

Real world data of carfilzomib once weekly dosing in patients with relapsed and refractory multiple myeloma: single center experience

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ABSTRACT

Aims: Relapsed or refractory multiple myeloma (RRMM) remains a therapeutic challenge due to treatment resistance, comorbidities, and limited options after multiple therapy lines. Carfilzomib, a second-generation proteasome inhibitor, has demonstrated efficacy when administered once weekly at 70 mg/m² in combination with dexamethasone (wKd70), offering a convenient and effective alternative to twice-weekly schedules. We conducted a retrospective analysis of 32 RRMM patients treated with wKd70 between 2018 and 2023 at a single referral center.

Methods: Thirty-two RRMM patients were analyzed retrospectively. Patients with RRMM who received at least one course of carfilzomib at a dose of 70 mg/m² (administered on days 1, 8, and 15 of 28-day cycles) in combination with dexamethasone 40 mg/week were included in the study.

Results: The median age was 57.5 years (range: 43-75), and patients had received a median of three prior therapy lines. The overall response rate (ORR) was 62.1%. Median progression-free survival (PFS) was 16 months, and median overall survival (OS) was 51 months. Prior autologous stem cell transplantation was associated with significantly improved PFS and OS. Adverse events were common but mostly mild (grades 1-2) forms.

Conclusion: Our findings support wKd70 as an effective and well-tolerated treatment option for RRMM, even in heavily pretreated patients. The favorable survival outcomes compared to historical trials suggest a role for earlier use of this regimen.

Keywords: RRMM, carfilzomib, dexamethasone, progression free survival, autologous stem cell transplantation

INTRODUCTION

Quadruplet therapies, including an anti-CD38 monoclonal antibody, are the standard of care for patients with newly diagnosed, transplant-eligible or ineligible multiple myeloma (MM). In the relapsed refractory setting, the situation is more complex and depends on various factors, including prior therapies, the patient's performance status, comorbidities, and access to novel drugs or cellular therapies.¹

Carfilzomib is an irreversible proteasome inhibitor approved both as a single agent and in combination with dexamethasone or lenalidomide for relapsed refractory MM (RRMM).² In the phase Ib/II CHAMPION trial, the maximum tolerated dose of once-weekly carfilzomib was established at 70 mg/m², resulting in an overall response rate

(ORR) of 77 % and a median progression-free survival (PFS) of 12.6 months.³ The phase III ARROW trial demonstrated that once-weekly carfilzomib at 70 mg/m² was superior to twice-weekly carfilzomib at 27 mg/m² regarding PFS and ORR, without increased toxicity.⁴ Once-weekly dosing offers fewer hospital visits without sacrificing efficacy, making it a popular regimen, especially during the COVID-19 pandemic and thereafter.^{5,6}

In this study, we analyzed the retrospective outcomes of RRMM patients treated with once-weekly carfilzomib at 70 mg/m² in combination with dexamethasone (wKd70), as followed up in a referral hospital of a faculty of medicine.

METHODS

The research protocol was approved by the Ethics Committee for Non-drug and Non-medical Device Researches at Marmara University Faculty of Medicine (Date: 24.02.2025, Decision No: 09.2024.1292). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. Thirty-two RRMM patients followed by the department of hematology between 2018 and 2023 were analyzed retrospectively. Clinical and follow-up data were obtained from medical records. Patients with RRMM who received at least one course of carfilzomib at a dose of 70 mg/m² (administered on days 1, 8, and 15 of 28-day cycles) in combination with dexamethasone 40 mg/week at our institution after 2018 were included in the study. Patients who received carfilzomib at doses other than 70 mg/m² or those who received carfilzomib in combination with lenalidomide and dexamethasone were excluded. Patient demographics, disease characteristics, response to wKd70, and adverse event profiles were analyzed.

Genetic abnormalities, such as t(4;14), t(14;16), and deletion of 17p determined by fluorescence in situ hybridization (FISH), along with a complex karyotype identified through cytogenetics, were categorized as high-risk genetics. PFS was calculated from the date of wKd70 initiation to the date of documented disease relapse/progression or the date of death, whichever occurred first. Overall survival (OS) was calculated from the date of wKd70 initiation to the date of death from any cause or for surviving patients, censored at their last known alive visit. Response to wKd70 was assessed according to the International Myeloma Working Group (IMWG) criteria.⁷ Treatment-emergent adverse events (TEAEs) were analyzed from medical records and graded according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

Statistical Analysis

All data analyses were performed using IBM SPSS for Windows version 20.0 (SPSS, Chicago, IL, USA). Kolmogorov-Smirnov and Shapiro-Wilk tests were used to assess the assumption

of normality. Continuous variables were presented based on normal distribution as mean±standard deviation or (in cases of non-normal distribution) as median (25th-75th percentile). Categorical variables were summarized as counts (percentages). Comparisons of continuous variables between groups were conducted using the Mann-Whitney U test and the Kruskal-Wallis test, given that the normality assumption did not hold. The Kaplan-Meier method was utilized for survival analysis. Associations between continuous variables were determined using Spearman correlation analysis, while the association between two categorical variables was examined using the Chi-square test. All statistical analyses were carried out with a significance level of 5%, considering a two-sided p-value <0.05 as statistically significant.

RESULTS

A total of 14 female and 18 male patients with RRMM who received wKd70 were retrospectively analyzed. The median age was 57.5 years (range: 43-75 years). The characteristics of the patients at the initiation of wKd70 are summarized in Table 1. IgG kappa and IgG lambda were the most frequent MM subtypes, respectively. International Staging System (ISS) scores were distributed as follows: 1-37.5%, 2-25%, and 3-37.5%. More than half of the patients exhibited standard-risk genetic abnormalities, while 12.5% were classified in the high-risk group; however, results were missing or not available for 9 patients. Twenty-five patients had at least one comorbid disease. Approximately one-third of the patients presented with extramedullary plasmacytoma, among 9 patients with extramedullary disease, 6 (66.6%) had paraosseous plasmacytoma and 3 had true extramedullary soft tissue involvement. The median number of prior therapy lines was three (range: 1-6). Only 9.7% of patients had received an anti-CD38 monoclonal antibody prior to wKd70. Autologous stem cell transplantation (ASCT) was performed in 87.5% of the patients in previous lines of treatment.

Response assessments were conducted in 22 patients at the time of data analysis; the 10 patients not analyzed were either receiving their first two courses of wKd70 or had discontinued

Table 1. Characteristics of patients at wKd70 initiation					
Characteristics	Number (n)	Frequency (%)	Characteristics	Number (n)	Frequency (%)
Age (years)	Median 57.5 (43-75)		Number of previous lines	Median 3 (1-6)	
Gender			Previous antiCD38 exposure		
Male	18	56.3	Absent	28	90.3
Female	14	43.7	Present	3	9.7
MM type			ISS		
Ig G kappa	15	46.9	Stage I	12	37.5
Ig G lambda	4	12.5	Stage II	8	25
Ig A kappa	3	9.4	Stage III	12	37.5
Ig A lambda	3	9.4	Lenalidomide refractorines		
Kappa light	5	15.6	Absent	7	21.9
Lambda light	2	6.3	Present	25	78.1
Extramedullary disease			Genetics		
Absent	23	71.9	Missing	9	28.1
Present	9	28.1	Standard risk	19	59.4
Comorbidity			High risk	4	12.5
			Previous ASCT		
Absent	7	21.9	Yes	28	87.5
Present	25	78.1	No	4	12.5
Total	32	100	Total	32	100

ASCT: Autologous stem cell transplantation, Ig: Immunoglobulin, MM: Multiple myeloma, ISS: International Staging System

therapy for various reasons. Response to wKd70 was available in 22 patients, with a median duration of wKd70 treatment of 12 months. Half of the patients exhibited a partial or greater response (see Table 2). Cytogenetic factors, lenalidomide refractoriness, the number of previous lines of therapy, and the presence of extramedullary disease were not associated with wKd70 response. Patients with a complex karyotype or those lacking cytogenetic data showed more progressive disease compared to patients with standard cytogenetics, though this difference was not statistically significant.

The majority of patients experienced both hematological and non-hematological adverse events with wKd70, though the severity was primarily mild (grades 1-2). Thrombocytopenia and anemia were the most pronounced hematological adverse events. Three patients discontinued carfilzomib due to toxicities, two of them were due to grade 3 pneumonia, and one was due to grade 3 neuropathy, while 17 patients discontinued due to disease progression. The median duration of follow-up was 20 months (range: 3-85 months), and 19 patients were alive at the time of data analysis. The median PFS was 16 months, with PFS rates at 2 and 5 years being 27.3% and 7.8%, respectively. The median OS was 51 months, with OS rates at 2 and 5 years being 62.6% and

33.7%, respectively. There was no association between gender, ISS stage, cytogenetic status, the number of previous lines of therapy, and PFS or OS. Only patients who had received ASCT exhibited longer PFS and OS compared to those who had not (Table 3).

DISCUSSION

This retrospective analysis of patients with RRMM receiving wKd70 therapy contributes valuable insights into the treatment's effectiveness and safety profile. Our cohort, comprising 14 female and 18 male patients with a median age of 57.5 years, presents characteristics consistent with the typical RRMM population, including a significant proportion of individuals with standard-risk genetic abnormalities. Notably, the ISS scores were evenly distributed between stages 1 and 3, with 37.5% of patients falling into each category. These demographic and clinical traits highlight the heterogeneity of RRMM and underscore the importance of personalized treatment approaches.

The study demonstrated that patients received a median of three prior therapy lines, implying that the cohort had undergone considerable therapeutic interventions. A

Table 2. Efficacy and safety analysis of wKd70

Parameter	Number (n)	Frequency (%)	Parameter	Number (n)	Frequency (%)
Carfilzomib response					
VGPR	10	31.3	Number of carfilzomib cycles	Median 12 (1-84)	
PR	6	18.3			
SD	4	12.5			
PD	2	6.3			
N/A	10	31.3			
Hematological AE			Non-hematological AE		
Absent	4	12.5	Absent	5	15.6
Present	28	87.5	Present	27	84.4
Anemia			Cause of carfilzomib discontinuation		
Grade 1	13	40.6	Progression	17	53.1
Grade 2	12	37.5	Toxicity	3	9.4
Grade 3	5	15.6	Ongoing	12	37.5
Grade 4	2	6.3			
Thrombocytopenia			Duration of follow-up on carfilzomib (months)	Median 20 (3-85)	
Grade 1	9	28.1			
Grade 2	16	50.0			
Grade 3	5	15.6			
Grade 4	2	6.3			
Total	32	100	Total	32	100

AE: Adverse event, VGPR: Very good partial response, PR: Partial response, SD: Stable disease, PD: Progressive disease, NA: Not applicable

Table 3. Univariate analysis of association of wKd70 response and subgroups

Parameter	N/A n (%)	VGPR n (%)	PR n (%)	SD n (%)	PD n (%)	p
Cytogenetics						
Unknown	3 (30)	3 (30)	2 (33.7)	0 (0)	1 (50)	0.193
Standard	6 (60)	7 (70)	4 (66.7)	2 (50)	0 (0)	
High risk	1 (10)	0 (0)	0 (0)	2 (50)	1 (50)	
Lenalidomide refractoriness						
Absent	1 (10)	4 (40)	1 (16.7)	0 (0)	1 (50)	0.298
Present	9 (90)	6 (60)	5 (83.3)	4 (100)	1 (50)	
Extramedullary disease						
Absent	7 (70)	6 (60)	6 (100)	2 (50)	2 (100)	0.337
Present	3 (30)	4 (40)	0 (0)	2 (50)	0 (0)	
Number of previous line						
1	1 (10)	0 (0)	1 (16.7)	0 (0)	0 (0)	0.868
2	5 (50)	2 (20)	1 (16.7)	1 (25)	0 (0)	
3	2 (20)	5 (50)	2 (33.3)	2 (50)	1 (50)	
≥4	2 (20)	3 (30)	2 (33.3)	1 (25)	1 (50)	

Fisher's Exact test, p<0.05 statistical significant. VGPR: Very good partial response, PR: Partial response, SD: Stable disease, PD: Progressive disease, NA: Not applicable

minority of patients had previously been treated with an anti-CD38 monoclonal antibody, which may indicate the evolving treatment landscape and the potential for leveraging new agents in combination therapies. The high percentage (87.5%) of patients undergoing ASCT prior to wKd70 aligns with established treatment protocols and emphasizes the role of ASCT in managing RRMM.

Regarding treatment responses, we observed that half of the patients achieved at least a partial response to wKd70, with response data available for 22 individuals. This suggests that wKd70 is an effective treatment option for this cohort, despite a relatively high rate of prior therapies. Interestingly, factors such as cytogenetic abnormalities, lenalidomide refractoriness, and extramedullary disease were not significantly associated with response rates. This finding suggests that wKd70 may offer consistent efficacy across diverse patient profiles, although the absence of significant statistical findings calls for further investigation into the influence of these variables. Our cohort exhibited an ORR of 62.1%, similar to the ARROW trial, but the distribution of responses was different.⁴ None of our patients achieved CR, while 7% in the ARROW trial did. Most of our patients achieved VGPR, slightly surpassing the original cohort. This discrepancy can be explained by the higher proportion of advanced disease of ISS stage 3 patients in the ARROW trial.^{4,8} The Korean group reported higher ORRs of 71.1%, but the intensity of responses was not mentioned.⁹ The Japanese group reported an ORR comparable to our cohort, with partial responses comprising the majority of responses, similar to our patients. Despite these differences, the ORR reported in the Japanese study was 66.1%, surpassing our observed response rate of 62.6%.¹⁰ Earlier introduction of carfilzomib in treatment regimens has been linked to better response rates, further supported by various studies.^{11,12} While only one patient in our cohort received wKd70 as second-line therapy, 17.5% of patients in the Japanese study received this same treatment as second-line therapy, highlighting potential differences in treatment strategies among regions. Another prospective multicenter observational study of 300 patients with RRMM from Asia Pacific region reported an ORR of 54.5% for patients receiving Kd but dose of carfilzomib was not detailed suggesting biweekly dosing schema that requires discontinuation of therapy by the 18th cycle. Mean age at carfilzomib initiation was 66.3 years. Patients with high risk genetic abnormalities constituted 37.7% of total cohort and the frequency of ISS stage 3 patients was 26.3%.¹³

Our cohort exhibited a median PFS of 16 months, which is a notably longer duration compared to the 11.2 months reported in the phase 3 ARROW trial for patients receiving once-weekly carfilzomib.⁴ Moreover subgroup analysis of the ARROW trial demonstrated a similar median PFS of 12.2 months in patients younger than 65 years old.⁸ This difference in median PFS may be attributed to demographic variations in the patient populations, as a larger proportion of standard-risk patients were included in our study. Specifically, only 20% of participants in the ARROW trial were classified as standard risk, while 59.4% of our retrospective cohort fell into this category. The variance in outcomes may also be influenced by the age distribution of the studied populations, with a median age of 66 years in the ARROW trial compared to our cohort's median age of 57 years. This younger demographic in

our study likely correlates with a better overall performance status, which may lead to improved treatment responses.

Similar trends are observed in other studies involving Kd70 therapy. For instance, a recent evaluation from four referral centers in Korea reported a shorter median PFS of 5.6 months, despite also having a median age of 66 years.⁹ The dose of carfilzomib was biweekly 56 mg/m² in a majority of patients but a subset of patients received wKD70 after May 2021 in this trial. This cohort included a higher proportion of high-risk genetic abnormalities (18.4%), which may explain the decreased survival compared to both the ARROW trial and our cohort. Their definition of high-risk status relied solely on the presence of t(4;14) or t(14;16), while our criteria included additional factors such as deletion 17p by FISH and complex karyotype analyses.

Moreover, another retrospective study assessing treatment adherence and effectiveness in carfilzomib-based regimens reported a median PFS of 13.4 months among patients receiving Kd, although the specific dosing of carfilzomib was not detailed.¹⁴ In contrast, the Japanese observational study indicated a median PFS of 9.5 months among 120 RRMM patients.¹⁰ The higher percentage of high-risk patients (29.2%) in the Japanese cohort and a median age of 70 years likely contributed to less favorable outcomes compared to our younger cohort, which had a lower proportion of high-risk patients. Furthermore, fewer patients in Japanese study had previously undergone ASCT compared to our cohort, a factor that has been associated with longer PFS and OS in our analysis. Median time to progression was 23.7 months in Kd group in the prospective observational trial from Asia Pacific region.¹³

The median OS of 51 months, along with 2- and 5-year OS rates of 62.6% and 33.7%, reflects favorable long-term outcomes. In the ARROW trial median follow up for OS was 13.2 months and the data was immature at the interim analysis. Median OS was reported to be of 24 months by Park et al.⁹ and was 41.6 months by Quach et al.¹³ whereas it was not reached in Abe et al.'s¹⁰ study. Notably, patients who had undergone ASCT exhibited considerably longer PFS and OS, reinforcing the established premise that ASCT remains a critical determinant of survival in RRMM patients.

Safety data revealed that while adverse events were common, they were primarily of mild severity (grades 1-2). Thrombocytopenia and anemia were the most frequently reported hematological adverse events, which underscores the need for vigilant monitoring during treatment. The discontinuation of therapy primarily due to disease progression rather than toxicity illustrates the treatment's overall tolerability in this patient population. Any grade adverse events occurred in 93% of our cohort, comparable to the ARROW study.⁴ Treatment-related adverse events leading to treatment discontinuation occurred in 9.4% of our patients, whereas it was 8% in the ARROW trial. Anemia and thrombocytopenia were the most frequent hematological adverse events in our group, with anemia being the most prevalent in the ARROW trial. In the Korean study, the total frequency of any grade adverse events was not mentioned, but neutropenia and lymphopenia were the most reported hematological adverse events.⁹ The Japanese group reported

an incidence of adverse events leading to discontinuation of 21.7%, which was higher than our rates. The most frequent hematological adverse events in this cohort were thrombocytopenia and anemia, similar to our findings.¹⁰ Asia Pacific group also reported a rate of 7.9% for adverse events leading to discontinuation.¹³

Limitations

Our study has several limitations that should be acknowledged. First, only a small proportion of patients had previously received anti-CD38-based induction therapy, which may limit the generalizability of our findings to contemporary treatment settings where anti-CD38-containing regimens are increasingly used. The relatively low use of anti-CD38-based induction therapy in our cohort largely reflects the treatment landscape and reimbursement policies during the study period. In addition, the retrospective, single-center design and the relatively small sample size may have introduced selection bias and limited the statistical power of the study. Finally, the absence of a direct comparison with the conventional twice-weekly 27 mg/m² carfilzomib regimen precludes definitive conclusions regarding the comparative efficacy and safety of the once-weekly schedule. The retrospective nature of our study also limits the accurate reporting of adverse events, and the lack of standardized records makes comparison difficult. Limited number of patients is also a disadvantage but most of the literature discussed above are composed of multicenter data compared to our single center records.

CONCLUSION

As a result, this study provides compelling evidence that wKd70 therapy is associated with meaningful treatment responses and a manageable safety profile in a diverse cohort of RRMM patients. Future research should aim to validate these findings in larger, multi-center studies and explore the optimally sequencing of wKd70 with other novel therapies, particularly in patients with high-risk disease characteristics.

ETHICAL DECLARATIONS

Ethics Committee Approval

The research protocol was approved by the Ethics Committee for Non-drug and Non-medical Device Researches at Marmara University Faculty of Medicine (Date: 24.02.2025, Decision No: 09.2024.1292).

Informed Consent

This retrospective study used pre-existing anonymized patient data. No additional intervention was performed, and there was no direct patient contact. The study was approved by the Ethics Committee, and the requirement for written informed consent was waived by the ethics committee.

Peer Review Process

This manuscript was subject to external peer review.

Conflict of Interest

The authors declare no conflicts of interest related to this study.

Financial Disclosure

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Author Contributions

Concept: MUM, ATT; Design: MUM, ITS, ATT; Control: MUM, ITS, FA; Data Collection and Processing: ITS, FA, SS, AMY, OC, DD, HGG, AFY, TT, IA; Analysis and Interpretation: MUM, ITS, FA; Literature Review : MUM, ITS, FA, SS, AMY, OC, DD, HGG, AFY, TT, IA; Article Writing: MUM; Critical Review: MUM, ITS, ATT.

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