Detection of “Incidentalomas” on Brain and Body 68Ga-DOTATOC-PET Scans: A Retrospective Study and Case Illustration

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Abstract. Background/Aim: One of the main limitations of standard imaging modalities is microscopic tumor extension, which is often difficult to detect on magnetic resonance imaging (MRI) and computer tomography (CT) in the early stages of the tumor. (68)Ga-DOTA(0)-Phe(1)-Tyr(3)-octreotide positron-emission tomography/computed tomography (68Ga-DOTATOC PET/CT) has shown efficacy in detecting lesions previously undiagnosed by neuroimaging modalities, such as MRI or CT, and has enabled the detection of multiple benign tumors (like multiple meningiomas in a patient presenting with a single lesion on MRI) or additional secondary metastatic locations.

Patients and Methods: We retrospectively reviewed data from the Cannizzaro Hospital on brain and body 68Ga-DOTATOC PET/CT “incidentalomas”, defined as tumors missed on CT or MRI scans, but detected on 68Ga-DOTATOC PET/CT scans. “Incidentalomas” were classified into “brain” and “body” groups based on their location. The standardized uptake values (SUVs) were compared between the two groups. Results: A total of 61 patients with “incidentalomas” documented on the 68Ga-DOTATOC PET/CT were identified: 18 patients with 25 brain lesions and 43 patients with 85 body lesions. The mean SUV at baseline was 9.01±7.66 in the brain group and 14.8±14.63 in the body group. Conclusion: We present the first series on brain and body “incidentalomas” detected on 68Ga-DOTATOC PET/CT. Whole-body 68Ga-DOTATOC PET/CT may be considered in selected patients with brain tumors with high expression of somatostatin receptors to assist radiosurgical or surgical planning and, simultaneously, provide accurate follow-up with early detection of potential metastases.

Somatostatin receptor subtype 2 (SSTR2)-based positron emission tomography (PET), in the form of Gallium-68 DOTA-Phe1-Tyr3-Octreotide (68Ga-DOTATOC), Gallium 68 (68Ga) 1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetic acid (DOTA)–octreotate (68Ga-DOTATE), and 68Ga-Labeled (1,4,7,10-tetraazacyclodecane-N,N',N'',N'''-tetraacetic acid)-1-NaI3-octreotide (68Ga-DOTANOC), has been reported as a useful diagnostic tool in patients with meningiomas, with level II evidence for its use in tumor contouring for radiotherapy planning (1). While planning stereotactic radiosurgery (SRS) for patients with meningiomas, the primary treatment goal is to target all clonogenic tumor cells within the lesion and plan a clinical target volume (CTV), defined as the tumor volume comprising the gross tumor volume (GTV), and subclinical malignant disease (2). However, the main limitation of this technique relates to the
microscopic extension of targeted lesions, which can be missed by current imaging techniques and lead to incomplete treatment. Studies on the use of positron emission tomography/computer tomography (PET/CT) or PET/magnetic resonance imaging (MRI) $^{68}$Ga-DOTATOC, $^{68}$Ga-DOTATATE, and $^{68}$Ga-DOTANOC have shown good safety and efficacy rates of these techniques for planning CyberKnife and GammaKnife radiosurgery (GKSRS) (3).

In some cases, nuclear imaging modalities have demonstrated the ability to detect lesions that are not immediately visible by standard diagnostic modalities. However, only a few reports are currently available, and these are largely related to the use of fluorodeoxyglucose (FDG)-PET scans for detecting “incidentalomas” located within the thyroid (4). FDG-PET scans have poor sensitivity for particular tumors, such as carcinoids, and thus, offer limited benefit in their management. Meanwhile, $^{68}$Ga-DOTATOC-PET scans use different markers that have a higher affinity for somatostatin receptor 2 (SSTR2) receptors and SSTR2-expressing tumors, such as carcinoids (5). For this reason, $^{68}$Ga-DOTATOC-PET scans may be used for the assessment of disease extension in patients with carcinoid tumors. Further, since meninomas also present with a high expression of SSTR2 receptors, $^{68}$Ga-DOTATOC-PET scans may be implemented to detect extra-cranial lesions that are often missed on standard MRI scans.

In this study, we retrospectively analyzed data from our Institute (Cannizzaro Hospital, Catania, Italy) on brain and body $^{68}$Ga-DOTATOC PET/CT “incidentalomas”, defined as tumors missed on CT/MRI, but detected on $^{68}$Ga-DOTATOC PET/CT scans.

Patients and Methods

Patient selection. At our institution, the Cannizzaro Hospital, Catania, Italy, brain and body $^{68}$Ga-DOTATOC PET/CT scans are performed as routine follow-up in patients with SSTR2-expressing tumors or for GKSRS planning. An Institutional retrospective review was conducted to analyze all consecutive $^{68}$Ga-DOTATOC PET/CT exams performed from January 2015 to November 2021. In view of the retrospective observational nature of this study, the need for ethical approval was waived by our Institution’s Ethics Committee. This study was performed in accordance with the Principles of the Declaration of Helsinki. Two authors (P.P., A.C.) independently evaluated a total of 1,000 examinations (MRI and/or CT). We selected patients showing $^{68}$Ga-DOTATOC PET/CT lesions that were not detected on baseline MRI/CT (“incidentalomas”). Five independent authors (R.C., F.P., L.B., A.S., G.S.) collected patient-level data on demographics, clinical and oncological history, tumor histology, PET characteristics, management, and follow-up via telephone interviews and/or outpatients visits. Patients with $^{68}$Ga-DOTATOC PET/CT “incidentalomas” were divided into two groups: i) “brain” group, comprising patients with “incidentalomas” located in the brain; and ii) “body” group, comprising patients with “incidentalomas” located outside the brain. Two radiologists (C.C., G.C.) and two nuclear medicine specialists (S.C., M.I.), all with more than 10 years of experience, confirmed the absence of “incidentalomas” on MRI and CT scans obtained during the same period of $^{68}$Ga-DOTATOC PET/CT scans, and an additional independent radiologist (D.R.V.) confirmed the results.

$^{68}$Ga-DOTATOC PET/CT protocols. Brain scan. Patients were requested to remain nil-per-oral for a minimum of 8 h before the scan. The PET/CT tracer $^{68}$Ga-DOTATOC (DOTA0-D-Phe1-Tyr3-octreotide) and two dedicated PET/CT scanners; a Biograph Horizon 16 (Siemens Healthcare GmbH, Erlangen, Germany) and a GE Discovery 690 (GE Healthcare, Chicago, IL, USA), were used. For each examination, 110 MBq of $^{68}$Ga-DOTATOC were administered intravenously 50 min before scanning, and PET/CT scan was performed with the patient in the supine position. The PET scan of the skull was acquired in the three-dimensional list mode for 15 min. The CT component was of diagnostic quality for both scanners (120 kV; 250 mAs; 3 mm slice). The PET reconstruction settings were subjected to CT-based attenuation correction using an ordered subset expectation maximization (OSEM) algorithm (for the Biograph Horizon: method=TrueX+TOF, iterations=12, subsets=10, image matrix=512, voxel size=full width at half maximum (FWHM) 2 mm; for the GE Discovery 690: method=Vue Point FX, iterations=5, subsets=16, image matrix=256, voxel size=FWHM 3.2 mm). A Gaussian filter of 2 mm in FWHM was then applied to all images after reconstruction. The PET slice thickness was 2 mm.

Whole body scan. PET/CT scans were performed using the $^{68}$Ga-DOTATOC (DOTA0-D-Phe1-Tyr3-octreotide) tracer and two PET/CT scanners; a Biograph Horizon 16 and a GE Discovery 690, were operated. The $^{68}$Ga-DOTATOC was manually synthesized with a $^{68}$Ga generator (Eckert & Ziegler, Berlin, Germany) and Good Manufacturing Practices (GMP) grade DOTATOC (ABX advanced biochemical compounds, Radeberg, Germany) in the cyclotron laboratory of our Institution. Quality control was performed according to European Pharmacopoeia; the synthesized $^{68}$Ga-DOTATOC satisfied all quality control criteria. The radiochemical purity of the $^{68}$Ga-DOTATOC was 98.2±1.0% as measured by high-performance liquid chromatography. One hour before the procedure, 110 MBq of $^{68}$Ga-DOTATOC were administered intravenously to each patient. The PET/CT scan was then performed with the patient in the supine position. We acquired the emission PET scans for 3 min for at each posture, and whole-body PET/CT was performed from skull vertex to the proximal thigh. The CT component was low dose (120 kV; effective exposure, 40 mA; 3 mm slice). The PET reconstruction settings were subjected to CT-based attenuation correction using an ordered subset expectation maximization (OSEM) algorithm.

Statistical analysis. Inter-observer agreement for the review was calculated by the Cohen’s Kappa Statistic, achieving a $\kappa$-value of 0.89. The distribution of “incidentalomas” between the brain and body and their respective SUV values were calculated. Continuous variables are expressed as means±SD while frequencies are expressed as n (%). All statistical analyses were performed using the SPSS version 25 (IBM Inc., Armonk, NY, USA).

Results

A total of 1,000 $^{68}$Ga-DOTATOC PET/CT exams were reviewed. A total of 907 patients showed no “incidentalomas” and were consequently excluded. Thirty-two patients with
Location of “incidentalomas” | Brain, n (%) | Location of “incidentalomas” | Body, n (%)
--- | --- | --- | ---
Frontal lobe | 7 (28%) | Bones | 30 (35.39%)
Parietal lobe | 5 (20%) | Vertebrae | 14 (16.47%)
Temporal lobe | 3 (12%) | Liver | 12 (14.11%)
Occipital lobe | 2 (8%) | Lymph nodes | 12 (14.11%)
Sphenoid wing | 2 (8%) | Lung | 3 (3.52%)
Leptomeninges | 1 (4%) | Thyroid | 2 (2.35%)
Middle cranial fossa | 1 (4%) | Pancreas | 2 (2.35%)
Posterior fossa | 1 (4%) | Intestine | 2 (2.35%)
Parasagittal region | 1 (4%) | Prostate | 1 (1.17%)
Cavernous sinus | 1 (4%) | Abdominal wall | 1 (1.17%)
Lateral ventricle | 1 (4%) | Others | 6 (7.05%)
Total | 25 | Total | 85
Mean SUV of “incidentalomas”* | 9.01±7.66 | Mean SUV of “incidentalomas” | 14.8±14.63

SUV, Standardized uptake value. *Values are mean±SD.

$^{68}$Ga-DOTATOC PET/CT “incidentalomas” were excluded from the analysis because of the following reasons: missing telephone or email contact data or failed attempts at contact (n=21), declination of initial consent to proceed with the research topic (n=8), and refusal from relatives of patients who died (n=3). Finally, 61 patients were included in this analysis; 18 patients were included in the brain group and 43 patients in the body group.

Of the 61 patients with “incidentalomas” documented with the $^{68}$Ga-DOTATOC PET/CT included in the present analysis, a total of 25 “incidentalomas” were detected in the brain of 18 patients, and 85 in the body of 43 patients. Thirty-four patients (55.73%) were males and 27 (44.26%) were females. As for the sex distribution based on the location of the “incidentaloma,” the male:female ratio was 4:5 in the brain group and 26:17 in the body group. The average age was 69.50±7.90 years (mean±SD) in the brain group and 64.07±14.85 years in the body group.

The primary tumor diagnoses in the 18 patients in the brain group were: meningioma in 10 (55.55%) patients, neuroendocrine tumor in 3 (16.67%), vestibular schwannoma in 3 (16.67%), brain metastasis from prostatic cancer in 1 (5.55%), and brain metastasis from thyroid cancer in 1 (5.55%). The 25 “incidentalomas” identified in the brain group were distributed as follows: 7 (28%) in the frontal lobe, 5 (20%) in the parietal lobe, 3 (12%) in the temporal lobe, 2 (8%) in the occipital lobe, 2 (8%) in the sphenoid wing, and 1 (4%) each in the lateral ventricle, leptomeninges, middle cranial fossa, posterior fossa, parasagittal region, and cavernous sinus (Table I).

The primary tumor diagnoses in the 43 patients of the body group were: neuroendocrine tumor in 32 (74.41%) patients, lung cancer in 6 (13.95%), breast cancer in 1 (2.32%), glomus tumor in 1 (2.32%), medullary carcinoma of the thyroid in 1 (2.32%), ovarian cancer in 1 (2.32%), and paraganglioma in 1 (2.32%). A total of 85 body “incidentalomas” were identified in 43 patients, with the involved sites being: 30 (35.39%) in the bones, 12 (14.11%) in the liver, 14 (16.47%) in the vertebrae, 12 (14.11%) in the lymph nodes, 3 (3.52%) in the lung, 2 (2.35%) in the thyroid, 2 (2.35%) in the pancreas, 2 (2.35%) in the intestine, 1 (1.17%) in the prostate, 1 (1.17%) in the abdominal wall and 6 (7.05%) in other sites, including stomach, peritoneum, subcutaneous region, adrenal gland, muscle, and diffuse spinal ganglia (Table I). These “incidentalomas” were treated with a combination of chemotherapy, radiotherapy, pharmacological therapy (such as long-acting octreotide), or immunotherapy, as appropriate.

The SUVs of “incidentalomas” on $^{68}$Ga-DOTATOC PET/CT ranged from 2.40 to 51.44 in the overall study population. The mean baseline SUV was 7.76±4.57 for benign non-metastatic tumors and 14.86±14.52 for malignant metastatic tumors. The mean SUV at baseline was 9.01±7.66 in the brain group and 14.8±14.63 in the body group (Table I).

Case report. Brain “incidentaloma”. We present a 40-year-old female affected by a small, 2-cm, right fronto-polar meningioma. She underwent a brain MRI with contrast (Figure 1) indicated for asymmetry of the forehead. The patient was referred as a candidate for GKSRS. A $^{68}$Ga-DOTATOC PET/CT scan performed for GKSRS planning showed extended bony involvement of the roof of the orbit, frontal bone, and frontal sinuses (Figure 2).

During simulation at the gamma-plan station, the whole lesion could not be effectively targeted with GKSRS due to extensive bone involvement. Surgical removal was thus...
deemed more appropriate, and one-step cranioplasty was performed, extended to include the orbital roof and frontal bone. The intradural tumor was removed, and after careful hemostasis and duroplasty, a custom-made titanium alloy cranioplasty prosthesis was positioned to reconstruct the bone defect. Minimal tumor infiltrate in the bone at the level of the frontal sinus overlaying the superior sagittal sinus was not removed to reduce the risks of infectious complications. The postoperative head CT scan showed satisfactory bone reconstruction (Figure 3). Histological examination confirmed the diagnosis of meningioma, WHO grade I.

Discussion

As of yet, the pathophysiology of “incidentalomas” remains unclear. A possible explanation could be related to the presence of lesions within the bone amongst complex anatomical structures, making detection with standard imaging difficult, thus being misdiagnosed as a part of normal tissue. However, metabolic studies have the intrinsic ability to detect the microscopic components of tumors that are not visible on MRI/CT scans.

The interest in the clinical use of gallium-PET radiotracers is rising, particularly for radiosurgery planning, surgical planning, and post-treatment follow-up. Due to the high volume of brain and whole-body $^{68}$Ga-DOTATOC PET/CT scans performed at our Institution, we identified a considerable number of previously unknown lesions, defined as “incidentalomas”, with notable clinical interest. $^{68}$Ga-DOTATOC PET/CT is fundamental for accurately planning upfront GKSRS in the absence of histological confirmation. This is especially true in selected patients who are not eligible for surgery, and in whom the indication for stereotactic radiosurgery is based on neuroimaging alone (2, 3).

The reduction of target volume using $^{68}$Ga-DOTATOC-PET-based planning than with standard MRI/CT-based planning has been established with photon, proton and gamma treatments (3, 6). Gehler et al., reported extensively on the utility of $^{68}$Ga-DOTATOC-PET for tumor treatments with intensity-modulated radiation therapy (1). The authors documented a better evaluation of the planning target volume (PTV) in 26 patients (65%); the GTV had lower values compared to CT/MRI in 38%, had higher values in 50%, and was equivalent in 12%.

PET-CT studies are used to define the clinical target volume (CTV) related to microscopic extension of the tumor close to organs at risk (OAR). However, PET-CT scans are significantly limited by the inability to show all the clonogenic tumor cells, thereby hindering SRS planning. One of the most important characteristics of $^{68}$Ga-DOTATOC-PET is the concordance between PTV and GTV, which provides detailed definition of the target edges and allows for safe GKSRS and fractionated stereotactic radiotherapy, which are often performed for lesions sites near OARs. $^{68}$Ga-DOTATOC-PET scans also increase the target volume in GKSRS treatment, though this aspect has limited clinical correlation given that a sharp fall of dose occurs at the target margins, maximizing the delivery of energy and thus increasing the treatment’s efficacy (2).
In our previous study, $^{68}$Ga-DOTATOC-PET influenced GKSRS planning by revealing tissue infiltration not visible on MRI and extending the target volume (2). We defined these as microscopic “incidentalomas,” which have a marked influence on GKSRS planning, treatment indication, and efficacy. We previously reported the utility of extending the target volume in a large lesion likely to have infiltrated the sinuses and skull base, which have recently been subjected to GKSRS hypofractionated treatments (3). In the abovementioned study, we had also documented the use of $^{68}$Ga-DOTATOC-PET in the follow-up post GKSRS after single-fraction or hypofractionated regimes. We observed a reduction in 58% and stability in 17% of post GKSRS-SUVs, thereby demonstrating the biological effect of the lesion and accounting for 75% of positive response as reported in literature (2, 7-10). Notably, none of the patients in our previous series had an increase in the volume during post-GKSRS follow-up (2).

In this setting, brain $^{68}$Ga-DOTATOC PET/CT scans proved to be beneficial in confirming GKSRS planning, guiding PTV, and tumor contouring. Brain $^{68}$Ga-DOTATOC PET/CT scans may also allow identification of tumor infiltration to the bone, not visible on CT and MRI, as shown in the case illustration discussed above. This may suggest the inappropriateness of GKSRS therapies in such scenarios involving high PTV, and a shift from GKSRS approach to one-step surgical removal and custom made cranioplasty approach is more favorable. Finally, brain $^{68}$Ga-DOTATOC PET/CT scans may also enable detection of multiple lesions, such as “incidentalomas” of the brain, that could be managed with additional GKSRS or, in selected cases, with $^{68}$Ga-DOTATOC PET/CT and MRI follow-up.

The more recent use of whole-body $^{68}$Ga-DOTATOC PET/CT offers new possibilities for total body assessment. Benign intracranial tumors, like meningiomas, can present as extracranial meningiomas at the level of the soft tissues (muscles, skin) and mainly, the lungs (11-17). This advantage of $^{68}$Ga-DOTATOC PET/CT can be of particular importance in cases of neurofibromatosis as well, which typically show an extensive multiorgan involvement. In this study, we suggest the use of $^{68}$Ga-DOTATOC PET/CT scans as new assessment tools for brain and body oncology patients, given their ability to detect SSTR2-positive multiple lesions in case of benign tumors, secondary metastatic lesions, as well as metastatic tumors, which may go undetected on standard MRI or CT scans.

However, $^{68}$Ga-DOTATOC-PET examination is available in dedicated centers and only a few PET centers can synthesize this radiotracer. Further, it has been introduced relatively recently and there is a lack of guidelines on its application. Thus, it is clear that this examination modality is not available on a daily basis; however, at our Center, $^{68}$Ga-DOTATOC-PET scans are performed in a dedicated section based on the clinical need and number of requests. With growing demand over the years, we now perform DOTATOC-PET scans more frequently for inpatients, outpatients, follow-up patients post GKSRS, during post-operative procedures, and oncology patients in general.

This study was conducted in a retrospective fashion, with intrinsic risks of recall and reporting biases. This study is the first to analyze the incidence of “incidentalomas” in one Institution from clinically-oriented observations in routine clinical practice; thus, it could not have been performed prospectively. Follow-up data were often lacking since our Institution alone offers $^{68}$Ga-DOTATOC PET/CT exams in the whole region, meaning that many patients were referred to the nuclear medicine outpatient Department only to undergo $^{68}$Ga-DOTATOC PET/CT scans, and they continued their clinical course in other hospitals. For this reason, we were not able to gather a comprehensive understanding on how the diagnosis of $^{68}$Ga-DOTATOC PET/CT “incidentalomas” modified the management of affected patients. Based on available follow-up data for patients managed at our Institution, we noted that the diagnosis of $^{68}$Ga-DOTATOC PET/CT “incidentalomas” significantly modified their clinical strategy. Hence, it is reasonable to consider this to be also true for the remaining patients in the brain and body groups. With regard to the strength of this study, this is the first institutional report of $^{68}$Ga-DOTATOC PET/CT “incidentalomas”, showing that these need to be considered during the follow-up of the patients with SSTR2-positive tumors as they can modify the therapeutic strategies.

**Mixed reality-assisted redaction image registry.** In this study, we provide a link accessible using mixed-reality devices to interactively read the manuscript and view the images. To the best of our knowledge, this is the first paper that can be read using mixed-reality devices. This could deeply revolutionize the editorial approach to scientific content. Mixed reality offers an immersive environment where images (18, 19), videos, tables, text can be easily read, but the most important aspect is about transparency. The platform used to upload the whole manuscript may also contain the DICOM files, to give the opportunity to the scientific community to evaluate the entire dataset and not only the few images usually present in the papers. In this way, reviewers, editors, and readers can verify the complete amount of DICOM information.

**Conclusion**

In this retrospective, observational study, we present the first series on brain and body “incidentalomas” detected by $^{68}$Ga-DOTATOC PET/CT. Based on our findings, brain or whole body $^{68}$Ga-DOTATOC PET/CT may be considered in selected patients affected by tumors with high expression of somatostatin receptors for assisting GKSRS or surgical planning while also providing accurate follow-up with early
detection of potential metastases. The detection of lesions previously unknown entails a better understanding of the disease, and thereby influencing the therapeutic strategy.

Supplementary Material

The whole paper and images can be read using mixed reality devices like Hololens2 and similar, by using a code that lasts 6 month, at: www.apoqlar.com/anticancer-incidentaloma

Conflicts of Interest

The first Author G.E.U. is member of the advisory board of ApoQlar and one of the founding members of The Holomedicine Association. He declares no conflicts of interest since his activity is for research purpose only and pro-bono. The other Authors report no conflict of interest in relation to this study.

Authors’ Contributions

Giuseppe E. Umana: Conceptualization, methodology, data analysis, writing – original draft preparation; Gianluca Ferini: writing, resources, reviewing, editing; Mandara Muralidhar Harikar, Tejas Venkataram: Resources, writing – reviewing and editing, statistics; Gianluca Scalia, Paolo Palmisciam, Roberta Costanzo, Rosario Maugeri, Antonio Cena, Lara Brunasso, Andrea Sciortino, Sebastiano Cosentino, Federica Paolini, Concetto Cristaudo, Gabrielle Corsale: Resources, data collection; Massimo Ippolito, Gabriella Sabini, Giacomo Cuttone, Valerio Da Ros, Fabio Barone, Francesco Inserna: Editing, supervision.

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