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CASE REPORT

# Safety and efficacy of atezolizumab plus bevacizumab combination therapy in patients with unresectable hepatocellular carcinoma undergoing dialysis: a case series

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## Abstract

Three patients aged 79, 75, and 81 years with unresectable hepatocellular carcinoma (HCC) and undergoing maintenance hemodialysis were treated with a combination of atezolizumab and bevacizumab. The patients, respectively, received their 22nd, 2nd, and 4th treatment cycles, and one achieved long-term stable disease. No serious adverse events, including immune-related adverse events, were observed in any patient. Remarkable progress has been made in chemotherapy for cancer; however, the efficacy and safety of chemotherapy in patients undergoing hemodialysis have not been adequately elucidated. This report provides novel insights into the feasibility and outcomes of atezolizumab and bevacizumab combination therapy in patients with HCC undergoing hemodialysis, highlighting its potential as a viable treatment option with manageable side effects.

**Keywords** Hepatocellular carcinoma · Hemodialysis · Chemotherapy · IrAE

## Abbreviations

| | |
|---|---|
| HCC | Hepatocellular carcinoma |
| CKD | Chronic kidney disease |
| CT | Computed tomography |
| RECIST | Response Evaluation Criteria in Solid Tumors |
| SD | Stable disease |
| PD | Progressive disease |
| IrAE | Immune-related adverse events |
| ESRD | End-stage renal disease |
| BCLC | Barcelona Clinic Liver Cancer |
| PIVKA-II | Protein induced by vitamin K absence or antagonist-II |

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## Introduction

Among patients on maintenance hemodialysis, malignant neoplasms are the third leading cause of death, with liver cancer being the second most prevalent cancer [1]. Remarkable progress has been made in chemotherapy for cancer; however, the efficacy and safety of chemotherapy in patients undergoing hemodialysis have not been adequately elucidated. In 2020, combination therapy with atezolizumab, a humanized monoclonal anti-programmed death ligand-1 antibody, and bevacizumab became available for the treatment of unresectable hepatocellular carcinoma (HCC) [2]. However, the safety of this regimen in patients undergoing hemodialysis has not been sufficiently elucidated. Herein, we report three cases of patients with unresectable HCC undergoing hemodialysis who received combination therapy with atezolizumab and bevacizumab.

## Case report

### Case 1

A 79-year-old man with chronic kidney disease (CKD) underwent segment 5 hepatectomy for HCC 4 years before

he visited our department for treatment. One year before he was referred to our department, he had started hemodialysis because of CKD progression. Routine abdominal computed tomography (CT) scans revealed multiple HCC recurrences (Fig. 1a), which eventually led to the referral to our department for treatment. Blood tests performed during his first visit revealed elevated protein levels (199 mAU/mL) induced by vitamin K absence or antagonist-II (PIVKA-II). Albumin level (3.6 g/dL) and prothrombin time (85%) were normal. He had a small amount of ascites, no hepatic encephalopathy, and a Child-Pugh score of 6 (Child-Pugh grade A). After further examination, the patient was diagnosed with Barcelona Clinic Liver Cancer (BCLC) Stage B HCC (Table 1). Atezolizumab (1200 mg) and bevacizumab (15 mg/kg) combination therapy (AB therapy) was initiated as one course over 3 weeks. Grade 1 hypothyroidism and grade 1 skin disorder were observed during the second and fourth cycles, respectively. However, AB therapy was continued, and he received his 22nd cycle of AB therapy until tumor progression; no other immune-related adverse events (irAEs) and hemodialysis-related issues, especially concerning blood pressure, were observed until his death. The best response according to the Response Evaluation Criteria in Solid Tumors (RECIST) was stable disease (SD) (Fig. 1b), progression-free survival (PFS) of 480 days, and overall survival (OS) of 631 days (from the initial administration of AB therapy to death).

## Case 2

The patient was a 75-year-old woman with a medical history of acute myocardial infarction and end-stage renal disease (ESRD) who had been receiving hemodialysis because of diabetic nephropathy. She has undergone a left hepatectomy for a large HCC mass in segment 4 two years before she visited our department. Routine abdominal CT revealed that the patient had experienced multiple HCC recurrences (Fig. 2a). She was then referred to our department for further diagnosis and management. Blood tests performed during her first visit revealed a normal albumin level (3.7 g/dL) and prothrombin time (120%). Serum alpha-fetoprotein (AFP) (2351 ng/mL) and PIVKA-II (2189 mAU/mL) levels were elevated. She had a small amount of ascites, no hepatic encephalopathy, and a Child–Pugh score of 6 (Child–Pugh Grade A). After further examination, the patient was diagnosed with BCLC stage C HCC (Table 1) and AB therapy (atezolizumab 1200 mg plus bevacizumab 15 mg/kg) therapy was initiated. The patient experienced grade 1 general malaise and grade 1 arthralgia during the first cycle. Following the second treatment cycle, the patient was hospitalized because of a pathological fracture of the left subtrochanteric femur. The CT scan performed at that time revealed growth of the HCC (Fig. 2b), bone metastasis to the spine and the left rib (Fig. 2c, d), and a small nodule in the right lung, which was considered lung metastasis. Based on the above findings, the patient was diagnosed with progressive disease (PD), and AB therapy was discontinued. The best response

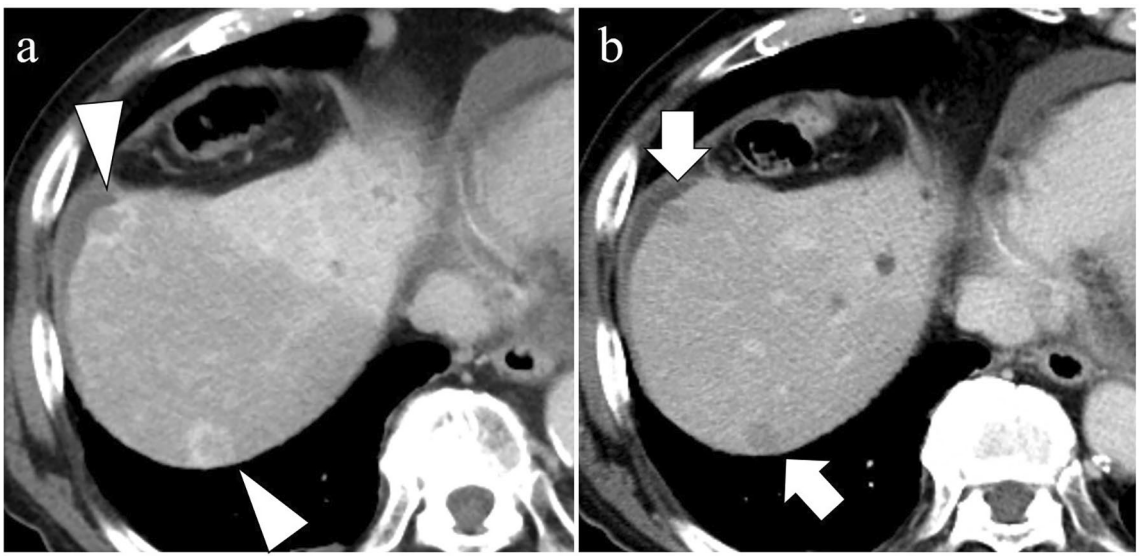


**Fig. 1** Computed tomography (CT) images of before and after atezolizumab plus bevacizumab combination therapy (AB therapy) in Case 1. (**a**) Contrast-enhanced CT shows multiple hepatocellular carcinoma (HCC, arrowheads) in the remnant liver. (**b**) Four months after first administration of AB therapy, no alteration in the size of the tumor was noted (arrows), leading to a classification as Stable Disease (SD)

**Table 1** A summary of patient's characteristics and clinical course

| No | Age | Gender | Blood biochemistry data | | | | | | CP score | Tumor markers | | Tumor conditions | | | | Vascular involvement | Extrahepatic metastasis | 1st-line | 2nd-line | PFS of | BR of | OS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | AST[*1] | ALT[*1] | T-Bil[*2] | PT[*3] | Plt[*4] | Alb[*5] | | AFP[*6] | PIVKA-II[*7] | Gross classification | Location | Maximum size | Number | | | chemotherapy | chemotherapy | AB therapy | AB therapy | |
| 1 | 79 | male | 10 | 5 | 0.4 | 85 | 16.7 | 3.6 | 6 | <2 | 199 | Multinodular | Right lobe | 17 mm | 6 | None | None | AB | None | 480 days | SD | 631 days (dead) |
| 2 | 75 | female | 31 | 13 | 0.6 | 120 | 17.1 | 3.7 | 6 | 2351 | 2189 | Multinodular | Right lobe | 25 mm | 10 | None | None | AB | None | 32 days | PD | 68 days (to last survival confirmation date) |
| 3 | 81 | male | 10 | 12 | 0.3 | 110 | 13.1 | 3.8 | 5 | 2 | 292 | Single nodular type with extranodular growth | Right lobe | 72 mm | >15 | None | None | AB | Tremelimumab + Durvalumab | 84 days | PD | 159 days (to last survival confirmation date) |

[*]1 Unit is U/L, *2 Unit is mmol/L, *3 Unit is %, *4 Unit is $10^4/\mu L$, *5 Unit is g/dL,*6 Unit is ng/mL, *7 Unit is mAU/mL

*AST* aspartate aminotransferase, *ALT* alanine aminotransferase, *T-Bil*, total bilirubin, *PT* prothrombin time, *Plt* platelet, *Alb* serum albumin, *CP* Chilid-Pugh, *AFP* Alpha Fetoprotein, *PIVKA-II* protein induced by vitamin K absence or antagonist-II, *AB* atezolizumab and bevacizumab, *PFS* progression-free survival, *BR* best response, *SD* stable disease, *PD* progressive disease, *OS* overall survival

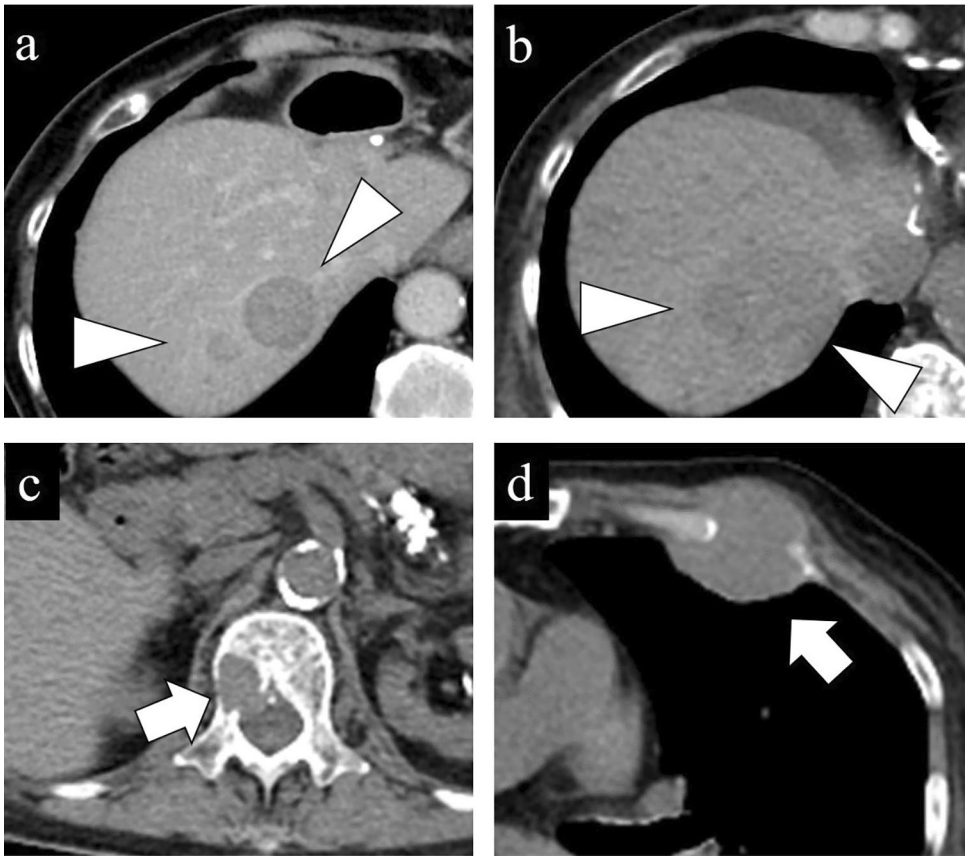


**Fig. 2** Computed tomography (CT) images of before and after atezolizumab plus bevacizumab combination therapy (AB therapy) in Case 2. (**a**) Contrast-enhanced CT shows multiple hepatocellular carcinoma (HCC, arrowheads) in remnant liver. (**b**, **c**, **d**) Plane CT shows the growth of the HCC (b, arrowheads) and bone metastasis to the spine (c, arrow) and the left rib (d, arrow) after 2 months from initiation of AB therapy

according to RECIST was PD with a PFS of 32 days and OS of 68 days (from the initial administration of AB therapy to the last survival confirmation date). During AB therapy, she didn't experience any hemodialysis-related issues during AB therapy.

### Case 3

The patient was an 81-year-old man with a medical history of hypothyroidism, for which he was undergoing hormone replacement therapy, and ESRD. He was undergoing hemodialysis because of diabetic nephropathy and had received transcatheter arterial embolization (TAE) of segment 4/8 because of HCC 10 years before he visited our department. Routine abdominal ultrasonography revealed multiple recurrences of HCC (Fig. 3a). The patient underwent additional examinations. Blood tests revealed normal albumin level (3.8 g/dL) and prothrombin time (110%). PIVKA-II level was elevated (292 mAU/mL). He had no ascites nor hepatic encephalopathy, and his Child–Pugh score was 5 (Child–Pugh grade A). CT during hepatic arteriography showed HCC of the simple nodular type with extranodular growth in the anterior segment of the liver. Small tumors were diffusely detected in the anterior and posterior segments of the liver. The patient was diagnosed as having BCLC stage B HCC (Table 1). Because the lesions were diffusely present in the liver, systemic chemotherapy was considered desirable to maintain liver function, and therefore, AB therapy (atezolizumab 1200 mg plus bevacizumab 15 mg/kg) was initiated. After the fourth cycle, increased levels of tumor markers and enlargement of the primary tumor were observed; therefore, the patient was diagnosed with PD (Fig. 3b). The treatment regimen was switched to tremelimumab plus durvalumab combination therapy and continued for 2 months. No adverse events, especially IrAEs and hemodialysis-related blood pressure issues, occurred during the treatment. The best response according to RECIST was PD, with a PFS of 84 days and OS of 159 days (from the initial administration of AB therapy to the last survival confirmation date).

## Discussion

To our knowledge, this is the first report in the English literature describing the use of AB therapy in patients with unresectable HCC undergoing hemodialysis. No severe adverse events were observed, and none of our patients tolerated the combination chemotherapy.

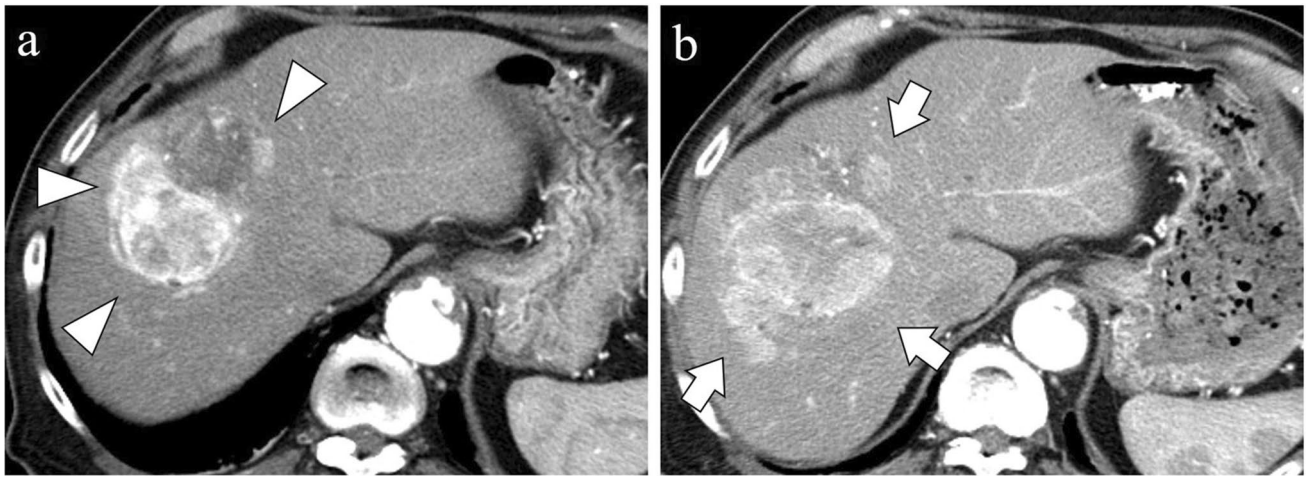


**Fig. 3** Computed tomography (CT) images of before and after atezolizumab plus bevacizumab combination therapy (AB therapy) in Case 3. (**a**) Contrast-enhanced CT shows the low-density area in Segment 4/8 is post-TAE lesion, and hepatocellular carcinoma (HCC) of simple nodular type with extranodular growth is in the right robe of the liver (arrowheads). (**b**) Three months after initiation of AB therapy, the size of HCC is increased (arrows)

HCC is the seventh most common cancer in the world [3]. There are several treatments for HCC, including local therapy, transarterial chemoembolization (TACE), and chemotherapy, and treatment is determined based on the condition of the tumor and patient. Among patients on maintenance hemodialysis, malignant neoplasms rank as the third leading cause of death, with liver cancer being the second most prevalent cancer [1]. However, there is limited evidence for the treatment of these patients, and it can be difficult to decide on a treatment strategy based on the patient's condition. Thus, there is no clear treatment policy for patients with HCC undergoing hemodialysis.

Bevacizumab (molecular mass: 149 kDa) is a recombinant humanized monoclonal antibody against vascular endothelial growth factors. The main elimination pathway of bevacizumab is proteolytic catabolism throughout the body rather than hepatic metabolism or renal excretion [4]. Thus, bevacizumab is not dialyzable [5, 6], and its pharmacokinetic parameters in patients on hemodialysis are similar to those reported in patients with normal renal function [6]. Although no reports on bevacizumab therapy for HCC have been published, there are several reports on chemotherapy, including bevacizumab, for other cancers. According to a PubMed search conducted in November 2023, 13 patients with unresectable/recurrent colorectal cancer or renal cell carcinoma and undergoing hemodialysis received chemotherapy, including bevacizumab. Except for one patient, no serious bevacizumab-related side effects were observed (Table 2) [7–16]. The patient who experienced serious adverse events was a 50-year-old woman with recurrent renal cell carcinoma. After receiving cytokine-based therapy along with bevacizumab for 7 months, hemorrhagic gastritis due to angiodysplasia and intracerebral hemorrhage developed [14]. The other 12 patients and three patients described herein did not have grade 3–4 toxicities due to bevacizumab (e.g., hypertension or hemorrhage). However, as ESRD patients are generally at higher risk of cerebrovascular events, cardiovascular events and organ damage due to thrombosis, the risks associated with bevacizumab administration should be fully assessed and carefully explained to patients. This is particularly important because the safety of bevacizumab use in patients undergoing hemodialysis is not currently clear. Additionally, patients should be followed more carefully than non-ESRD patients for adverse vascular events, such as increased blood pressure during administration. Lee et al. have reported that patients who received lower doses of bevacizumab (< 15 mg/kg per dose) had non-inferior PFS and OS compared with those receiving a standard dose of bevacizumab and the incidence of proteinuria of all grades (15.8%) was less common when lower doses of bevacizumab were used [17]. For dialysis patients, who often experience hypertension or a propensity for bleeding, atezolizumab plus low-dose bevacizumab therapy could be considered a viable option.

Similarly, immune checkpoint inhibitors are not eliminated by hemodialysis because of their high molecular weight (the molecular mass of atezolizumab is 145 kDa) [18]. Antibodies are slowly cleared from circulation, mainly through catabolism, and no dose adjustments are required [19]. A previous study of patients with lung, renal cell, bladder, and head/neck cancer, or melanoma treated with pembrolizumab or nivolumab showed that the incidences of immune-related adverse events were comparable between the ESRD and non-ESRD groups [20].

**Table 2** Reported cases of bevacizumab therapy in heamodialysis patients

| No | Author | Year | Age | Gender | Disease | Treatment regimen | Treatment cycles | Response to treatment | Adverse events | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Hypertention | Bleeding | Others |
| 1 | Horimatsu et al | 2011 | 50 s | male | CRC | mFOLFOX6 + Bevacizumab | 8 times | SD | n/d | n/d | Grade1 peripheral neuropathy |
| 2 | Kuwabara et al | 2011 | 58yo | female | CRC | FOLFORI + Bevacizumab | 21 times | SD | n/d | n/d | Grade4 neutropenia, Grade3 anemia |
| 3 | Syrios et al | 2013 | 50yo | female | RCC | IFNα-2b 6 MU + Bevacizumab | n/d | PR | n/d | hemorrhagic gastritis, intracerebral hemorrhage | n/d |
| 4 | Sato et al | 2013 | 67yo | male | CRC | 1st line mFOLFOX6 + Bevacizumab<br>2nd line sLV5FU2 + Bevacizumab | 2 + 16 times | CR | n/d | n/d | Grade1 anorexia, Grade1 nausea, Grade3 neutropenia |
| 5 | Matsuda et al | 2013 | 68yo | male | CRC | FOLFIRI + Bevacizumab | 6 times | PD | n/d | n/d | n/d |
| 6 | Takeda et al | 2015 | 73yo | male | CRC | XELOX + Bevacizumab | 18 times | SD | n/d | n/d | n/d |
| 7 | Berlo et al | 2017 | 77yo | male | CRC | neoadjuvant FOLFOX + Bevacizumab | 3 times | n/d | n/d | n/d | n/d |
| 8 | Aimono et al | 2018 | 50 s | male | CRC | mFOLFOX6 + Bevacizumab | 7 times | PR | n/d | n/d | Grade3 neutropenia, Grade1 anorexia, Grade1 hiccups |
| 9 | Watanabe et al | 2018 | 54yo | male | CRC | Bevacizumab + Capecitabine | 15 times | SD | n/d | n/d | n/d |
| 10 | Takayama et al | 2020 | 66yo | male | CRC | Bevacizumab + UFT | 63 times | n/d | n/d | n/d | n/d |
| 11 | Takayama et al | 2020 | 67yo | male | CRC | Bevacizumab + UFT | 22 times | n/d | n/d | n/d | n/d |
| 12 | Takayama et al | 2020 | 75yo | male | CRC | Bevacizumab + UFT | 49 times | n/d | n/d | n/d | n/d |
| 13 | Takayama et al | 2020 | 71yo | male | CRC | Bevacizumab + UFT | 32 times | n/d | n/d | n/d | n/d |
| 14 | Our case | 2024 | 79yo | male | HCC | Atezolizumab + Bevacizumab | 22 times | SD | n/d | n/d | Grade1 skin disorder |
| 15 | Our case | 2024 | 75yo | male | HCC | Atezolizumab + Bevacizumab | 2 times | PD | n/d | n/d | Grade1 general malaise, Grade1 arthralgia |
| 16 | Our case | 2024 | 81yo | male | HCC | Atezolizumab + Bevacizumab | 4 times | PD | n/d | n/d | n/d |

*n/d* not described, *IrAE* immune-related adverse events, *CRC* colorectal cancer, *RCC* renal cell carcinoma, *HCC* hepatocellular carcinoma, *CR* complete response, *PR* pertial response, *SD* stable disesase, *PD* progressive disease searched for "bevacizumab, dialysis" on PubMed

Case2, 4, 5,6,8,9,10, 11, 12, 13 are reported in only Japanease literature

**Table 3** Reported cases of atezolizumab therapy in heamodialysis patients

| No | Author | Year | Age | Gender | Disease | Treatment regimen | Treatment duration | Response to treatment | Adverse events | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | IrAE | Others |
| 1 | Parisi et al | 2019 | n/d | male | BSC | Atezolizumab | 6 months | n/d | n/d | Grade1 itching, asthenia, nausea, dysgeusia, constipation |
| 2 | Watari et al | 2021 | 73yo | male | ES-SCLC | Atezolizumab + Carboplatin + Etoposide | 9 months | PR | n/d | Febrile neutropenia, moderate to severe hematological toxicity |
| 3 | Watari et al | 2021 | 69yo | male | ES-SCLC | Atezolizumab + Carboplatin + Etoposide | 6 times | PR | n/d | Grade3 neutropenia, Grade4 thrombocytopenia |
| 4 | Imai et al | 2023 | 70 s | male | LCNEC | Atezolizumab + Etoposide | 4 months | PR | n/d | n/d |
| 5 | Our case | 2024 | 79yo | male | HCC | Atezolizumab + Bevacizumab | 22 times | SD | Grade1 hypothroidism | Grade1 skin disorder |
| 6 | Our case | 2024 | 75yo | male | HCC | Atezolizumab + Bevacizumab | 2 times | PD | n/d | Grade1 general malaise, arthralgia |
| 7 | Our case | 2024 | 81yo | male | HCC | Atezolizumab + Bevacizumab | 4 times | PD | n/d | n/d |

*n/d* not described, *IrAE* immune-related adverse events, *BSC* bladder sarcomatoid cartcinoma, *LCNEC* large cell neuroendocrine carcinoma, *ES-SCLC* extensive-stage small cell lung cancer, *HCC* hepatocellular carcinoma, *PR* pertial response, *SD* stable disease, *PDq* progressive disease searched for "atezolizumab, dialysis" on PubMed

According to data from the PubMed search, four patients underwent hemodialysis and received atezolizumab treatment for any cancer, none of whom had serious IrAE (Table 3) [21–23]. Although these data were derived from non-HCC cases, they suggest that the safety profile of AB therapy may be acceptable in clinical practice.

A previous study showed that the disease control rate due to AB therapy for unresectable HCC was 74% [24]. Only one of our three patients experienced prolonged SD. Although not indexed in PubMed, a study by Oda et al., in Japanese, indicated that the use of AB therapy in patients with HCC undergoing hemodialysis may achieve long-term prognosis [25]. However, it is difficult to evaluate the efficacy of this therapy in patients undergoing hemodialysis because of the limited number of cases. Further studies are required to determine efficacy.

In conclusion, our findings demonstrate that the three patients with unresectable HCC undergoing hemodialysis were successfully treated with AB therapy, with no serious adverse events. AB therapy could be considered a treatment option for patients undergoing hemodialysis, however, more careful adverse event monitoring is needed during the AB treatment period due to the lack of sufficient reported cases.

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**Author contributions** Koki Sakaguchi and Tatsunori Satoh: manuscript drafting, Tatsunori Satoh: conception and design. All authors reviewed and approved the final version of the manuscript for submission.

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## Declarations

**Conflict of interest** The authors have no conflicts of interest to declare.

**Human and animal rights** All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and later versions.

**Patient consent** Informed consent was obtained from the patients.

**Informed consent** Informed consent was obtained from the patient included in this study.

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