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Rapid versus conventional initiation of antiretroviral therapy in patients with HIV/AIDS: A meta-analysis of effectiveness and adherence

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Abstract: A systematic search of PubMed, Web of Science, CNKI, and VIP databases was conducted to identify clinical studies comparing rapid and conventional ART initiation in patients with HIV/AIDS. Two researchers independently performed literature screening and data extraction, and meta-analysis was conducted using Review Manager 5.4 software. A total of 20 clinical studies (19 cohort studies and 1 randomized controlled trial) were ultimately included, comprising 136,192 patients in the rapid initiation group and 234,945 patients in the conventional initiation group. The meta-analysis indicated that the rapid initiation group had a significantly higher viral suppression rate [$RR = 1.04, 95\%CI: (1.01, 1.08), P = 0.01$] compared to the conventional initiation group. Furthermore, the mortality rate [$RR = 0.67, 95\%CI: (0.52, 0.87), P = 0.003$] and loss to follow-up rate [$RR = 0.62, 95\%CI: (0.50, 0.77), P < 0.0001$] in the rapid initiation group were significantly lower than those in the conventional initiation group. Compared with conventional initiation, the rapid ART initiation strategy can significantly improve the viral suppression rate and effectively reduce all-cause mortality and the risk of loss to follow-up among HIV/AIDS patients, demonstrating superior clinical effectiveness and treatment adherence.

1. Introduction

Acquired immunodeficiency syndrome (AIDS) is a systemic disease caused by infection with the human immunodeficiency virus (HIV). Despite continuous advancements in prevention and control, HIV/AIDS remains a formidable global public health challenge[1]. As of 2020, there were approximately 1.05 million people living with HIV (PWH) in China. Over the past decade, HIV management strategies have undergone a paradigm shift; the therapeutic philosophy has evolved from delayed treatment to the implementation of universal and immediate antiretroviral therapy (ART) for all PWH[2]. This strategy is referred to as "rapid ART initiation." The World Health Organization (WHO) defines this approach as initiating treatment within seven days of an HIV

diagnosis, and encourages same-day initiation for patients who are clinically ready[3]. Evidence-based data demonstrate that this strategy effectively accelerates the process of virological suppression and promotes the recovery of immune function[4-6].

The rapid ART initiation strategy has been widely recognized as a core pillar in achieving the Joint United Nations Programme on HIV/AIDS (UNAIDS) "95-95-95" targets (i.e., achieving a 95% diagnosis rate, a 95% ART coverage rate, and a 95% virological suppression rate). Currently, this strategy is extensively recommended by authoritative international guidelines, including those from the WHO, the US Department of Health and Human Services (DHHS), and the European AIDS Clinical Society (EACS)[7, 8]. In alignment with the global consensus on HIV management, China also explicitly recommends in the Chinese Guidelines for Diagnosis and Treatment of HIV/AIDS (2024 Edition) and the National Free Antiretroviral Therapy Manual (2023 Edition) that treatment should be initiated as early as possible within 30 days of diagnosis, while encouraging eligible patients to further shorten the initiation window to within seven days[9, 10].

The theoretical advantage of rapid ART initiation lies in its potential to significantly reduce the risks of severe HIV-related complications and all-cause mortality by intervening before peak viral load[11, 12]. However, with the widespread scale-up of this strategy, significant clinical controversies have emerged regarding its effectiveness and adherence in real-world settings. Regarding effectiveness, although several meta-analyses based on randomized controlled trials (RCTs) have confirmed that rapid initiation helps accelerate virological suppression, no significant improvement in mortality has been observed; consequently, its theoretical "survival benefit" is widely questioned in practice[13-15]. In terms of adherence, existing research conclusions also exhibit notable contradictions. While some clinical evidence suggests that same-day initiation can enhance patient retention in care[16, 17], an observational review published by Ford et al.[13] in 2018 indicated that rushed ART initiation might significantly increase the risk of loss to follow-up due to patients' inadequate psychological preparation. Given the apparent discrepancies between clinical trial findings and real-world study results, this study aims to systematically integrate the latest real-world data to objectively evaluate the differential impacts of rapid versus standard ART initiation on effectiveness and adherence among PWH.

Strictly adhering to the PRISMA guidelines, this study systematically searched major English and Chinese databases and ultimately included 20 clinical studies comparing rapid versus standard ART initiation. By applying the Cochrane systematic review methodology, we conducted a meta-analysis on core indicators, including virological suppression, mortality, and loss to follow-up rates. Ultimately, this study aims to provide high-quality, evidence-based support for optimizing ART initiation strategies for people living with HIV/AIDS.

2. Materials and methods

2.1. Search Strategy

We systematically searched English and Chinese databases, including PubMed, Web of Science, CNKI (China National Knowledge Infrastructure), and VIP. The search strategy combined Medical Subject Headings (MeSH) and free-text terms. Core search terms included "HIV," "Human Immunodeficiency Virus," "Antiretroviral Therapy," "ART," "Rapid," "rapid initiation," "immediate initiation," "effectiveness," and "adherence." The search period was from January 1, 2021, to December 31, 2025, and the language was restricted to English and Chinese articles.

2.2. Inclusion and Exclusion Criteria

Inclusion criteria: (1) Study design: Observational cohort studies evaluating real-world

effectiveness or randomized controlled trials (RCTs) meeting the definition of rapid ART initiation. (2) Interventions: The experimental group received the rapid ART initiation strategy, while the control group received the standard ART initiation strategy. (3) Target population: People living with HIV/AIDS (PWH). (4)Outcome measures: Primary effectiveness indicators included virological suppression and mortality rates; the adherence indicator was the loss to follow-up (LTFU) rate.

Exclusion criteria: (1) Full text unavailable. (2) Duplicate publications or studies with overlapping data sources. (3) Reviews, conference proceedings, case reports, etc. (4) Studies not reporting the outcome measures of interest (e.g., those only reporting the increase in CD4+ T-cell counts). (5)Control group receiving non-standard initiation therapy (e.g., internal comparisons between different rapid initiation regimens).

2.3. Data Collection and Quality Assessment

Two researchers independently screened the literature based on the inclusion and exclusion criteria. In the primary screening, irrelevant articles were excluded by reviewing titles and abstracts. In the secondary screening, full texts were reviewed to determine final inclusion. Any disagreements were resolved through consultation with a third senior researcher. Extracted data primarily included: first author, year of publication, study region, sample size, specific definitions of interventions and controls, baseline characteristics, and outcome data. The Newcastle-Ottawa Scale (NOS) was used to assess the quality of the included cohort studies, with a score of > 6 points considered high quality.

2.4. Statistical Analysis

Meta-analysis was performed using Review Manager 5.4 software. For dichotomous data, the effect size was expressed as the risk ratio (RR) with its 95% confidence interval (CI). Heterogeneity among studies was evaluated using theχ^2 test and the I^2 statistic. If$I^2 < 50\%$and theχ^2test $P > 0.1$, the heterogeneity was considered acceptable, and a fixed-effects model was used for pooled analysis. If$I^2 \geq 50\%$ or theχ^2 test$P \leq 0.1$, indicating significant heterogeneity, a random-effects model was applied. For cases of substantial heterogeneity($I^2 \geq 75\%$), a sensitivity analysis using the leave-one-out method was conducted to assess the robustness of the results. All statistical tests were two-sided, and $P < 0.05$was considered statistically significant.

3. Results

3.1. Literature Search Results

The initial literature search yielded a total of 4,753 relevant records. First, 71 duplicate records were removed using EndNote software. Subsequently, during the primary screening of titles and abstracts, 4,634 irrelevant records were excluded. Finally, a full-text review was conducted on the remaining 48 articles. After strictly applying the inclusion and exclusion criteria to remove ineligible articles, 20 clinical studies were ultimately included. The detailed literature screening process and results are illustrated in Figure 1.

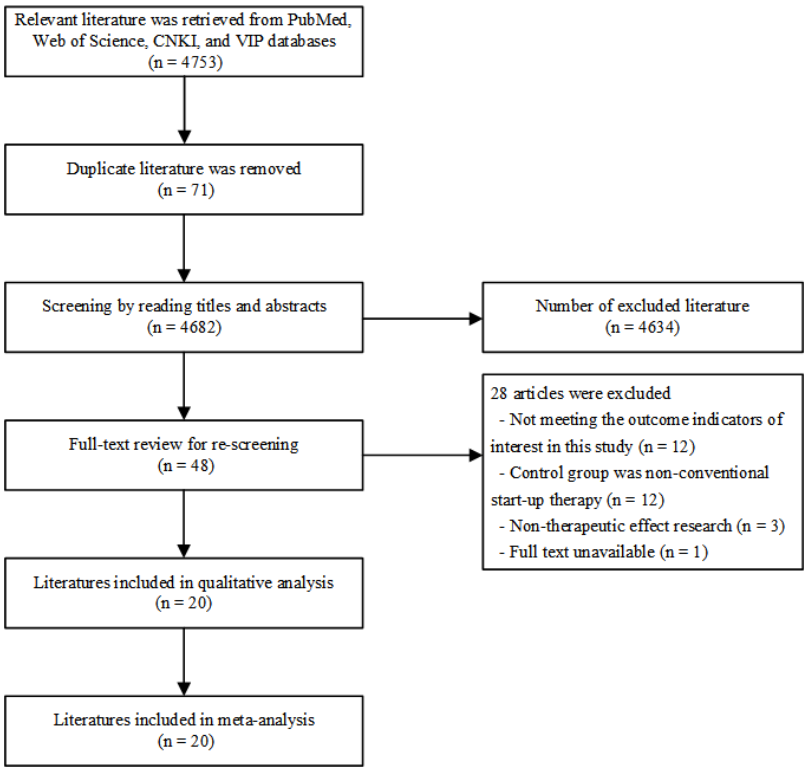


Figure 1: The process and results of literature screening.

3.2. Characteristics of the Included Studies

A total of 20 clinical studies comparing the efficacy of rapid versus standard ART initiation were included in this review, comprising 19 cohort studies and one randomized controlled trial (RCT). In terms of geographic distribution, the majority of the studies were conducted in China (11, 55%), followed by the United States (4, 20%), and other countries such as Thailand (5, 25.00%). Regarding the study populations, seven studies (35%) focused on adult PWH, six (30%) targeted adolescents with HIV, and the remaining seven (35%) did not explicitly specify the population characteristics. Furthermore, the definitions of the timeframe for rapid initiation varied across the studies: seven studies (35%) defined it as within 7 days of an HIV diagnosis, five (25%) as within 14 days, five (25%) strictly as same-day initiation, and the other three (15%) used alternative time definitions. The detailed baseline characteristics of the included studies are summarized in Table 1.

Table 1: Basic characteristics of the included literature.

Study	Year	Country	Study Design	Study Period	Study Population	Time of Initiation		Sample Size	Outcome Indicators			NOS
						Intervention Group (Rapid Initiation Group)	Control Group (Non-Rapid Initiation Group)		MR	VSR	LTFU	
Teeraananchai et al. [18]	2025	Thailand	Retrospective cohort study	Jan 1, 2014 – Dec 31, 2022	Newly diagnosed HIV/AIDS patients aged ≥ 15 years	Within 7 days of HIV diagnosis	8–30 days, 31–90 days, and >91 days after HIV diagnosis	252239	√	√	×	7
Zhang et al. [19]	2025	China	Retrospective cohort study	Jan 1, 2017 – Jun 30, 2022	Newly diagnosed HIV/AIDS patients aged ≥ 18 years	Within 14 days of HIV diagnosis	>14 days after HIV diagnosis	1538	×	√	√	8
Duggan et al. [20]	2025	United States	Retrospective cohort study	Jan–Dec 2015 and Jan–Dec 2017	Newly diagnosed HIV/AIDS patients	Within 3 days of HIV diagnosis	2–4 weeks after HIV diagnosis	59	√	√	√	8
Mauleti et al. [21]	2025	Indonesia	Retrospective cohort study	Jan 1, 2018 – Dec 31, 2022	Newly diagnosed HIV/AIDS patients aged ≥ 18 years	Within 7 days of HIV diagnosis	8–60 days and >61 days after HIV diagnosis	326	√	×	√	8
Wang et al. [22]	2024	China	Randomized clinical trial	Mar 2021 – Jul 2022	Newly diagnosed HIV/AIDS patients aged ≥ 18 years	Within 14 days of HIV diagnosis	>14 days after HIV diagnosis	300	√	√	√	7
Mgbako et al. [23]	2023	United States	Retrospective cohort study	Jan 1, 2018 – Dec 31, 2019	Newly diagnosed HIV/AIDS patients	Day of HIV diagnosis	After the day of HIV diagnosis	107	×	√	×	7

Ross et al. [24]	2023	Sub-Saharan Africa	Retrospective cohort study	From "Treat-All" policy implementation to Jan 2019	Newly diagnosed HIV/AIDS patients aged ≥ 15 years	Day of HIV diagnosis	1–7 days, 8–30 days, and >31 days after HIV diagnosis	29017	√	√	×	8
Eamsakulrat et al. [25]	2022	Thailand	Retrospective cohort study	Jan 1, 2015 – Dec 31, 2017	Newly diagnosed HIV/AIDS patients aged ≥ 18 years	Within 14 days of HIV diagnosis	>14 days after HIV diagnosis	270	√	√	√	8
Kimanga et al. [26]	2022	Kenya	Longitudinal cohort analysis	Second half of 2015 – First half of 2018	Newly diagnosed HIV/AIDS patients aged ≥ 15 years	Within 14 days of HIV diagnosis	>14 days after HIV diagnosis	8592	√	√	√	7
O'Shea et al. [27]	2022	United States	Retrospective cohort study	Jan 2012 – Dec 2016 and Jan 2017 – Feb 2020	Newly diagnosed HIV/AIDS patients	Day of HIV diagnosis	After the day of HIV diagnosis	116	×	√	×	8
Zhao et al. [28]	2022	China	Retrospective cohort study	Jan 1, 2016 – Dec 31, 2019	Newly diagnosed HIV/AIDS patients	Within 7 days of HIV diagnosis	8–30 days and >31 days after HIV diagnosis	2494	×	√	×	8
Bacon et al. [29]	2021	United States	Retrospective cohort study	Jan 1, 2013 – Dec 31, 2017	Newly diagnosed HIV/AIDS patients	Within 5 days of HIV diagnosis	6–30 days, 31–90 days, and >91 days after HIV diagnosis	1148	×	√	×	8
Yang et al. [30]	2021	China	Retrospective cohort study	1995 – 2016	Newly diagnosed HIV/AIDS patients aged ≥ 15 years	Within 3 months of HIV diagnosis	>3 months after HIV diagnosis	11905	√	×	×	7
Yang Bolin et al. [31]	2025	China	Retrospective cohort study	Jan 1, 2016 – Dec 31, 2024	Newly diagnosed HIV/AIDS patients aged ≥ 18 years	Within 7 days of HIV diagnosis	>7 days after HIV diagnosis	3029	×	√	×	8
Xin et al. [32]	2025	China	Retrospective cohort study	Jan 1, 2016 – Dec 31, 2021	Newly diagnosed HIV/AIDS patients aged ≥ 15 years	Day of HIV diagnosis, 1–7 days, and 8–30 days after HIV diagnosis	31–90 days, 91–180 days, and 181–365 days after HIV diagnosis	44244	×	√	×	7
Tian et al. [33]	2024	China	Retrospective cohort study	Jan 2018 – Dec 2022	Newly diagnosed HIV/AIDS patients aged < 18 years	Within 7 days of HIV diagnosis	>7 days after HIV diagnosis	2755	√	√	√	8
Zhai et al. [34]	2024	China	Retrospective cohort study	Apr 1, 2022 – Mar 31, 2023	Newly diagnosed HIV/AIDS patients aged ≥ 18 years	Within 14 days of HIV diagnosis	>14 days after HIV diagnosis	472	√	√	√	8
Zhou et al. [35]	2023	China	Retrospective cohort study	Jan 1, 2018 – Dec 31, 2020	Newly diagnosed HIV/AIDS patients	Within 7 days of HIV diagnosis	>7 days after HIV diagnosis	547	×	√	×	8
Peng et al. [36]	2023	China	Prospective cohort study	Jul 1, 2016 – Dec 31, 2020	Newly diagnosed HIV/AIDS patients aged ≥ 18 years	Within 7 days of HIV diagnosis	>7 days after HIV diagnosis	413	√	√	√	7
Du et al. [37]	2021	China	Retrospective cohort study	Jan 1, 2010 – Dec 31, 2019	Newly diagnosed HIV/AIDS patients	Day of HIV diagnosis, 1–7 days, and 8–30 days after HIV diagnosis	31–90 days, 91–180 days, and 181–365 days after HIV diagnosis	11271	×	√	×	7

*MR: Mortality Rate,VSR: Virological Suppression Rate,LTFU: Loss to Follow-up

3.3. Meta-Analysis Results

3.3.1. Effectiveness

This study selected virological suppression and mortality rates as the core indicators for evaluating effectiveness.

Regarding mortality, 10 clinical studies were included (90,281 cases in the experimental group and 207,414 cases in the control group)[18, 20-22, 24, 25, 27, 30, 33, 36]. The heterogeneity test revealed high heterogeneity among the studies($I^2 = 95\%, P < 0.00001$); therefore, a random-effects model was used for the pooled analysis. The meta-analysis results indicated that the mortality rate in the rapid initiation group was significantly lower than that in the standard initiation group, and the difference was statistically significant [$RR = 0.67, 95\%CI: (0.52, 0.87), P = 0.003$]. See Figure 2 for details.

In terms of the virological suppression rate, 18 clinical studies were included (128,334 cases in the experimental group and 230,228 cases in the control group)[18-20, 22-29, 31-37]. The heterogeneity test showed significant heterogeneity($I^2 = 98\%, P < 0.00001$); thus, a random-effects model was adopted for the analysis. The meta-analysis demonstrated that the virological suppression rate in the rapid initiation group was significantly superior to that in the standard initiation group, with a statistically significant difference [$RR = 1.04, 95\%CI: (1.01, 1.08), P = 0.01$]. See Figure 3 for details.

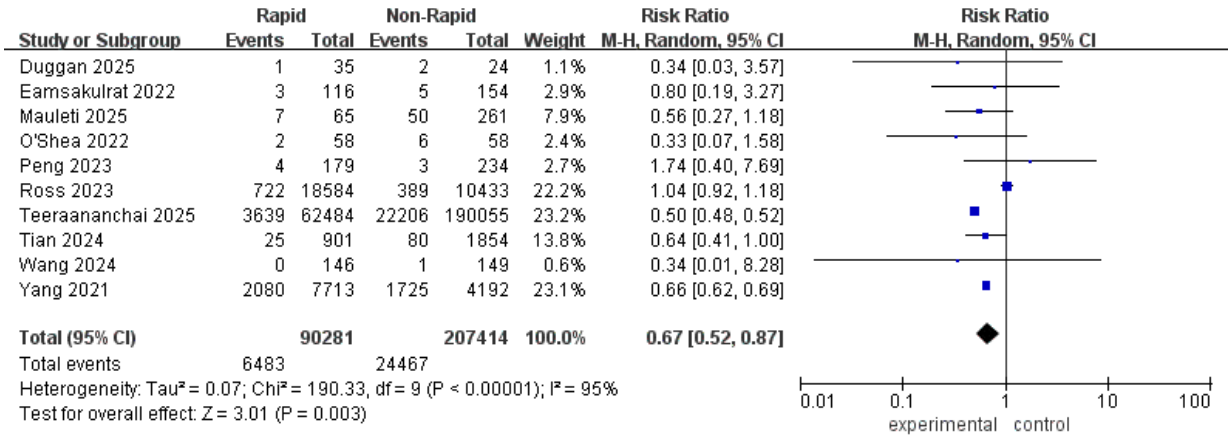


Figure 2: Forest plot of death rate.

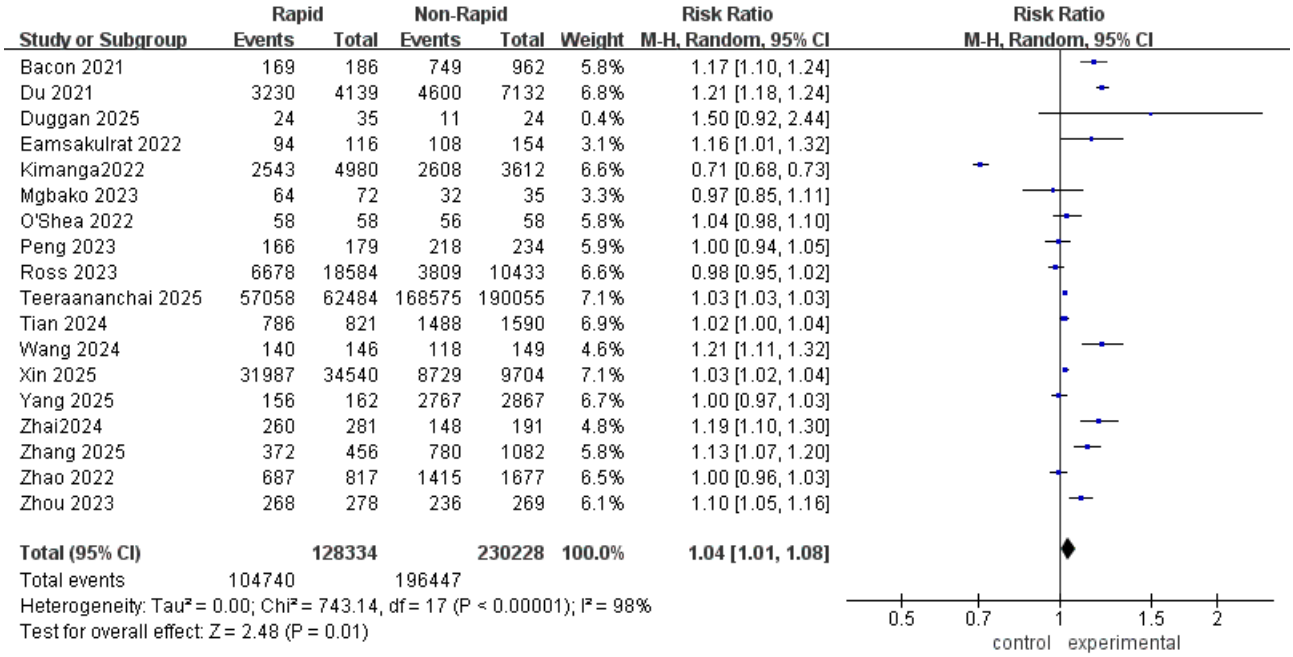


Figure 3: Forest plot of virologic suppression rate.

3.3.2. Adherence

This study selected the loss to follow-up (LTFU) rate as the indicator for evaluating adherence. This analysis included eight clinical studies (2,186 cases in the experimental group and 3,723 cases in the control group)[20, 22, 23, 25, 28, 33, 34, 36]. The heterogeneity test indicated no statistical heterogeneity among the studies($I^2 = 0\%, P = 0.69$). Therefore, a fixed-effects model was used for the analysis. The meta-analysis results showed that the LTFU rate in the experimental (rapid initiation) group was significantly lower than that in the control (standard initiation) group, and the difference was statistically significant [$RR = 0.62, 95\% CI: (0.50, 0.77), P < 0.0001$]. See Figure 4 for details.

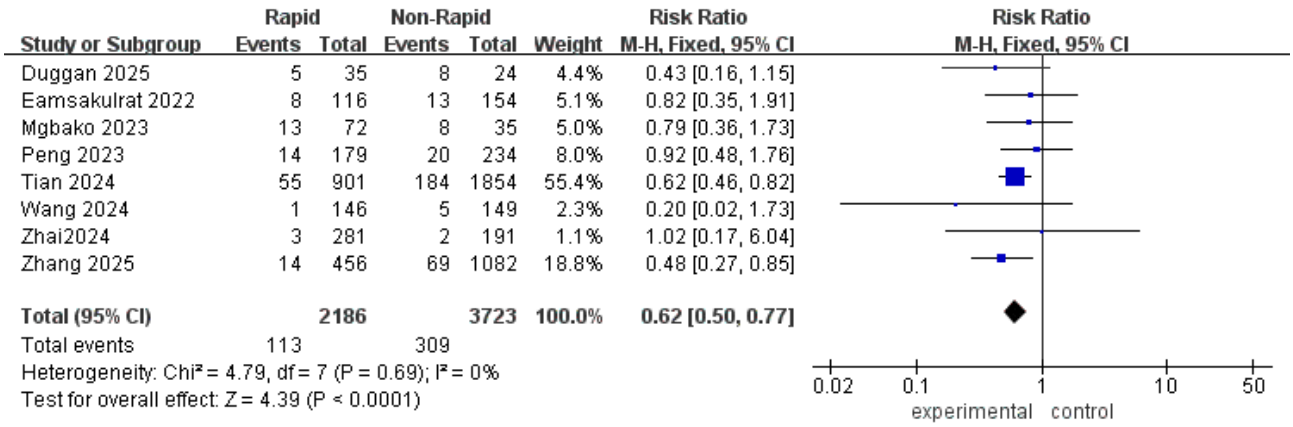
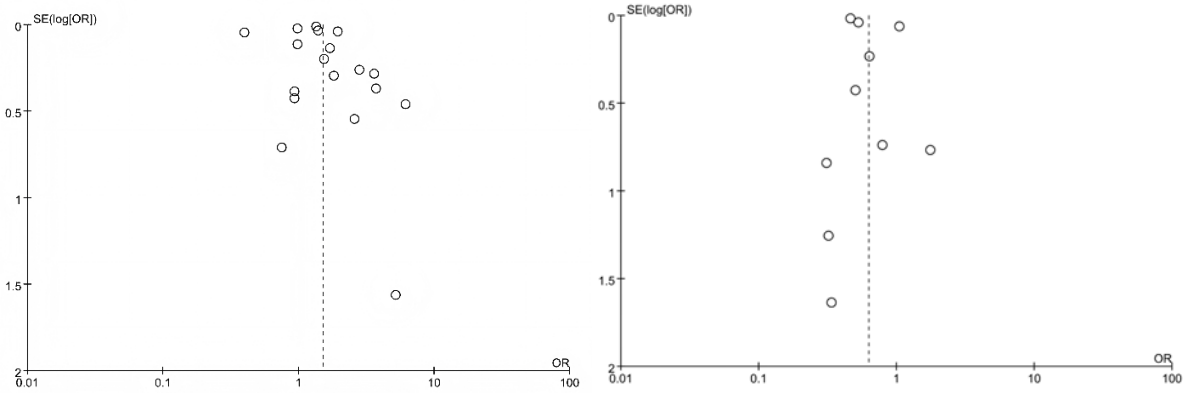


Figure 4: Forest plot of loss to follow-up rate.

3.4. Sensitivity Analysis and Publication Bias

For indicators with at least 10 included studies (i.e., virological suppression and mortality rates), visual assessment was performed by constructing funnel plots, as illustrated in Figure 5. The scatter points in the funnel plot for the virological suppression rate were symmetrically distributed around the pooled effect size, indicating no obvious publication bias. However, the funnel plot for the mortality rate exhibited a certain degree of asymmetry, suggesting a potential risk of publication bias in the pooled results for this indicator.

To evaluate the reliability of the conclusions, a sensitivity analysis was further conducted using the leave-one-out method. The results showed that after sequentially excluding each included study, the recalculated pooled effect sizes and their directions remained highly consistent with the original analysis. This confirms that the conclusions of this meta-analysis were not unduly influenced by any single study or small-sample research, demonstrating the robust nature of the overall findings.



A Funnel plot for virological suppression rate. B Funnel plot for mortality rate.

Figure 5: Funnel plot.

4. Discussion

Currently, rapid ART initiation has emerged as a core strategy in the global advancement of HIV/AIDS prevention and control. To ascertain the actual benefits of this strategy in real-world clinical settings, it is imperative to synthesize existing evidence to comprehensively evaluate the differences in its effectiveness and adherence compared with standard initiation. This study systematically reviewed and included 20 clinical studies to conduct a meta-analysis. The results

strongly demonstrate that, as an initiation strategy for HIV/AIDS, rapid ART initiation exhibits significant clinical advantages in improving virological suppression rates, reducing all-cause mortality, and lowering the risk of loss to follow-up.

In terms of effectiveness indicators, this study demonstrated that the virological suppression rate in the rapid initiation group was significantly improved [$RR = 1.04, 95\%CI: (1.01, 1.08), P = 0.01$]. This result is highly consistent with the findings of multiple previous randomized controlled trials (RCTs) and systematic reviews, further reinforcing the positive role of the rapid initiation strategy in accelerating the achievement of virological suppression[14,15]. Notably, this study found a significantly reduced risk of mortality in the rapid initiation group [$RR = 0.67, 95\%CI: (0.52, 0.87), P = 0.003$], which differs from the conclusions of some early RCTs where no significant improvement in mortality was observed[11]. The results of early RCTs might have been limited by their stringent participant screening criteria and relatively short follow-up periods. In contrast, this study pooled a large volume of recent real-world cohort data, more objectively reflecting the complex realities of clinical practice. Particularly in a real-world context characterized by the uneven distribution of medical resources and higher baseline risks among patients[16], early intervention can effectively shorten the duration patients spend in a period of high viral load, thereby translating into long-term cumulative benefits of reduced all-cause mortality and deaths from severe HIV-related complications.

Regarding adherence, the loss to follow-up rate in the rapid initiation group was significantly lower than that in the standard initiation group [$RR = 0.62, 95\%CI: (0.50, 0.77), P < 0.0001$]. This result contradicts the findings of early observational studies by Ford et al. Exploring the underlying reasons, this improvement may be attributed to the increasingly refined HIV clinical support systems and the widespread popularization of the "Treatment as Prevention" (TasP) concept in recent years. This further suggests that rapid ART initiation should not be merely regarded as a temporal strategy that simply advances the timepoint of drug administration, but rather be understood as a comprehensive disease management model that deeply integrates early diagnosis, psychological intervention, and long-term follow-up[13].

Although this study yielded positive clinical conclusions, high statistical heterogeneity was observed across the outcome indicators, which may be attributed to the following factors:(1)Variations in defining the initiation window: The included studies exhibited a span in the definition of "rapid" (e.g., same-day initiation, within 7 days, or within 14 days of an HIV diagnosis). Such subtle differences in the timing of the intervention may directly affect patients' short-term clinical outcomes. (2)Inherent differences in baseline populations: The studies encompassed diverse demographic groups, including adults and adolescents. Patients at different stages of physiological and psychological development naturally differ in their medication responses and treatment adherence. (3)Macro-level heterogeneity of healthcare systems: The included literature spanned a broad geographic distribution, encompassing countries with distinct healthcare systems and varying levels of economic development. Disparities in the accessibility of healthcare resources and socio-cultural backgrounds inevitably introduced clinical heterogeneity.

This study also has certain limitations. First, the number of included studies was relatively limited and mostly concentrated within the past five years. Although they were confirmed as high-quality based on the NOS scale, potential temporal bias is inevitable. Second, while real-world observational studies closely reflect actual clinical practice, they cannot completely eliminate the interference of unmeasured confounding factors. Future research should focus on designing more rigorous, large-sample prospective cohort studies or randomized controlled trials to further control for confounding bias and validate the clinical conclusions of this study.

5. Conclusion

In conclusion, the rapid ART initiation strategy has demonstrated comprehensive advantages in real-world settings by improving virological suppression rates, reducing mortality, and enhancing adherence. Moving forward, it is imperative to further standardize the criteria for the optimal initiation window to continuously optimize the standardized clinical management of HIV/AIDS.

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