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PRESS RELEASE

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Financial burden of immune checkpoint inhibitor maintenance therapy in Japan

Researchers from Iwate Medical University have shown that long-term maintenance therapy with immune checkpoint inhibitors (ICIs) accounts for a disproportionate share of outpatient anticancer drug expenditures, despite being used in only a small fraction of patients. The study analyzed regimen-based billing data from Iwate Medical University Hospital during fiscal year 2022 and highlights the need to optimize the duration of high-cost cancer therapies, potentially supported by biomarkers such as circulating tumor DNA (ctDNA). These findings were published online on Aug 21, 2026, in the international peer-reviewed cancer research journal “Cancer Treatment and Research Communications”.

【Highlights】

- The study analyzed 1,425 patients, 8,179 treatment opportunities, and 178 therapeutic regimens across 16 cancer types at Iwate Medical University Hospital during fiscal year 2022. The annual total cost was approximately 2.6 billion JPY.
- ICI-containing regimens accounted for the majority of total outpatient anticancer drug expenditures, and ICI monotherapy alone represented 44% of total drug expenditure.
- ICI maintenance therapy was administered to only 47 patients (3%) and represented 473 treatment opportunities (6%), but it accounted for 272 million JPY, or 11% of total expenditure. ICI maintenance therapy also represented 64% of all maintenance therapy costs.
- These findings identify prolonged ICI maintenance therapy as a concentrated driver of financial burden in routine cancer care and support the need for strategies to reassess treatment duration.

【Background】

Immune checkpoint inhibitors (ICIs) have transformed the treatment of many cancers by restoring antitumor immune responses. Since their introduction, ICIs have been widely used across multiple cancer types. However, ICIs are expensive, and their increasing use has created substantial financial pressure on publicly funded healthcare systems.

For patients with advanced or recurrent unresectable cancer who do not show disease progression, ICIs may be continued for prolonged periods. The optimal duration of ICI therapy remains uncertain. Continuing treatment may help maintain disease control, but prolonged therapy also increases outpatient visits, laboratory testing, drug costs, and patient burden. At the same time, stopping treatment can cause anxiety for patients, even when disease appears controlled on imaging.

Circulating tumor DNA (ctDNA) is fragmented tumor-derived DNA released into the bloodstream. Although ctDNA monitoring was not evaluated in the present study, ctDNA and other sensitive biomarkers may help inform future strategies for reassessing physical tumor burden and optimizing treatment duration in patients receiving high-cost cancer therapies.

【Methods】

This retrospective cohort study used deidentified regimen-based billing data from patients who received outpatient anticancer drug therapy at Iwate Medical University Hospital during fiscal year 2022, from April 2022 to March 2023. The dataset included 16 cancer types, including breast, lung, colon, gastric, pancreatic, urothelial, renal, liver, head and neck, endometrial, esophageal, cervical, melanoma, prostate, leukemia, and Hodgkin lymphoma.

Medical costs included drug costs as well as same-day outpatient visit and laboratory costs associated with treatment administration. Costs related to hospitalization, emergency visits, imaging performed on non-treatment days, and management of immune-related adverse events were not included. Regimens using the same drug but different dosing intervals were analyzed separately because dosing interval affects visit frequency and same-day costs.

Maintenance therapy was defined as a single unchanged regimen continued for at least 13 months. This definition was based on an ongoing randomized trial in Japan that uses one year as a benchmark for long-term response.

【Results】

The analysis included 1,425 patients, 8,179 treatment opportunities, and 178 therapeutic regimens (Figure 1A). The annual total cost was approximately 2.6 billion JPY. Chemotherapy alone was the most common treatment category by patient number, whereas ICI-containing regimens represented 68% of total costs (Figure 1B).The average cost per treatment opportunity by regimen was concentrated within the range of 0.2M JPY or less, and all chemotherapy agents fell within this range (Figure 1C). This suggests that conventional chemotherapy agents continue to play a major role in cancer drug therapy even today.

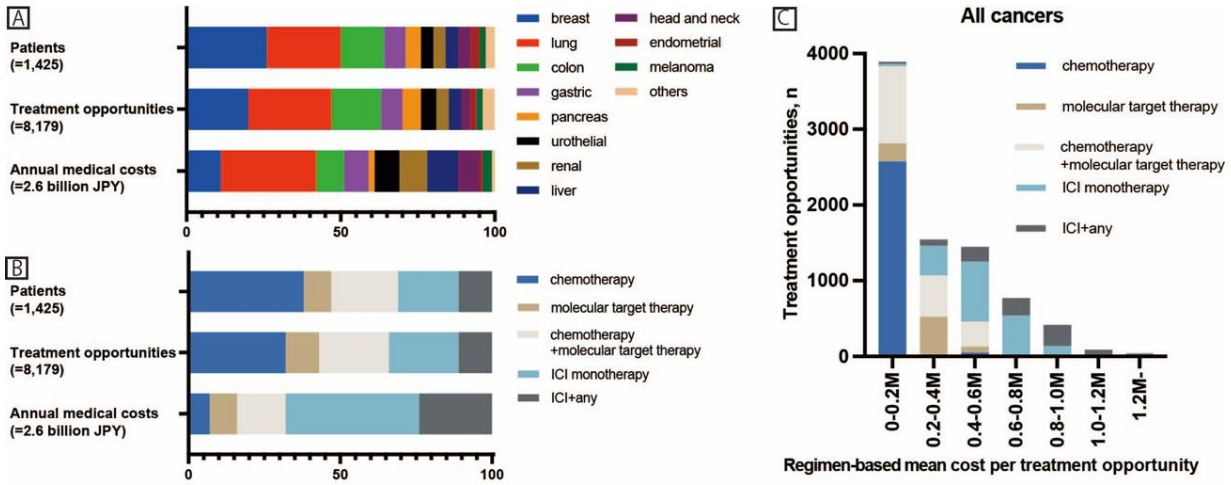

Figure 1. Fraction of core parameters and distribution of treatment opportunities by cost bin range.
Fraction of the number of patients, treatment opportunities, and total medical costs for the entire cohort are shown by cancer type (A) and treatment category (B). Treatment opportunities are further organized by treatment category and cost-bin range for all cancers (C). Costs are in JPY. ICI, immune checkpoint inhibitor.

Maintenance therapy was administered to 148 patients, accounting for 10% of the total (Figure 2). Of these, 47 patients (32% of those receiving maintenance therapy) were on ICI maintenance therapy, which accounted for 272 million yen (64% of those receiving maintenance therapy) in total annual medical expenses.Among patients receiving ICI monotherapy, 16% were on maintenance therapy, accounting for 25% of treatment opportunities and 24% of annual medical costs (Figure 3).

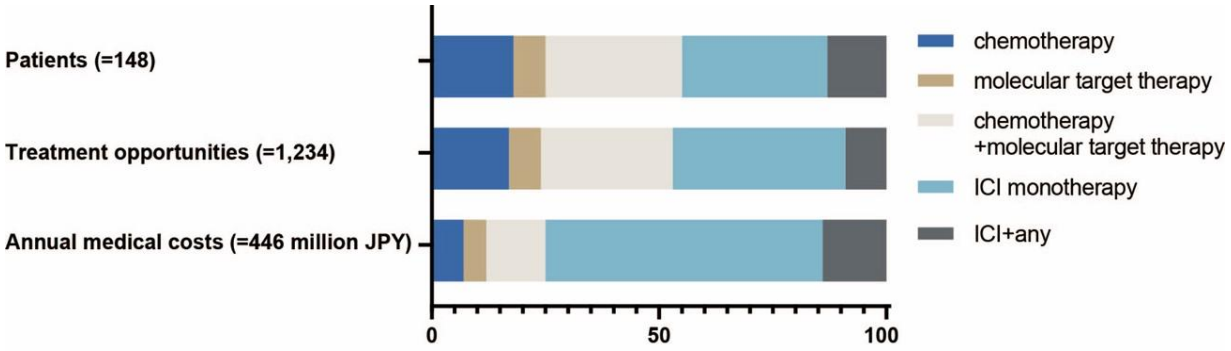

Figure 2. Fraction of core parameters in terms of treatment category for the MT subset cohort.
Fraction of the number of patients, treatment opportunities, and total medical costs of the MT subset cohort are shown by treatment category. ICI, immune checkpoint inhibitor; MT, maintenance therapy.

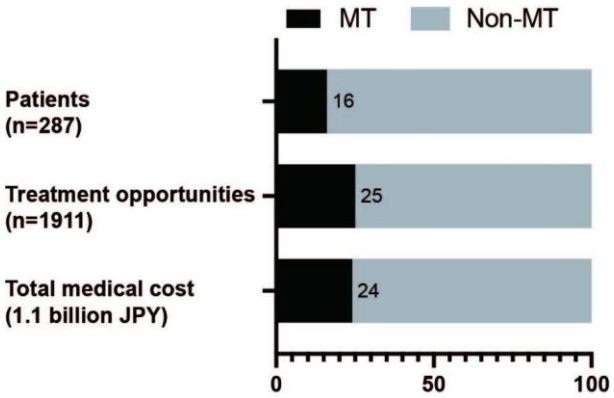

Figure 3. Fraction of ICI monotherapy for core parameters.
The fraction of ICI monotherapy is illustrated for the number of patients, treatment opportunities, and total medical costs. ICI, immune checkpoint inhibitor; MT, maintenance therapy.

【Conclusion】

This single-center, real-world, regimen-based analysis showed that ICI maintenance therapy accounted for a disproportionate share of outpatient anticancer drug expenditures despite being used in only a small number of patients. Optimizing the duration of prolonged ICI therapy may reduce healthcare costs and patient visit burden while preserving the benefits of immunotherapy.

【Prospective】

- Future studies should evaluate whether sensitive biomarkers such as ctDNA can help identify patients who may safely pause ICI maintenance therapy.
- Sustained undetectable ctDNA may help reduce patient anxiety during treatment reassessment by providing biological support for a low likelihood of relapse or regrowth.
- A prospective interventional study is needed to determine whether ICI maintenance therapy can be safely suspended under ctDNA monitoring and to quantify the potential financial impact on healthcare systems.
- Iwate Medical University Hospital has started ctDNA monitoring as a Laboratory Developing Test (OTS-Assay) since April 2022. If you are interested, please refer to the following website.

https://www.hosp.iwate-med.ac.jp/hospital/gancenter/service/ots.html

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【Glossary】

1. Immune checkpoint inhibitors (ICIs): Drugs that block inhibitory immune checkpoint pathways, such as PD-1, PD-L1, or CTLA-4, thereby enhancing antitumor immune responses.
2. Maintenance therapy: A treatment strategy in which the same regimen is continued for a prolonged period in patients without disease progression. In this study, maintenance therapy was defined as an unchanged regimen lasting 13 months or longer.
3. Circulating tumor DNA (ctDNA): Short fragments of tumor-derived DNA released into the bloodstream. ctDNA can potentially be used to monitor tumor burden and disease dynamics through blood testing.
4. Digital PCR (dPCR): Digital PCR is a technique for quantification by counting individual molecules in a sample. Compared with conventional PCR methods, it can identify and quantify rare molecules present at very low fractions, such as approximately 0.01%.
5. Financial toxicity: The financial burden associated with cancer treatment that can negatively affect patients' quality of life and access to care.

【Original paper】

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