Combination of vinorelbine capsules and the small molecule anti-angiogenic drug apatinib for first-line treatment of advanced triple-negative breast cancer with schizophrenia after failure of anthracycline and taxane therapy: A case report

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Received November 20, 2025; Accepted June 12, 2026

DOI: 10.3892/ol.2026.15862

Abstract. Patients with metastatic triple-negative breast cancer (mTNBC) face a poor prognosis, with limited treatment options and short progression-free survival. Chemotherapy remains a cornerstone in the treatment of mTNBC, but median overall survival is limited to 2-3 years. Oral vinorelbine, whether used alone or in combination with other agents, has demonstrated efficacy in treating metastatic breast cancer. Anti-angiogenic drugs also hold promise for managing advanced breast cancer. The present study reports a case of a patient with advanced TNBC and schizophrenia who progressed following adjuvant chemotherapy with anthracyclines and taxanes. Following recurrence and metastasis, the patient was treated with first-line vinorelbine capsules combined with the small molecule anti-angiogenic drug apatinib, and achieved partial remission. The initial time to first progression (due to patient-led treatment discontinuation) was 14 months; however, despite multiple interruptions and rechallenges, the combination provided long-term disease control spanning over 6 years from the start of first-line therapy. Due to the high cost of apatinib, the patient discontinued it and switched to a regimen of vinorelbine capsules combined with capecitabine. The present case demonstrated that while the combination showed efficacy, treatment adherence and cost were major limitations. These findings indicated that vinorelbine capsules combined with apatinib offered notable efficacy and acceptable safety in this patient with schizophrenia, thus representing a potential therapeutic option for advanced TNBC, but further study is warranted. Notably, the combined treatment did not induce or worsen the patient's schizophrenia. Overall, the present case provided valuable insights in treating patients with breast cancer with schizophrenia.

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Key words: metastatic breast cancer, triple-negative, vinorelbine, schizophrenia, small molecule anti-angiogenic drugs

Introduction

Breast cancer is the most common cancer among women in China, with a rising global incidence (1). Approximately 15-25% of breast cancer cases are classified as triple-negative breast cancer (TNBC), a subtype characterized by the absence of progesterone, estrogen and human epidermal growth factor receptor-2 (HER-2) expression (2). TNBC predominantly affects younger women, is associated with a poor prognosis and has a high risk of metastasis (3). Despite advancements in treatment options, such as poly (ADP-ribose) polymerase inhibitors for BRCA-mutated patients, immunotherapy targeting programmed cell death-1 (PD-L1) positive tumors, and antibody-drug conjugates, chemotherapy remains the primary treatment for TNBC (4). However, extensive clinical research and practice indicate limited benefits from chemotherapy, with a median overall survival of 12.5 to 13.4 months and a median progression-free survival (PFS) of 2.8 to 5.3 months (5-8), highlighting the need for additional treatment options (9). Given the critical role of angiogenesis in tumor growth and metastasis, anti-angiogenic therapy is an important strategy in managing metastatic breast cancer (mBC) (10). The vascular endothelial growth factor (VEGF)/VEGF receptor (VEGFR) signaling pathway is critical in tumor angiogenesis and

essential for tumor growth and metastasis (11). Previous studies have shown that patients with TNBC have higher VEGF levels compared with patients that are non-TNBC (12). Apatinib, an oral tyrosine kinase inhibitor (TKI), selectively targets VEGFR-2 to inhibit tumor angiogenesis (13). In 2014, a multicenter phase II trial by Hu *et al* (14) found that apatinib monotherapy showed potential efficacy in heavily pretreated patients with TNBC, with a median PFS time of 3.3 months and overall survival time of 10.6 months. The results indicate that an apatinib dose of 500 mg rather than 750 mg is the recommended starting dose for the heavily pretreated mTNBC patients, with a measurable rate of partial response and PFS. In another phase II trial, camrelizumab (an immune checkpoint inhibitor) combined with apatinib was administered to patients with advanced TNBC who had received fewer than three lines of systemic therapy (15). The combination demonstrated good efficacy and safety, with a median PFS of 3.7 months. Additionally, a phase II trial involving locally advanced and patients with metastatic TNBC who had received at least one line of chemotherapy (including anthracyclines or taxanes) treated with camrelizumab plus apatinib and eribulin (16) showed a median PFS of 8.1 months, with manageable toxicity.

Vinorelbine, a semisynthetic vinca alkaloid chemotherapeutic agent, inhibits microtubule assembly, blocking mitosis at the G_2-M phase and leading to cell death (17-19). Compared with intravenous administration, oral administration provides higher quality of life and lower disease burden for patients (20). Oral vinorelbine, either as monotherapy or in combination with other agents (capecitabine and trastuzumab), has shown efficacy in treating mBC (21). Previous studies reported that the objective response rate (ORR) for oral vinorelbine monotherapy as first-line treatment for mBC was 29-31%, with a median PFS of 17.4 weeks to 5.2 months (22,23). However, when combined with capecitabine as first-line therapy, the ORR increased to 44.2-51%, and the PFS reached 8.4 months (24,25).

Approximately 1% of the global population suffers from schizophrenia (SCZ) (26). Previous meta-analyses have shown that women with SCZ have an increased risk of developing breast cancer compared with the general female population (27-29). A retrospective study in 2010 indicated that SCZ does not affect the treatment process or outcomes for patients with breast cancer (30). The current understanding of the relationship between SCZ and breast cancer remains limited, but both conditions require long-term care (31-33).

Oral vinorelbine monotherapy for first-line treatment of mBC has shown low ORRs and short median PFS (22,23). Current research data suggests that anti-angiogenic drugs are primarily used for second-line and beyond treatment in advanced breast cancer, with limited use in first-line treatment (34). The present report examined the efficacy and safety of the combination of oral vinorelbine and apatinib in first-line treatment of a patient with advanced TNBC and SCZ, after failure of anthracyclines and taxanes in the adjuvant setting.

Case report

A 52-year-old female patient with a history of pregnancy and no family hereditary diseases, weighing 79 kg, with a height of 152 cm, a body surface area of 1.78 m^2, a BMI of 37.65 kg/m^2 and an Eastern Cooperative Oncology Group performance status of 1 was first admitted to National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital and Shenzhen Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College (Shenzhen, China) in January 2018. In July 2013, the patient had visited an external hospital due to bilateral breast mass and underwent a bilateral modified radical mastectomy for breast cancer (data not shown). Postoperative pathology reported: Primarily ductal carcinoma *in situ* in both breasts, with local infiltration, histological grade II for the infiltrative part, no vascular invasion, right breast tumor size 7.5x5x4 cm, left breast tumor size 2.5x2 cm, left axillary lymph nodes 0/18, right axillary lymph nodes 0/28. Immunohistochemistry results: ER(-), PR(-), CerbB-2(-), Ki-67 (20-30% +). From September 2013 to February 2014, the patient received 4 cycles of EC regimen chemotherapy (epirubicin 150 mg IV + cyclophosphamide 1 g IV, every 3 weeks) followed by 4 cycles of T regimen chemotherapy (docetaxel 180 mg IV, every 3 weeks). The patient also underwent adjuvant radiotherapy, followed by regular follow-ups twice a year. In November 2017, the patient noticed a gradually enlarging left cervical lymph node, accompanied by a cough and left chest wall pain. The patient presented to the National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital and Shenzhen Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College for the first time in January 2018. A thoracoabdominal enhanced CT scan revealed multiple nodules in the chest wall, the largest being ~1.8x1.4 cm, with enhancement observed post-contrast, which suggested metastatic tumors. There was the destruction of the sternum bone with the formation of soft tissue masses, indicating metastasis. Multiple lymph node metastases were detected in the bilateral supraclavicular fossa and mediastinum, the largest being ~2.2x1.5 cm. Multiple liver metastases were found, with the largest located in segment S2 of the left lobe, ~3.0x3.0 cm. Multiple lymph nodes in the bilateral neck regions II-IV were also identified, the largest being ~1.4x1.3 cm, which was suggestive of metastasis. Metastatic sites included the chest wall, sternal bone destruction with soft tissue masses, multiple lymph nodes (bilateral supraclavicular, mediastinal and bilateral cervical), and the liver. Imaging showing significant metastatic lesions (Fig. 1). At 2 days post-admission in January 2018, the patient underwent a fine-needle aspiration biopsy of the left cervical lymph node. Postoperative pathology, performed as previously described (35), confirmed mBC to the lymph nodes. Immunohistochemistry results showed ER(-), PR(-), Ki67 (~80% +), AR (30% positive cells, moderate staining intensity), HER-2 (2+), CK5/6(-), TOPOII (~50%+), E-Cad(+), EGFR(+) and p53 (100%, mutant type) and HER-2 fluorescence *in situ* hybridization gene testing was negative (Figs. 2 and 3). The patient exhibited progressive disease (PD), with a disease-free survival of 53 months. The patient had a history of SCZ for >10 years, was currently treated with risperidone dispersible tablets and benzhexol, and was regularly followed at Kangning Hospital (a specialized psychiatric hospital; Shenzhen, China) with stable disease control. The patient also had a history of diabetes and hypertension; ongoing treatment for hypertension and diabetes has kept these conditions stable.

Overall, the patient had a history of SCZ and breast cancer, with recurrence and metastasis of breast cancer; however, the patient's treatment adherence was poor and refused intravenous chemotherapy. Considering the diagnosis of TNBC, which is known for its aggressive biological behavior, high

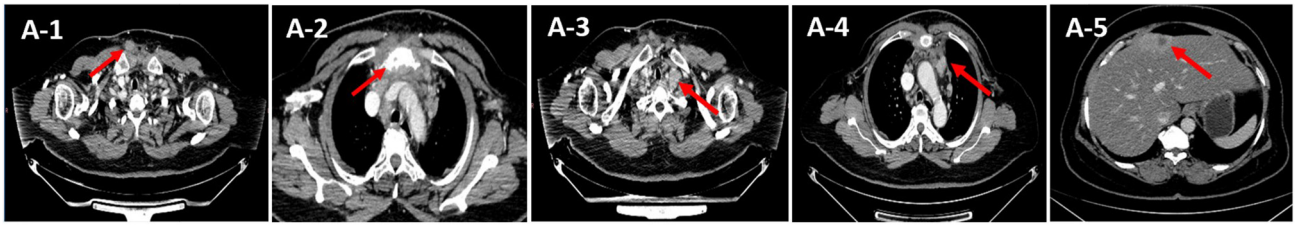

Figure 1. Chest and abdominal CT scans showing metastatic lesions. (A-1) Chest wall metastasis (1.8x1.4 cm). (A-2) Sternal bone destruction with soft tissue mass formation (4.2x3.5 cm). (A-3) Left supraclavicular lymph node metastasis (2.0x2.5 cm). (A-4) Mediastinal lymph node metastasis (2.2x1.5 cm). (A-5) Liver metastasis (3.0x3.0 cm). Red arrows indicate metastases. CT, computed tomography.

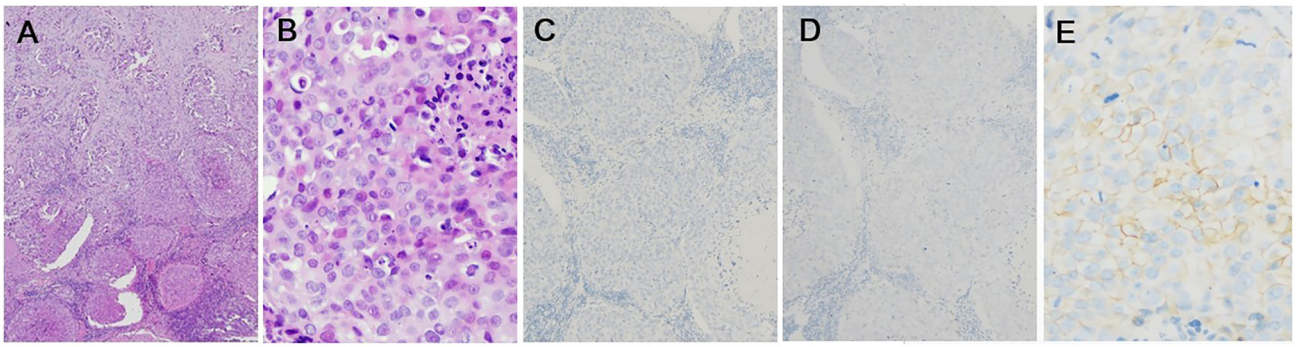

Figure 2. Histopathological and immunohistochemical findings of metastatic breast cancer in the lymph node: (A) H&E staining showing destruction of lymph node structure with infiltrative growth of metastatic breast carcinoma cells (magnification, x40). (B) H&E staining showing pleomorphic cancer cells with mitotic figures, apoptosis and necrosis (magnification, x400). (C) Immunohistochemistry for ER (negative; magnification, x100). (D) Immunohistochemistry for PR (negative; magnification, x100). (E) Immunohistochemistry for HER2 (2+; magnification, x400).

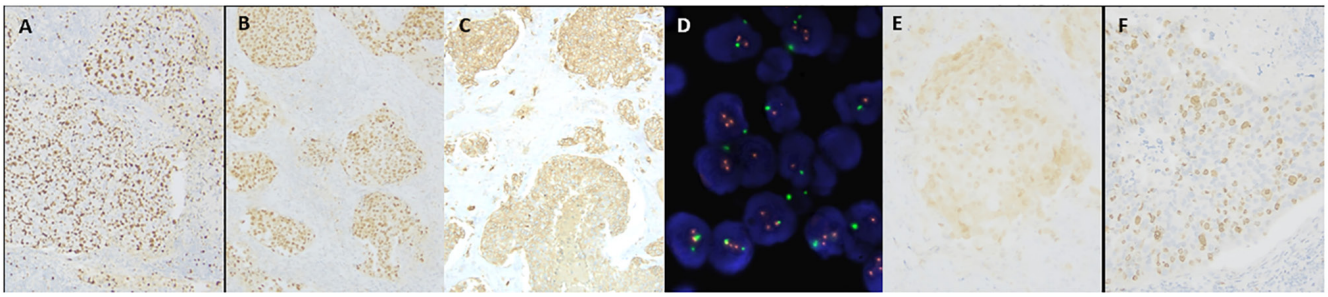

Figure 3. Immunohistochemical and FISH analysis of metastatic breast cancer: (A) Immunohistochemistry for Ki-67 (proliferation index ~80%; magnification, x100). (B) Immunohistochemistry for p53 (100% positive, mutant type; magnification, x100). (C) Immunohistochemistry for E-cadherin (positive; magnification, x100). (D) FISH analysis for HER2 gene (no amplification, HER2:CEP17 ratio <2; magnification, x400). (E) Immunohistochemistry for AR (30% positive cells, moderate staining intensity; magnification, x200). (F) Immunohistochemistry for TOPOIIA (~50% positive; magnification, x200). AR, androgen receptor; CEP17, chromosome enumeration probe 17; FISH, fluorescence in situ hybridization; HER2, human epidermal growth factor receptor 2; Ki-67, marker of proliferation Ki-67; p53, tumor protein p53; TOPOIIA, DNA topoisomerase II α.

drug resistance, limited treatment options and poor prognosis, angiogenesis is a critical factor in tumor progression and metastasis. Combining drugs with different mechanisms of action can provide survival benefits. A study has shown that anti-angiogenic agents combined with chemotherapy can significantly extend PFS time (16). Following biopsy and diagnosis, at 2 days post-admission in January 2018, the patient began first-line treatment with oral vinorelbine capsules (140 mg on days 1 and 8, every 3 weeks) combined with the small-molecule anti-angiogenic drug apatinib at a reduced dose of 0.25 g (one tablet), once daily. Concurrently, 4 mg zoledronic acid (intravenous infusion every 4 weeks) was administered to prevent bone destruction, along with calcium supplementation and symptomatic pain relief. The chemotherapy-induced adverse reactions included grade I nausea and grade I neutropenia, which were well-tolerated. Apatinib-related adverse events were closely monitored. Given that standard-dose apatinib (0.5 g once daily) is associated with frequent hypertension, a reduced dose of 0.25 g once daily was administered. The patient had pre-existing hypertension and diabetes mellitus, both well-controlled using oral valsartan-hydrochlorothiazide and metformin. During apatinib treatment, blood pressure remained stable without the need for additional antihypertensive therapy. Urinalysis performed every 2-4 weeks was mostly negative for protein; trace to 1+ proteinuria was noted on isolated occasions, which

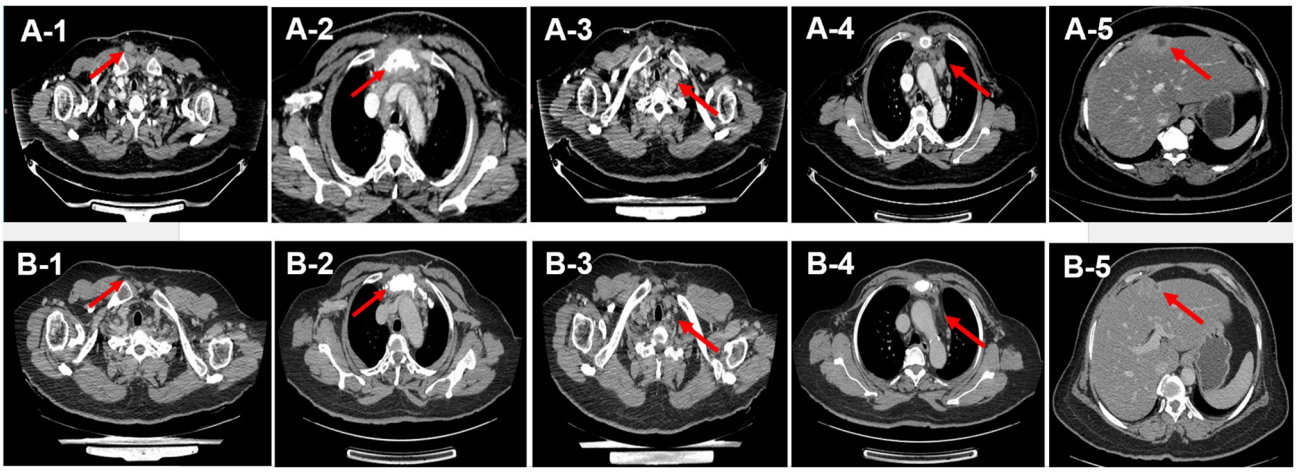

Figure 4. Chest and abdominal CT scans showing response to oral vinorelbine combined with apatinib: Baseline images and images after two cycles of treatment are shown. The efficacy was evaluated as partial response. (A-1, B-1) Chest wall metastasis , (A-2, B-2) Sternal bone destruction with soft tissue mass formation, (A-3, B-3) Left supraclavicular lymph node metastasis, (A-4, B-4) Mediastinal lymph node metastasis and (A-5, B-5) Liver metastasis. Metastatic lesion size reduction: (A-1) 1.8x1.4 cm to (B-1): 0 cm, (A-2) 4.2x3.5 cm to (B-2): 1x1 cm, (A-3) 2.0x2.5 cm to (B-3): 1.2x1.0 cm, (A-4) 2.2x1.5 cm to (B-4): 0.8x0.5 cm and (A-5) 3.0x3.0 cm to (B-5): 1.0x0.5 cm. Red arrows indicate metastases. CT, computed tomography.

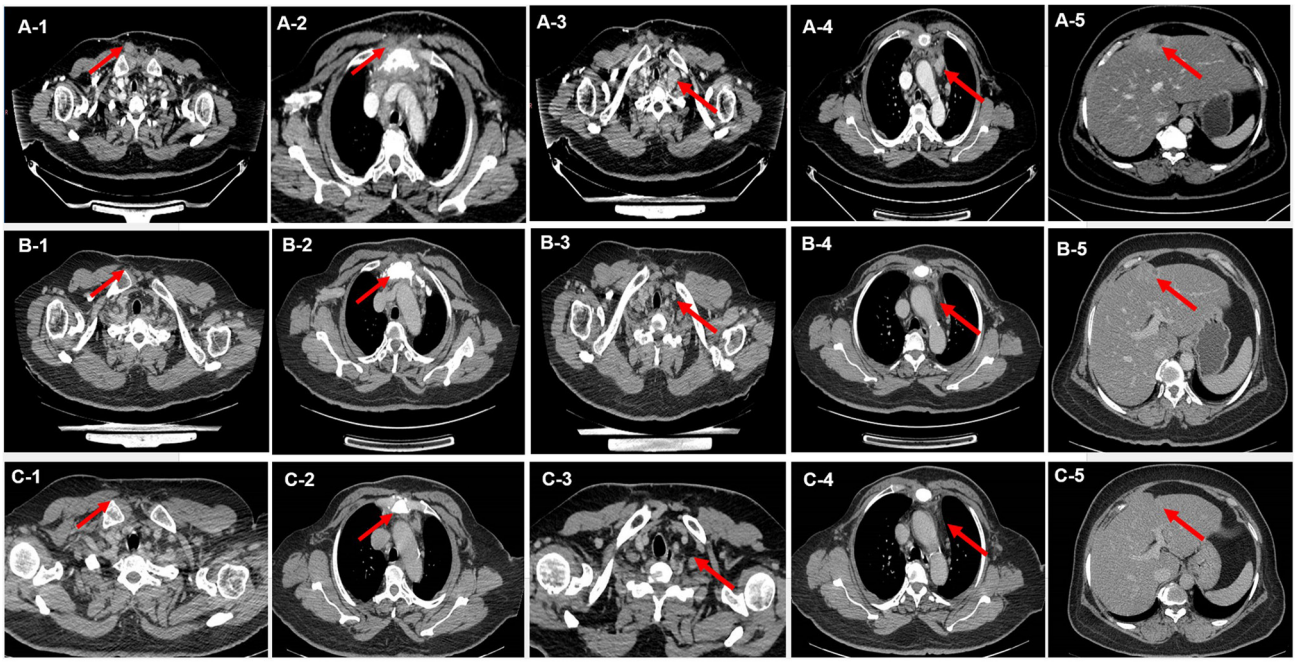

Figure 5. Chest and abdominal CT scans showing sustained partial response after multiple cycles of oral vinorelbine combined with apatinib. (A-1, B-1 and C-1) Chest wall metastasis. (A-2, B-2 and C-2) Sternal bone destruction with soft tissue mass formation. (A-3, B-3 and C-3) Left supraclavicular lymph node metastasis. (A-4, B-4 and C-3) Mediastinal lymph node metastasis. (A-5, B-5 and C-3) Liver metastasis. (A-1, A-2, A-3, A-4 and A-5) Baseline images (January 2018), (B-1, B-2, B-3, B-4 and B-5) images after two cycles (March 2018), and (C-1, C-2, C-3, C-4 and C-5) images after multiple cycles (December 2018) are shown. Metastatic lesion size reduction: (A-1) 1.8x1.4 cm to (B-1) 0 cm to (C-1) 0 cm, (A-2) 4.2x3.5 cm to (B-2) 1x1 cm to (C-2) 1x0.8 cm, (A-3) 2.0x2.5 cm to (B-3) 1.2x1.0 cm to (C-3) 1.0x1.0 cm, (A-4) 2.2x1.5 cm to (B-4) 0.8x0.5 cm to (C-4) 0.8x0.4 cm and (A-5) 3.0x3.0 cm to (B-5) 1.0x0.5 cm to (C-5) 0 cm. CT, computed tomography.

could not be definitively attributed to apatinib given the patient's long-standing diabetes. The patient developed grade 1 hand-foot syndrome, which was effectively managed with oral mecobalamin and topical moisturizers. The patients SCZ remained stable throughout and maintained regular follow-ups at Kangning Hospital while continuing the prescribed risperidone and benzhexol. No structured psychiatric scale was used, but clinical assessments confirmed no worsening of psychotic symptoms. After one treatment cycle, the chest wall mass decreased in size, and the cough improved. After two cycles, the efficacy evaluation indicated partial response PR (Fig. 4). Treatment continued with evaluations every two cycles, and the patient-maintained PR (Fig. 5). After seven treatment cycles, between December 2018 and March 2019, the patient discontinued treatment for 3 months. At the end of March 2019, the patient returned for a follow-up chest and upper abdominal CT scan, which revealed multiple lymph node metastases in the anterior mediastinum, with the largest short diameter of

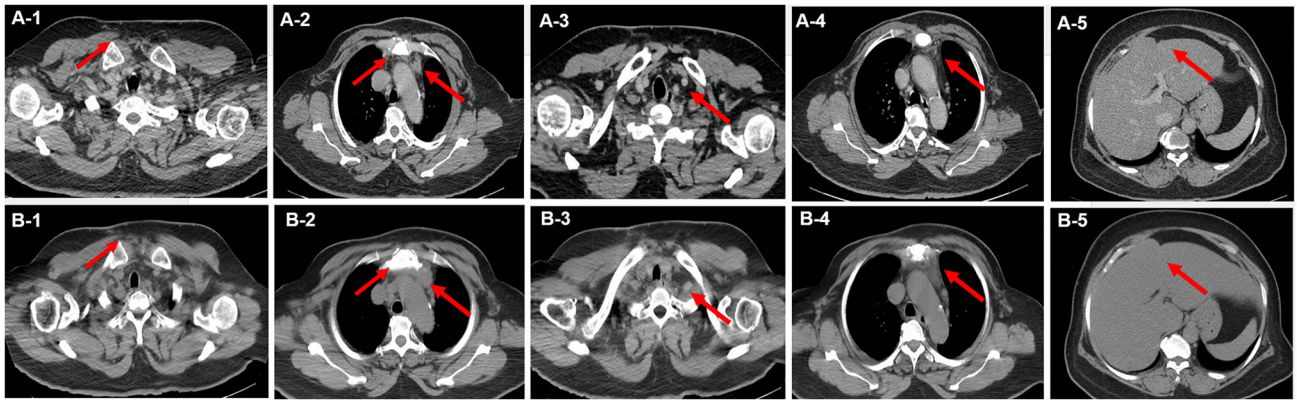

Figure 6. Chest and abdominal CT scans showing disease progression after discontinuation of oral vinorelbine and apatinib. (A-1 and B-1) Chest wall metastasis. (A-2 and B-2) Sternal bone destruction with soft-tissue mass formation. (A-3 and B-3) Left supraclavicular lymph node metastasis. (A-4 and B-4) Mediastinal lymph node metastasis. (A-5 and B-5) Liver metastasis. (A-1, A-2, A-3, A-4 and A-5) Baseline images (December 2018) and (B-1, B-2, B-3, B-4 and B-5) images after treatment discontinuation (March 2019) are shown. Metastatic lesion size enlargement: (A-1) 0 to (B-1) 0 cm, (A-2) 1x0.8 to (B-2) 2x1.5 cm, (A-3) 1.0x1.0 to (B-3) 2x2.2 cm, (A-4) 0.8x0.4 to (B-4) 2.0x1.5 cm and (A-5) 0 cm to (B-5) 0 cm. CT, computed tomography.

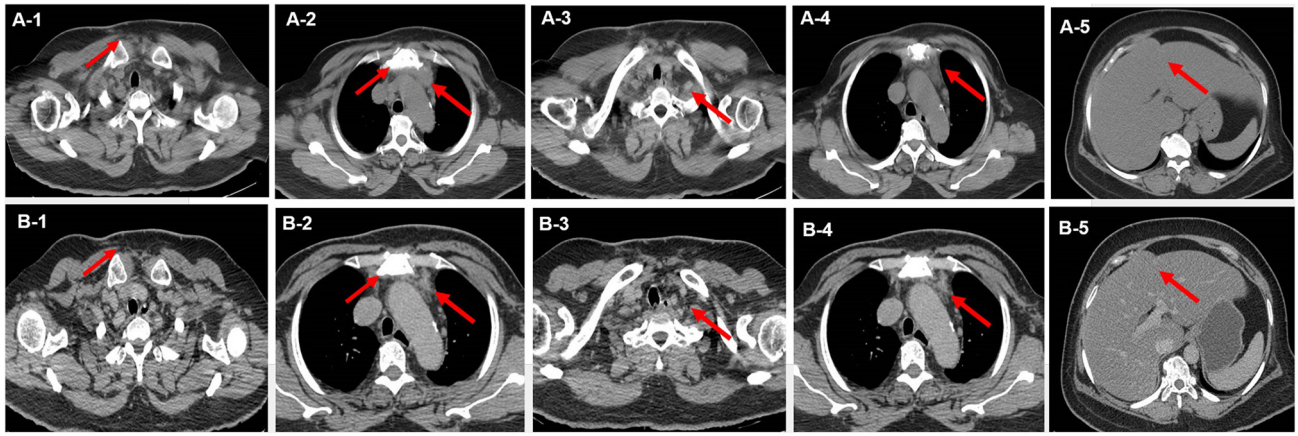

Figure 7. Chest and abdominal CT scans showing re-partial response after resuming oral vinorelbine and apatinib: (A-1 and B-1) Chest wall metastasis. (A-2 and B-2) Sternal bone destruction with soft-tissue mass formation. (A-3 and B-3) Left supraclavicular lymph node metastasis. (A-4 and B-4) Mediastinal lymph node metastasis. (A-5 and B-5) Liver metastasis. (A-1, A-2, A-3, A-4 and A-5) Baseline images (March 2019) and (B-1, B-2, B-3, B-4 and B-5) images after two cycles of treatment (May 2019) are shown. Metastatic lesion size reduction: (A-1) 0 cm to (B-1) 0 cm, (A-2) 2x1.5 cm to (B-2) 1x0.8 cm, (A-3) 2x2.2 cm to (B-3) 1x1 cm, (A-4) 2.0x1.5 cm to (B-4)1.8x1.0 cm and (A-5) 0 cm to (B-5) 0 cm. CT, computed tomography.

~2 cm, showing progression from previous scans. The sternum and body bone metastases had worsened (Fig. 6), indicating PD due to the first discontinuation of medication. The time from first-line initiation to this first progression was ~14 months but this was not a treatment-refractory progression; rather, it followed patient-led discontinuation.

Due to disease progression after discontinuation of treatment, the patient resumed the aforementioned vinorelbine plus apatinib regimen at the end of March 2019. After two cycles, a follow-up CT scan indicated multiple left anterior mediastinal lymph node metastases, with the largest short diameter reduced to ~1.2 cm, showing notable improvement. The sternal and body bone metastases showed reduced osteolytic components and increased osteogenic changes, indicating improvement. The efficacy was evaluated as PR (Fig. 7). The patient continued the treatment regimen, maintaining PR on subsequent evaluations (Fig. 8). After being discharged in January 2020, the patient did not return for treatment due to the COVID-19 pandemic. In April 2020, a follow-up CT scan revealed multiple lymph nodes in the mediastinal 3A area, appearing slightly enlarged and possibly fused, with the largest short diameter of ~1.1 cm, raising suspicion of lymph node metastasis. The efficacy was evaluated as PD due to the second discontinuation of medication (Fig. 9).

Due to disease progression likely associated with the treatment discontinuation during the pandemic, the patient resumed the vinorelbine soft capsules plus apatinib regimen for one cycle. In May 2020, a follow-up CT scan of the neck, chest and upper abdomen revealed multiple left anterior mediastinal lymph node metastases, reduced in size compared with previous scans. The lymph nodes in the mediastinal 3A area also decreased in size. The efficacy was evaluated as PR (Fig. 10). The patient continued the same treatment regimen but did not follow a regular treatment schedule from August 2022. In February 2023, a follow-up CT scan of the neck, chest, abdomen and pelvis indicated multiple enlarged lymph nodes in the right supraclavicular area and mediastinal 3A area, indicating an increase in size and number, with the largest measuring ~2.3x2.2 cm, which suggested metastasis. Multiple sternal and body bone metastases with

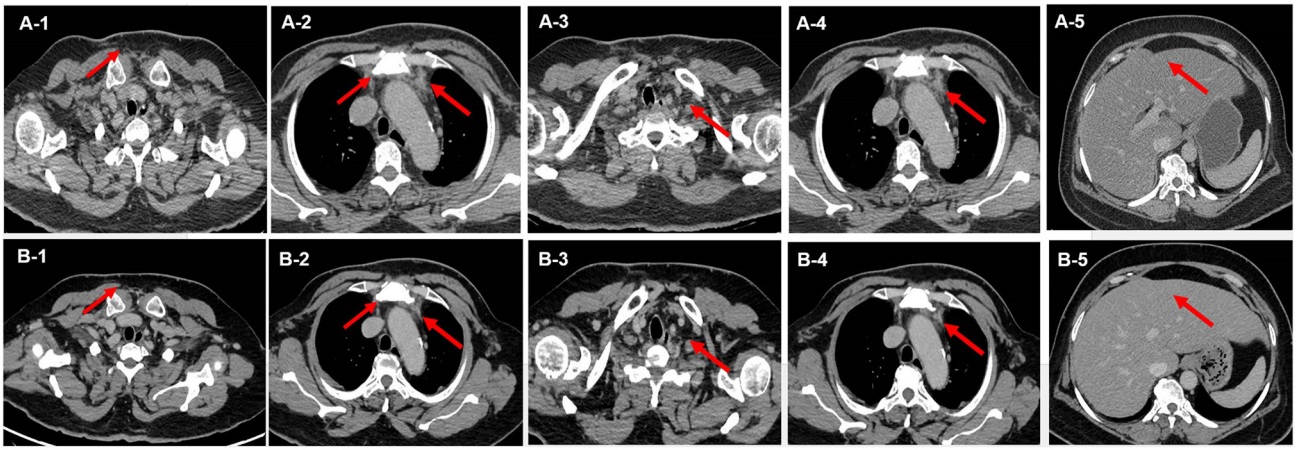

Figure 8. Chest and abdominal CT scans showing sustained partial response after multiple cycles of resumed treatment. (A-1 and B-1) Chest wall metastasis. (A-2 and B-2) Sternal bone destruction with soft-tissue mass formation. (A-3 and B-3) Left supraclavicular lymph node metastasis. (A-4 and B-4) Mediastinal lymph node metastasis. (A-5 and B-5) Liver metastasis. (A-1, A-2, A-3, A-4 and A-5) Baseline images (May 2019) and (B-1, B-2, B-3, B-4 and B-5) images after multiple cycles (January 2020) are shown. Metastatic lesion size reduction: (A-1) 0 cm to (B-1) 0 cm, (A-2) 1x0.8 cm to (B-2) 0.5x0.5 cm, (A-3) 1x1 cm to (B-3) 1x1 cm, (A-4) 1.8x1.0 cm to (B-4) 1.8x0.9 cm and (A-5) 0 cm to (B-5) 0 cm. CT, computed tomography.

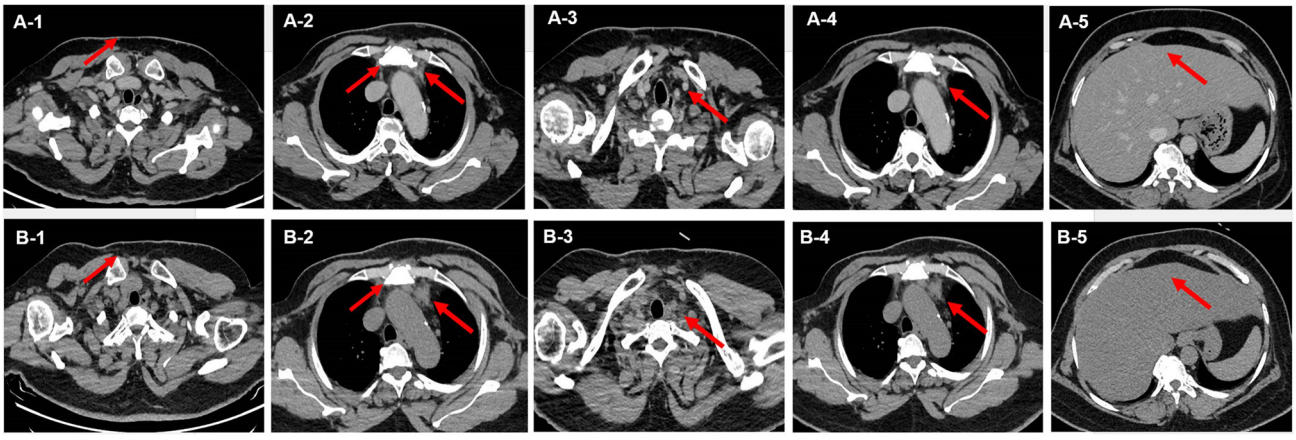

Figure 9. Chest and abdominal CT scans showing disease progression after the second discontinuation of oral vinorelbine and apatinib. (A-1 and B-1) Chest wall metastasis. (A-2 and B-2) Sternal bone destruction with soft-tissue mass formation. (A-3 and B-3) Left supraclavicular lymph node metastasis. (A-4 and B-4) Mediastinal lymph node metastasis. (A-5 and B-5) Liver metastasis. (A-1, A-2, A-3, A-4 and A-5) Baseline images (January 2020) and (B-1, B-2, B-3, B-4 and B-5) images after treatment discontinuation (April 2020) are shown. Metastatic lesion size enlargement: (A-1) 0 cm to (B-1) 0 cm, (A-2) 0.5x0.5 cm to (B-2) 2x2 cm, (A-3) 1x1 cm to (B-3) 1.5x1.2 cm, (A-4) 1.8x0.9 cm to (B-4) 2x1.2 cm and (A-5) 0 cm to (B-5) 0 cm. CT, computed tomography.

increased osteogenic changes were observed, accompanied by thickening of the soft tissues behind the sternum and the presence of a mass, partially worsening from previous scans. The largest mass measured ~3.3x1.5 cm and had indistinct borders with the posterior aortic arch, adjacent pericardium and bilateral internal mammary areas, which suggested metastasis. The irregular medication adherence led to disease progression, and the efficacy was evaluated as PD (Fig. 11).

Given the patient's localized lymph node progression and no evidence of prior liver metastases, continuing the original treatment regimen was recommended. However, as apatinib is a self-funded medication, the patient refused to continue with apatinib treatment. Therefore, from February 2023, the patient was maintained on oral vinorelbine monotherapy. A follow-up CT scan in June 2023, showed a reduction in the size of the cervical lymph nodes, with the tumor assessment showing stable disease (SD) with some reduction SDa (Fig. 12), though not achieving PR, which indicated the efficacy of the monotherapy. In January 2024, a follow-up CT scan revealed multiple enlarged metastatic lymph nodes in the right supraclavicular area, mediastinal 3A area and left internal mammary area, which had increased in size compared with the previous scan. There was also thickening of the soft tissues behind the sternum and a worsened mass, with the largest lesion measuring ~3.4x2.2 cm. The efficacy was evaluated as PD (Fig. 13). Due to the patient's refusal to continue apatinib or intravenous antitumor therapy, a second-line treatment regimen of oral vinorelbine (140 mg taken orally on days 1 and 8, every 3 weeks) plus capecitabine (1.0 g taken orally twice a day for 14 days, followed by a 7-day rest, every 3 weeks), both within the scope of medical insurance reimbursement, was initiated in January 2024. The final CT scan in April 2024, showed that the tumor was stable but with some enlargement SDb (Fig. 14). The patient discontinued the medication intermittently. At the end of December 2025, the tumor progression was rechecked. The patient had low expression of

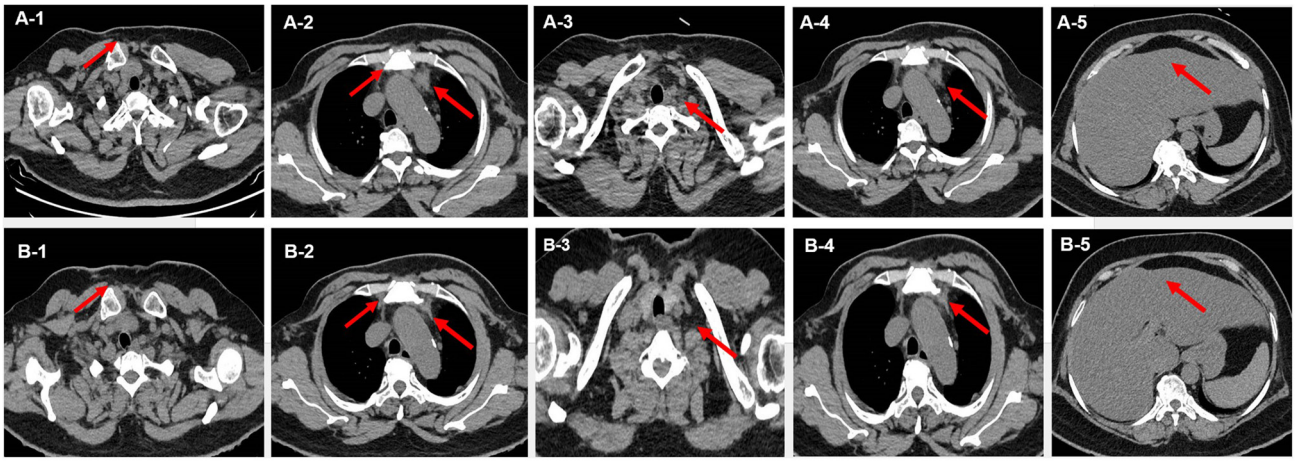

Figure 10. Chest and abdominal CT scans showing re-partial response after resuming oral vinorelbine and apatinib during the COVID-19 pandemic. (A-1 and B-1) Chest wall metastasis. (A-2 and B-2) Sternal bone destruction with soft-tissue mass formation. (A-3 and B-3) Left supraclavicular lymph node metastasis. (A-4 and B-4) Mediastinal lymph node metastasis. (A-5 and B-5) Liver metastasis. (A-1, A-2, A-3, A-4 and A-5) Baseline images (April 2020) and (B-1, B-2, B-3, B-4 and B-5) images after one cycle of treatment (May 2020) are shown. Metastatic lesion size reduction: (A-1) 0 cm to (B-1) 0 cm, (A-2) 2x2 cm to (B-2) 0.8x0.7 cm, (A-3) 1.5x1.2 cm to (B-3) 1.0x0.8 cm, (A-4) 2x1.2 cm to (B-4) 1.2x0.8 cm and (A-5) 0 cm to (B-5) 0 cm. CT, computed tomography.

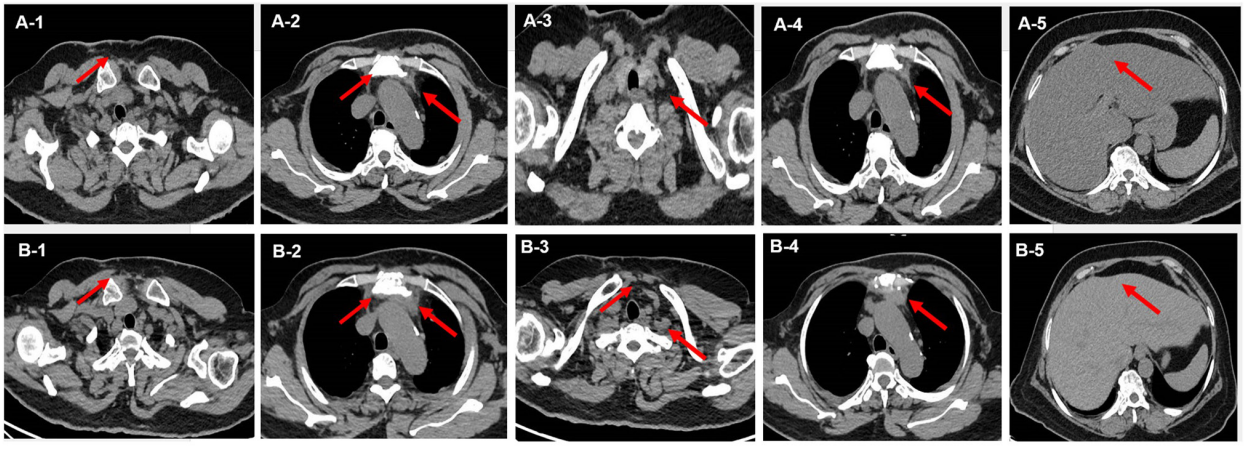

Figure 11. Chest and abdominal CT scans showing disease progression due to irregular use of oral vinorelbine and apatinib. (A-1 and B-1) Chest wall metastasis. (A-2 and B-2) Sternal bone destruction with soft-tissue mass formation. (A-3 and B-3) Left supraclavicular lymph node metastasis. (A-4 and B-4) Mediastinal lymph node metastasis. (A-5 and B-5) Liver metastasis. (A-1, A-2, A-3, A-4 and A-5) Baseline images (May 2020) and (B-1, B-2, B-3, B-4 and B-5) images after irregular treatment (February 2023) are shown. Metastatic lesion size enlargement: (A-1) 0 cm to (B-1) 0 cm, (A-2) 0.8x0.7 cm to (B-2) 1.8x2 cm, (A-3) 1.0x0.8 cm to (B-3) 1.5x1.4 cm, (A-4) 1.2x0.8 cm to (B-4) 1.8x1.1 cm and (A-5) 0 cm to (B-5) 0 cm. CT, computed tomography.

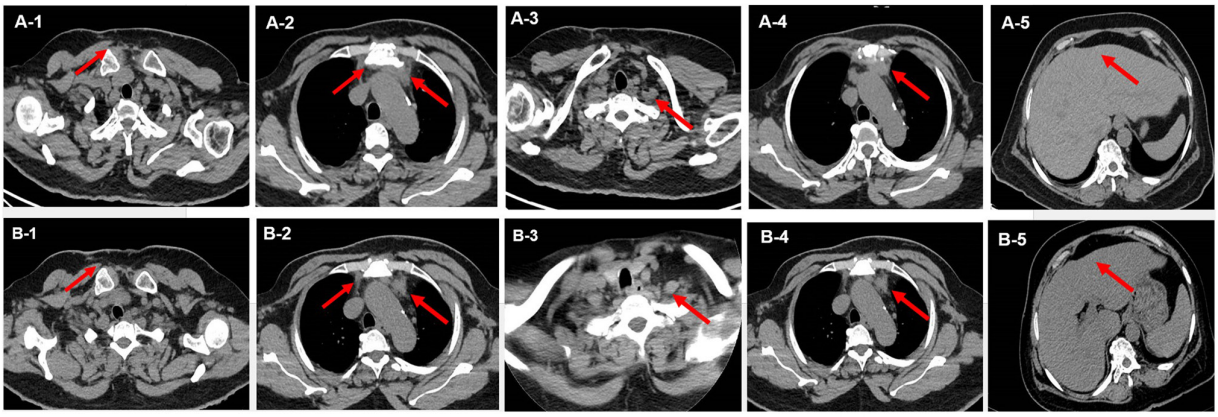

Figure 12. Chest and abdominal CT scans showing tumor stabilization with vinorelbine monotherapy. (A-1 and B-1) Chest wall metastasis. (A-2 and B-2) Sternal bone destruction with soft-tissue mass formation. (A-3 and B-3) Left supraclavicular lymph node metastasis. (A-4 and B-4) Mediastinal lymph node metastasis. (A-5 and B-5) Liver metastasis. (A-1, A-2, A-3, A-4 and A-5) Baseline images (February 2023) and (B-1, B-2, B-3, B-4 and B-5) images after vinorelbine treatment (July 2023) are shown. Metastatic lesion size reduction: (A-1) 0 cm to (B-1) 0 cm (A-2) 1.8x2 cm to (B-2) 1.6x1.7 cm, (A-3) 1.5x1.4 cm to (B-3) 1.4x1.4 cm, (A-4) 1.8x1.1 cm to (B-4) 1.6x1.0 cm and (A-5) 0 cm to (B-5) 0 cm. CT, computed tomography.

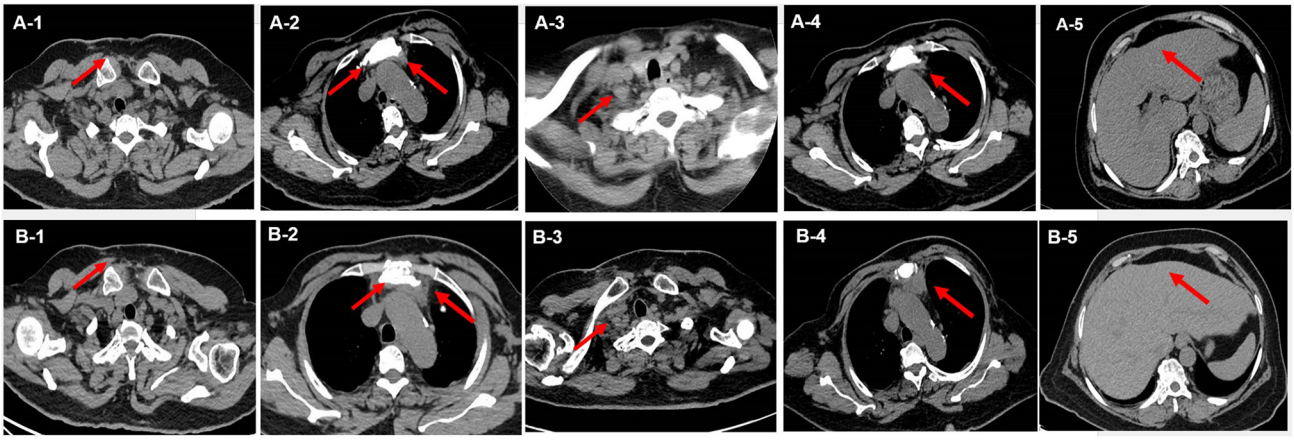

Figure 13. Chest and abdominal CT scans showing disease progression with vinorelbine monotherapy. (A-1 and B-1) Chest wall metastasis. (A-2 and B-2) Sternal bone destruction with soft-tissue mass formation. (A-3 and B-3) Left supraclavicular lymph node metastasis. (A-4 and B-4) Mediastinal lymph node metastasis. (A-5 and B-5) Liver metastasis. (A-1, A-2, A-3, A-4 and A-5) Baseline images (July 2023) and (B-1, B-2, B-3, B-4 and B-5) images after vinorelbine treatment (January 2024) are shown. Metastatic lesion size enlargement: (A-1) 0 cm to (B-1) 0 cm, (A-2) 1.6x1.7 cm to (B-2) 2.1x2.0 cm, (A-3) 1.4x1.4 cm to (B-3) 2.0x1.9 cm, (A-4) 1.6x1.0 cm to (B-4) 2.4x2.0 cm and (A-5) 0 cm to (B-5) 0 cm. CT, computed tomography.

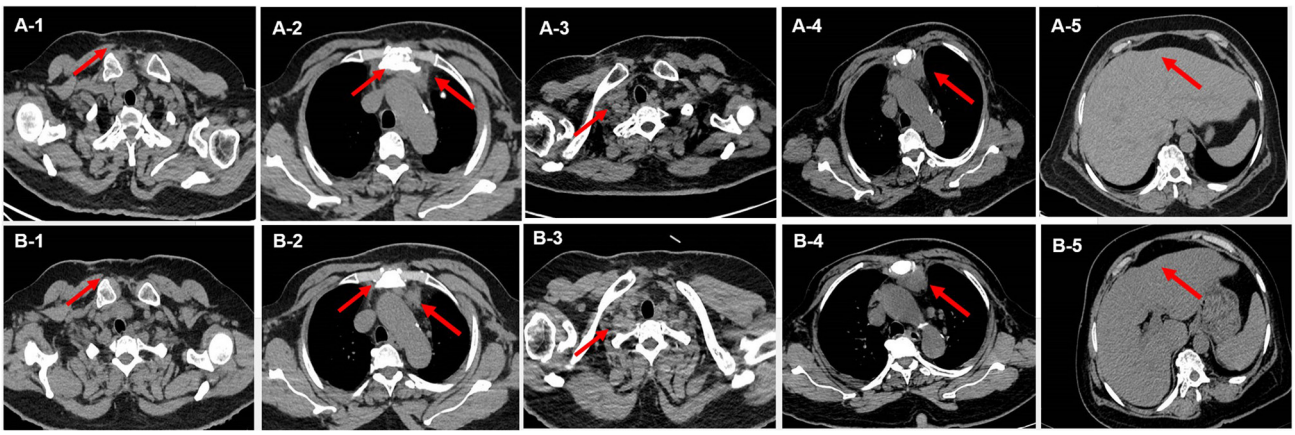

Figure 14. Chest and abdominal CT scans showing steady augmentation (SDb) with vinorelbine combined with capecitabine. (A-1 and B-1) Chest wall metastasis. (A-2 and B-2) Sternal bone destruction with soft-tissue mass formation. (A-3 and B-3) Left supraclavicular lymph node metastasis. (A-4 and B-4) Mediastinal lymph node metastasis. (A-5 and B-5) Liver metastasis. (A-1, A-2, A-3, A-4 and A-5) Baseline images (January 2024) and (B-1, B-2, B-3, B-4 and B-5) images after treatment (April 2024) are shown. Metastatic lesion size enlargement: (A-1) 0 cm to (B-1) 0 cm, (A-2) 2.1x2.0 cm to (B-2) 2.1x2.2 cm, (A-3) 2.0x1.9 cm to (B-3) 2.0x2.2 cm, (A-4) 2.4x2.0 cm to (B-4) 2.5x2.1 cm, (A-5) 0 cm to (B-5) 0 cm. CT, computed tomography.

HER2. Since mid-December 2025, the patient has received 6 cycles of trastuzumab deruxtecan treatment, and the best assessment of efficacy is PR.

Overall, from the start of first-line therapy in January 2018 to the last follow-up in April 2024, the patient maintained disease control (albeit with several interruptions) for >6 years.

Discussion

TNBC is associated with poor prognosis, especially in heavily pretreated patients (19). Chemotherapy remains a critical component in TNBC treatment, but extensive clinical studies and practices have shown limited benefits, with a median PFS of 2.8 to 5.3 months for pretreated TNBC (20-23). There is an urgent need for new treatment strategies. Angiogenesis is closely linked to tumor growth and metastasis, making anti-angiogenic therapy an important strategy in the treatment of mBC (24).

Apatinib is a highly selective and effective VEGFR TKI with a high affinity for VEGFR2. It selectively binds to and inhibits VEGFR-2 activity, blocking tumor angiogenesis and inhibiting tumor growth (10). Additionally, apatinib is administered orally, avoiding injections and reducing hospitalization, with daily dosing to maintain stable blood drug levels. A previous study demonstrated the benefits of apatinib for patients with TNBC (14). The combination of anti-angiogenic drugs with chemotherapy may act synergistically, though further research is needed to confirm and improve patient outcomes (26). In the present case, the combination of apatinib with oral vinorelbine was well-tolerated with only grade 1 nausea, grade 1 neutropenia and grade 1 hand-foot syndrome. Notably, a reduced apatinib dose (0.25 g daily) was used to minimize toxicity. Despite the patient's baseline hypertension and diabetes, no grade >2 hypertension or clinically significant proteinuria developed. Mild, intermittent proteinuria (trace to 1+) was observed but could not be unequivocally separated

from diabetic nephropathy. The patient's SCZ remained stable under regular psychiatric follow-up at Kangning Hospital. These observations suggested that low-dose apatinib combined with oral vinorelbine has a manageable safety profile, even in a patient with multiple comorbidities and a major psychiatric disorder.

TNBC is known for its high risk of recurrence and metastasis. For first-line treatment, if patients are sensitive, re-administration of taxanes can be considered. For those resistant to taxanes, options include vinorelbine, capecitabine, gemcitabine, platinum-based regimens or immunotherapy. However, most of these chemotherapeutic agents require intravenous administration, with limited options available for oral chemotherapy (23). The present study reported a case of a patient with SCZ, whose condition was managed with long-term oral medication. Given the patient's adherence and the risk of exacerbating SCZ, an oral antitumor treatment regimen was chosen. Although anti-angiogenic drugs are mainly used in second-line and beyond for advanced TNBC, a study has confirmed the efficacy of combining chemotherapy with anti-angiogenic drugs (14). Low-dose apatinib not only reduced toxic side effects but also showed good efficacy and safety when combined with chemotherapy in the present case. For the present patient, an individualized treatment plan was implemented, combining oral vinorelbine capsules with the oral anti-angiogenic drug apatinib. This regimen achieved a long period of disease control (>6 years from the start of first-line therapy, despite several interruptions). However, it is should be noted that the patient did not experience a continuous 6-year PFS. The first progression occurred after voluntary treatment cessation at 14 months; subsequent progressions were also related to non-adherence or the COVID-19 pandemic. Each time the original regimen was reintroduced, a PR was regained. Therefore, the durable disease control reflects intermittent treatment benefit, rather than a single unbroken PFS. However, due to poor adherence and the impact of the COVID-19 pandemic, treatment interruptions led to disease progression. Upon resuming vinorelbine and apatinib, partial remission remained achievable. Since apatinib is an off-label drug not covered by insurance, the patient signed an informed consent form for off-label use before treatment and initially agreed to the regimen. However, the patient eventually discontinued apatinib due to its cost and switched to vinorelbine monotherapy. The best-evaluated efficacy of monotherapy was SDa. Although vinorelbine alone had some efficacy, it was less effective than the combination of vinorelbine and apatinib. The disease eventually progressed, and the patient refused intravenous chemotherapy. Consequently, the second-line treatment was adjusted to a combination of vinorelbine and capecitabine (dual vinorelbine), with the best-evaluated efficacy SDb.

A direct comparison between the combination and vinorelbine alone or vinorelbine plus capecitabine is not feasible due to sequential treatment, changing tumor biology and different lines of therapy. Vinorelbine alone was given after prolonged prior exposure, and vinorelbine plus capecitabine was used in a more treatment-refractory setting. Thus, it cannot be concluded that the combination is superior to either of these subsequent regimens. The most robust observation is that retreatment with the original combination after a break led to partial remission. It could be considered that if the patient had no financial constraints and maintained good adherence to the vinorelbine plus apatinib regimen, the disease may have been better controlled, potentially achieving an even longer PFS (>6 years). Throughout the treatment, the patient experienced mild side effects and tolerated the regimen well, highlighting the importance of individualized treatment to improve symptoms, enhance quality of life and extend survival for patients with advanced breast cancer.

In the current case report, the treatment strategy for a patient with advanced breast cancer is presented, which highlighted the sustained efficacy of using vinorelbine capsules in a cross-line approach. For advanced breast cancer, it is essential to avoid immediate medication changes upon disease progression and to assess the metastasis sites. Initially, the patient's metastases included the chest wall, multiple lymph nodes, sternum and liver. Following treatment with vinorelbine capsules and apatinib, the liver lesions achieved clinical complete remission (CR). A previous study suggested that vinorelbine alone may not be highly effective against liver metastases (36), highlighting the significant benefit of combining chemotherapy with anti-angiogenic therapy (14). During treatment, the patient experienced disease progression twice due to treatment discontinuation and once due to irregular medication adherence. After evaluating the disease progression, the medication was not changed, but continued with the original regimen, achieving partial remission. Later, due to financial constraints, the patient discontinued apatinib and continued with vinorelbine monotherapy, leading to disease progression. Given the patient's refusal of intravenous chemotherapy and the limited oral treatment options (such as capecitabine), and considering that liver lesions remained in clinical CR while progression was mainly in multiple lymph nodes and bones without new lesions or metastasis to vital organs such as the lungs or brain, a cross-line approach with vinorelbine capsules combined with capecitabine was chosen.

The present case and previous related studies (14,26) indicated that the combination of chemotherapy and anti-angiogenic drugs has a synergistic effect. This combination shows efficacy in second-line and subsequent lines of treatments, and provides greater benefits in first-line treatment. Consequently, it could be suggested that the combination of chemotherapy and anti-angiogenic drugs can achieve notable efficacy in first-line treatment, and potentially extend PFS beyond the median PFS reported in previous studies. However, given the single-case nature, these findings are hypothesis-generating rather than definitive. Further prospective studies are needed to confirm this hypothesis.

Notably, key molecular data are missing from the present study. Germline BRCA status and PD-L1 expression were not tested. These tests were recommended to the patient, but the patients family declined due to the out-of-pocket cost and the patient's multiple comorbidities. In addition, given the patient's poor adherence and refusal of intravenous therapy, the clinical utility of these tests for guiding treatment in this specific setting was considered limited. Therefore, potential homologous recombination deficiency or immunotherapy responsiveness could not be evaluated in the present case. This

limitation underscores that the present findings are specific to a highly selected patient population.

Additionally, throughout the treatment, the patient's SCZ remained stable without exacerbation. SCZ is a chronic disorder with an unknown etiology. Data on the natural progression of breast cancer in patients with SCZ are limited. Meta-analyses have indicated a 31% increased risk of breast cancer in patients with SCZ, though significant heterogeneity exists among studies (3,37). Clinical data on patients with breast cancer with SCZ are scarce due to the lower incidence of breast cancer among women with SCZ (1), the low genetic correlation between the two diseases (24,25), and the small proportion of SCZ genetic factors influencing breast cancer risk (27). A prospective cohort study revealed that the treatment protocol from consent to chemotherapy for patients with breast cancer with SCZ is comparable to that of patients without SCZ. A history of severe mental illness should not automatically exclude individuals from research studies. Furthermore, there was no observed correlation between disease progression and worsening psychological symptoms during treatment (38). Evidence suggests that SCZ does not affect the treatment process or prognosis of breast cancer. The relationship between breast cancer and SCZ is complex, with limited studies addressing the management of patients with cancer and SCZ. A previous study reported that patients with SCZ might struggle to adhere to comprehensive treatment plans, often facing difficulties in daily functioning and social interactions, which imposes a significant economic burden (10). Various behaviors may complicate clinical management; patients with SCZ are 4-6 times more likely to exhibit violent behavior compared with the general population (11), and the suicide rate is 5-13% higher. The risk of developing breast cancer from long-term use of antipsychotic medications remains controversial.

During the COVID-19 pandemic, numerous patients with cancer experienced delays in receiving intravenous treatments. Oral vinorelbine capsules combined with apatinib offers a convenient treatment alternative for patients with advanced TNBC. In conclusion, the present case report illustrates that vinorelbine capsules combined with low-dose apatinib as first-line treatment achieved tumor control in a patient with advanced TNBC and SCZ who progressed after anthracycline and taxane adjuvant therapy. The regimen was well-tolerated, with only mild adverse events, and did not worsen psychiatric symptoms. However, the findings are limited to a single patient, and molecular characterization (such as BRCA and PD-L1 status) was not performed. Direct comparisons with other regimens are confounded by treatment history and adherence issues. This approach may represent a personalized strategy for similar complex patients with contraindications to intravenous therapy, but requires prospective validation.

Acknowledgements

Not applicable.

Funding

The present study was supported by Shenzhen High-level Hospital Construction (grant no. SZXK013) and Sanming Project of Medicine in Shenzhen (grant nos. SZSM202211012 and SZSM202411002).

Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

XB and CD designed the study and wrote the manuscript. DW, WK, ML and XB obtained medical images and examined patient information. XB, XC, LS and LC contributed to the study's conceptualization, general design and quality assurance. XB, ML, XC, LS and LC confirm the authenticity of all the raw data. All authors have read and approved the final version of the manuscript.

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The present study was granted an exemption from ethics approval approved by the Ethics Committee of National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital and Shenzhen Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College (Shenzhen, China).

Patient consent for publication

The patient's daughter provided written informed consent for the publication of this case report and any related images.

Competing interests

The authors declare that they have no competing interests.

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