Retrospective study of infusion-related reactions in subcutaneous daratumumab administration in Japan

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Abstract. The subcutaneous formulation of daratumumab (DARA-SC), an improved version of the intravenous formulation, has reduced administration time compared to the latter. However, real-world data regarding its infusion-related reactions (IRRs) remain limited. The present study evaluated the incidence rate, timing and risk factors for IRRs associated with the first dose of DARA-SC. This retrospective analysis included 65 patients who received their first DARA-SC dose at Gifu Municipal Hospital, Japan between May 2021 and June 2024. IRRs occurred in 10 patients (15.4%), and all cases were mild, categorized as grade 1 or 2. The median time to IRR onset was 10 h (range, 0.5-46 h), and delayed-onset IRRs (occurring after 24 h) accounted for 30% of cases. Univariate analysis identified a history of allergies as a potential factor associated with IRR occurrence (P=0.04). Older patients (≥70 years) tended to experience delayed-onset IRRs. Although these findings should be interpreted cautiously because of the limited cohort size, careful monitoring during initial DARA-SC administration might be important, particularly in patients with a history of allergies and in older patients, considering the possibility of delayed-onset IRRs.

Introduction

Daratumumab (DARA) is a human immunoglobulin G1κ monoclonal antibody that exerts its effects by binding to the CD38 antigen expressed on the surface of tumor cells in hematologic malignancies. Although DARA is available as an intravenous formulation (DARA-IV, Darzalex®), infusion-related reactions (IRRs) are frequently reported following its administration (1). To prevent IRRs, DARA-IV administration requires a large infusion volume (500-1000 ml) and long infusion time (3-7 h) (2). To reduce the burden on patients and healthcare providers during administration, a subcutaneous formulation combining DARA with recombinant human hyaluronidase PH20 (rHuPH20), Darzquro® (DARA-SC), was developed.

DARA-SC was non-inferior to DARA-IV (16 mg/kg) in a phase III multinational study (MMY3012: COLUMBA) evaluating monotherapy in patients with relapsed or refractory multiple myeloma (MM) (3). Furthermore, the efficacy and safety of DARA-SC were confirmed for combination therapies, D-MPB (DARA-SC added to bortezomib, melphalan, and prednisone) and D-Ld (DARA-SC added to lenalidomide and dexamethasone) regimens, in a phase-III MMY2040: PLEIADES study (4). Based on these findings, DARA-SC was approved for the treatment of MM in Japan in March 2021. Additionally, in the phase III MMY3013: APOLLO study, which compared the efficacy and safety of DPd (DARA, pomalidomide, and dexamethasone) and Pd (pomalidomide and dexamethasone) treatment in patients with relapsed or refractory MM, DPd treatment demonstrated greater efficacy and safety (5).

IRRs are characteristic adverse events associated with DARA administration. Two mechanisms are considered to underlie the development of IRRs: immune-mediated (IgE-associated allergic) and non-immune-mediated responses. Non-immune-mediated reactions are more likely to occur during the first infusion and are thought to be triggered by the release of cytokines (6). Although DARA-SC is associated with lower administration burden and IRR incidence than DARA-IV, IRRs still occur and may occasionally present with delayed onset (2,6,7). Delayed-onset IRRs are clinically important because symptoms may develop after completion of routine post-administration monitoring, potentially affecting patient safety and appropriate observation strategies. Delayed IRRs associated with DARA-SC often occur after the post-administration observation period, when patients have left the medical facility (8). Therefore, identifying the risk factors and patterns of delayed IRRs is important for improving the safety of DARA-SC treatment by informing

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Abbreviations: DARA-IV, intravenous daratumumab; DARA-SC, subcutaneous daratumumab; IRR, infusion-related reaction; LDH, lactate dehydrogenase; MM, multiple myeloma

Key words: infusion-related reaction, subcutaneous daratumumab, delayed onset, allergies, Japanese patients

appropriate observation strategies and enabling advance guidance for high-risk patients on how to respond if delayed IRRs occur. Several risk factors for IRRs associated with DARA-IV, including respiratory disease, history of allergies, and hematologic parameters, have been reported (9-12). However, no studies have investigated the risk factors of IRRs associated with subcutaneous formulations.

In addition, previous studies have reported lower IRR incidence with DARA-SC than with DARA-IV, although the reported frequency varies depending on the study design and observation period (3,13).

In the COLUMBA study, Japanese patients accounted for only a limited proportion of the study population, and detailed analyses of IRR risk factors were not performed (3,14). Identifying patients at a higher risk for IRRs and understanding the characteristics of IRRs may contribute to safer monitoring and management strategies during DARA-SC treatment and improvement of patient safety. Accordingly, in this study, we investigated the incidence and risk factors of IRRs associated with DARA-SC in real-world clinical practice.

Materials and methods

Patients. In this study, we retrospectively reviewed the medical records of patients who had received their first dose of subcutaneous DARA (DARA-SC, Darzquro®) at Gifu Municipal Hospital between May 2021 and June 2024. All patients were hospitalized under 24-h medical supervision. Patients who switched from DARA-IV to DARA-SC or had a history of DARA administration at another hospital were excluded. The main aim of this assessment was to investigate IRRs. This study was conducted in compliance with the Ethical Guidelines for Life Sciences and Medical Research Involving Human Subjects. This study was approved by the Ethics Committees of Gifu Municipal Hospital (Approval No. 836) and Gifu Pharmaceutical University (Approval No. 6-10).

Treatment decision. According to The JSH Practical Guidelines for Hematological Malignancies 2018 (15), the standard treatment for untreated MM not eligible for transplantation is daratumumab, lenalidomide, and low-dose dexamethasone (D-Ld treatment). In addition, at Gifu Municipal Hospital, in accordance with The JSH Practical Guidelines for Hematological Malignancies 2018, D-Ld treatment is administered as the standard treatment for untreated MM in patients who are not eligible for transplantation, considering each patient's circumstances. DARA, a component of the D-Ld regimen, is available as intravenous (DARA-IV) and subcutaneous (DARA-SC) formulations, which have equivalent efficacy (4). However, DARA-SC is preferred over DARA-IV due to its shorter administration time and lower risk of IRRs (3).

Study parameters. The following parameters were retrospectively collected:

- Patient information: age, sex, weight, and history of allergies and adverse events.
- Disease-related information: type of myeloma, International Staging System stage, and treatment history and regimen.
- Clinical laboratory findings: white blood cell, neutrophil, lymphocyte, and platelet counts; hemoglobin, aspartate aminotransferase, alanine aminotransferase, serum creatinine, lactate dehydrogenase (LDH), serum calcium, serum potassium, total protein, albumin, and serum β2-microglobulin levels.
- Other parameters: premedication at the time of DARA-SC administration, presence and severity of IRRs based on the Common Terminology Criteria for Adverse Events version 5, and timing of IRR onset.

IRRs were defined as symptoms such as anaphylaxis, nasal congestion, cough, chills, eye disturbances, bronchospasm, hypoxia, and dyspnea, as described in the package insert, observed and diagnosed by a physician based on a comprehensive assessment. IRRs were identified based on clinical symptoms documented in the medical records after DARA-SC administration. The severity of IRRs was graded according to the Common Terminology Criteria for Adverse Events version 5.0. For IRR onset timing, the observation period was set at 48 h post-administration, based on prior studies referenced in the Darzquro® Appropriate Use Guide (16).

Statistical analysis. Data of cases with missing values were retained in the overall dataset to maximize data utilization. For each statistical analysis, only patients with available data for the relevant variable were included (available-case analysis), and no imputation methods were applied. Continuous variables are expressed as the median (minimum-maximum). Variables included in the univariate analysis were those reported as risk factors for IRRs associated with DARA and other monoclonal antibodies, considered clinically relevant, evaluated in related studies, or included to account for potential heterogeneity in baseline patient characteristics within the study population (9-12,17-21). Fisher's exact test was used to compare categorical variables in the patients' backgrounds. The Mann-Whitney U test was used to compare the median values of continuous variables. The significance level was set at $P<0.05$. All statistical analyses were conducted using IBM SPSS Statistics ver. 29 (Armonk, New York, USA).

Results

Patient background. Table I presents the baseline characteristics of the 65 patients included in the analysis at the initiation of DARA treatment. Among them, 32 were men and 33 were women, with a median age of 69 (range: 41-93) years. The cohort included 5 patients with amyloidosis and 60 with MM. All patients received dexamethasone, acetaminophen, and diphenhydramine as premedications before DARA-SC administration. Montelukast was administered to 53 (81.5%) patients.

Incidence of IRRs. Table II summarizes the incidence of IRRs. IRRs occurred in 10 (15.4%) patients. The severity was grade 1 in six patients and grade 2 in four patients. The reported symptoms included fever (n=4), headache (n=2), chills (n=1), itching (n=1), nasal discharge (n=1), nausea/vomiting (n=1), transient vision loss (n=1), dizziness (n=1), and facial flushing (n=1) (some patients experienced multiple symptoms).

The median time to IRR onset was 10 h (range: 0.5-46 h), with three patients experiencing delayed IRRs (onset after

Table I. Patient (n=65) characteristics.

Characteristic	Group	Value
Age, years (range)	Median	69 (41-93)
Sex	Man	32
	Woman	33
Weight, kg (range)	Median	56.6 (35.6-89.0)
Diagnosis	Multiple myeloma	60
	AL amyloidosis	4
	Renal amyloidosis	1
Type of myeloma	IgG	31
	BJ	14
	IgA	11
	IgD	1
	IgM	1
	Non-secretary	1
	Unknown	6
No. of treatment lines, line (range)	Lines	2 (1-8)
Regimen	DLd	37
	DPd	11
	DBd	6
	DKd	5
	D-CyborD	5
	DVMP	1
Premedication	Dexamethasone	65
	Acetaminophen	65
	Diphenhydramine	65
	Montelukast	53
ISS	I	17
	II	15
	III	13
	Unknown	20

BJ, Bence Jones protein; DLd, daratumumab, lenalidomide, dexamethasone; DPd, daratumumab, pomalidomide, dexamethasone; DBd, daratumumab, bortezomib, dexamethasone; DKd, daratumumab, carfilzomib, dexamethasone; D-CyborD, daratumumab, cyclophosphamide, bortezomib, dexamethasone; DVMP, daratumumab, bortezomib, melphalan, prednisolone; ISS, International Staging System.

24 h). Table III shows the relationship between patient age and time to IRR onset. Among patients who developed IRRs within 24 h, 28.6% (2 out of 7) were aged ≥ 70 years, whereas among those with IRR onset after 24 h, 66.7% (2 out of 3) were aged ≥70 years. Fisher's exact test showed no significant difference (P=0.33), although a tendency toward a higher incidence of delayed IRR was observed in older patients.

Analysis of IRR risk factors. Univariate analysis was performed to identify the risk factors for IRR occurrence (Table IV). The only significant risk factor identified was a history of allergies (P=0.04). No significant association was observed with montelukast use (P=0.27) or with the duration of steroid administration (1 vs. 2 days, P=0.44). Owing to the limited cohort size and the small number of events in the IRR group (n=10), we could not perform multivariable logistic regression analysis to fully adjust for potential confounding factors such as age, underlying comorbidities, and concomitant medications.

Discussion

The IRR incidence in this study was 15.4%, which was similar to that reported in the COLUMBA trial (12.7%) and Japanese subgroup analysis (16.7%) (3,14). Recent studies have reported even lower IRR incidences, ranging from 2.9 to 4% (13,17). However, these differences may be attributed to variations in the observation period. For instance, the COLUMBA trial monitored patients for up to 48 h to detect delayed IRRs (16). In contrast, the shorter observation periods in other studies (3-5 h) may have resulted in IRR underreporting (13,17). Beyond the observation period, several other factors might have contributed to the higher incidence observed in our study. First, ethnic predispositions may play a role. The Japanese

Table II. IRR expression status (n=10).

IRR expression	Value
Grade	
I	6
II	4
III	0
Symptoms (including duplicates)	
Fever	4
Headache	2
Chills	1
Itching	1
Nasal discharge	1
Nausea and vomiting	1
Transient vision loss	1
Dizziness	1
Facial flushing	1
Median time to IRR onset, h (range)	10 (0.5-46)
Within 24 h	7
24-48 h	3

IRR, infusion related reaction.

Table III. Patient age and time to IRR onset.

Age (years)	Time to IRR onset (h)
74	0.5
70	4
62	6
64	10
69	10
46	10
63	24
78	29
63	30
74	46

IRR, infusion related reaction.

subgroup analysis of the COLUMBA trial highlighted a median onset of IRRs (27.5 h) notably later than that indicated by global data, which suggests a unique pharmacokinetic or immunological response pattern in this population. Second, the difference may stem from the rigor of symptom reporting. In our clinical practice, even Grade 1 symptoms are meticulously recorded and managed, whereas such minor events might be under-reported or categorized differently in some trial environments. Furthermore, variations in premedication protocols might explain the lower incidence in previous studies. For instance, De Novellis *et al* (13) administered dexamethasone not only as a premedication but also on the day following DARA-SC injection. In contrast, in our study, only 57% of patients received corticosteroids for 2 days. This extended steroid coverage likely suppressed delayed cytokine release and inflammatory responses, potentially accounting for the exceptionally low IRR rate. Nevertheless, the overall IRR incidence with DARA-SC remains low, with most cases being grade 1 or 2, which is consistent with our findings.

In this study, the median time to IRR onset was 10 h, with an observation period of 48 h. Other trials reported varying medians: 27.5 h (COLUMBA Japanese subgroup), 3.8 h (PLEIADES), and 3.2 h (APOLLO), with varying onset times. Most IRRs occurred on the first day of administration. In this study, the time to IRR onset also showed a similar trend to that reported previously: 60% IRRs occurred on the day of administration, and 70% occurred within 24 h. Previous reports have not examined the age at IRR onset. Although the number of analyzable cases was limited, a higher proportion of older patients experienced delayed-onset IRRs. Therefore, the possibility of delayed IRR onset in older patients should be considered during post-administration monitoring.

In this study, univariate analysis of collectable background factors revealed that participants with a history of allergies were more likely to develop IRR. This finding is similar to the results of the DARA-IV trial (12). A similar trend has been observed with other monoclonal antibodies in the same drug class as DARA, such as rituximab (18) and cetuximab (19), which share similar drug structures. A history of allergies has been identified as a risk factor for IRR. However, this finding should be interpreted cautiously because of the limited cohort size and lack of adjustment for potential confounding factors.

Studies on rituximab and obinutuzumab have identified several IRR predictors, including elevated soluble interleukin-2 receptor (sIL-2R), LDH, and absolute lymphocyte counts (20,21). These factors, along with B symptoms and bulky disease, suggest that a higher tumor burden and more advanced disease state correlate with increased IRR risk due to enhanced cytokine release.

In this study, the use of a leukotriene receptor antagonist (LTRA, montelukast) did not significantly reduce the incidence of IRR. This is consistent with previous reports on DARA-IV (11,12). Although the incidence of IRR was slightly reduced with DARA-SC administration accompanied by LTRA premedication, LTRA was not recognized as a significant protective factor (13). Regarding other premedications, Padmaraju *et al* (17) reported that the type and duration of premedication have little effect on IRR occurrence. The Darzquro® Proper Use Guide (16) recommends the use of oral corticosteroids after administration to reduce delayed IRR. However, in the short-term comparison of steroid administration examined in this study, no significant difference was observed in the delayed IRR occurrence rate. Among patients who developed IRR, the sample size for those with delayed-onset IRR was quite small, limiting statistical power. Further investigation is also needed regarding the type and dose of steroids, as well as the duration of postmedication medication.

Some limitations of the study should be considered: This was a single-center study with a limited sample size. Owing to the retrospective nature of the work, all patient data, including allergy history data, were obtained from medical records without direct patient interviews. Accordingly,

Table IV. Univariate analysis.

Characteristics	IRR (n=10)	Non-IRR (n=55)	P-value	(Refs.)
Male, n (%)	5 (50.0)	27 (49.1)	0.61[a]	-
Allergy history, n (%)	9 (90.0)	31 (56.4)	0.04[a]	(12,18,19)
Montelukast premedication, n (%)	7 (70.0)	46 (83.6)	0.27[a]	(9,10)
Duration of Dexamethasone 2 days use, n (%)	5 (50.0)	32 (58.2)	0.44[a]	(16)
Multiple myeloma, n (%)	10 (100.0)	50 (91.0)	0.42[a]	-
Previous peripheral blood stem cell transplantation, n (%)	3 (30.0)	11 (20.0)	0.37[a]	-
History of immunomodulatory drugs use, n (%)	5 (50.0)	21 (38.2)	0.36[a]	-
History of proteasome inhibitors use, n (%)	7 (70.0)	27 (49.1)	0.19[a]	-
No. of therapy lines, n (range)	2 (1-6)	2 (1-8)	0.47[b]	-
Age, years (range)	67 (46-78)	69 (41-93)	0.40[b]	-
Body weight, kg (range)	55.8 (42.1-83.4)	56.8 (35.6-89.0)	0.64[b]	-
Median white blood cells levels, $10^3/\mu$l (range)	3.80 (2.14-9.05)	4.53 (1.59-15.10)	0.28[b]	-
Median neutrophil levels, $10^3/\mu$l (range)	2.04 (0.88-6.43)	2.59 (0.33-13.86)	0.20[b]	-
Median hemoglobin levels, g/dl (range)	10.1 (7.9-12.6)	10.7 (6.7-16.8)	0.51[b]	(12)
Median lymphocyte levels, $10^3/\mu$l (range)	1.38 (0.50-1.99)	1.40 (0.04-10.00)	0.64[b]	(20)
Median platelet levels, $10^4/\mu$l (range)	20.4 (11.4-50.3)	19.2 (1.6-50.4)	0.31[b]	-
Median serum creatinine levels, mg/dl (range)	0.78 (0.47-1.14)	0.85 (0.24-9.43)	0.19[b]	-
Median creatinine clearance, ml/min (range)	68.2 (40.0-106.9)	59.6 (10.5-136.5)	0.21[b]	-
Median serum lactate dehydrogenase levels, U/l (range)	211 (147-302)	183 (93-554)	0.17[b]	(21)
Median albumin levels, g/dl (range)	3.7 (2.5-5.0)	3.5 (0.8-5.5)[c]	0.29[b]	-
Median serum calcium levels, mg/dl (range)	9.7 (9.4-10.9)	9.6 (8.5-13.5)[d]	0.10[b]	-
Median β2-microglobulin levels, mg/dl (range)	2.9 (1.5-4.3)[e]	3.1 (1.6-89.8)[f]	0.41[b]	-

[a]Fisher's exact test; [b]Mann-Whitney U test. [c]n=53; [d]n=54; [e]n=4; [f]n=41. IRR, infusion related reaction.

undocumented or incompletely documented IRRs may not have been captured, potentially introducing information bias. There are no standardized diagnostic criteria for IRRs, making assessments based on medical records challenging. In addition, underlying comorbidities were not systematically evaluated because of the limited sample size and small number of IRR events, which restricted the number of variables that could be meaningfully analyzed. Therefore, residual confounding due to unmeasured comorbidities cannot be excluded and may have influenced the observed associations. Patients with both MM and amyloidosis were included, and we were not able to evaluate potential differences between these populations. Although DARA-SC is used to manage both MM and amyloidosis, there are apparent differences between the diseases. MM is primarily characterized by the proliferation of neoplastic plasma cells in the bone marrow, presenting with CRAB (Calcium level increase, Renal dysfunction, Anemia, Bone lesions) findings such as bone lesions and anemia. In contrast, in amyloidosis, the abnormally produced light chains are deposited in organs as amyloid fibrils, causing damage to multiple organs, including the heart and kidneys. Furthermore, there are differences in the transcriptional profiles related to the differentiation stage of tumor cells; MM exhibits characteristics closer to peripheral blood plasma cells and newborn bone marrow plasma cells, whereas AL is shown to be more similar to lymphoid tissue-derived plasma cells (22). Amyloidosis is an extremely rare disease. Although it might be possible to secure sufficient number of patients to stratify amyloidosis based on incidence (23) by extending the study period by several years, new treatments could be developed during that time, rendering DARA-SC obsolete. The development of both MM and amyloidosis is based on the proliferation of neoplastic plasma cells, and they have a common feature that the tumor cells exhibit abnormalities in the transcriptional programs corresponding to the developmental process of normal plasma cells. Therefore, as DARA-SC is effective against both diseases-which are caused by the same plasma cells-by targeting the same CD38 antibody, we considered them to be related diseases and included amyloidosis in the analysis. We could not perform multivariable logistic regression analysis owing to the limited cohort size and small number of events in the IRR group (n=10). This statistical limitation constrains the generalizability and robustness of our conclusions; therefore, the identified risk factors should be interpreted as exploratory.

All cases of IRR in patients administered DARA-SC were mild. A history of allergies and older age may be related to IRR occurrence and delayed onset, respectively. Careful monitoring after the first DARA-SC administration may be particularly important in patients with a history of allergies and in older patients, considering the possibility of delayed-onset IRRs.

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Availability of data and materials

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

Authors' contributions

YI, KT, FI, NY, FT, MY and SK designed the study. KT, FI, NY and FT collected clinical data. YI, KT, FI and NY confirmed the authenticity of all raw data. YI, FI, NY, MY and SK performed statistical analysis. YI, KT and SK validated and visualized the study. YI, KT, MY and SK wrote the first draft of the manuscript. YI, KT, FI, NY, FT, MY and SK critically revised the manuscript and provided valuable feedback. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Gifu Municipal Hospital Clinical Research Review Board (approval No. 836) and the Ethics Committees of Gifu Pharmaceutical University (approval No. 6-10) and complied with the Ethical Guidelines for Medical Research Involving Human Subjects. The accumulated patient data were used after allowing patients to refuse to participate with an opt-out form. The requirement for informed consent was waived owing to the retrospective nature of this study.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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