Clinical significance of atypical ^{68}Ga-DOTATOC prostatic uptake on PET/CT: A ten-year review

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Abstract

Objective: Gallium-68-DOTA-D-Phe1-Try3-Octreotide (^{68}Ga-DOTATOC) is a radiolabeled somatostatin receptor (SSTR) analog that is widely used in the imaging of neuroendocrine tumors (NET). Benign and malignant prostate tumors have been observed to express SSTR. Diffuse symmetric DOTATOC uptake in the prostate is a normal positron emission tomography (PET) finding. The aim of this study was to evaluate the frequency and clinical significance of incidental atypical prostatic uptake in men undergoing ^{68}Ga-DOTATOC PET/computed tomography(CT). **Subjects and Methods:** A retrospective review of consecutive male patients who underwent ^{68}Ga-DOTATOC PET/CT studies at Aalborg University Hospital, Denmark, from November 2010 to April 2020 was performed. Positron emission tomography/CT reports were searched for text words or phrases indicating incidental atypical prostatic uptake. In the resulting cohort, PET/CT were re-evaluated, and DOTATOC uptake in the prostate gland was categorized as focal, diffuse or mixed. The intensity of the uptake was visually graded using the Krenning visual score. Follow-up was based on all available clinical, biochemical, imaging, and pathology follow-up. **Results:** A total of 178 male patients underwent 193 ^{68}Ga-DOTATOC PET/CT scans. Incidental atypical uptake of ^{68}Ga-DOTATOC on PET/CT in the prostatic bed was observed in eight patients (4.5%) (mean age 67 years, range 58-85 years). Six patients (75%) had diffuse uptake; two (25%) patients had focal uptake. Four patients out of eight with incidental findings (50%) had uptake less than or equal to that of the liver (Krenning score 2); four patients (50%) had uptake greater than that of the liver (score 3). All patients had measurements of serum prostate-specific antigen and were referred for urological evaluation. Five patients (62%) underwent a transrectal ultrasound, and three required a biopsy of the prostate. No cases of prostate malignancy (including prostatic cancer) were diagnosed. **Conclusions:** During a 10-year period, we found that 4.5% of men exhibited prostate incidentalomas on ^{68}Ga-DOTATOC PET/CT. No malignancy was found in the prostate in this population. Our data indicate absent malignancy among incidental ^{68}Ga-DOTATOC findings in the prostate.

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Introduction

Imaging of somatostatin receptors (SSTR) with positron emission tomography (PET) tracers obtained with DOTA-coupled somatostatin agonists (including gallium-68-DOTA-D-Phe1-Try3-Octreotide (^{68}Ga-DOTATOC), ^{68}Ga-DOTANOC and ^{68}Ga-DOTATATE) plays a major role in the management of neuroendocrine tumors (NET) [1]. Accordingly, the use of SSTR-PET/CT scans has increased during the last decade, and the frequency of incidental findings is increasingly common. The understanding of incidental findings is important for the evaluation and interpretation of SSTR-PET/computed tomography (CT) scans. A normal prostate contains a small degree of neuroendocrine cells, which may function to regulate the growth, differentiation, and secretion of the prostate gland [2]. The number of neuroendocrine cells increases in high-grade prostate cancer, especially in castration-resistant and dedifferentiated types. However, prostate cancer does not routinely overexpress SSTR, and SSTR-PET/CT is not part of the routine staging of prostate cancer. Nevertheless, a few case reports showed malignancy in the prostate gland by incidental uptake on SSTR-PET/CT [3, 4]. Uptake in the prostate gland on SSTR-PET/CT scans is not necessarily associated with malignancy in the prostate but may represent both physiologic uptake [2, 5, 6] and benign conditions such as benign prostatic hyperplasia and prostatitis [7-9] as well as malignancy [10, 11]. However, to the best of our knowledge, the frequency and cause of abnormal incidental SSTR-PETuptake in the prostate have not yet been investigated systematically. The aim of this study was to evaluate the frequency and clinical significance of incidental atypical prostatic uptake in men undergoing ^{68}Ga-DOTATOC PET/CT.

Subjects and Methods

Patients

A retrospective review of consecutive male patients who underwent ^{68}Ga-DOTATOC PET/CT studies at the Nuclear Medicine Department, Aalborg University Hospital, from November 2010 to April 2020 was performed. In the case of more than one ^{68}Ga-DOTATOC PET/CT scan for a patient, only the first PET/CT scan with incidental prostatic uptake was included in the analysis. Positron emission tomography/CT reports were searched for text words or phrases indicating incidental atypical prostatic uptake. These reports were further narrowed by reviewing the context of the electronic reports. Men with a history of prostate cancer were excluded from further analysis.

DOTATOC PET/CT

Positron emission tomography/CT scans were performed with the ^{68}Ga-DOTA-D-Phe1-Try3-Octreotide (^{68}Ga-DOTATOC) ligand. Gallium-68 was eluted locally at Aalborg University Hospital from a ^{68}Ge/^{68}Ga generator (IGG100-50 M, Eckert & Ziegler RadiopharmaGmBH, Berlin, Germany). Gallium-68-DOTATOC was produced using two different methods: 1) synthesis using the synthesis module Pharmtracer (Eckert & Ziegler RadiopharmaGmBH, Berlin, Germany) and 2) advanced accelerator application according to the manufacturer's instructions using the product SOMAKit TOC (SAM Nordic, Nacka Strand, Sweden). All patients received 150MBq (±10%) ^{68}Ga-DOTATOC, and image acquisition was started 60min (±10 minutes) after injection. The PET/CT scans were performed using two different PET/CT scanners: 1) Biograph mCT 64 Flow (Siemens Healthineers GmbH, Erlangen, Ger-many) and 2) VCT discovery True 64 PET/CT (GE Healthcare, Chicago, Illinois, USA). The examination field extended from the basis cranii to the mid-thigh with a bed speed of 0.5 mm/sec.

Positron emission tomography images were reconstructed using iterative construction and low-dose CT without contrast enhancement for attenuation correction and anatomic localization. The CT parameters were 70-200mA and 120kV for GE VCT Discovery True and 30mA and 120kV for Siemens Biograph. Some patients had a PET/CT with contrast enhancement.

Image analysis

The DOTATOC PET/CT scans were evaluated on a Syngo Via-workstation (Siemens Healthineers GmbH, Erlangen, Germany). The ^{68}Ga-DOTATOC uptake in the prostate gland was categorized as focal, diffuse, or mixed. The intensity of the uptake was visually graded by comparing the prostatic uptake to the background uptake in the liver and spleen (Krenning visual score) [12]. The maximum standardized uptake value (SUVmax) was also measured. Diffuse, symmetric, very low DOTATOC uptake in the prostate (Krenning score ≤1) was considered a normal finding. This definition aligns with our internal guidelines governing the reporting of DOTATOC PET/CT scans. The prostate volume (CT-measured prostate volume as follows: prostate volume=0.52×width×length×height [13]) was estimated and categorized into normal-sized (≤30cc), slightly enlarged (>30-60cc) and enlarged (>60cc) prostate glands.

Follow-up

Follow-up was based on all available clinical, biochemical, imaging, and pathology follow-up for at least one year after the incidental ^{68}Ga-DOTATOC PET/CT finding. The unique Danish personal identifier system allowed the tracking of medical information, irrespective of the site of contact. The national pathology file system was reviewed for any prostate investigations. For patients with at least 12 months of follow-up and no malignant findings in the prostate by cytology or histology at the end of follow-up (February 2022), the incidental findings on ^{68}Ga-DOTATOC PET/CT were categorized as benign.

Statistical analysis

Descriptive statistics included the calculation of frequencies/proportions for categorical data, whereas quantitative values were expressed as medians and ranges.

Approvals

This study was approved by the Danish Patient Safety Authority (31-1521-193), who provided a waiver for patient informed consent to access the patient files. According to national legislation, retrospective studies do not require approval from the ethics committee.

Results

Patients

In the study period, 193 ^{68}Ga-DOTATOC PET/CT scans were performed on 178 men over 18 years of age. Incidental atypical uptake of ^{68}Ga-DOTATOC on PET/CT in the prostatic bed was observed in eight patients (4.5%) (mean age 67 years, range 58-85 years). Six patients (75%) had diffuse uptake; two (25%) patients had focal uptake. Four patients out of eight patients with incidental findings (50%) had uptake less than or equal to that of the liver (Krenning score 2); four patients (50%) had uptake greater than that of the liver (score 3). The median SUVmax was 13 (range 8.4-21) in all patients. All patients had either slightly enlarged or enlarged prostate glands (mean prostate volume 65.8cc, range 32-239) (Table 1).

Follow-up and findings

Follow-up was conducted in all patients within 12 months of detection of the prostate incidentaloma identified on ^{68}Ga-DOTATOC PET/CT. All patients had measurements of serum prostate-specific antigen (PSA) and were referred for urological evaluation. The mean PSA of all patients was 3ng/mL (range 0.6-7) at the time of ^{68}Ga-DOTATOC PET/CT. Five patients (62%) underwent a transrectal ultrasound based on DOTATOC report and subsequent measurement of PSA level, during which three of them required a biopsy. One biopsy showed inflammatory changes, and two biopsies showed

Table 1. *Characteristics of patients with prostate incidental findings on ^{68}Ga-DOTATOC PET/CT.*

ID	Age (years)	Type of uptake	Krenning Visual score	SUVmax	Prostate volume	Follow-up (months)	Urological examination	PSA (ng/mL)	TRUS	Biopsy	Clinical diagnosis
1	85	Diffuse	3	12.2	Enlarged	82	Yes	7.0	Yes	-	Benign prostate hyperplasia
2	58	Diffuse	3	12.7	Enlarged	77	Yes	4.3	Yes	Benign	Benign prostate hyperplasia
3	65	Diffuse	3	14.0	Slightly enlarged	54	Yes	0.7	-	-	-
4	72	Diffuse	2	13.7	Slightly enlarged	48	Yes	1.1	-	-	-
5	70	Diffuse	2	12.0	Slightly enlarged	47	Yes	7.0	Yes	Inflammatory	Prostatitis
6	61	Focal	2	8.4	Slightly enlarged	44	Yes	0.9	Yes	Benign	-
7	63	Focal	3	21.0	Slightly enlarged	22	Yes	0.6	Yes	-	-
8	64	Diffuse	2	9.6	Slightly enlarged	30	Yes	1.9	-	-	-

SUVmax: maximum standardized uptake value; PSA: prostate-specific antigen; TRUS: transrectal ultrasound; '-' means not conducted

Follow-up and findings

Follow-up was conducted in all patients within 12 months of detection of the prostate incidentaloma identified on ^{68}Ga-DOTATOC PET/CT. All patients had measurements of serum prostate-specific antigen (PSA) and were referred for urological evaluation. The mean PSA of all patients was 3ng/mL (range 0.6-7) at the time of ^{68}Ga-DOTATOC PET/CT. Five patients (62%) underwent a transrectal ultrasound based on DOTATOC report and subsequent measurement of PSA level, during which three of them required a biopsy. One biopsy showed inflammatory changes, and two biopsies showed no abnormal findings. None of the subjects, presented any discernible clinical manifestations. Moreover, all subsequent assessments and interventions, such as PSA measurements, transrectal ultrasound, and biopsy, were performed strictly in adherence to the our DOTATOC reports.

Based on transrectal ultrasound, biopsy and clinical investigation, two men were diagnosed with benign prostate hyperplasia (median SUVmax 12.4), one was diagnosed with prostatitis (SUVmax 12), and the remaining 5 patients were diagnosed with unexplained ^{68}Ga-DOTATOC uptake in a normal prostate. No patient underwent prostatectomy. No cases of prostate malignancy (including prostatic cancer) were diagnosed (Table 1).

Follow-up was continued for all patients on average for 50 months (range 22-82 months) until February 2022 through the National Danish Pathology system without any evidence of prostate malignancy in these patients – this was conducted to validly exclude prostate malignancies.

An example of a ^{68}Ga-DOTATOC-avid prostate lesion with prostatitis is shown in Figure 1. This 70-year-old patient presented with a carcinoid tumor in the lower lobe of the right lung (well-differentiated, low-grade NET with a Ki-67 of 3%) and was referred to the Nuclear Medicine Department for primary staging; PET/CT scan showed incidentally diffuse moderate uptake of the prostate with an SUVmax of 12 (Krenning score 2). The patient was clinically without urinary symptoms (PSA 7 ng/mL and C-reactive protein 39 mg/l); however, due to the PET findings, he underwent TRUS-guided biopsy, which showed chronic inflammation as well as many intraluminal neutrophilic granulocytes in the prostate gland. The final diagnosis was asymptomatic inflammatory prostatitis.

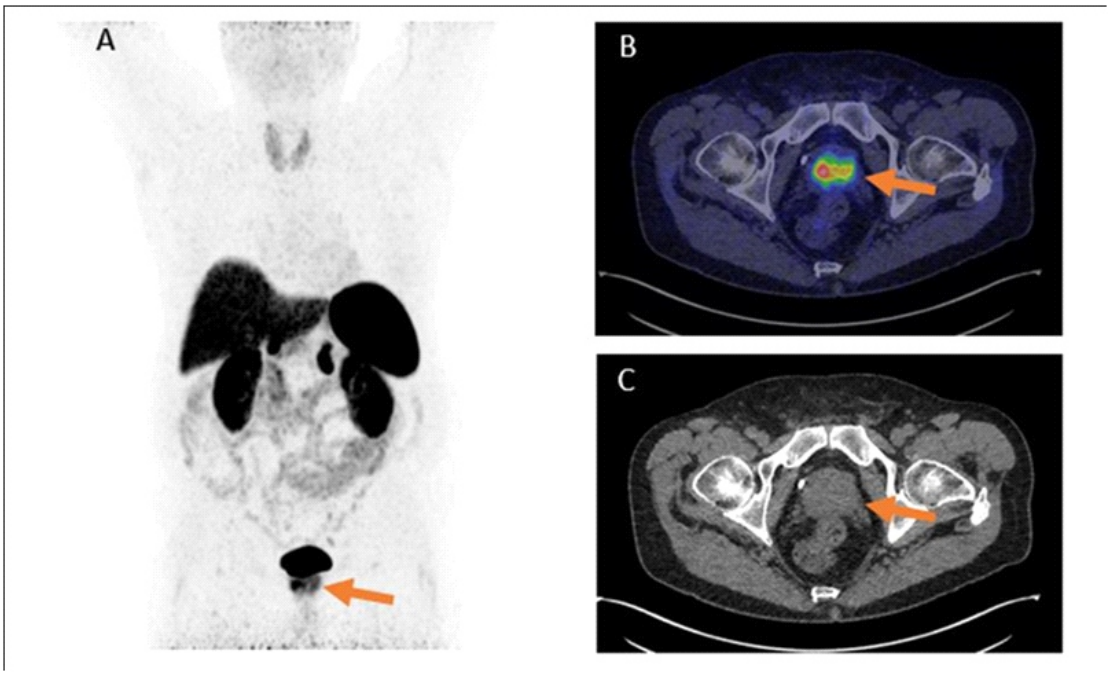

Figure 2. A 70-year-old man underwent a ^{68}Ga-DOTATOC PET/CT scan for staging of a carcinoid tumor in the lower lobe of the right lung, which did not present pathological ^{68}Ga-DOTATOC uptake. Maximum-intensity projection (A) and fused axial PET/CT (B) showed an incidental finding in the prostate gland (arrows) with moderately increased ^{68}Ga-DOTATOC uptake (SUVmax 12.0). Computed tomography (C) showed a slightly enlarged prostate gland. The patient underwent TRUS-guided biopsy, and the diagnosis of prostatitis was confirmed.

Discussion

To the best of our knowledge, this is the first study to systematically report the prevalence and clinical importance of unexpected ^{68}Ga-DOTATOC-avid prostate lesions. To validate this assertion, an exhaustive search was performed on PUBMED until June 2023, which did not yield any novel findings. Additionally, no other scholarly articles addressing the occurrence and clinical significance of unexpected prostatic uptake in relation to other DOTA-coupled somatostatin receptors were found. We found a 4.5% incidence of prostate incidentalomas in consecutive patients without a history of prostate cancer undergoing ^{68}Ga-DOTATOC PET/CT imaging. Two patients were diagnosed with benign prostate hyperplasia, and one patient was diagnosed with prostatitis. No cases of prostate malignancy, including metastatic deposits in the prostate, were diagnosed.

Gallium-68-DOTATOC PET/CT scans have high diagnostic accuracy in neuroendocrine tumors, with the affinity to mainly bind SSTR subtype 2 [14]. Due to the increasing use of SSTR-PET/CT in oncology, it has become common to encounter patients with incidental findings in various organs, including the prostate gland. However, the most common type of prostate cancer, i.e., conventional adenocarcinoma, is not typically SSTR-PET-avid. Overexpression of SSTR has been documented in neuroendocrine-type prostate malignancies (NEPCa) [15, 16]. We excluded patients with a history of prostate cancer; thus, only new cases of NEPCa could be detected. Neuroendocrine-type prostate malignancy has a very low incidence compared to adenocarcinomas of the prostate. Zaffuto et al. (2017) identified only 309 cases of NEPCa within a cohort of 510,913 patients with prostate cancer, corresponding to an incidence rate of less than 1 per 1,000,000 person-years [17]. Considering the very low incidence rate of NEPCa, it is not surprising that our cohort did not show any patients with primary NEPCa.

All patients in our cohort with atypical ^{68}Ga-DOTATOC uptake had slightly enlarged/enlarged prostate glands, and since no clinical diagnosis was made during the long follow-up period, atypical prostatic uptake was considered to represent variations in physiological uptake. Moradi et al. (2016) [18] reported moderate physiologic DOTATATE uptake (mean SUVmax=6.27, SD 2.57), and Shastry et al. (2010)[6] observed low-grade DOTATATE uptake (mean SUVmax=4.4, range 3.5-5.2) in normal prostate tissue; however, in our study, the mean SUVmax was 12.95 and thus much higher than in these reports. Todorovic et al. (2014) showed a strong correlation between patient age, size of the prostate gland and DOTATOC uptake in 64 patients with normal prostate tissue [2]. Based on this knowledge, it could be speculated that the range of physiological uptake in the prostate gland can increase with increasing prostate volume and age. These factors could be considered when reporting atypical prostate uptake in SSTR-PET/CT scans, and the threshold of physiological uptake in these patients might be higher. However, large population-based cohort studies are needed to validate this assumption.

Incidental prostatic uptake has been reported by other PET tracers, especially by PET/CT with fluorine-18-fluorodeoxyglucose (^{18}F-FDG). The detection rate of ^{18}F-FDG PET pros-

tatic incidental findings varies between 1%-2%; however, the risk of malignancy in patients with further follow-up is reported to be between 7.5%-17% [19-25]. Our results are in contrast to these studies, with a detection rate of prostate incidental findings by ^{68}Ga-DOTATOC PET/CT being two times more frequent than with ^{18}F-FDG PET/CT; however, the risk of malignancy with ^{68}Ga-DOTATOC uptake is very low. This may be explained partly by ^{18}F-FDG PET-positive conventional adenocarcinoma of the prostate, which is not normally ^{68}Ga-DOTATOC-positive.

We identified one case of prostatitis showing diffuse ^{68}Ga-DOTATOC-avid lesions in our cohort without clinical symptoms. Atypical incidental uptake of SSTR-PET tracers has been reported in patients with inflammatory disease in the prostate gland [8], possibly explained by overexpression of SSTR in white blood cells [12]. Asymptomatic inflammatory prostatitis is mostly diagnosed incidentally after elevated PSA or infectious blood markers. However, this study shows that it is also important when reporting atypical incidental prostatic uptake on SSTR-PET/CT to be aware of possible differential diagnoses such as inflammatory disease in the prostate gland.

There are some limitations to this retrospective study. In addition to being a small cohort study, prostate incidental findings were identified based on reviews of ^{68}Ga-DOTATOC PET/CT reports without reviewingthe original ^{68}Ga-DOTATOC PET/CT scans, and therefore there was risk of exclusion bias based on the reviewer's opinion of normal versus pathologic ^{68}Ga-DOTATOC uptake. However, follow-up was conducted in all patients with atypical ^{68}Ga-DOTATOC uptake in the prostate gland, and there was no loss of data.

In conclusion, during a 10-year period, we found that 4.5% of men exhibited prostate incidentalomas on ^{68}Ga-DOTATOC PET/CT. No malignancy was found in the prostate in this population despite thorough examination and a long follow-up period. It is important to exercise caution when generalizing this result due to the limitations inherent in our study.

The authors declare that they have no conflicts of interest.

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