegrates by beta emission, and it also emits gamma rays. It was chosen to use average energy for beta emissions and the peak energies gamma emissions, with probabilities calculated per 100 disintegrations, as sourced from Nucléide Lara (Nucléide-Lara).

Fifteen geometric elements (geometry cells in MCRP), corresponding to the six organs: spine, sternum, kidneys, liver, salivary glands and bladder, have been considered as sources, based on studies on the likelihood of metastasis (Kabasakal et al., 2017; Gabriela et al., 2022; Ricaurte Fajardo, Osborne and Sawoszczyk, 2023), to create a general-purpose model, even though not all patients have disease in all these organs. To define the organs as sources, the Abaqus/CAE program is used (Company Dassault Systemes, 2014), which allows the visualization and modification of the MRCP.

Once the sources are defined in Abaqus, the only part of the simulation parameters that is modified to perform simulations for different clinical cases is the radiation emission probability of each organ according to its lutetium absorption intensity. Although the study in this work is conducted with a phantom, the source model and methodology using MC simulation are intended to be utilized in images of real patients. For this reason, a source model that includes all described organs has been established. In this way, future patients who do not have the disease spread to certain organs, and they are considered to have zero probability of emission. Furthermore, as the treatment progresses, there is reduced uptake by some organs due to the elimination of part of the disease. This also leads to a change in the emission probability between cycles.

2.3.2. Dose measurement registration (Tallies)

In order to study the dose distribution in a patient undergoing lutetium treatment, after each cycle as well as after the complete treatment (4 cycles in this case), various dose recording cards available in MCNP have been used. The tally F6, with which the average energy deposited per unit mass on a cell (MeV/g particle) is obtained, was used to measure the dose in each tetrahedron of the mesh, allowing visualization of the three-dimensional dose distribution throughout the patient. In addition, a dose tally (+F6) has been set in each relevant organ (source organs) to obtain the specific dose in that organ, considering its mass. A conversion card is used to obtain the results on the grid elements directly in units of Gy/particle.

2.4. Specific characteristics of the case study

The case study delved into a recent clinical investigation (Ricaurte Fajardo, Osborne and Sawoszczyk, 2023), focusing on a patient exhibiting PSMA-avid bone and soft tissue lesions as revealed by pretherapeutic whole-body PET/CT Ga-68-PSMA-11 scans. This individual, representing the typical profile of a patient with a history of positive PSMA and mCRPC, underwent a treatment regimen comprising four cycles of Lu-177-PSMA-617 following prior therapeutic interventions.

The intervals between each cycle varied between 6 and 8 weeks. Although the recommended activity of the injection is 200 mCi (7.4 GBq), in this case study, due to the patient's responses to therapy this activity was adapted, thus varying the administration in each cycle as can be seen in Table 1.

The organs where prostate cancer metastasis commonly occurs and their corresponding activity during cycle 1 of this case study treatment are detailed in Table 2 (Ricaurte Fajardo, Osborne and Sawoszczyk, 2023). Biokinetics of Lu-177 has not been considered because, being bound to PSMA molecule, its behavior differs from the ionic form of Lu-177 (Mostafa et al., 2019). It is believed that Lu-177-PSMA-617, although distributed throughout the body after injection, only accumulates on the surface of cancer cells, where overexpressed PSMA is found.

3. Results

After identifying the radioisotope's location within various organs of

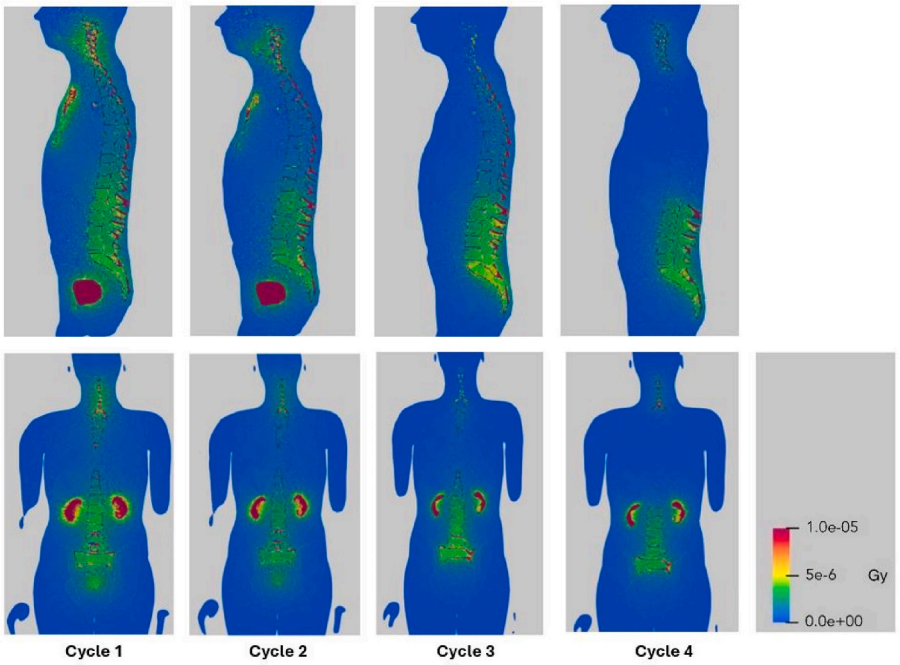

Fig. 3. Evolution of the dose distribution (Gy) obtained from the simulations for each cycle. Sagittal and frontal plane.

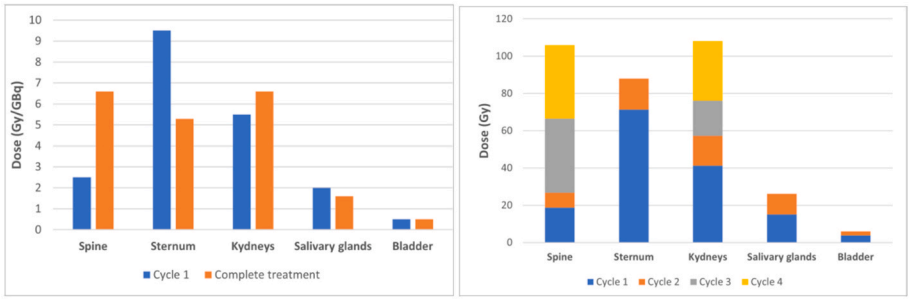

Fig. 4. Absorbed dose received per organ after cycles and total dose after completion of treatment.

the body based on the intensity marked in the SPECT images taken during each treatment cycle, the simulations executed enable a detailed analysis of the doses administered to the patient. For every simulation, parameters such as dose distribution and dose in each organ of interest were obtained. Fig. 3 shows (in Paraview) the dose distribution (Gy) in the image section of interest after each of the four treatment cycles.

In order to convert the simulation dose results (F6 tally) from Gy/particle to actual Gy, it's crucial to consider the specific activity level of the source utilized in each treatment cycle (Table 1). Take into account that the obtained results represent point doses at the moment of irradiation. The developed methodology ensures precise calculation of the point absorbed dose values in Gy, enhancing the clinical relevance and comprehensibility of the data. By summing the dose contributions from all cycles, the cumulative dose received by each organ at the end of treatment is determined, as represented in Fig. 4, which shows the dose in Gy per organ and per GBq of Lu-177-PSMA injected.

In the case under study, the kidneys exhibit notably higher doses compared to other organs. This is attributed to their integral role in the body's excretory system, responsible for the elimination of radioactive substances from the organism. Notice that it is considered that approximately 50% of the injected activity is eliminated through urine within the first 6 h (Violet et al., 2019). The other organs (spleen, liver, lungs …) are not represented in the graph because, according the Lu-177-PSMA distribution at metastatic regions in the case studied, values were insignificant compared to the five shown.

Table 3
Dose comparison for salivary gland between those obtained in this work and other found in the literature.

	1st treatment cycle		Complete treatment	
Work	Violet et al. (2019)	This work	Delker et al. (2016)	This work
Dose in salivary glands (Gy/GBq)	0.1–1.8	1.9	1.4	1.8

It is crucial to highlight that the intervals of absorbed dose in each organ can vary widely due to differences in the biodistribution of the radiopharmaceutical in the various body studies reported in the literature. According to Violet et al. (2019), during the first treatment cycle, the absorbed dose in the parotid glands can range from 0.1 to 1.8 Gy/GBq. In the case studied, the parotid glands received a dose of 1.9 Gy/GBq in the first cycle. When comparing the total dose received throughout the entire treatment (1.8 Gy/GBq after 4 cycles) with the doses reported by Delker et al. (2016), the results are very similar. The results obtained, along with the dose comparison for salivary glands, are summarized in Table 3.

For kidney, however, median renal doses were slightly higher than those reported by Delker et al. (2016) who also used SPECT/CT to derive

their activity maps, perhaps reflecting overlying bowel or liver activity on the technique of SPECT grays intensity transfer to source activity in MC.

In the study of Kabasakal et al. (2017), one treatment cycle absorbed dose reference limits (in Gy) for organs considered critical in Lu-177-PSMA-617 treatment are outlined: 30 Gy for the parotid glands, 23 Gy for the kidneys, and 2 Gy for the bone marrow. Comparing these limits with MC simulation results from the first treatment cycle, the parotid glands receive 15 Gy (Fig. 4, right), below the limit (30 Gy). However, the kidneys and spine receive doses considerably higher than those dose limits.

4. Conclusions

Predicting how a patient will respond to treatment based on the amount of radiopharmaceutical absorbed by the tumor is crucial. However, accurately determining the absorbed activity presents significant challenges that are essential to the patient's health, especially when multiple metastatic tumor regions may absorb and retain the drug differently. The common practice of measuring the dose in the primary tumor and other organs at risk may not suffice to capture this variability. To improve this, a new strategy has been studied: not only measuring the amount of radiopharmaceutical in the primary tumor but also calculating the absorbed dose after its distribution throughout the body and in the organs. It is thought that this approach might provide a better understanding of how the treatment will work.

The primary aim of this study was to perform radiation dosimetry in a case study of a patient with advanced metastatic prostate cancer using a meshed phantom, using pretherapeutic Ga-68-PSMA-11 PET and SPECT as a predictor of probability of accumulation location of Lu-177-PSMA-617 for source definition simulation. The organ dose results obtained from the simulations after the four cycles have been compared with clinical data from literature on similar treatments, yielding clearly consistent outcomes. It is worth noting that while each patient may develop metastases in different areas, the results remain coherent.

Likewise, it is verified from the results of the last cycle that the evolution of the patient on completing the treatment has been favorable, since he has a significantly lower tumor burden than at the beginning of the treatment.

This work demonstrates the possibility of using MC simulation to perform dosimetric studies in nuclear medicine targeted therapies with the novel radiopharmaceutical Lu-177-PSMA-617 in a detailed phantom. Crucially, armed with pertinent information from hospitals regarding metastasis locations and precise dosage administration, these simulations could be tailored to real patients, thereby facilitating treatment verification.

In clinical practice, employing MC simulations for dose calculations can often be excessively time-consuming, particularly when the simulation involves a significant portion of the patient's body. However, MC simulations can become viable with the utilization of computing clusters. This approach enables the acquisition of results with high statistical validity within a reasonable timeframe, typically around 5 h, which is considered acceptable.

Having observed the effectiveness of the methodology, a future direction will involve transitioning from using a meshed phantom to employing a personalized and patient-specific phantom based on CT and PET/SPECT images.

CRediT authorship contribution statement

V. Ribes: Writing – original draft, Validation, Software, Methodology, Investigation. **S. Oliver:** Writing – review & editing, Software, Methodology, Investigation, Conceptualization. **B. Juste:** Writing – review & editing, Validation, Supervision, Methodology, Conceptualization. **R. Miró:** Writing – review & editing, Validation, Supervision, Methodology, Conceptualization. **G. Verdú:** Writing – review & editing, Validation, Supervision, Funding acquisition.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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