GILEAD | Medical Information

Veklury® (remdesivir) Real-World Mortality Data

This document is in response to your request for information regarding Veklury® (remdesivir [RDV]) and real-world mortality data. This response was developed according to principles of evidence-based medicine and only contains data from large, retrospective real-world studies (N≥50,000) that were published in peer-reviewed journals and included patients infected with COVID-19 during the Omicron-predominant variant of concern (VOC) period to present.

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The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.

Summary

Real-World Data on RDV Use and Mortality

A retrospective comparative effectiveness cohort study during the Omicron VOC (December 2021–February 2024) analyzed data from the PINC AI Healthcare Database to assess all-cause in-hospital 14- and 28-day mortality rates in patients who received RDV treatment within 2 days of hospital admission vs patients who received no RDV treatment during hospitalization. Cohorts of adults, patients aged ≥65 years, and patients with COVID-19 pneumonia were assessed; patients were further categorized by whether they did or did not require supplemental O_2 support.[1]

- A total of 56,170 adult patients who received RDV within the first 2 days of hospitalization (age ≥65 years, n=39,715; COVID-19 pneumonia, n=36,385) were PS-matched 1:1 to 56,170 patients who did not receive RDV during hospitalization.
- The 14- and 28-day mortality rates, when adjusted for differences in baseline and clinical covariates, were significantly lower among patients who received RDV compared with those who did not receive RDV; these results were consistent across all cohorts regardless of supplemental O_2 requirement (each, $P<0.0001$).

Real-World Data on RDV Use and Mortality

US PINC AI Healthcare Database: PS-Matched Cohort Study[1]

Study design and demographics

A retrospective, comparative effectiveness cohort study analyzed data from the PINC AI Healthcare Database (formerly the Premier Healthcare Database) to assess all-cause

in-hospital mortality in patients who received RDV treatment within 2 days of hospital admission vs patients who received no RDV treatment during hospitalization. Data from adult patients with a primary discharge diagnosis of COVID-19 that was also present on admission during the early Omicron period (December 2021–December 2022) or late Omicron period (January 2023–February 2024) were included in the analysis. Exclusion criteria included the following: pregnancy, incomplete data, death or discharge within 2 days of admission, transfer to or from another hospital, transfer from hospice, admission to the hospital for an elective procedure, use of extracorporeal membrane oxygenation at admission, or initiation of RDV >2 days after hospital admission. Patients in the RDV cohort received ≥1 dose of RDV during the first 2 days of admission, whereas those in the non-RDV cohort did not receive RDV during their hospitalization. The number of RDV doses received was not reported.

The primary outcome was 14- and 28-day all-cause inpatient mortality (defined as a discharge status of “expired” or “hospice”). Cohorts of adults aged ≥18 years, patients aged ≥65 years (overall, aged 65–75 years, 75–84 years, and ≥85 years), and patients with COVID-19 pneumonia were analyzed; patients were further categorized by requiring no supplemental O_2 support and requiring supplemental O_2 support.

After 1:1 PS matching, 56,170 adult patients who received RDV within the first 2 days of hospitalization (age ≥65 years, n=39,715; COVID-19 pneumonia, n=36,385) were matched to 56,170 patients who did not receive RDV during hospitalization (Table 1). The absolute standardized differences for baseline covariates between the RDV and non-RDV groups were <0.15.

Table 1. Baseline Demographics and Disease Characteristics: PS-Matched Cohort (Mozaffari et al)[1]

Key Demographics and Characteristics		RDV (n=56,170)	Non-RDV (n=56,170)
Age, n (%)	18–49 years	4325 (7.7)	4325 (7.7)
	50–64 years	10,875 (19.4)	10,875 (19.4)
	≥65 years	40,970 (72.9)	40,970 (72.9)
Female, n (%)		28,735 (51.2)	28,718 (51.1)
Race, White/Black/Asian/other, %		77/14/2/7	76.7/14.2/2/7.1
Ethnicity, Hispanic/Non-Hispanic/unknown, %		7.9/85.7/6.4	8.2/85.4/6.4
Omicron period, %	Early	72	72
	Late	28	28
Baseline comorbidities, %	Cardiovascular disease	88.3	88.3
	Diabetes mellitus	39.5	39.5
	COPD	36.5	36.2
	Renal disease	30.9	31.4
	Obesity	28.2	28.4
	Immunocompromising condition	17	17.1
	Cancer	7.2	7.1
Other treatments at baseline, %	Corticosteroids	77.8	77.8
	Anticoagulants	74.6	74.6
	Baricitinib	5.9	6
	Tocilizumab	3	3
	Oral antivirals	0.3	0.3

Key Demographics and Characteristics		RDV (n=56,170)	Non-RDV (n=56,170)
Baseline O_2 requirements, n (%)	No supplemental O_2	27,704 (49.3)	27,704 (49.3)
	LFO	17,682 (31.5)	17,682 (31.5)
	HFO/NIV	9277 (16.5)	9277 (16.5)
	Invasive mechanical ventilation	1507 (2.7)	1507 (2.7)

Abbreviations: COPD=chronic obstructive pulmonary disease; HFO=high-flow O_2; LFO=low-flow O_2; NIV=noninvasive ventilation.

Mortality outcomes

The unadjusted mortality rates at 14 and 28 days were numerically lower in the RDV group compared with the non-RDV group (Table 2).

Table 2. Unadjusted 14- and 28-Day Mortality Rates by Cohort for the Entire Omicron Period (Mozaffari et al)[1]

Cohort	O_2 Status	14-Day Mortality, %		28-Day Mortality, %	
		RDV	Non-RDV	RDV	Non-RDV
Adults	**Overall**	**7.2**	**9**	**9.5**	**11.5**
	No supplemental O_2	4.5	5.6	5.7	6.8
	Supplemental O_2	9.8	12.3	13.2	16
Age ≥65 years	**Overall**	**8.1**	**10.5**	**10.5**	**13**
	No supplemental O_2	5.3	6.7	6.7	8
	Supplemental O_2	11.2	14.7	14.6	18.5
COVID-19 pneumonia	**Overall**	**9.1**	**11.3**	**12.4**	**14.9**
	No supplemental O_2	5.7	7.4	7.7	9.4
	Supplemental O_2	11.4	14	15.6	18.6

After adjusting for differences in baseline and clinical covariates, mortality risk was significantly lower at Day 14 and Day 28 in patients who received RDV than in those who did not across all cohorts and regardless of supplemental O_2 use (Table 3). Mortality rate estimates were adjusted in a Cox proportional hazards model according to age, month of admission, intensive care unit vs general ward at admission, and time-varied treatments coadministered at baseline (eg, baricitinib, tocilizumab, and oral antivirals).

Table 3. Adjusted 14- and 28-Day Mortality by Cohort for the Entire Omicron Period (Mozaffari et al)[1]

Cohort	O_2 Status	aHR (95% CI)[a]		*P*-Value
		14-Day Mortality	28-Day Mortality	
Adults	**Overall**	**0.77 (0.73–0.81)**	**0.79 (0.75–0.83)**	**<0.0001**
	No supplemental O_2	0.75 (0.69–0.82)	0.77 (0.72–0.83)	<0.0001
	Supplemental O_2	0.76 (0.72–0.81)	0.79 (0.74–0.83)	<0.0001
Age ≥65 years[b]	**Overall**	**0.75 (0.71–0.79)**	**0.77 (0.74–0.81)**	**<0.0001**
	No supplemental O_2	0.75 (0.69–0.81)	0.79 (0.73–0.85)	<0.0001
	Supplemental O_2	0.73 (0.69–0.78)	0.75 (0.71–0.8)	<0.0001
COVID-19 pneumonia	**Overall**	**0.78 (0.74–0.82)**	**0.8 (0.76–0.85)**	**<0.0001**
	No supplemental O_2	0.74 (0.67–0.81)	0.77 (0.71–0.84)	<0.0001
	Supplemental O_2	0.79 (0.74–0.84)	0.81 (0.76–0.86)	<0.0001

Abbreviation: aHR=adjusted hazard ratio.
[a]For comparisons of RDV treatment vs no RDV treatment.
[b]Results by age subcategory (65–74 years, 75–84 years, and ≥85 years) were consistent with the results reported here for the overall group aged ≥65 years.
Note: Findings by early and late Omicron periods were consistent with the results for the entire Omicron period.

Sensitivity analyses performed using inverse probability of treatment weighting that compared RDV initiation within the first 2 days of hospital admission vs no RDV initiation in the first 2 days were consistent with the overall results.

Additional safety outcomes were not reported.

Reference

1. Mozaffari E, Chandak A, Berry M, et al. Management of Vulnerable Patients Hospitalized for COVID-19 With Remdesivir: A Retrospective Comparative Effectiveness Study of Mortality in US Hospitals. *Clin Infect Dis.* 2024;79(Suppl 4):S137-S148.

Abbreviations

O_2=oxygen
PINC AI=Premier Inc. Artificial Intelligence
PS=propensity score
RDV=remdesivir
VOC=variant of concern

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Veklury US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

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