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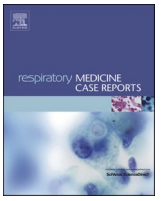

Case Report

Efficacy and safety of lenvatinib in a case of thymic carcinoma complicated with interstitial lung disease and anti-melanoma differentiation-associated gene 5 antibody-positive dermatomyositis: A case report

Yuki Hatakeyama [a], Jun Sakakibara-Konishi [a,b,*], Masato Tarumi [c], Kosuke Tsuji [a], Hirofumi Takahashi [a], Megumi Furuta [a], Yuta Takashima [a], Hidenori Kitai [a], Tetsuaki Shoji [a], Yasuyuki Ikezawa [a], Satoshi Konno [a]

[a] *Department of Respiratory Medicine, Faculty of Medicine, Hokkaido University, Sapporo, Hokkaido, Japan*
[b] *Medical Network and Welfare Center, Hokkaido University Hospital, Sapporo, Hokkaido, Japan*
[c] *Department of Rheumatology, Endocrinology and Nephrology, Faculty of Medicine and Graduate School of Medicine, Hokkaido University, Sapporo, Japan*

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ABSTRACT

Based on the results of a multicenter phase II study of patients with previously treated thymic carcinoma, lenvatinib administration for unresectable thymic cancer has been covered under insurance in Japan since 2021. However, patients with interstitial lung disease (ILD) were excluded from that study; therefore, the efficacy and safety of lenvatinib in these patients remain unknown. Herein, we report the case of a woman in her 50s who was diagnosed with thymic carcinoma complicated with ILD. In August 2016, the patient developed ILD with anti-melanoma differentiation-associated gene 5 (MDA5) antibody-positive dermatomyositis (DM). She received triple therapy comprising prednisolone, tacrolimus and azathioprine. In October 2021, the patient complained of lateral chest pain and back pain. In January 2022, computed tomography (CT) revealed an anterior mediastinal tumor, and percutaneous biopsy resulted in a diagnosis of thymic carcinoma with Masaoka classification IVb. In March 2022, first-line treatment with four cycles of carboplatin (area under the curve, 6) + paclitaxel (200 mg/m^2) was initiated. Although a partial response was achieved, in September 2022, CT demonstrated progressive disease (PD). Therefore, in October 2022, Lenvatinib (24 mg) was started as the second-line treatment. The best response was stable disease; moreover, although lenvatinib dose reduction was required owing to adverse events, such as biliary-tract infection and stomatitis. The patient did not experience ILD exacerbation. Lenvatinib (14 mg) was continued until PD was observed in March 2023. Our findings suggest that lenvatinib is a viable treatment option for thymic carcinoma with ILD.

* Corresponding author. Department of Respiratory Medicine, Faculty of Medicine, Hokkaido University, N 15, W 7, Kita-ku, Sapporo, 0608638, Japan.
E-mail address: konishj@med.hokudai.ac.jp (J. Sakakibara-Konishi).

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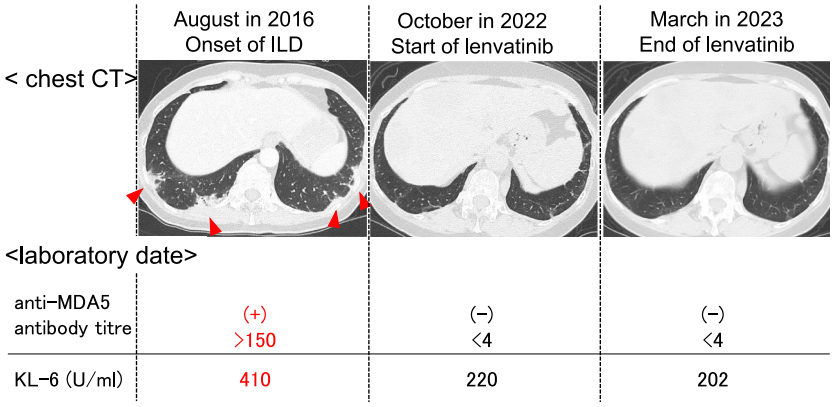

Fig. 1. Changes in interstitial lung disease on chest computed tomography, anti-MDA5 antibody titre and KL-6 levels.

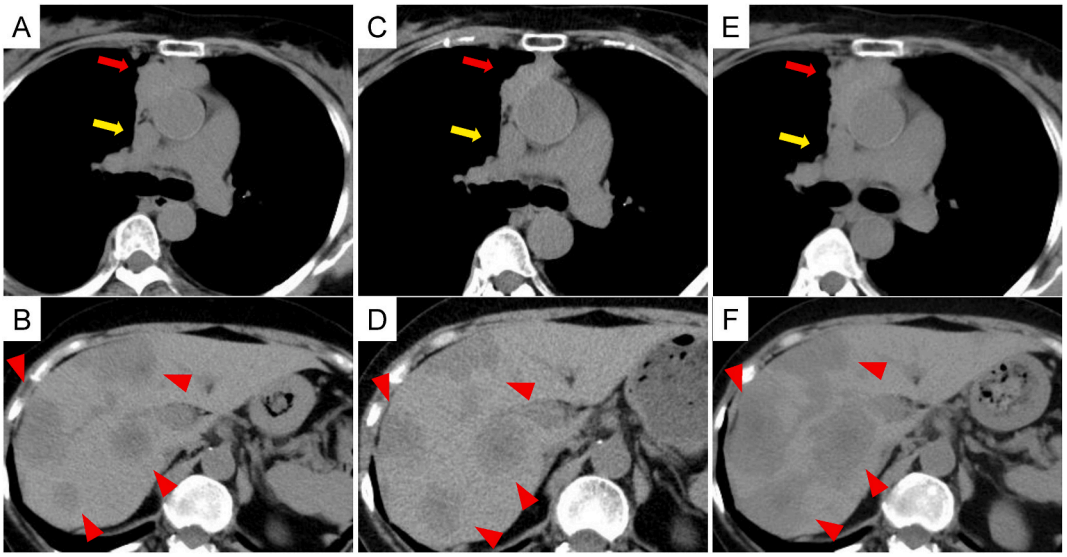

Fig. 2. Chest and abdominal computed tomography (CT) performed in September of 2022 shows the primary tumor and mediastinal lymph-node metastasis (A) and multiple liver metastases (B). CT performed in December of 2022 shows shrinkage of the primary tumor (C), and mild enlargement of the liver metastases (D). CT performed in March of 2023 shows progression of the primary tumor (E) and liver metastases (F).

1. Introduction

Thymic carcinoma is a rare disease, affecting 0.02 per 100,000 people per year [1]. Platinum in combination with paclitaxel or amrubicin is often used as the first-line treatment for unresectable or recurrent thymic carcinoma in practice, with reported response rates of 30–40 % [2]. Lenvatinib is a kinase inhibitor with multiple targets, including vascular endothelial growth factor (VEGF) receptors 1–3, RET and KIT proto-oncogenes, fibroblast growth factor (FGF) receptors 1–4, and platelet-derived growth factor (PDGF) receptors. Recently, a Japanese multicenter phase II study reported that lenvatinib is an effective treatment option for previously treated thymic carcinoma with a response rate of 38 % and a disease control rate of 95 % [3]. Based on the results of this study, lenvatinib administration for unresectable thymic cancer has been covered under insurance in Japan since 2021.

However, patients with interstitial lung disease (ILD) were excluded from that study; therefore, the efficacy and safety of lenvatinib in these patients remain unknown. Here, we report a case in which lenvatinib was safely administered to a patient with thymic carcinoma complicated with ILD and resulted in stable disease.

2. Case presentation

In August 2016, a woman in her 50s developed ILD with anti-melanoma differentiation-associated gene 5 (MDA5) antibody-positive dermatomyositis (DM), and was treated with prednisolone (PSL), tacrolimus (TAC), and cyclophosphamide (CY), followed by triple therapy with PSL, TAC and azathioprine. In October 2021, the patient complained of lateral chest pain and back pain, and in

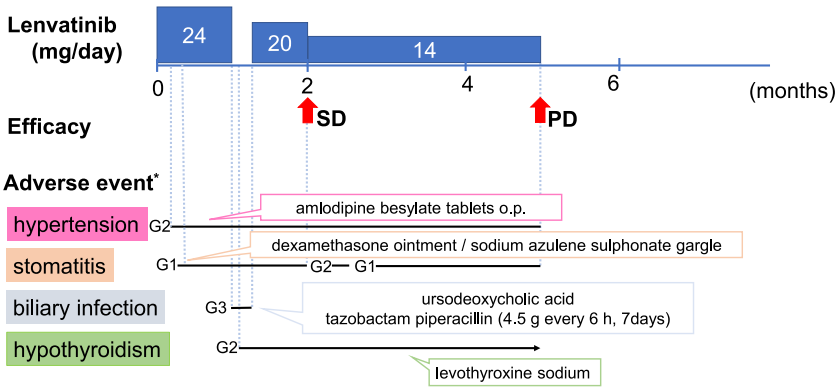

Fig. 3. Clinical course after second-line treatment with lenvatinib.

January 2022, computed tomography (CT) revealed an anterior mediastinal tumor. The patient's medical history included idiopathic osteonecrosis of the bilateral femoral heads. No history of smoking was reported. Percutaneous biopsy yielded a diagnosis of thymic squamous cell carcinoma, Masaoka classification IVb (pericardial invasion, pleural dissemination, mediastinal lymph node and liver metastasis). First-line treatment comprising 4 cycles of carboplatin [AUC = 6] + paclitaxel [200 mg/m^2] was administered in March 2022, resulting in a partial response. However, in September 2022, CT revealed progression of the primary tumor, pleural dissemination, and lymph node and liver metastases.

When the second line treatment was considered, she was treated for ILD with PSL 10 mg/day, TAC 2 mg/day, azathioprine 25 mg/day. The performance status (PS) was 1, and the patient's respiratory status was stable. Laboratory data related to ILD or DM were within the normal limits, and the anti-MDA5 antibody titer was negative. CT showed a linear shadow just below the pleura in the bilateral lower lobes, which was thought to be a scar after previous treatment for ILD (Fig. 1). Pulmonary function test results indicated the following: forced vital capacity (FVC), 2.60 L (105.6 %); forced expiratory volume in 1 s (FEV1), 2.13 L (104.4 %); and FEV1/FVC, 81.9 %. Based on these data, lenvatinib was administered, although the risk of ILD exacerbation was a concern.

Lenvatinib 24 mg once daily was initiated in October 2022. The details of the treatment efficacy are shown in Fig. 2. On Day 26 after lenvatinib treatment initiation, CT revealed shrinkage of the primary tumor, mediastinal lymph nodes, and pericardial and pleural lesions and no enlargement of the liver metastases compared to CT at lenvatinib initiation. Subsequently, several lesions in liver metastases showed a tendency to increase in size; however, most liver metastases, and intrathoracic lesions remained unchanged on Day 61 which were evaluated as stable disease (SD). CT on Day 152 demonstrated progression of the primary tumor and liver metastases, resulting in PD. Thus, progression-free survival (PFS) with lenvatinib was 5.0 months. The clinical course of the patient is shown in Fig. 3. On Day 5 of lenvatinib treatment, the patient developed grade 2 hypertension and was started on amlodipine besylate tablets. On Day 6, grade 1 stomatitis appeared, and dexamethasone ointment and sodium azulene sulphonate gargling were started. On Day 33, the patient developed a grade 3 biliary infection. Lenvatinib was temporarily withdrawn, ursodeoxycholic acid was initiated, and an intravenous infusion of tazobactam piperacillin was administered for 1 week. On Day 39, hypothyroidism was observed, and levothyroxine sodium was initiated. Results of tests for thyroid autoantibodies were negative. After the biliary infection improved, lenvatinib was resumed at the next lower dose level of 20 mg once daily on Day 43 because Lenvatinib-related biliary infection could not be ruled out. As stomatitis worsened to grade 2 after restarting lenvatinib, the dose of lenvatinib was further reduced to 14 mg once daily on Day 61. Chest CT images and changes in anti-MDA5 antibody and Krebs von den Lungen (KL)-6 levels are shown in Fig. 1. At the onset of ILD with anti- MDA5 antibody-positive DM in August 2016, an infiltrative shadow with a tendency to contract just below the pleura was observed in the bilateral lower lobes, and anti-MDA-5 antibody and KL-6 levels were elevated. When lenvatinib was initiated, only a linear shadow was observed in the same area, and no deterioration was observed on CT in March 2023. The anti-MDA5 antibody titre was negative at lenvatinib treatment initiation, and no elevation was observed during treatment. Serum KL-6 levels were within the normal limits throughout the duration of lenvatinib treatment.

3. Discussion

In this case, lenvatinib was introduced as the second-line treatment for thymic carcinoma with ILD complicated with anti- MDA5 antibody-positive DM. The patient was treated effectively with lenvatinib without ILD exacerbation. To the best of our knowledge, this is the first report of the efficacy and safety of lenvatinib in patients with ILD complicated with anti-MDA5 antibody-positive DM.

In the REMORA study, 42 patients with thymic carcinoma who had been previously treated with platinum-based combination therapy were treated with lenvatinib. At a median follow-up of 15.5 months, the median PFS was 9.3 months (95 % confidence interval [CI], 7.7–13.9) and the median overall survival was not reached (95 % CI. 16.1–not reached). The objective response rate was 38 % (90 % CI, 25.6–52.0, $p < 0.0001$), and the disease control rate was 95 % (95 % CI. 83.8–99.4) [3]. In our patient, the primary and metastatic intrathoracic lesions showed a favorable response to lenvatinib; however, no shrinkage of the liver metastases was observed. Several studies have reported that liver metastasis is observed in 15–20 % of patients with thymic carcinoma and is associated with poor outcomes [4,5]. Moreover, Tateishi et al. reported that a reverse response, in which only liver metastasis increased

Table 1
Details of 16 patients who developed interstitial pneumonia after lenvatinib administration.

No.	Age	Sex	Diagnosis	Respiratory complications	Smoking status	Onset (days)	Outcome
1	70s	M	thyroid cancer	pulmonary metastasis	former	16	death
2	60s	M	thyroid cancer	pulmonary metastasis	N/A	51	death
3	60s	M	thyroid cancer	–	former	30	recovery
4	70s	M	hepatocellular carcinoma	ILD, pulmonary metastasis	former	28	death
5	70s	M	hepatocellular carcinoma	ILD	former	43	death
6	70s	M	hepatocellular carcinoma	ILD	former	46	death
7	50s	M	hepatocellular carcinoma	pulmonary metastasis	former	9	death
8	60s	M	hepatocellular carcinoma	ILD,COPD, pulmonary metastasis	former	40	recovery
9	70s	M	hepatocellular carcinoma	ILD	never	6	recovery
10	70s	F	hepatocellular carcinoma	N/A	N/A	87	recovery
11	80s	M	hepatocellular carcinoma	(Pneumonia) (emphysema)	N/A	109	recovery
12	70s	M	hepatocellular carcinoma	–	former	63	recovery
13	70s	F	hepatocellular carcinoma	–	never	125	recovery
Kimura-Tsuchiya et al. [6]	60s	M	occult cancer	–	former	35	recovery
Kotani et al. [7]	50s	M	hepatocellular carcinoma	ILD	former	52	recovery
Imakura et al. [8]	80s	M	hepatocellular carcinoma	–	former	approximately 2 months	recovery

M, male; F, female; ILD, interstitial lung disease; COPD, chronic obstructive pulmonary disease; N/A, not analyzed.

despite the shrinkage of other lesions, was observed in 20 % (4/20) of patients treated with lenvatinib, and the size of liver metastases increased by more than two times that of other lesions in 25 % (5/20) of patients treated with lenvatinib [5]. Therefore, in the future, new treatments or combinations with other treatments, such as local treatment, should be considered when the therapeutic efficacy of lenvatinib for liver metastasis is not favorable compared to that for other lesions.

Although an association between grade 3 billiary infection and lenvatinib could not be ruled out, no ILD exacerbation was observed, and adverse events in this patient were generally controlled and acceptable. Grade 3 drug-induced pneumonia as an adverse event was observed in 2 % (1/42) of patients in REMORA study, although patients with ILD at baseline were excluded [3]. Reports of ILD as an adverse event of lenvatinib are limited, including in patients with ILD as a complication. In a post-marketing survey of patients with hepatocellular carcinoma and thyroid cancer treated with lenvatinib in Japan (as of December 20, 2018), 13 cases of serious ILD were reported as adverse reactions. In addition, three cases of interstitial pneumonia after lenvatinib administration have been reported in case reports [6–8]. The 16 cases are summarized in Table 1. Among patients who developed ILD, a relatively large proportion were male and former smokers, and more than half of these patients recovered. Of the six patients with ILD at baseline, three died. Other tyrosine kinase inhibitors, such as gefitinib and erlotinib, are known to induce interstitial pneumonia, and as risk factors, PS2–4, smoking history, and complications of ILD have been reported [9,10]. Risk factors for lenvatinib-induced ILD were unknown, so far. In our patient, ILD was stable, Moreover, the never-smoker status, female sex, and good PS might have contributed to the lack of ILD exacerbation. Further studies are warranted to identify risk factors for lenvatinib -induced pneumonitis for appropriate patient selection.

The relationship between the activation of VEGF pathway and the damage of acute lung injury has been reported [11,12]. The incidence of ILD exacerbation in patients receiving bevacizumab, VEGF monoclonal antibody, combined with chemotherapy and in those with chemotherapy is 0 % and 22.6 %, respectively, and the difference is statistically significant. Moreover, nintedanib, a multi-tyrosine kinase inhbitor targeting VEGF receptor, FGF receptor, and PDGF receptor, reduced FVC decline and ILD exacerbation frequency in patients with ILD [13]. Furthermore, phase 3 trial was conducted in Japan to evaluate the efficacy and safety of nintedanib plus chemotherapy in non-small cell lung cancer with ILD and the results showed that while nintedanib did not reduce the occurrence of exacerbation of ILD, it could be administered safely [14]. The relationships between these molecules and ILD have been the focus of much attention. Lenvatinib is a multitarget kinase inhibitors similar to nintedanib and may have a relatively protective effect against ILD, similar to that in our case, although caution should be exercised in patients with ILD exacerbation.

DM is a form of idiopathic inflammatory muscle disease with typical cutaneous manifestations, and malignancy is more frequently observed in patients with DM than in the general population [15]. In addition, DM positivity for anti-MDA5 antibodies is frequently associated with rapidly progressive ILD and has a poor prognosis [16]. However, to the best of our knowledge, only six cases of DM complicated with thymic carcinoma have been reported [17–22], and such complications have not been reported in anti-MDA5 antibody-positive cases. In anti-MDA5 antibody-positive DM, the anti-MDA5 antibody titre reflects the treatment responsiveness of DM and the course of ILD [23]. Furthermore, serum KL-6 levels reflect disease activity in patients with ILD associated with DM [24]. In our patient, the anti-MDA5 antibody titre and KL-6 were useful for evaluating the response to ILD treatment and stability of ILD.

4. Conclusion

In this report, lenvatinib showed antitumor efficacy without deterioration of co-existed ILD. Although we would not emphasize that lenvatinib needs to be considered in any patients with ILD, lenvatinib might be a viable treatment option for thymic carcinoma with ILD.

CRediT authorship contribution statement

Yuki Hatakeyama: Writing – original draft. **Jun Sakakibara-Konishi:** Writing – original draft. **Masato Tarumi:** Writing – review & editing. **Kosuke Tsuji:** Writing – review & editing. **Hirofumi Takahashi:** Writing – review & editing. **Megumi Furuta:** Writing – review & editing. **Yuta Takashima:** Writing – review & editing. **Hidenori Kitai:** Writing – review & editing. **Tetsuaki Shoji:** Writing – review & editing. **Yasuyuki Ikezawa:** Writing – review & editing. **Satoshi Konno:** Writing – review & editing.

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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.

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