

Consideration of the Cost of Adverse Events for Oncology Treatment: A Review of Cost-Effectiveness Evaluations in Japan

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INTRODUCTION

- Cost-effectiveness evaluation (CEE) guidelines for Japan recommend, in principle, that the estimation of healthcare costs (HCs) include not only the costs of the selected technology and its comparator(s) but also HCs associated with adverse events (AEs) for cost-effectiveness analyses (CEA).
- In the case of oncology treatment, a certain frequency of AEs is inevitable, and it is common for treatments to be continued while appropriately addressing AEs.
- However, AEs may differ by treatment in terms of their severity and frequency.

OBJECTIVE

- We consider HCs associated with AEs for CEEs for oncology treatments in Japan in terms of AE severity and frequency.

METHODS

- We reviewed published academic group analyses for CEEs for oncology treatments that were evaluated in Japan between April 2019 and December 2023.
- Only base-case analyses were included. For HCs associated with AEs, we examine their severity and frequency based on their grades and rates, respectively.

RESULTS

- 13 reports covering seven treatments / indications were identified, and their details are shown in Table 1.
- Of these, 12 included HCs associated with AEs, summarized in Figure 1.
- In terms of severity, only HCs associated with AEs of Grade 3 or higher were considered for most reports (n=9, 75.0%) and three reports (25.0%) did not report AE grade.
- Among the 12 reports, six (50.0%) considered HCs associated with an AE frequency of 5% or more. Two reports (16.7%) used a bespoke definition for AE frequency (e.g., 2% or more difference between the selected treatment and the comparator).
- Others (n=4, 33.3%) did not report the frequency of AEs.

CONCLUSIONS

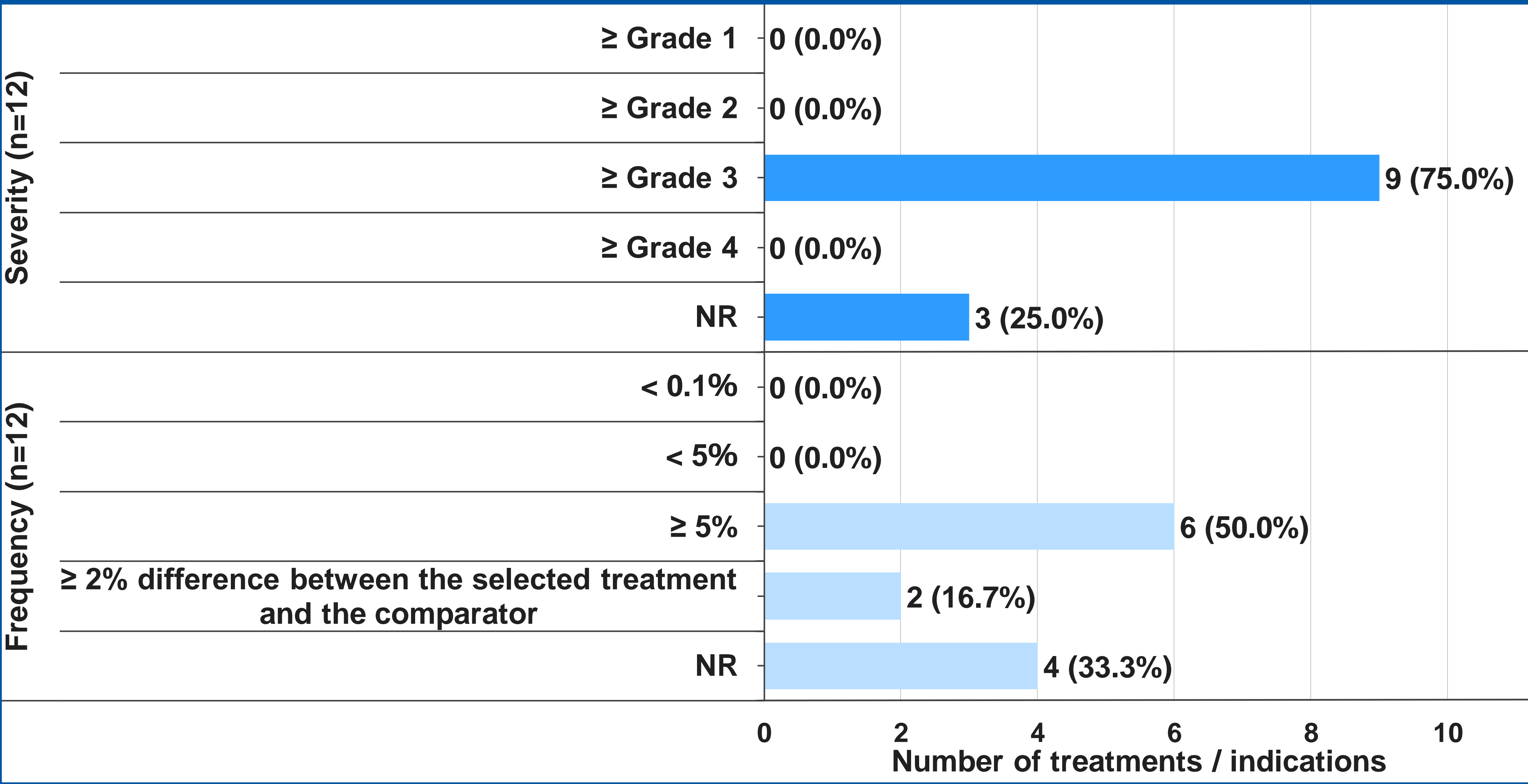
- AEs from oncology treatments, even those that are mild and infrequent, are likely to affect the physical and psychological quality of life of patients but are rarely considered in CEEs in Japan.

Table 1: Consideration of Severity and Frequency of AE in CEE

Treatments	Indications	Considering Severity and Frequency of AEs
tisagenlecleucel (Kymriah)	B-ALL	AE costs were only considered for grade 3 or 4 CRS and B-cell aplasia.
	DLBCL	AE costs were only considered for tisagenlecleucel to be conservative, which comprised of costs for treating grade 3/4 CRS and B-cell aplasia.
cabozantinib (Cabometyx)	First-line therapy for RCC	Grade 3 or 4 AEs occurring in 5% or more patients were considered.
	Second-line or subsequent therapy for RCC	Grade 3 or 4 AEs occurring in 5% or more patients were considered.
	HCC	AEs treatment costs were not considered in the base-case analysis.
trastuzumab deruxtecan (Enhertu)	BC	Grade 3 or higher AEs occurring in 5% or more patients, and AEs of clinical interest for the selected treatment or comparator were considered in the treatment cost calculation.
	GC	Grade 3 or higher AEs occurring in 5% or more patients, and AEs of clinical interest for the selected treatment or comparator were considered in the treatment cost calculation.
polatuzumab vedotin-piiq (Polivy)	DLBCL	Grade 3 or higher AEs were considered.
daratumumab and vorhyaluronidase alfa (Darzquro)	Systemic AL Amyloidosis	The CUA model included grade 3 or 4 AEs occurring in 5% or more patients in any treatment arm.
	MM	Grade 3 or higher IRR were considered. For non-IRR AEs, only grade ≥3 AEs occurring in ≥5% of study subjects in any daratumumab arms were considered.
selpercatinib (Retevmo)	NSCLC	Grade 3 or higher AEs with a difference in frequency of 2% or more between interventions were considered.
	TC	Grade 3 or higher AEs with a difference in frequency of 2% or more between interventions were considered.
enfortumab vedotin (Padcev)	UC	Do not reported for AEs.

Abbreviations: AE, adverse event; B-ALL, B-cell acute lymphoblastic leukemia; DLBCL, diffuse large B-cell lymphoma; RCC, renal cell carcinoma; HCC, hepatocellular carcinoma; BC, breast cancer; GC, gastric cancer; AL, amyloid light-chain; MM, multiple myeloma; CUA, cost-utility analysis; IRR, infusion-related reactions; NSCLC, non-small cell lung cancer; TC, thyroid cancer; UC, urothelial carcinoma

Figure 1: Criteria of Severity and Frequency of AE in CEE



Abbreviations: AE, adverse event; NR, not reported