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Somatostatin Receptor Imaging of Small Cell Lung Cancer (SCLC) by Means of ^{111}In -DTPA Octreotide Scintigraphy

E. Bombardieri, F. Crippa, I. Cataldo, A. Chiti, E. Seregni, E. Soresi, R. Boffi, G. Invernizzi and G.L. Buraggi

Somatostatin receptors have been described on the membrane of neoplastic cells derived from the APUD system and their expression has also been demonstrated on small cell lung cancer (SCLC) *in vitro* and *in vivo*. 21 patients with SCLC were studied using ^{111}In -octreotide (^{111}In -OCT) scintigraphy. Scintigraphic examinations were performed following intravenous (i.v.) injection of 111 MBq ^{111}In -OCT with whole-body scintigraphy and planar scintigraphy of the thorax as well as the SPET technique. No short-term side effects were described following ^{111}In -OCT administration. We studied the ^{111}In -OCT biodistribution in 3 patients with serial scintigraphies at 1, 5 and 24 h. We used the 5 h as standard scanning time for the following 18 patients. The scintigraphic results were compared with those of other conventional diagnostic procedures. ^{111}In -OCT detected 86% (48/56) of the lesions already known at the time of scintigraphy. It was positive in all 20 SCLC patients and negative in one lung adenocarcinoma. ^{111}In -OCT showed high sensitivity for mediastinal metastases (94%) and good sensitivity for bone metastases (75%) and abdominal lymph node metastases (71%). ^{111}In -OCT did not detect two liver metastases. ^{111}In -OCT detected five unknown lesions which were confirmed by other diagnostic examinations. ^{111}In -OCT was also effective in cancer patients with low levels of NSE. Our study shows that ^{111}In -OCT scintigraphy is a reliable, non-invasive technique to detect primary SCLC and its locoregional or distant metastases. The clinical utility of receptor status characterisation obtained with ^{111}In -OCT scintigraphy should be evaluated by means of an appropriate prospective study.

Key words: small cell lung cancer, somatostatin analogues, ^{111}In -octreotide scintigraphy
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INTRODUCTION

SMALL CELL lung cancer (SCLC) represents 20–25% of all malignant lung tumours with an estimated incidence in Europe of 25 new cases per 10⁵ inhabitants [1]. Even with combined treatments (chemotherapy and radiotherapy), the median survival is currently not more than 63 weeks for patients with localised disease and 40 weeks for patients with extended disease [2–4]. The prognosis of SCLC patients depends on several factors such as sex and age, performance status, disease extension and tumour marker expression [1, 5, 6]. The management of SCLC could be improved with the discovery of new prognostic factors that would affect therapy planning, and with the use of new diagnostic tools capable of giving additional information for staging and treatment monitoring.

Somatostatin (SS) receptors have been described on the cell membranes of tumours derived from the APUD system, and

their presence has also been demonstrated on SCLC cells both *in vitro* (cell line cultures and biopsies from SCLC patients) and *in vivo* (SCLC grown in nude mice) [7, 8]. The *in vivo* radiolocalisation of SS receptors was recently obtained using ^{125}I labelled octreotide [9–12] and ^{111}In -labelled octreotide [13, 14]. This possibility has potential clinical utility since radiolabelled SS analogues, that are currently employed for the diagnosis of neuroendocrine tumours of the gastrointestinal tract, could similarly be used for lung tumours [15–16]. Moreover, since SS and its analogues have shown relevant antiproliferative action in lung cancer with SS receptors, the *in vivo* characterisation of the receptor status of lung cancer could influence the therapeutic approach [17–19].

This paper presents our experience with SS receptor imaging of SCLC with ^{111}In -OCT scintigraphy in a series of consecutive patients from the National Cancer Institute and from the Niguarda Hospital, Milan, Italy.

MATERIALS AND METHODS

Radiotracer

The SS analogue DTPA-D-Phe-1-octreotide (Octreoscan) and ^{111}In -chloride were obtained from Mallinckrodt Medical (Petten, The Netherlands). Single-step radiolabelling of DTPA-

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D-Phe-1-octreotide with ^{111}In -chloride was carried out according to Mallinckrodt's instructions. Each patient received a slow intravenous (i.v.) injection of 111 MBq of ^{111}In -octreotide (^{111}In -OCT).

Patients

21 patients (19 males and 2 females; mean age 61 years, range 49–76) with a histological diagnosis of SCLC entered the study after having given their informed consent (Table 1). 17 patients were diagnosed at tumour presentation and they underwent staging procedures including ^{111}In -OCT scintigraphy, chest X-ray, serum enolase test (NSE), fibre optic bronchoscopy, bone scintigraphy, abdominal ultrasound, chest and brain CT scan. ^{111}In -OCT scintigraphy and other diagnostic investigations were performed as restaging procedures in 4 patients with SCLC already having been treated with surgery and/or chemotherapy.

Scintigraphic procedures

Patients were studied using a Toshiba GCA 901/A gamma camera equipped with a medium energy collimator. The first 3 patients were studied at 1, 5 and 24 h after the injection by whole-body scintigraphy followed by planar scintigraphy (256 × 256 matrix) and SPET (64 × 64 matrix, 360°, 60 steps, 30 s/step) of the thorax. Since the ^{111}In -OCT tumour uptake and tumour/background ratio at 24 h (Table 2) did not show clear advantages over earlier examination and the quality of SPET images worsened at 24 h we adopted 5 h as the scanning time for the following patients. The scintigraphic images were analysed by three observers who gave independent judgements of the results. In addition, a semiquantitative evaluation of the ^{111}In -OCT tumour uptake was made by means of the region-of-interest (ROI) technique. ROIs on the lung lesions and normal contralateral lung (as background) were drawn and the tumour/background index obtained.

Table 1. Main characteristics of patients studied with ^{111}In -OCT

Patients	Sex	Age (years)	Stage*	Previous treatment
1	M	50	ED	No
2†	M	62	ED	No
3	M	61	ED	No
4†	M	51	ED	No
5	M	58	LD	No
6	M	76	ED	No
7	M	65	LD	No
8	M	65	LD	No
9	F	69	ED	No
10	M	56	LD	No
11	M	54	ED	Yes
12	M	59	LD	No
13	M	49	LD	No
14	M	52	LD	No
15	M	68	LD	No
16	M	59	LD	No
17	F	57	LD	No
18‡	M	51	ED	Yes
19‡	M	71	ED	Yes
20‡	M	72	LD	Yes
21	M	71	LD	No

* ED = extended disease; LD = local disease.

† Pts 2 and 4 had second ^{111}In -OCT scintigraphy after chemotherapy

‡ Pts 18, 19 and 20 had second ^{111}In -OCT scintigraphy.

Table 2. ^{111}In -OCT scanning time and lesion detectability

Lesion	1 h lesion detection (T/B)	5 h lesion detection (T/B)	24 h lesion detection (T/B)
Pt-1 primary tumour	+ (1.4)	+++ (1.6)	++ (1.8)
Pt-2 primary tumour	+++ (2)	+++ (8.7)	+++ (9.1)
Pt-3 primary tumour	+ (1.8)	+++ (2.8)	+++ (3.1)
Pt-1 mediastinal nodes	± (1.3)	++ (1.8)	++ (1.8)
Pt-2 mediastinal nodes	+ (1.6)	++ (3.1)	+ (2.9)
Pt-3 mediastinal nodes	± (1.2)	++ (1.9)	++ (2)

T/B, tumour background index.

+ low intensity image

++ medium intensity image

+++ high intensity image.

RESULTS

Table 3 summarises the results of ^{111}In -OCT scintigraphy in 56 lesions already detected with other diagnostic procedures. ^{111}In -OCT scintigraphy showed an overall sensitivity of 86% (48/56). ^{111}In -OCT scintigraphy detected 20 of the 21 lung tumours; the one negative tumour (patient 20), submitted to further evaluations, resulting in a final histological diagnosis of adenocarcinoma, developed as a second tumour. In our study, all 20 SCLC expressed SS receptors. When the SPET technique was used, ^{111}In -OCT scintigraphy showed very high sensitivity for mediastinal lymph node metastases (94%). Because of the low compliance of the patients, we performed SPET acquisitions for thoracic lesions only. In fact, tomographic studies with our single headed gamma-camera required patients to stand for an additional 40 min. For this reason, it was not possible to evaluate SPET contribution on localisation of all the lesions. For mediastinal involvement, SPET was positive in 17/18 (94%) cases, while whole-body imaging was positive in 15/18 (83%) cases. We did not observe any difference between SPET and whole-body imaging in the detection of primary lung lesions, as

Table 3. Results of ^{111}In -OCT scintigraphy in lesions detected with other procedures

Site of lesions	Positive scans/number of lesions
Thoracic lesions	37/39 (95%)
Lung tumours (19 primary lesions, two relapses)	20/21 (95%)
Mediastinal lymph nodes	17/18 (94%)
Non-thoracic lesions	11/17 (65%)
Lymph nodes	5/7 (71%)
Bone	6/8 (75%)
Liver	0/2
Total	48/56 (86%)

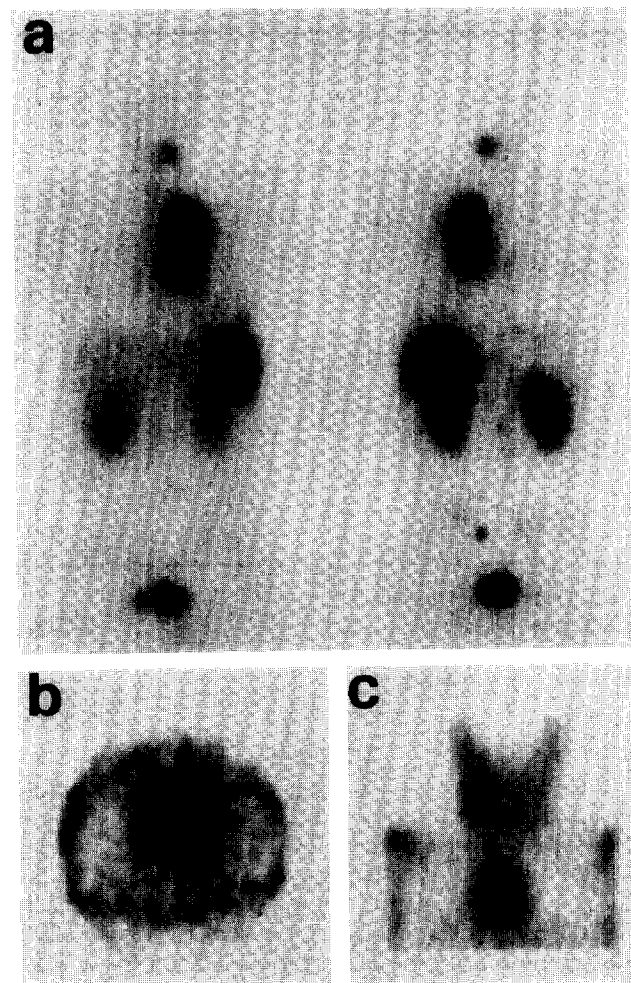


Figure 1 (a). Whole body scintigraphy. Note ¹¹¹In-OCT uptakes in the lung tumour, lymph node metastases (mediastinum and abdomen) and bone metastases (cervical vertebra, lower left rib and pelvis). Normal ¹¹¹In-OCT uptakes are present in the liver, spleen, kidneys and bladder. (b) Axial reconstruction from SPET acquisition of the thorax. Note ¹¹¹In-OCT uptakes in patient with bilateral mediastinal lymph node metastases. (c) Coronal reconstruction from SPET acquisition of the thorax. Note ¹¹¹In-OCT uptakes in patient with lung tumour and lymph node metastases in the mediastinum and the right neck.

there were 20/21 patients with positive octreotide imaging with both techniques. With regard to lesions outside the thorax, the sensitivity was 71% for abdominal lymph node metastases (5/7) and 75% for bone metastases (6/8) (Figure 1). By contrast, the detection of liver metastases was disappointing (0/2).

¹¹¹In-OCT scintigraphy showed five unexpected lesions (three lymph node metastases, one bone and one brain metastases; Table 4) which were subsequently confirmed by other diagnostic

Table 4. Unexpected lesions detected with ¹¹¹In-OCT and confirmed with other procedures

Site of lesions	Patient number	Confirmation
Lymph nodes	3	CT, MRI
Brain	1	CT
Bone	1	MDP scan, Rx
Total	5	

procedures. In particular, an asymptomatic patient showed ¹¹¹In-OCT brain uptake following an inconclusive brain CT. Two months later, repeated CT showed multiple brain metastases.

In our study, we did not observe any difference in the ¹¹¹In-OCT uptake between patients having received previous chemotherapeutic treatment and patients not yet submitted to therapy. We could also detect lesions in patients with low levels of circulating neuroenolase. No evident correlation was found between ¹¹¹In-OCT tumour/background ratio and serum concentrations of NSE (Figure 2).

Finally, no side effects following i.v. injection of ¹¹¹In-OCT were noted in our patients.

DISCUSSION

Many studies with different radiopharmaceuticals have been carried out for the *in vivo* detection of lung cancer, in particular SCLC. Since SCLC originates from the APUD system, various authors have used iodinated MIBG for scintigraphy, but have produced poor results [20, 21]. Radiolabelled monoclonal antibodies have also been proposed for radioimmunoscintigraphy of SCLC; antiCEA monoclonal antibodies seem to give better results than MIBG and are still under investigation [22–24]. More recently, radiolocalisation studies of SS receptors in SCLC patients have been carried out. Kwekkeboom attempted to detect SCLC with a radioiodine-labelled somatostatin analogue (¹²³I-octreotide) [11]. Maini and colleagues recently evaluated ¹¹¹In-OCT in 15 patients with SCLC and reported tumour detection in 13 of 15 primary tumours [13]. These preliminary but promising results led us to conduct a study aimed at assessing if SCLC could reliably be detected by SS receptor scintigraphy with ¹¹¹In-OCT, and if ¹¹¹In-OCT could provide additional information on the extent of the disease with respect to the conventional diagnostic procedures. We decided not to study patients with non-SCLC, since the absence of somatostatin receptors on non-SCLC has been reported [8], although we did find a non-SCLC as a second tumour.

Before discussing our results, we should explain why scintigraphy was performed 5 h after the ¹¹¹In-OCT injection. We studied the biodistribution of ¹¹¹In-OCT in 3 patients (serial scintigraphies at 1, 5 and 24 h) without observing any significant improvement in lesion detection in delayed, compared with early, examinations. Moreover, some authors who repeated the scintigraphic examination at 24 h reported better imaging in a few cases, but no substantial differences in the scintigraphic results [11]. It is our opinion that there is no significant difference

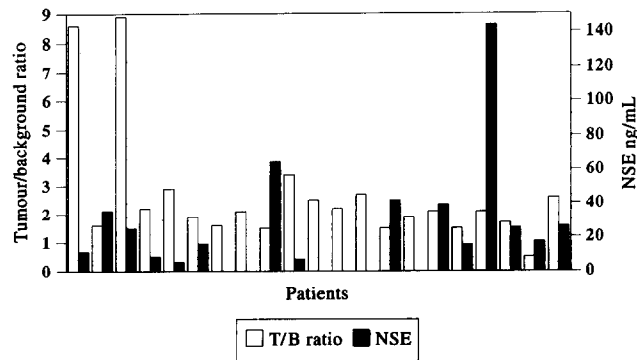


Figure 2. Relationship between ¹¹¹In-OCT tumour/background ratio and NSE serum levels.

between 4 and 5 h acquisition, and, as we found no diagnostic advantages in 24 h imaging, we choose 5 h imaging for logistical problems. None of the patients studied at 1, 5 and 24 h after the radiotracer injection had liver metastases. We did not perform acquisition after 24 h in the 2 patients with liver metastasis because, at the time of scanning, we were unaware of the presence of such an involvement. Therefore, we cannot evaluate if there was some diagnostic improvement in abdominal imaging after 24 h.

In our study, ^{111}In -OCT showed very high sensitivity in the detection of lung cancer lesions. Scintigraphy was positive in all 20 SCLC lesions (19 primary tumours and one relapse). ^{111}In -OCT did not show any uptake in one lung lesion which was at first diagnosed as SCLC relapse but, after histological re-examination, was discovered to be a lung adenocarcinoma. However, this does not allow ^{111}In -OCT scintigraphy to be used to distinguish SCLC from non-SCLC since, as already stated, somatostatin receptors are not present on non-SCLC, but octreotide uptake has been reported in the tissue surrounding the tumour [14].

When discussing the diagnostic potential of ^{111}In -OCT with respect to metastasis detection, one has to consider the SS receptor density and the site of the metastatic spread. In fact, metastatic cells probably have different types of SS receptors and a different receptor density on their membrane, derived from the primary tumour which, of course, can play an important role in tumour detection. The site and the size of metastatic lesions also affect the scintigraphic result. In our study, ^{111}In -OCT gave the best results in the diagnosis of mediastinal involvement (sensitivity 94%) and good results were obtained both in the detection of abdominal lymph node metastases and bone metastases (sensitivity 71 and 74%, respectively). In contrast, two liver metastases remained undetected due to the high background activity.

The possibility of detecting unknown lesions is important for the evaluation of the extent of the disease. In our study, ^{111}In -OCT detected five unexpected lesions (three lymph nodes, one bone and one brain metastases), and this is particularly interesting in view of the possibility of studying the whole body with a very simple scintigraphic technique. However, it should be remembered that there is a normal ^{111}In -OCT uptake in various organs, such as the pituitary gland, thyroid gland, liver, spleen, kidney and bladder [14]. Normal, as well as activated, lymphocytes and macrophages have also shown SS receptors [25–28]. In our series of patients, in addition to the uptakes described above, we also observed ^{111}In -OCT uptake attributable to inflammatory or posttraumatic alterations in a lymph node tuberculosis (1 patient), bone (3 patients) and brain (1 patient).

Moreover, ^{111}In -OCT is also able to detect lesions in patients with low levels of circulating NSE, and this can be useful in studying patients with a clinical suspicion of tumour relapse, but negative tumour markers.

In conclusion, our findings suggest that in the pretherapeutic staging of patients ^{111}In -OCT scintigraphy cannot substitute for the other diagnostic investigations but, in combination with the latter, it can provide integrative information on the extent of the disease. Moreover, ^{111}In -OCT offers the possibility of obtaining an *in vivo* localisation of SS receptors on tumours, which might have important implications for prognosis and therapeutic planning; however, this is still to be investigated in a prospective study. Finally, ^{111}In -OCT could play an important role in patient

re-evaluation during follow-up or after therapy, increasing the possibility of early diagnosis of tumour persistence or relapse.

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Treatment of Poor Prognosis Epidemic Kaposi's Sarcoma with Doxorubicin, Bleomycin, Vindesine and Recombinant Human Granulocyte–Monocyte Colony Stimulating Factor (rh GM-CSF)

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The efficacy and toxicity of doxorubicin, bleomycin and vindesine in epidemic Kaposi's sarcoma, and the role of rh GM-CSF in chemotherapy-induced neutropenia were evaluated in this Phase II study. Patients with progressive Kaposi's sarcoma were eligible, and were staged according to ACTG criteria. Treatment consisted of 20 mg/m² doxorubicin, and a fixed dose of 15 mg bleomycin and 4 mg vindesine every 2 weeks. All patients continued antiretroviral medication with severe myelosuppression, patients received subcutaneous 5 µg/kg rh GM-CSF (Leucomax) from days 2–12. Response and toxicity were measured according to ACTG and WHO criteria. 27 patients were evaluable, 25 patients classified as having a poor prognosis. The response rate was 70% (3 CR, 16 PR), the duration of response was 18 weeks (range 8–25) and the median survival 30 weeks (range 4–63+). The cause of death was mostly opportunistic infection. 4 patients died of pulmonary Kaposi's sarcoma. The toxicity of this regimen was mainly myelosuppression and 13 patients were treated with rh GM-CSF. Complete recovery of the white blood cells occurred in seven of the 27 courses of rh GM-CSF (26%). No bacterial infections were recorded, but 5 patients (19%) developed an opportunistic infection during treatment. Peripheral neuropathy occurred in 16% of patients.

Combination chemotherapy is effective in poor prognosis Kaposi's sarcoma but has a shortlasting effect. The main toxicity of this treatment is severe myelosuppression which can be ameliorated by rh GM-CSF. It remains to be established whether rh GM-CSF is also able to reduce the incidence of opportunistic infections.

Key words: Kaposi's sarcoma, chemotherapy, hematopoietic growth factors, AIDS

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INTRODUCTION

KAPOSI'S SARCOMA (KS) was one of the first recognised manifestations of human immunodeficiency virus (HIV) infection. It is the most common malignancy associated with AIDS and occurs almost exclusively in homosexual men [1–3]. AIDS-associated

Kaposi's sarcoma of the skin can be easily recognised and generally presents as a multifocal tumour, with lymph node, gastrointestinal tract and pulmonary localisations as common manifestations. It appears that HIV-associated KS differs in many ways from a primary tumour with metastatic lesions.