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Impact of most promising Ebola therapies on survival: a secondary analysis during the tenth outbreak in the Democratic Republic of Congo

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Abstract

Background MAb114, REGN-EB3, Remdesivir, and ZMapp, which are monoclonal antibody-based treatments, have been compared and shown to be promising therapies against the Ebola Virus Disease (EVD). There has been no comparison between these medications and standard treatment (without antiviral). Our study aimed to examine the contribution of each regimen compared to standard treatment on the survival of EVD patients and assess whether this association was modified by EVD vaccination (rVSV-ZEBOV Ebola vaccine) status. Methodology: We performed a secondary analysis study using retrospective cohort data obtained from four EVD treatment centers located in Katwa, Mangina, Butembo, and Beni in the North Kivu region. The main outcome measure was mortality within a 28-day period among 781 included patients. A Cox model was used to identify predictors of survival in hospitalized EVD patients. Results: Vaccinated EVD patients were 1.7 times less likely to die compared to unvaccinated patients (3.70 days vs. 5.00 days; $p=0.0002$). Delaying care and treatment at EVD treatment centres increased mortality risk by 5% for each day following symptom onset. Compared to the standard treatment group, adjusted mortality rates were significantly reduced in the groups receiving MAb114 (0.27, $p<0.001$), REGN-EB3 (0.26, $p<0.001$), and Remdesivir (0.38, $p=0.005$). ZMapp also showed a reduction, though with borderline statistical significance (0.47, $p=0.032$). Conclusions: Prompt identification and treatment, along with enhanced supportive care (such as replenishing fluids and electrolytes and managing symptoms), significantly improve survival chances. Concurrently, administering vaccines and using mAb114, REGN-EB3, and, to some extent, Remdesivir further increase patient survival rates.

Keywords Promising therapies, Ebola virus disease, ZMapp, Remdesivir, REGN EB3, mAb114, Secondary analysis, Survival

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Background

The late 20th century and early 21st centuries have highlighted the personal and communal burden as well as the scientific and societal challenges posed by emerging infectious diseases, predominantly zoonotic and highly pathogenic in humans [1]. These viruses, an example of which is Ebola Virus Disease (EVD), cause severe infections with high mortality rates (50–90%) and can significantly spread from person to person [2, 3].

Central Africa has experienced numerous outbreaks of EVD due to the fact that its ecosystem supports the establishment of various ecological niches for zoonotic illnesses. In 2021, Africa witnessed around 28 occurrences of EVD, as reported by Tshiani et al. [4]. As of 11 June 2024, the Democratic Republic of Congo (DRC) is currently facing 16 outbreaks of EVD, with 8 provinces having already been affected by these epidemics. Between 1976 and 2022, there were a total of 4744 documented cases of EVD, resulting in 3207 deaths. This gives us an overall case–fatality rate of 67.6%, as stated in unpublished data. From 2018 to 2020, the most extended and lethal outbreak of EVD took place in the three provinces of North Kivu, South Kivu, and Ituri; this outbreak had a case–fatality rate of 66% [5].

Several most promising medications, including the triple monoclonal antibody ZMapp, the antiviral agent Remdesivir, the triple monoclonal antibody REGN-EB3, and the single monoclonal antibody MAb114, have undergone testing to treat this condition. These four medications were used during the tenth EVD outbreak in the DRC. Some of them have proven to be effective in treating patients who are suspected or confirmed to have EVD. This represents a significant milestone in the treatment of EVD when used alongside other preventive measures [6].

ZMapp was assessed in a randomized, controlled trial (RCT) and appeared to be beneficial, although the results did not satisfy the preset statistical threshold necessary to be considered effective [7]. The posterior probability that ZMapp plus the current standard of care was superior to the current standard of care alone was 91.2%. The overall 28-day crude mortality was 15% points lower among those assigned to ZMapp plus the current standard of care than among those assigned to the current standard of care alone (22% vs. 37%), which corresponds to a 40% lower relative risk of death with ZMapp. However, this outcome fell short of the prespecified 97.5% probability for superiority. A probability of 97.5% or more (akin to a one-sided type I error rate of 2.5%) was required to establish efficacy. An EVD RCT evaluated the safety and effectiveness of ZMapp, Remdesivir, REGN EB3, and MAb114, using the ZMapp group as control [8]. At 28 days, death had occurred in 61 of 174 patients (35.1%) in the MAb114 group, as compared with 84 of 169 (49.7%) in the ZMapp group ($P = 0.007$), and in 52 of 155 (33.5%) in the REGN-EB3 group, as compared with 79 of 154 (51.3%) in the ZMapp subgroup ($P = 0.002$). It was found that both MAb114 and REGN-EB3 were superior to ZMapp in reducing mortality from EVD. Due to ethical considerations, the trial did not assess the efficacy of these regimens against standard supportive treatment.

In the absence of comparisons to a standard treatment (supportive care without antiviral), it is impossible to determine if any of them are superior to the standard treatment or whether the observed effect is a result of the treatment itself or an external cause. Participants in this study also received an EVD vaccine (rVSV-ZEBOV Ebola vaccine), and the impact of the vaccine may have influenced the observed results. Does the comparison between these medicines and the standard treatment rely exclusively on statistical analysis, or do some of these pharmaceuticals fail to offer any further advantage in terms of survival compared to conventional treatment?

This secondary analysis aimed to examine the contribution of each regimen compared with the standard treatment on the survival of EVD patients and to assess whether the association between treatment type and survival rate was modified by vaccine status.

Materials and methods

Data

This is a study that examined existing data from the National Institute of Public Health (NPHI); we used secondary data obtained from four EVD treatment centers (ETCs) located in Katwa, Mangina, Butembo, and Beni in the North Kivu region. This analysis exclusively encompasses cases that were thoroughly reviewed and confirmed by the response team and that were subsequently admitted to an ETC. The timeframe for this analysis spans from 1 August 2018 to 14 February 2020. Furthermore, only cases that have explicit information regarding the treatment type and duration of observation in the patient's record or database were considered. A total of 7,028 cases were admitted to the four ETCs, with 5,928 being non-cases (cases that did not turn out to be EBV, but another illness) and 1,100 being confirmed cases. Out of the total of 1,100 confirmed cases, 822 received targeted treatment (Mab114, REGN-EB3, Remdesivir or ZMapp), 55 cases of No EVD-specific treatment and did not participate in the RCT for several reasons, and 223 cases had an unknown treatment status (see Fig. 1).

We used pre-existing data gathered from multiple ETCs, encompassing comprehensive information regarding the alert, such as ID number, alert number, age, gender, occupation, address, date of symptom onset, contact information, vaccination status, treatment particulars, date of treatment initiation, types of treatment administered, and end point (death, discharge, or end of the

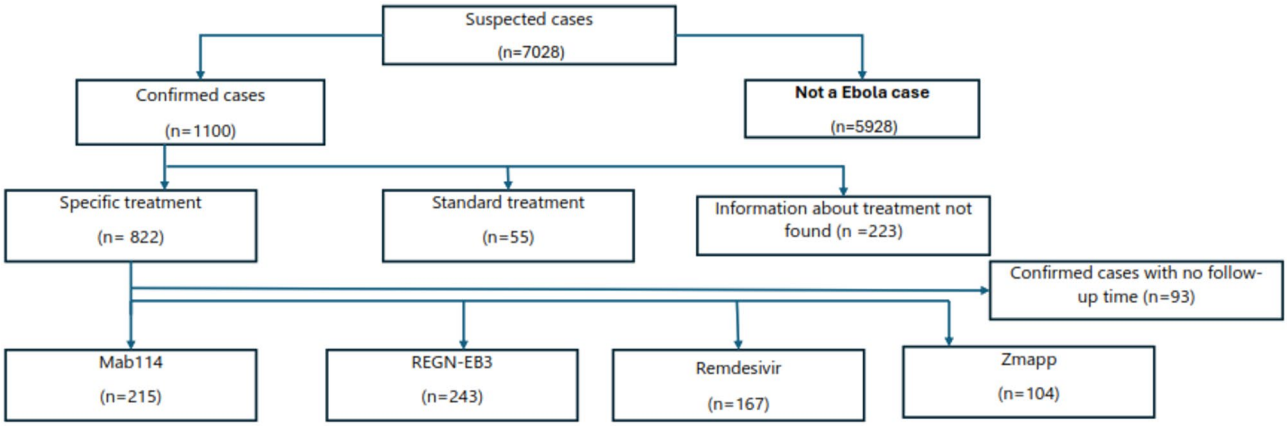

Fig. 1 Diagram illustrating the structure of our sampling

study). The data were transcribed into the Viral Hemorrhagic Fever (VHF) database, which utilizes an Epi-info input mask, and were subsequently exported to Excel and then to Stata for analyses.

Analysis

After inputting the database into Excel, we proceeded to export it to Stata version 17 (Stata Corp, College Station, TX, USA) for the purpose of processing, categorization, and analysis. Proportions and confidence intervals were computed for all the categorical variables. Quantitative variables were used to calculate the medians and interquartile ranges. The duration of follow-up for each patient was determined to start from the hospital admission. Descriptive data were used to characterize the EVD patients affected in each group.

The Kaplan–Meier method enabled us to analyze the likelihood of survival based on the duration between hospital admission and the occurrence of the final event (either death or the end of observation), while considering the presence of censored data. The main outcome measure was mortality within a 28-day period, which was utilized to compare our findings with a prior investigation involving the same group of patients [8]. The Wilcoxon test allowed us to compare survival curves based on predictors, while the Cox model was used to identify predictors of survival in patients hospitalized with EVD. To assess how the association between survival and treatment group might differ according to vaccine status, an interaction term between the treatment group and vaccine status was included in the Cox multivariable model, and the log-likelihood ratio test was used to assess its significance. If it was found to be insignificant, then this term was removed in the final model. Mortality rates (hazard ratios) were adjusted for patient's age, time from onset of illness to admission, gender, profession, vaccine status and treatment group.

The proportionality test based on Schoenfeld residuals verified compliance with the assumption of the proportionality of risks (refer to S1 Table). The Test of proportional hazards shown that the assumption was not violated as presented in S1 Fig. Overall, we would conclude that the final model fits the data very well (refer S2 Fig). We observed that the danger function roughly aligns with the 45-degree line, except for instances with longer time values. In summary, we can confidently state that the final model accurately aligns with the data. We evaluated the presence of multicollinearity by examining variance inflation factors (VIFs) (refer to S2 Table) that exceeded a threshold of 1.42. The tests were conducted using a two-tailed approach, with a confidence level of 95%; a result was deemed statistically significant if the p-value was less than 0.05.

Ethical considerations

This study was authorized by the Ministry of Public Health, Hygiene, and Prevention, which includes the National Institute of Public Health (NPHI), who considered the fundamental ethical principles of respect for people, beneficence, and justice. This study was carried out in accordance with the principles outlined in the Helsinki Declaration. The secondary analysis received approval from the ethics committee of the Kinshasa School of Public Health (reference number: ESP/CE/72B/2023). The study subjects were not subject to any invasive procedures, and we did not have any direct interaction with them. All patient data were analyzed anonymously and confidentially. The principal investigator maintained the electronic and physical records in a secure location, with password-protected access for the computer.

Results

During the specified time frame, a total of 1064 patients diagnosed with EVD were included in the study. A total of 283 patient records, which had incomplete information on treatment status and/or duration of follow-up, were eliminated from the study. This resulted in 781 records that satisfied the requirements for analysis, 73% of the initial total. In general, the patients who were removed from the analyses were comparable to those who were included in terms of age distribution (with an average age of 31 years), gender (with 54% being female), and profession (with 5% being health professionals). Nevertheless, the patients who were omitted from the analysis were more inclined to be non-vaccinated. Among them, only 6% were vaccinated, while 20% of the patients included in the analysis were vaccinated. Table 1 displays the characteristics of patients who were included and excluded in the analysis.

Out of the 781 individuals analyzed, approximately 31% were treated with REGN-EB3, 27% received MAb114, 21% were given Remdesivir, and 13% received a ZMapp-based regimen. Only 7% of the individuals included in the study had exclusively received the standard treatment. Vaccinated individuals had a shorter interval between admission and the onset of initial symptoms of a brief illness compared to non-vaccinated patients (3.70 days vs. 5.00 days; $p = 0.0002$).

The patients included in the studies exhibited a comparable age and gender distribution. The duration from the disease's commencement to admission was the same in the groups who underwent the novel treatment (promising treatment) but was significantly longer in the group that only received the standard treatment. Most patients who were healthcare professionals had not received the standard treatment. Patients who received the No EVD-specific treatment exhibited a lower vaccination coverage in comparison to the other groups, as seen in Table 2.

Predictors of mortality among cases of EVD

In this analysis, it was found that, among the patients with EVD, those who had received the vaccine were 1.7 times less likely to die compared to those who had not received the vaccine (relative risk: 0.59). A prolonged delay in receiving treatment (measured as the time elapsed from the onset of sickness to admission, in days) increased the likelihood of early mortality in patients, while a longer duration of symptoms prior to therapy correlated with significantly poorer outcomes. The

Table 1 Characteristics of patients included in and excluded from the analyses

	Excluded		Included		Overall		*p*
	n	%	*n*	%	*n*	%	
Age (mean ± SD)	31.03 ± 17.28		29.34 ± 16.24		29.82 ± 16.55		0.124
Gender							0.205
Female	173	54.2	455	58.3	628	57.1	
Male	146	45.8	326	41.7	472	42.9	
Total	319	100.0	781	100.0	1100	100.0	
Profession**							0.058
Others	301	94.4	701	89.8	1002	91.1	
Health professionals	16	5.0	69	8.8	85	7.7	
Butcher/religious leader	2	0.6	11	1.4	13	1.2	
Total	319	100.0	781	100.0	1100	100.0	
Type of treatment *							< 0.001
No EVD-specific treatment	0	0.0	55	7.0	55	6.3	
MAb114	32	33.3	214	27.4	246	28.1	
REGN-EB3	17	17.7	242	31.0	259	29.5	
Remdesivir	37	38.5	167	21.4	204	23.3	
ZMapp	10	10.4	103	13.2	113	12.9	
Total	96	100.0	781	100.0	877	100.0	
Vaccine status *							< 0.001
Not received	79	43.2	391	53.9	470	51.7	
Received	11	6.0	150	20.7	161	17.7	
Unknown	93	50.8	185	25.5	278	30.6	
Total	183	100.0	726	100.0	909	100.0	
Patient status *							< 0.001
Alive	98	34.6	462	59.2	560	52.6	
Deceased	185	65.4	319	40.8	504	47.4	
Total	283	100.0	781	100.0	1100	100.0	

*: there was missing information; SD: standard deviation; **: occupations classified according to the exposure risk

Table 2 Demographic and clinical characteristics on admission of patients included in the analyses, by treatment group

	No EVD-specific treatment		MAb114		REGN-EB3		Remdesivir		ZMapp		Overall		*p*
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	
Age (mean ± SD)	30.19		26.90		28.42		30.87		28.41		29.82		0.230
Time from onset of illness to admission (days)	8.84 **		4.71		4.82		5.17		4.75		5.13		< 0.001
Gender													0.504
Female	35	63.6	127	59.1	141	58.0	101	60.5	53	51.0	457	58.3	
Male	20	36.4	88	40.9	102	42.0	66	39.5	51	49.0	327	41.7	
Total	55	100.0	215	100.0	243	100.0	167	100.0	104	100.0	784	100.0	
Profession													0.019
Others	53	96.4	183	85.1	223	91.8	149	89.2	96	92.3	704	89.8	
Health professionals	1	1.8	26	12.1	19	7.8	18	10.8	5	4.8	69	8.8	
Butcher/religious leader	1	1.8	6	2.8	1	0.4	0	0.0	3	2.9	11	1.4	
Total	55	100.0	215	100.0	243	100.0	167	100.0	104	100.0	784	100.0	
Days from admission to initiation of specific treatment													0.003
Same day			149	69.6	147	60.7	101	60.5	81	78.6	478	65.8	
Not de same day			65	30.4	95	39.3	66	39.5	22	21.4	248	34.2	
Vaccine status*													0.008
Not received	27	81.8	88	44.4	127	54.0	86	54.8	63	61.2	391	53.9	
Received	3	9.1	47	23.7	46	19.6	34	21.7	20	19.4	150	20.7	
Unknown	3	9.1	63	31.8	62	26.4	37	23.6	20	19.4	185	25.5	
Total	33	100.0	198	100.0	235	100.0	157	100.0	103	100.0	726	100.0	
Patient status*													< 0.001
Alive	6	10.9	150	70.1	164	67.8	90	53.9	52	50.5	462	59.2	
Deceased	49	89.1	64	29.9	78	32.2	77	46.1	51	49.5	319	40.8	
Total	55	100.0	214	100.0	242	100.0	167	100.0	103	100.0	781	100.0	

*: there was missing information; SD: standard deviation. **: The post hoc test indicated a significant difference between this group and the others

mortality risk escalated by 5% every day following the onset of symptoms that the patient failed to present at the treatment facility. The mortality rate decreased in the MAb114, Remdesivir and REGN-EB3 groups compared to patients who received «No EVD-specific treatment», as shown in Table 3.

Discussion

This study aimed to assess the patient survival rate of four promising therapies (MAb114, REGN-EB3, Remdesivir, and ZMapp) compared to standard supportive treatment «No EVD-specific treatment. Adjusted patient survival rates were highest with MAb114 and REGN-EB3, followed by Remdesivir. The ZMapp group showed a reduction, albeit with borderline statistical significance.

Vaccinated patients had a lower-case fatality rate than non-vaccinated individuals, confirming findings from Neil et al.'s study [9]. Findings from the WHO indicate that the efficacy of the vaccine in preventing EVD onset ten days or more after vaccination is 97.5%, and its efficacy in preventing EVD onset at any time is 88.1% [10]. Out of the 726 patients included in this analysis, 150 (28% of 541) reported being vaccinated, based on the available information. Vaccinated patients were more likely to enroll in the respective studies used for our analysis sooner after experiencing symptoms and generally had more positive prognostic characteristics at the beginning of the studies. This suggests a connection between vaccination and the tendency to seek medical attention promptly, which in turn led to improved outcomes.

An unfavorable therapeutic response was linked to delayed therapy initiation after symptom onset (a 5% increase in mortality risk for each day that symptoms persisted before therapy initiation). Thus, the duration between the onset of the disease and admission to the treatment center was a reliable indicator of mortality risk. Patients receiving standard treatment were hospitalized 8.84 days after the initial manifestation of symptoms and had a case-fatality rate of 89.1%. These statistics emphasize the necessity of raising community awareness regarding the correlation between early diagnosis, prompt treatment, and improved survival rates. Our results align with findings reported by Malvy et al. [11] who suggested considering cultural factors is crucial for establishing trust within communities.

The high efficacy of MAb114 and REGN-EB3 compared to ZMapp and Remdesivir in this analysis may partially explained by the fact that MAb114 and REGN-EB3 were administered as single doses, while ZMapp and Remdesivir required multiple infusions [8], which may have been delayed due to staff shortages or other operational barriers.

It is worth noting that 97% of deaths in this study occurred within ten days of enrollment. While most baseline characteristics were similar among the five groups, patients who received the standard treatment had a lower vaccination rate (9%) compared to the other

Table 3 Predictors of mortality among EVD cases included in the analyses

	n	Duration *	Event**	Death Incidence /1000 Patient-Day	Hazard Ratio *			
					Crude	*p*	Adjusted	*p*
Age							1.01	0.179
Time from onset of illness to admission (days)							1.05	< 0.001
Gender								
Female	457	4888	198	40.5	1		1	
Male	327	3742	121	32.3	0.82	0.116	0.85	0.209
Profession								
Others	704	7685	298	38.8	1		1	
Health professionals	69	812	19	23.4	0.63	0.060	0.88	0.657
Butcher/religious leader	11	133	2	15.0	0.41	0.205	0.46	0.276
Vaccine status								
Not received	391	4317	170	39.4	1		1	
Received	150	1888	40	21.2	0.55	0.001	0.57	0.003
Unknown	185	2072	77	37.2	0.94	0.694	0.99	0.997
Harm								
No EVD-specific treatment	55	98	49	500.0	1		1	
MAb114	215	2566	64	24.9	0.20	< 0.001	0.27	< 0.001
REGN-EB3	243	2878	78	27.1	0.21	< 0.001	0.26	< 0.001
Remdesivir	167	1915	77	40.2	0.31	< 0.001	0.38	0.005
ZMapp	104	1173	51	43.5	0.37	< 0.001	0.47	0.032
Total	**784**	**8630**	**319**	**37.0**				

*: duration in days **: death

The survival benefits reported in the MAb114 and REGN-EB3 groups, relative to patients who received «No EVD-specific treatment», are verified in Figs. 2 and 3 below

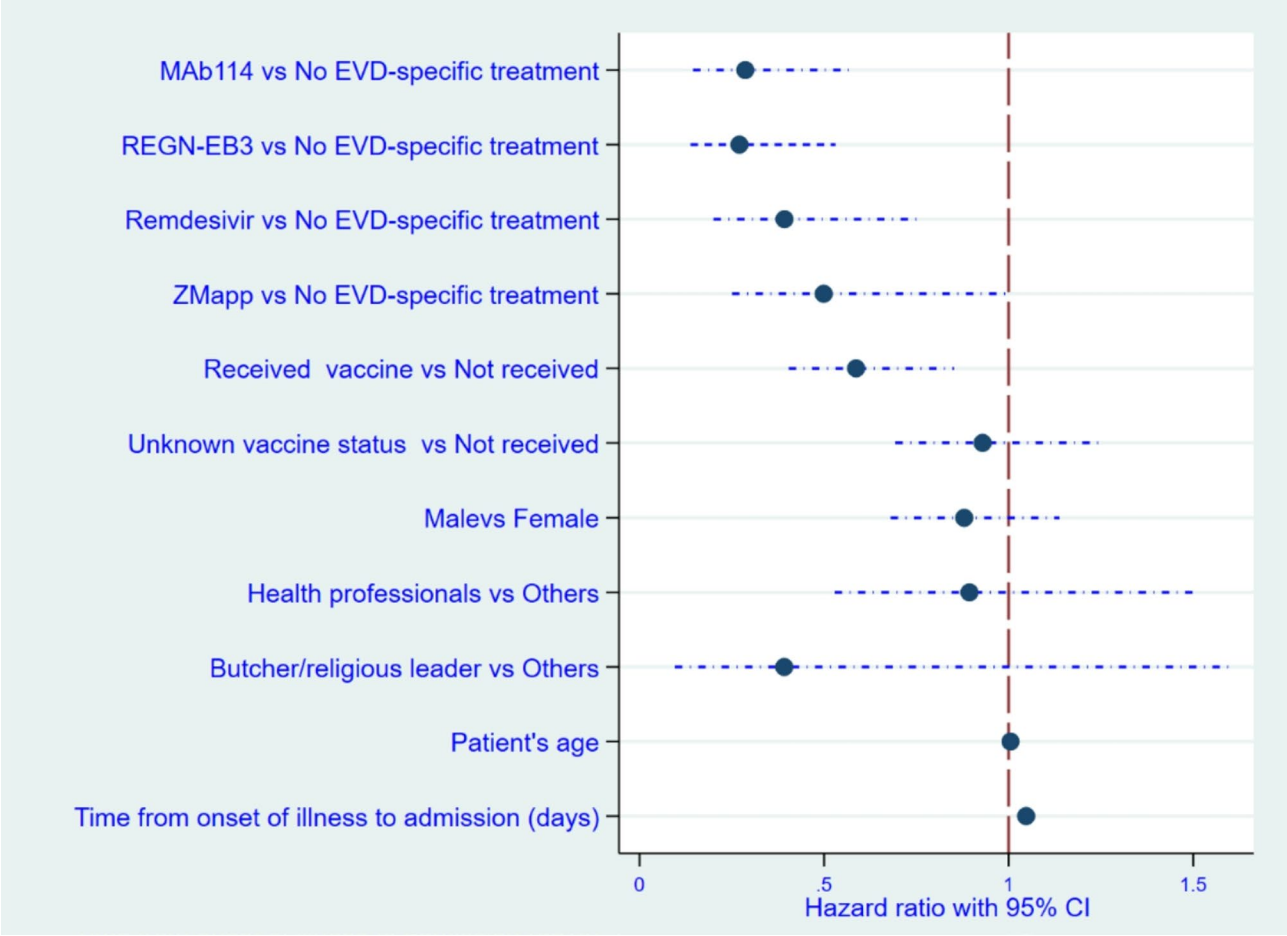

Fig. 2 Predictors of survival in EVD patients

four groups. Additionally, patients who received Remdesivir began treatment slightly later than the other groups, suggesting that these patients may have been more ill on average. This disparity in health status could potentially account for the study's findings.

Remdesivir underwent clinical trials for Ebola in 2014 but did not demonstrate sufficient efficacy to be considered an effective treatment for Ebola infection [7]. While the administration of ZMapp seemed to improve survival rates, the outcome did not meet the predetermined statistical threshold required to be deemed effective [7].

Nevertheless, the trial played a crucial role in facilitating additional research on monoclonal antibodies as potentially effective treatments for EVD. Our analysis, which has important limitations inherent to its design, lends support to the findings that showed efficacy of REGN-EB3 and mAb114 in reducing mortality in patients with EVD and provides further support for the updated guidelines by the World Health Organization [12].

This secondary analysis had limitations due to the use of previously collected data. Challenges included incomplete or even erroneous information. These results are additionally constrained by the patient's self-reported vaccination status. Since the primary trial did not consider vaccination status in randomization, conclusive statements about its impact on mortality cannot be made. This was not possible to describe what "No EVD-specific treatment" group receive and whether or patients receive supportive care in the same way to different patients and across different treatment centers. The issue is that those who receive an EVD-specific treatment may also be more likely to receive better supportive care than those who do not receive and this can influence the study outcome. The high mortality rate observed in the "No EVD-specific treatment" group, which falls within the upper range of most Case Fatality Rate (CFR) values found in the West Africa EVD epidemic, raises concerns about the representativeness of this group and suggests a potentially dismal prognosis among them. Nevertheless, this analysis is unable to provide further information. The absence of data from laboratory tests, such as viral load, poses challenges in interpreting our Cox regression results, as these metrics are crucial for assessing disease

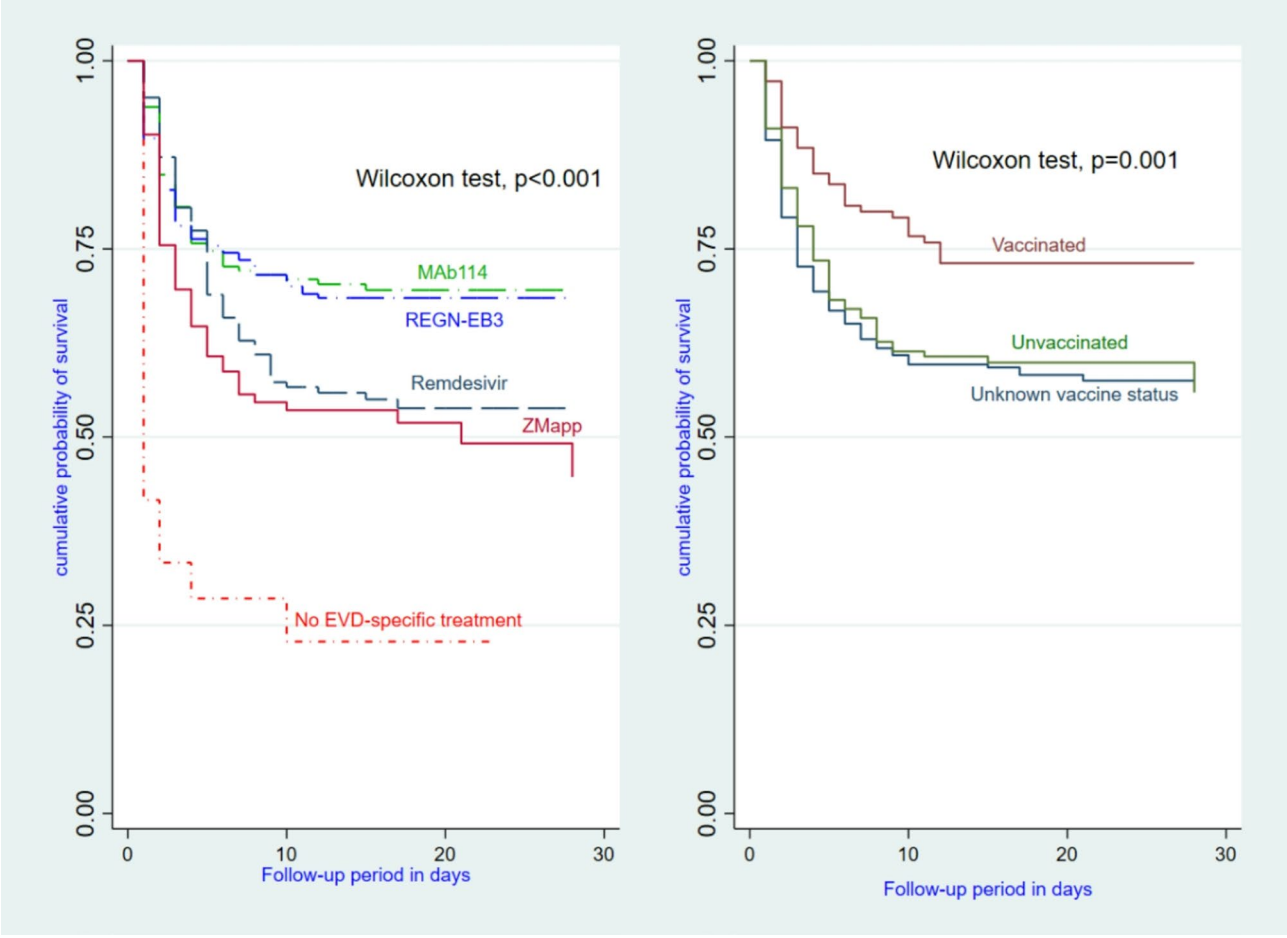

Fig. 3 Survival of EBV patients according to vaccination status and treatment group

stage and severity. Additionally, other factors that could affect treatment outcomes were not considered, such as genetics, lifestyle, literacy level, or region-specific factors.

Conclusions

The DRC experienced its eleventh outbreak of the Ebola virus since its initial identification in 1976. The outbreak occurred in a region affected by armed conflict, adding challenges to containment and management. Historical instances of Ebola outbreaks and actions taken demonstrated that prompt identification and treatment, together with enhanced supportive care (including replenishing fluids and electrolytes and addressing symptoms), significantly enhance survival chances. Today, administering vaccines and using mAb114, REGN-EB3, and, to some extent, Remdesivir will further enhance patient survival rates. Our analysis underscores the critical importance of consistently using EVD vaccines during every outbreak, guaranteeing an ample vaccine supply, maintaining a strategic reserve of mAb114 or REGN-EB3, enhancing public awareness about seeking prompt medical attention at the onset of symptoms.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12985-025-02766-y.

Supplementary Material 1

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Author contributions

EKM and APZ.; methodology, EKM and APZ.; software, EKM and APZ.; validation, EKM, TNT and APZ.; formal analysis EKM and APZ.; investigation, EKM.; resources, EKM and APZ.; data curation, EKM and APZ.; writing—original draft preparation, EKM, TNT, and APZ.; writing—review and editing, EKM, TNT, and APZ.; visualization, EKM, TNT and APZ.; supervision APZ project administration, EKM.; funding acquisition, EKM and APZ. All authors have read and agreed to the published version of the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Ethical clearance was obtained from the Ethics Committee of the KSPH (reference number: ESP/CE/72B/2023). Consent was obtained from each respondent during data collection. Privacy and confidentiality were maintained throughout the study.

Consent for publication

All co-authors consented to the publication of the latest version of the present article.

Competing interests

The authors declare no competing interests.

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