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报告编号:BC20250407164252409278291 2

检测时间:2025-04-07 16:42:52

篇名：Meta-Analysis

作者：崔博涵

检测类型：毕业设计

比对截止日期：2025-04-07

检测结果

去除本人文献复制比：0.8%　　去除引用文献复制比：0.8%　　总文字复制比：0.8%

单篇最大文字复制比：0.5%（Oral hygiene regimes for mechanically ventilated patients that use chlorhexidine reduce ventilator-associated pneumonia.）

重复字符数：[185]　　单篇最大重复字符数：[105]　　总字符数：[22341]

1.1%(185)　　1.1%(185)　　Meta-Analysis_第1部分（总16826字）

0%(0)　　0%(0)　　Meta-Analysis_第2部分（总5515字）

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1. Meta-Analysis_第1部分

总字符数：16826

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1	Oral hygiene regimes for mechanically ventilated patients that use chlorhexidine reduce ventilator-associated pneumonia. Richards Derek - 《英文比对库》- 2013-09-28	0.6%（105） 是否引证：否
2	The role of gap junctions in cell death and neuromodulation in the retina Gergely Szarka;Márton Balogh;ádám J. Teng?lics;Alma Ganczer;Béla V?lgyi;Tamás Kovács-?ller; - 《Neural Regeneration Research》- 2021-03-03	0.5%（80） 是否引证：否

原文内容

1. Introduction

Hematologic malignancy (HM) comprises a diverse group of conditions arising from cells in the bone marrow and lymphatic system(Miller et al., 2025). In the United States alone, approximately 1.4 million people are living with or in remission from HM(Rodriguez-Abreu, Bordoni, & Zucca, 2007). Therapeutic efficacy evaluation in hematologic malignancies poses unique challenges compared to solid tumors, requiring tailored methodologies to reduce bias and ensure reliable trial outcomes.

In hematology clinical trials, endpoints like progression-free survival (PFS) and objective response rate (ORR) are widely used and often rely on integrated evaluations incorporating imaging, histopathology, and molecular diagnostics in blood-based cancers. For instance, response criteria like the Lugano classification for lymphomas (Cheson et al., 2014) and the International Myeloma Working Group (IMWG) criteria for multiple myeloma (Narita et al., 2018) require interpretations of radiographic findings, circulating biomarkers, and bone marrow biopsies. This process is inherently vulnerable to subjectivity and variability. While these frameworks aim to standardize assessments, the assessment of progression is subject to measurement variability which may introduce error or bias(Dancey et al., 2009), particularly in open-label trials where investigator awareness of treatment allocation may influence outcome assessments. Subtle biases may lead to delayed identification of disease progression in patients receiving experimental therapies or premature discontinuation of treatment due to perceived safety concerns. These challenges are amplified in hematologic malignancies, where distinguishing disease progression from treatment-related complications can be clinically ambiguous. Even

in double-blind trials, investigators' knowledge of treatment allocation may persist due to treatment-specific adverse effects or distinct clinical progression patterns, particularly in hematologic malignancies Blinded independent central review (BICR)(Ford et al., 2009) improves objectivity through centralized analysis and standardized evaluation protocols, particularly valuable for novel therapies or rare hematologic malignancies lacking established response criteria.

However, BICR's applicability in hematologic research remains debated. While radiographic progression drives endpoint determination in solid tumors, hematologic malignancies frequently require supplementary diagnostic approaches—including flow cytometry, cytogenetic testing, and minimal residual disease (MRD) assessment—to comprehensively evaluate disease status. This complexity limits BICR's effectiveness given its primary focus on imaging analysis. Practical challenges such as review delays and the resource-intensive nature of cross-functional expert panels further complicate cost-benefit considerations for BICR in time-sensitive hematologic trials. Recent meta-analyses in solid tumors suggest minimal divergence between BICR and investigator (INV) for PFS and ORR. In 2024, Jacobs et al. found no significant differences in PFS by either local assessment or BICR from 24 studies enrolling 13,168 patients(Jacobs et al., 2024). Several studies have evaluated discordance rates between local investigators and BICR-assessed PFS in solid tumor trials (Liang et al., 2016; Zhang et al., 2018; Zhang et al., 2017), but none have specifically addressed hematologic malignancies, where endpoint definitions are more heterogeneous and may yield different conclusions.

To address this evidence gap, we conducted a meta-analysis of 42 clinical trials across hematologic malignancies, comparing treatment effect estimates for PFS and ORR from BICR versus investigator assessments. We included pivotal Phase III trials, diverse disease subtypes (including lymphomas, leukemias, and multiple myeloma) and emerging therapies such as CAR-T cells and bispecific antibodies. We evaluated the reliability of local evaluations and the added value of central review in detecting meaningful differences in treatment effects.

2. Materials and Methods

Searching Strategy and Study Selection

Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement(Moher, Liberati, Tetzlaff, & Altman, 2009), a PubMed search was conducted from 1 January 2014 to 27 November 2024.The eligible studies we included were phase III randomized controlled trials (RCTs) of Hematologic malignancy (N = 70) designed to assess the effectiveness of anticancer treatments in patients with hematological malignancies. A comprehensive search strategy was implemented to identify relevant studies for this meta-analysis. We search PubMed up to December 4, 2024, for articles using the search terms: "((Lymphoma [Mesh] OR Myeloma[Mesh] OR Leukemia[Mesh] OR Lymphoma [tiab] OR Myeloma[tiab] OR Leukemia[tiab] OR Hematologic [Mesh] OR Hematologic[tiab]) AND (progression free survival [Mesh] OR disease progression[Mesh] OR progression free survival[tiab] OR PFS[tiab] OR objective response[tiab] OR ORR[tiab] OR investigator OR independent review) AND ("Phase 3" OR "Phase III"OR"Phase 2" OR "Phase II") (English) AND (y_10[Filter])) AND (randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab] AND (y_10[Filter])) AND (y_10[Filter])). Truncation was used when appropriate to fine-tune the search and increase the number of relevant findings. Additionally, we searched the reference lists from retrieved articles to identify further relevant studies.

Inclusion and Exclusion Criteria

Studies were considered eligible for further analysis if all these conditions were met: i) phase III randomized controlled trials (RCTs) of Hematologic malignancy; ii) Clinical trials endpoints include PFS and/or ORR; iii) tumor response or progression was conducted by both central reviewers and local investigators; iv) studies written in English. The inappropriate articles, such as reviews, systematic reviews and/or meta-analyses, guidelines, and commentaries, were excluded.

Data extraction

The process of data extraction was carried out independently and double-blindly by two reviewers. Two authors extracted the data related to study characteristics and outcome measures including author, title, publication year, clinical trial name, NCT number, study phase, cancer type(lymphoma, leukemia, myeloma), specific cancer type, prior treatment, response assessment criteria , sample size, random ratio, arms, treatment, treatment size, control, control size, study design(superiority, noninferiority), final analysis/interim analysis, primary endpoint, key secondary endpoint, follow up time, EFS for PFS, PFS of BICR , HR for BICR-PFS, p value of BICR-HR, the PFS of INV, the HR for INV-PFS , p value of INV-HR , ORR of BICR, ORR of INV,p value of BICR-ORR, ORR of INV , p value of INV-ORR. Regarding overlapped data from more than one article on one trial, we selected data based on primarily larger analysis or recently updated analysis. A PRISMA flow diagram was created to illustrate the study selection process.

Statistical analysis

Regardless of trial results, in hematological malignancies, BICR and INV assessment results reported PFS and ORR, respectively. Eligible trials are Phase III randomized controlled trials that directly evaluate the efficacy of anticancer drugs in patients with hematoma. These trials play a crucial role in advancing cancer treatment by providing robust evidence on the effectiveness and safety of new therapies. In our subgroup

analysis, we stratified patients based on two characteristics:(1) the masking included blinded and open-label type, and (2) hematologic malignancy classifications, including but not limited to lymphoma (LYM), leukemia (LEU), and Multiple myeloma (MM). This stratification enabled us to evaluate potential heterogeneity in treatment responses and prognostic outcomes across these clinically relevant subgroups, thereby providing a more granular understanding of the intervention's efficacy and safety profile within distinct patient populations.

In such studies, researchers meticulously select participants who meet specific criteria to ensure the validity and reliability of the results. The primary objective of these Phase III trials is to compare the new anticancer drugs against existing standard treatments or placebos. This comparison helps determine whether the new drugs offer significant advantages in terms of tumor shrinkage, progression-free survival, overall survival, and quality of life for patients. The inclusion of patients with hematoma ensures that the study focuses on individuals who may benefit most from these novel treatments.

PFS Meta-analysis

Progression-free survival (PFS), defined as the time interval from randomization to the first documented disease progression (per protocol-specified criteria) or death from any cause, whichever occurred earlier, served as the primary efficacy endpoint. All events were adjudicated by blinded independent central review (BICR) and investigator assessment (INV), with censoring applied for patients lost to follow-up or without events at the data cutoff. The relationship between BICR and INV in terms of log (HR of PFS) was assessed using Pearson's correlation coefficient (r). To quantify the agreement between BICR- and INV-derived treatment effects, the coefficient of determination (R^2) was derived from a linear regression model, with log-transformed hazard ratios (log [HR]) from BICR as the dependent variable and INV-based log (HR) as the independent variable and weighted according to sample size. The level of concordance. The magnitude of agreement between BICR and INV for PFS was assessed using the Hazard Ratio Ratio:

Where and are the BICR- and INV-based PFS HRs, respectively, the Hazard Ratio Ratios (HRRs) were calculated for each individual comparison and subsequently categorized into four distinct intervals: $\leqslant 0.85$, (0.85, 1], (1, 1.15], and > 1.15. These intervals were then analyzed in relation to key study characteristics to explore potential associations between these characteristics（ Masking 、 Cancer type 、 Sample size 、 Follow-up duration ） and the HRRs. This stratification allowed for a more detailed understanding of how study design factors, such as treatment regimens, patient population, and assessment methodologies, may influence the magnitude of agreement between the BICR- and INV-based hazard ratios.

For studies where the protocol stipulated that progression-free survival (PFS) comparisons should be formally tested, statistical significance was determined by comparing the P-value to a pre-specified alpha boundary, categorizing statistical inferences as either “statistically significant” or “not statistically significant.” This approach ensured that only comparisons meeting the significance threshold were included in the final analysis.

To assess the consistency of statistical inferences between BICR and INV, a two-way contingency table was constructed, allowing for a direct comparison of PFS outcomes derived from both assessment methods. Cohen's kappa coefficient was then calculated to quantify the level of agreement between BICR- and INV-based assessments, providing a measure of inter-rater reliability. A kappa value closer to 1 indicated strong agreement, whereas a value closer to 0 suggested a lack of agreement, offering a clearer picture of how consistently BICR- and INV-based evaluations align in terms of statistical significance.

ORR Meta-analysis

The second primary outcome considered was the objective response rate (ORR). Similar to the PFS meta-analysis, Pearson's correlation coefficient (r) and the coefficient of determination (R^2) were computed to assess the relationship between BICR and INV based on the logarithm of the odds ratio (OR) for ORR. Additionally, the level of agreement between BICR and INV regarding ORR was measured using the Odds Ratio Ratio of the response：

WhereandA similar random effects model used in the PFS meta-analysis was applied to estimate the Odds Ratio Ratio (ORR) and its 95% confidence interval (CI) for all comparisons, as well as for double-blind and open-label comparisons, respectively.

3.Result

Based on article identification and selection Figure 1, we include a total of 42 phase-3 RCTs eligible articles to do the analysis of the consistency of data analysis between BICR and investigators, involving 36 PFS comparisons and 21 ORR comparisons. Table 1 shows the summarization of the characteristics of the investigated comparisons, such as the PFS comparisons and the ORR comparisons.

The agreement between the BICR and LE PFS results can be observed in Table 2. The comprehensive analysis encompassing 36 pairwise comparisons demonstrated a remarkably strong correlation between log() and log (), with an overall Pearson's correlation coefficient of r = 0.952 (95% CI, 0.907-0.975). The results of the subgroup analyses in the open-label (n = 27) and blinded (n = 9) comparisons agreed with the overall study. In the blinded and open-label groups, the degrees of correlation were 0.908 (95% CI, 0.613, 0.981) and 0.966 (95% CI, 0.927, 0.985), respectively. The disease-specific analyses showed strong correlations between log () and

log() across hematologic malignancies: lymphoma (n=26, r=0.913, 95% CI 0.799-0.964), leukemia (n=7, r=0.972, 95% CI 0.756-0.997), and myeloma (n=4, r=0.953, 95% CI -0.096-0.999). The limited sample size in myeloma and the combined lymphoma/leukemia subgroup (n=3) precluded reliable interpretation. Overall, the weighted linear regression model using log () as the explanatory variable explains 95.3% (R^2 = 0.953 [95% CI, 0.926, 0.980]) of the variability in the log (HR BICR), confirming the strong agreement between BICR and INV. The estimated overall HRR from the random effects model was 0.935 (95% CI: 0.892, 0.980), indicating an average difference of only 6.5% between HR BICR and HR INV. The estimated HRR in the open-label group was numerically slightly lower than that in the double-blind group (0.920 vs. 1.009), but both were close to 1 indicating a high degree of agreement in the PFS HR estimates overall.

The scatter plot Figure 1 demonstrates a strong correlation between Log ( ) and Log () for PFS comparisons. The data points cluster closely around the solid reference line, indicating a high overall agreement between the two assessment methods. However, distinct patterns emerge when considering the study type and sample size.

In open-label studies, the points generally fall above the reference line, suggesting that LE assessments may overestimate the treatment effect compared to BICR. This trend is particularly noticeable in smaller trials, where the deviation from the reference line is more pronounced. In contrast, larger open-label studies show better agreement, with points aligning more closely to the reference line.

In blinded studies, including both double-blind and blinded trials, the points are evenly distributed around the reference line, indicating no systematic bias and a consistent agreement between the two methods, regardless of sample size. Larger blinded studies exhibit even stronger consistency, with points clustering more tightly around the reference line. In general, the graph highlights a high level of agreement between the BICR and INV assessments but reveals a potential bias in open-label studies, particularly in smaller trials, where the INV assessments can overestimate the effect of treatment.

The analysis of hazard risk ratio (HRR) distribution among different study characteristics is presented in Table 1. Among the 36 studies analyzed, 22.22% (n=8) reported HRR ≤ 0.85, while 38.89% (n=14) had HRR between 0.85 and 1. The proportion of studies with HRR between 1 and 1.15 was 30.56% (n=11), and only 8.33% (n=3) exhibited HRR > 1.15. Among the five blind studies, none showed HRR ≤ 0.85, with the majority (60.00%, n=3) falling within the (0.85, 1] range, while two studies (40.00%) had HRR in the (1, 1.15] range. For double-blind studies (n=4), HRR was evenly distributed between ≤ 0.85 (0%), (0.85, 1] (50.00%), (1, 1.15] (25.00%), and > 1.15 (25.00%). In contrast, open-label studies (n=27) had a relatively higher proportion of HRR ≤ 0.85 (29.63%) compared to blind and double-blind studies, with 33.33% in the (0.85, 1] range, 29.63% in the (1, 1.15] range, and 7.41% in the > 1.15 category. The distribution of HRR under different research characteristics shows significant heterogeneity. Notably, the proportion of cases with HRR ≤ 0.85 in the open-label study group (32.1%) is significantly higher than that in the blinded design group (18.6%).

Table 4 summarizes the consistency of statistical inferences between BICR and INV based on PFS results. We denote a statistically significant PFS difference based on BICR assessment as “BICR+” and a not statistically significant difference as “BICR-“; “INV+” and “INV” are analogously defined for the INV-based assessment. 28 of the 36 comparisons were alpha-controlled, leading to statistical inferences. For the majority (75.0% [27/36]) of the 36 comparisons, BICR agreed with INV in terms of the resulting statistical inferences: 78.6% (22/36) of the comparisons led to an INV+/ BICR+ result and 17.9% (5/36) to an INV-/BICR- result. Discordant results, i.e., INV+/BICR- and INV-/BICR+ combinations, were observed in 1 (2.2%) and 0 (0%) of the comparisons, respectively. Cohen’s Kappa was 0.901, indicating a substantial agreement between BICR and INV. Overall, a high agreement between BICR and INV estimates of the PFS treatment effect was observed in the meta-analysis, while the agreement was slightly stronger in the double-blind subgroup than in the open-label group. At the individual-trial level, BICR and INV gave consistent statistical inferences in most of the comparisons, which is in line with the meta-analysis result.

The methodological approach for analyzing the objective response rate (ORR) was parallel to that employed for progression-free survival (PFS) analyses. Table 5 shows the consistency between BICR and LE results in ORR evaluation. We analyze 21 ORR comparisons, demonstrating the significant correlation between log () and log (). The Pearson correlation coefficient of 0.900 (95% CI, 0.765, 0.959) indicated a substantial connection between log () and log (), but slightly lower than that for PFS log (HR). The analysis results of the open-label group and the blinded group were consistent with the overall study. In the blinded group(n=4), the correlation

coefficient was 0.985 (95% CI: 0.457,1.000), and in the open-label group (17), it was 0.919(95% CI:0.786,0.971). While both groups demonstrated strong concordance, the point estimate in blinded trials was 7.2% higher than in open-label studies (0.985 vs 0.919), possibly reflecting the potential impact of different trial designs on the results. Disease-specific analysis showed significant correlations between log () and log() in lymphoma, leukemia, and myeloma among hematological malignancies. In the lymphoma group (n = 12), r = 0.961 (95% CI: 0.865,0.989); in the leukemia group (n = 5), r =0.987(95% CI:0.811,0.999). However, the limited sample size in myeloma and the combined lymphoma/leukemia subgroup restricted the accuracy of the analysis.

The weighted linear regression model, employing log () as the explanatory variable, effectively accounted for 82.3% of the variability in log () (R^2 = 0.823, 95% CI:0.728,0.918), further illustrating the strong correlation between BICR and INV assessment outcomes. The overall ORR estimated by the random-effects model was 0.870 (95% CI: 0.685,1.105). The ORR estimate in the open - label group (0.885,95% CI:0.666,1.175) was marginally superior to that in the blinded group (0.748,95% CI:0.581,0.962), however both values approached 1, emphasizing the consistency of ORR assessment across various trial settings.

4. Discussion and conclusion

To our knowledge, this is the first research article evaluating the differences between investigator evaluations (INV) and blinded independent central reviews (BICR) of PFS and ORR in phase III RCTs concerning Hematologic malignancy. While several systematic reviews(Dello Russo, Cappoli, & Navarra, 2020; Lian et al., 2024; Zhang et al., 2018) have examined this issue in solid tumors, the hematologic malignancy literature consists primarily of isolated analyses from phase III clinical trials, leaving significant gaps in our understanding of disease-specific assessment concordance. This paucity of comprehensive evidence is particularly concerning given the unique challenges of response evaluation in hematologic cancers, where factors like bone marrow involvement(Sorigue, Cañamero, & Miljkovic, 2021), circulating tumor cells(Lin et al., 2021), and distinct response criteria may differentially influence local versus central assessments.

The scatterplot demonstrates strong concordance between BICR and LE assessments overall, with most data points adhering closely to the equivalence line. However, deeper analysis reveals important contextual variations. In open-label trial designs, particularly those with limited enrollment (n<100), LE measurements systematically plot above the consensus line - a pattern suggesting potential inflation of treatment effects compared to blinded assessments. This divergence appears dose-dependent with sample size, as larger open-label trials (n≥300) show markedly improved alignment with central tendency.

The results demonstrate strong agreement between BICR and investigator assessments for response outcomes across hematologic malignancies, particularly in lymphoma and leukemia. The agreement appears slightly stronger in blinded studies compared to open-label studies, though both show excellent concordance. The limited data in myeloma and combined lymphoma/leukemia subgroups prevent meaningful conclusions for these populations. These findings complement the PFS agreement results shown in Table 2, showing that both time-to-event (PFS) and response outcomes demonstrate high concordance between central and investigator assessments in hematologic malignancies.

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Table and Graph

说明：1.总文字复制比:被检测文献总重复字符数在总字符数中所占的比例

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