

Ga-68 DOTATATE PET/CT in Neuroendocrine Tumors: Initial Experience

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ABSTRACT

Introduction: Neuroendocrine tumors (NET) are a heterogeneous group of neoplasms, majority of which express somatostatin (SST) receptors. Recently, with the widespread use of positron emission tomography/computed tomography (PET/CT) and development of novel PET tracers like Ga-68 DOTA peptide which specifically bind to somatostatin receptors (SSTR), Ga-68 DOTA peptide PET/CT is used in management of NET.

Objective: To study the various indications for which Ga-68 DOTATATE PET/CT scan was performed and the utility of the scans.

Materials and methods: Retrospective evaluation of the patients data was performed who underwent Ga-68 DOTATATE PET/CT as part of their diagnostic workup between June 2011 and July 2012. A total of 145 patients aged 1 to 71 years (mean: 37.4 years) were studied during this period.

Results: Ga-68 DOTATATE PET scan was positive in 23/39 patients referred for characterization or diagnosis, in 6/19 patients for localization, in 13/24 patients for detection of unknown NET primary, in 16/17 patients for staging, in 6/7 patients for recurrence assessment, 12/12 patients for response evaluation, 7/18 patients in restaging and in 5/5 differentiated thyroid cancer patients with thyroglobulin elevated but negative iodine scan.

Conclusion: Ga-68 DOTATATE PET/CT is a useful modality in characterization, localization, detection of unknown NET primary, staging, restaging, recurrence and response evaluation to treatment in patients with NET.

Keywords: Neuroendocrine tumors, Somatostatin, Gallium-68, DOTATATE, Positron emission tomography/computed tomography.

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INTRODUCTION

Neuroendocrine tumors (NET) are heterogeneous group of neoplasms that arise from endocrine cells of the glands (adrenal medulla, pituitary, parathyroid) or from endocrine islets in the thyroid, pancreas, or the respiratory and gastrointestinal tract. The majority of NETs express somatostatin (SST) receptors. Thus, they can be effectively imaged with radiolabeled SST analogs. 'Somatostatin receptor scintigraphy (SRS)' with In-111 and Tc-99m-

labeled SST analogs has been accepted as favored mode of imaging in the assessment of NET. Recently, with the widespread use of positron emission tomography/computed tomography (PET/CT) and development of novel PET tracers (Ga-68 DOTA-peptides), specifically binding to somatostatin receptors (SSTR) overexpressed on the surface of NET cells, allowed the visualization of NET with Ga-68 DOTA peptide PET/CT scans. PET/CT with Ga-68 DOTA peptides has been reported to present a higher sensitivity for the detection of well-differentiated NET than other imaging procedures (particularly CT and SRS).¹⁻⁴

We share our experience of using Ga-68 DOTATATE imaging started in the year 2011. The data was analyzed with the aims to analyze the various indications for which ⁶⁸Ga-DOTATATE PET/CT scan was performed and the utility of the scans thereof.

MATERIALS AND METHODS

We retrospectively reviewed all patients who underwent Ga-68 DOTATATE PET/CT in the department of nuclear medicine, PGIMER, Chandigarh, India, as part of their diagnostic workup between June, 2011 and July, 2012. A total 145 patients (male 66, female 79) were enrolled in this study. Age of the patients ranged from 1 to 71 years (mean: 37.4 years). Detailed clinical history was available for all patients.

Ga-68 DOTATATE was synthesized in the inhouse radiopharmacy of the Department of Nuclear Medicine. Ga-68 was eluted from a Ge-68/Ga-68 generator (ITG, Germany), and DOTATATE was labeled with Ga-68 following the recommended procedure. Studies were performed on a dedicated PET/CT scanner (DISCOVERY STE-16, GE Healthcare, Milwaukee, USA). Acquisition was started 45 to 60 minutes after intravenous injection of approximately 1.5 MBq/kg body weight of Ga-68 DOTATATE. Whole-body scans were acquired in overlapped bed positions from base of skull to mid-thigh with the arms extended above the head. After transmission scan, 3D PET acquisition was performed at 2 minutes per bed position. Additional leg view was acquired in some patients, if indicated. CT was performed using tube current of 80 to 150 mA, without injection of contrast media. Data obtained from CT acquisition was used for low noise attenuation correction of PET emission data and for fusion

of attenuation corrected PET images with corresponding CT images. Image reconstruction was done using iterative reconstruction (ordered subset expectation maximum) algorithm. Transaxial, coronal and sagittal images were obtained after reconstruction.

RESULTS

Ga-68 DOTATATE was performed in 145 patients for various indications, including characterization or diagnosis in 39 of 145 patients (26.9%), localization in 19 of 145 (13.1%), detection of unknown NET primary in 24 of 145 patients (16.5%), staging in 17 of 145 patients (11.7%), recurrence assessment in seven of 145 (4.8%), response to treatment in 12 of 145 (8.3%), restaging in 18 of 145 (12.4%), surveillance in four of 145 (2.7%) and in thyroglobulin-elevated negative iodine scan (TENIS) patients in differentiated thyroid cancer (DTC) in five of 145 (3.4%). Thirty-nine patients underwent Ga-68 DOTATATE PET/CT for diagnosis or characterization of a lesion (Table 1), 19 patients for localization of the disease (Table 2). All the patients referred with suspicion of insulinoma (n = 5) or having suspicion for pheochromocytoma (n = 5) were PET negative for SSTR expression. Out of eight patients, who were referred to look for the site of primary with suspicious tumor induced osteomalacia, six showed positive results in detecting the site of tumor. One patient with suspicion of primary aldosteronism, PET was negative.

Ga-68 DOTATATE PET/CT was performed in 24 patients with histologically or cytologically proven NET for detection of unknown primary (Table 3). PET/CT localized primary tumor sites in 13/24 patients (54%) accurately and excluded any other site/s of involvement.

Table 2: Ga-68 DOTATATE PET scan results in patients for localization of the disease

Clinical condition	Total no. of patients	Positive	Negative
Insulinoma?	5	0	5
Pheochromocytoma?	5	0	5
Tumor-induced osteomalacia (TIO)	8	6	2
Primary hyperaldosteronism?	1	0	1
Total	19	6	13

Two representative ⁶⁸Ga-PET/CT scans in patients in whom metastatic NET disease was confirmed on cytology but the site of primary disease was not known, are presented in Figures 1A to 2E. Liver was the site of presentation (metastases in 17 patients of which PET identified the site of primary in 6 patients).

Ga-68 DOTATATE PET/CT was performed in 17 patients, who were referred for staging of histologically or cytologically confirmed NET (Table 4). Ga-68 DOTATATE PET/CT was performed in seven patients with NET, for recurrence assessment (Table 5). PET was positive in 5/7 of patients (71%), while two patients were negative for recurrence. Ga-68 DOTATATE PET/CT study was done in 12 patients for response evaluation (Table 6). All the patients showed residual disease. Ga-68 DOTATATE PET/CT was performed in 18 patients with histologically or cytologically proven NET tumor for restaging after surgery (Table 7). PET/CT was positive in seven patients for SSTR expressing residual tumors. Ga-68 DOTATATE PET/CT was performed in five patients with TENIS syndrome in follow-up patients with DTC, for detection of dedifferentiated tumor (Table 8). PET/CT in all five patients

Table 1: Details of patients who underwent Ga-68 DOTATATE PET scan for lesion characterization

Clinical diagnosis	Total no. of patients	Positive	Negative	Comments
Neuroblastoma?	10	6	4 (2 positive at site other than primary)	Uptake also in bone in 6 and liver in one patient
Pheochromocytoma/ paraganglioma?	15	10	5	Multiple retroperitoneal nodes in one patient
Carcinoid?	3	2	1	Mesenteric carcinoid = 1, bronchial carcinoid = 1
Atypical hemangioma?	1	0	1	
Carotid body tumor?	1	1	-	
Nesidioblastosis?	1	1	-	Diffuse uptake in pancreas
Parathyroid adenoma?	1	0	1	
Pituitary microadenoma?	1	0	1	
MEN 1?	1	1	-	Uptake in head of pancreas and peripancreatic node
NET?	5	2	3	-
Total	39	23	16	

NET: Neuroendocrine tumor

Table 3: Ga-68 DOTATATE PET scan results in patients with histologically proven NET for localizing unknown primary site

Secondary	Positive	Primary identified
Liver (n = 17)	13	6 (pancreas = 2, multiple sites = 4)
Scalp (n = 1)	1	1 (meningioma)
Stomach (n = 3)	3	3 (stomach)
Cecum (n = 1)	1	1 (cecal carcinoid)
Neck node (n = 1)	1	1 (nasopharyngeal NET)
Postmediastinal mass (n = 1)	1	1 (postmediastinal mass)

Table 4: Ga-68 DOTATATE PET scan results in patients with histologically proven NET for initial staging of the disease

Primary	No. of patients	Positive	Negative	Comments
Carcinoid	4	4	–	Distant metastases = 3
Ganglioneuroma	1	1	–	Localized disease
NET breast	1	–	1	Primary was excised
NET pancreas	3	3	–	Distant metastases = 1
Neuroblastoma	6	6	–	Distant metastases = 5
Pituitary macroadenoma	1	1	–	Distant metastases = 1
Small-cell carcinoma pleural cavity	1	1	–	Locoregional metastases

Table 5: Ga-68 DOTATATE PET scan results in patients for evaluation of disease recurrence

Primary	No. of patients	Positive	Negative
Neuroblastoma	1	1	–
Carcinoid	3	2	1
Medullary thyroid cancer	1	1 (neck and mediastinum)	–
Pheochromocytoma	1	–	1
Pancreatic NET	1	1 (pancreas and greater omentum)	–

Table 6: Ga-68 DOTATATE PET scan results in patients studied for response evaluation

Primary	No. of patients	Positive for residual disease
Ileal carcinoid	5	5
Neuroblastoma	1	1
Medullary thyroid cancer	1	1
NET pancreas	3	3
NET ovary	1	1
NET lung	1	1

Table 7: Ga-68 DOTATATE PET scan results in patients studied for restaging

Primary	No. of patients	Positive	Negative
Carcinoid	6	1	5
Pheochromocytoma	1	–	1
Paraganglioma	3	1	2
NET pancreas	3	2	1
NET thymus	1	–	1
NET liver	1	–	1
NET arytenoid	1	1	–
Gastrinoma	1	1	–
Pituitary carcinoma	1	1	–

showed SRS-positive tissue. Ga-68 DOTATATE PET/CT surveillance scan was performed in four patients with NET (Table 9). All the four patients were negative for recurrence of disease.

DISCUSSION

NET, which constitutes a heterogeneous group of neoplasms, are generally considered as rare tumor.^{5,6} However, the surveillance, epidemiology, and end Results (SEER) database analysis shows an increase in the reported annual age-adjusted incidence of NETs from (1.09/100,000) in 1973 to (5.25/100,000) in 2004.⁷ Conventional imaging modalities (USG, CT, etc.) have limitation in detection of NET due to the small size, their variable anatomical location and the slow metabolic rate of well-differentiated forms. Scintigraphy with In-111 and Tc-99m-labeled SST analogs, has proven useful in diagnosing SSTR-positive tumors.^{8,9}

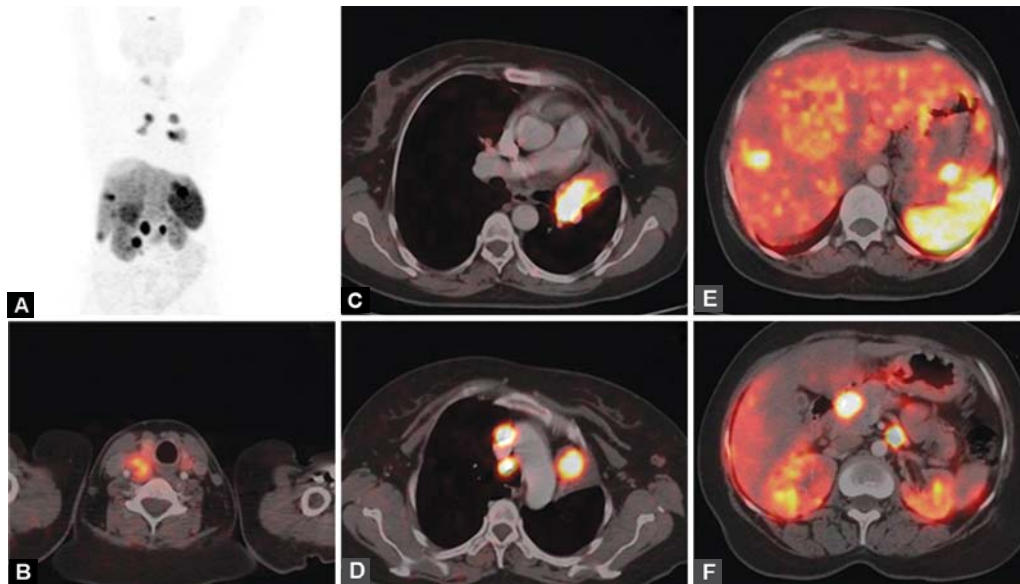
Table 8: Ga-68 DOTATATE PET scan results in patients studied for TENIS syndrome

Thyroglobulin level (ng/ml)	Positive SST receptor scan
115.5	Cervical nodes
17	Cervical nodes
17.90	Remnant and cervical nodes
30	Cervical nodes
82	Thyroid bed soft tissue nodule

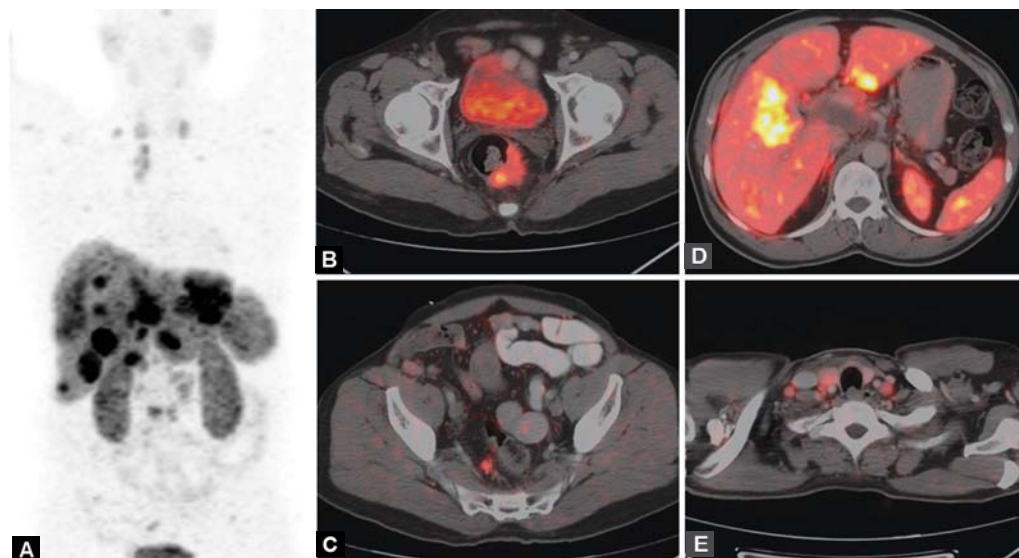
TENIS: Thyroglobulin-elevated negative iodine scintigraphy

Table 9: Ga-68 DOTATATE PET scan results in patients studied for surveillance

Primary	Ga-68 DOTATATE PET/CT findings
Ileal carcinoid	Negative
NET	Negative
MEN 1	Negative
Thymic carcinoid	Negative



Figs 1A to F: A 42 years old female patient presented with abdominal pain and swelling of face, feet and hand. Ultrasonography of abdomen revealed multiple heterogeneously echoic lesions of varying sizes in both lobes of liver which revealed NET on FNAC. Ga-68 DOTATATE PET/CT scan: (A) MIP showed SSTR-expressing lesions at multiple sites which were further localized in the, (B) left lobe of thyroid gland (likely medullary thyroid cancer), (C) left lung (likely bronchial carcinoid), (D) mediastinal lymph nodes, (E) liver and stomach, (F) head of pancreas and abdominal lymph nodes. The PET scan findings are indicative of multiple endocrine neoplasia



Figs 2A to E: Ga-68 DOTATATE PET/CT images of a 55 years old male patient with metastatic NET in liver and unknown primary showing multiple sites of SSTR-expressing lesions on MIP image: (A) In the rectum, (B) pararectal lymph nodes, (C) liver, (D) and cervical and mediastinal lymph nodes, (E) indicative of likely primary site in rectum with widespread metastases

The detection rate was reported to be between 80 and 100% in different studies. Moreover, SSTR expression has been correlated well with the prognosis, as SSR expressing NET shows good response to treatment with SST analogs.¹⁰

Recent introduction of PET/CT and its wide availability has lead to search for several new positron emitting radiotracers. One among this is SST analogs labeled with Ga-68 (Ga-68-DOTA peptides), which has several advantages over conventional SRS. Firstly, gallium-68 is generator produced and labeling of Ga-68 with DOTA peptides is relatively easy. Secondly, resolution of PET/CT imaging is far better than gamma camera, thus better

visualization of lesion is a benefit. Also, this is less time-consuming than SRS (roughly 1.5 hours, instead of up to 24 hours acquisition in SRS). Finally, PET/CT provides advantage of semiquantification of the lesions.

Ga-68 DOTA-peptides have high affinity for SSTR.^{11,12} SST is a small, cyclic neuropeptide that is present in neurons and endocrine cells; it has a high density in the brain, peripheral neurons, endocrine pancreas and gastrointestinal tract. The majority of NETs express SSTR, so they can be effectively targeted and visualized with radiolabeled SST analogs *in vivo*.¹² Gastroenteropancreatic tumors (both functioning and nonfunctioning), pheochromocytoma,

paraganglioma, neuroblastoma and ganglioneuroma, medullary thyroid carcinoma, pituitary adenoma, Merkel cell carcinoma, small-cell lung cancer usually show high SSTR expression.^{4,13-19} Low receptor expression is seen in the breast cancer, melanoma, lymphomas, prostate cancer, non-small cell lung cancer, sarcomas, renal cell carcinoma, DTC, astrocytoma, meningioma.^{20,21}

Structurally Ga-68 DOTA peptides are made of three parts, the radioisotope (Ga-68), chelate (DOTA) and a peptide (TOC, NOC, TATE). This later component binds directly to SSTR. Six different types (1, 2A, 2B, 3, 4 and 5) of SSTR have been identified in humans. The three available tracers (DOTA-TOC, DOTA-NOC, DOTA-TATE) differs in their ability to bind with different SST subtypes.²² All three can bind to SSTR 2, whereas DOTA-NOC also shows good affinity for SSTR 3 and 5 and DOTA-TOC also binds to SSTR 5 (although with lower affinity than DOTA-NOC). ⁶⁸Ga-DOTATATE presents a predominant affinity for SSTR 2.

The main clinical indication of Ga-68 DOTA-peptides PET/CT is the imaging of NETs. It can be used in some cases of non-NET, if treatment with radiolabeled therapeutic SST analogs is considered. Ga-68 DOTA peptides imaging can be used in NET to localize primary tumors, staging, restaging, recurrence detection^{4,13-19,23-25} monitor the response to therapy,²⁶ to determine SSTR status to select the patients for SSTR radionuclide therapy.^{26,27} In the present study, Ga-68 DOTATATE PET scan was positive in 23/39 (59%) patients referred for characterization or diagnosis, in 6/19 (31.5%) patients for localization, in 13/24 (54%) patients for detection of unknown NET primary, in 16/17 (94%) patients for staging, in 6/7 (85%) patients for recurrence assessment, 12/12 (100%) patients for response evaluation and 7/18 (38.8%) patients in restaging. All the five DTC patients, who underwent ⁶⁸Ga-DOTATATE PET scan for TENIS syndrome showed tracer uptake, thus guiding the further management in these patients.

Usually no patient preparation is needed before the test and there is no need for fasting before the test, unlike FDG PET/CT study. Some experts recommend temporary withdrawal of SST analog therapy, if possible, to avoid SSTR blockade. The time interval between withdrawal of therapy and Ga-68 DOTA peptides scan depends on the type of drugs used: One day is suggested for short-lived molecules and 3 to 4 weeks for long-acting analogs. However, this issue is still controversial. The minimum recommended administered activity for adult patient is 100 MBq. Maximal tumor activity accumulation is reached 50 to 90 minutes postinjection.²

Physiological tracer uptake is seen in the liver, spleen, kidneys and pituitary. The thyroid and salivary glands are

faintly visible. The prostate gland and breast glandular tissue may show diffuse low-grade Ga-68 DOTA-conjugate peptides uptake. The pancreas shows variable uptake of Ga-68 DOTA peptides, due to physiological presence of SSTR 2. A potential pitfall in image interpretation may be the uptake of tracer in the pancreatic head due to accumulation of islets in one pancreatic region, which may mimic focal tumor disease.⁴ Inflammation may be the another potential cause of pitfalls in image interpretation, since SST are expressed on activated lymphocytes, and therefore Ga-68 DOTA peptides may be falsely positive in inflamed areas. Moreover, an accessory spleen or physiological activity at the adrenal level should be borne in mind while interpreting the images.

One point the referring physician should be aware of, is the positive findings on ⁶⁸Ga-DOTA peptides PET/CT reflects increased density of SSTR rather than malignant disease. Thus, a poorly differentiated NET, i.e. poorly SSTR expressing tumor, may not show tracer uptake. Also heterogeneous expression of SSTR subtypes may influence the affinity for ⁶⁸Ga-DOTA peptides.

CONCLUSION

Ga-68 DOTATATE PET/CT is useful in characterization, localization, unknown NET primary, staging, restaging, recurrence and response evaluation to treatment in NET.

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