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RESEARCH

Meta-analysis of the comparative efficacy and safety of new drugs in combination with chemotherapy in primary plasmoblastic lymphoma

Bingling Guo[1] · Xi Quan[1] · Zailin Yang[1] · Jieping Li[1] · Yao Liu[1]

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Abstract

To systematically evaluate the efficacy and safety of regimens combining new drugs (bortezomib, etc.) with chemotherapy in the treatment of plasmaoblastoid lymphoma (PBL). PubMed, Embase, Web of Science, American Society of Hematology Annual Meeting Proceedings, Cochrane Controlled Trials Center Registry, Cochrane Library, Science Citation Index, and meeting abstracts were searched for quality evaluation based on Cochrane Risk and Jadad scores and other assessment tools. Patients were divided into subgroup 1 (traditional treatment vs. no treatment) and subgroup 2 (traditional treatment vs. combination of new drugs) based on medication use, and Revman 5.4 software was applied for statistical analysis. A total of 12 papers were included, including 410 patients with PBL. Meta-analysis results: the objective remission rate (ORR) of patients in the combination of new drugs group was higher than that of the traditional treatment group [56.8% (25/44) vs. 70.2% (66/94); OR = 2.18, 95%CI 1.58–2.78, $P = 0.002 < 0.05$], and the progression-free survival (PFS) rate of patients in the combination of new drugs group was higher than that of the traditional treatment group. the progression survival (PFS) was better than traditional treatment group (HR = 2.22, 95%CI 1.71–2.90, $P < 0.001$), and the heterogeneity between the results of each study I = 95%; there was no statistically significant difference between the two groups in terms of overall survival (OS) (HR = 1.81, 95%CI 0.44–7.46, $P = 0.41$), and grade 3–4 adverse events (AE) (HR = 0.85, 95%CI 0.27–7.46, $P = 0.002 < 0.05$). 95%CI 0.27–2.71, $P = 0.78$) were not statistically different. The regimen combining new drugs is an effective means to improve the prognosis of PBL, with better ORR and PFS than the traditional regimen, and there is no statistically significant difference between the two adverse events. However, the small sample size of this study increases the possibility of bias and the results need to be treated with caution.

Keywords Plasmoblastic lymphoma · Bortezomib · Therapeutic efficacy · Adverse effects

Introduction

Plasmablastic lymphoma (PBL) is a rare, highly aggressive non-Hodgkin lymphoma characterized by drug resistance and poor survival [1]. Currently, there is no standard treatment for PBL, with the main focus being on medium- to high-intensity combination chemotherapy [2]. Commonly used regimens are derived from the treatment of HIV-related NHL [3], including CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) or CHOP-like regimens, hyper-CVAD-MA (cyclophosphamide, vincristine, doxorubicin, dexamethasone, and high-dose methotrexate and cytarabine), CODOX-M/IVAC, etc. The NCCN Guidelines (2024.1 version) [4] recommend regimens stronger than CHOP. To further improve treatment outcomes and overcome drug resistance, there is an urgent need for novel drugs, such as bortezomib, lenalidomide, and ixazomib, but randomized controlled trials are limited. Therefore, we conducted a systematic review of relevant literature to compare the efficacy, survival, and safety of combined novel drugs (such as bortezomib) and traditional regimens (EPOCH, CHOP-like regimens, and/or radiotherapy) in the treatment of newly diagnosed plasmablastic lymphoma (PBL).

✉ Yao Liu
liuyao77@cqu.edu.cn

[1] Department of Hematology-Oncology, Chongqing University Cancer Hospital, No.181 HanYu Road, Chongqing 400030, China

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Materials and methods

Inclusion and exclusion criteria

Inclusion criteria: ① Prospective randomized controlled trials (RCTs) and retrospective analyses from domestic and international studies; ② Study subjects were newly diagnosed PBL patients; ③ All the diagnosis of PBL was established by histopathologic examination and immunohistochemistry (IHC) studies. ④ Minimum sample size of the study subjects was 10; ⑤ The study must report the treatment outcomes of response rate, progression-free survival, or overall survival (OS). Exclusion criteria: ① Literature for which full text could not be obtained; ② Literature reviews and conference papers; ③ Literature with incomplete information extraction; ④ Repeatedly published literature.

Literature search and screening (PROSPERO registration number: CRD42024578897)

PubMed, Embase, Medline, Web of Science, Cochrane Central Register of Controlled Trials, Cochrane Library, Science Citation Index, and conference abstracts were searched, with a cut-off date of August 2024. Keywords included "plasma cell lymphoma", "plasmablastic lymphoma", "treatment", and "management". Search terms were MeSH terms, and the PubMed search string was ((((Plasmablastic Lymphoma[MeSH Terms]) OR (Plasmablastic Lymphoma*)) OR (Lymphoma, Plasmablastic)) OR (Plasmablastic Diffuse Large B-cell Lymphoma)) OR (Plasmablastic Diffuse Large B cell Lymphoma)) OR (Plasmablasts Diffuse Large B-cell Lymphoma)) AND ((((Treatment[MeSH Terms]) OR (Therapeutic)) OR (Therapies)) OR (Therapy)) Sort by: Most Recent. Language restrictions were not applied, and all patients were pathologically confirmed to have PBL. Data extraction from the included literature was mainly performed by two reviewers (Guo and Quan) separately, including general information, study characteristics, study design, subjects, and outcome observation indicators. The two reviewers independently completed the pre-designed data extraction table. Discrepancies in data extraction were resolved through consensus. The original articles were consulted, and support was sought from the original authors when necessary. A consensus was reached through discussion between the two reviewers. If disagreements arose, further discussion or third-party evaluation was conducted. Based on whether the treatment included new drugs, the included study subjects were divided into two groups.

Literature quality assessment

The two reviewers used the Newcastle–Ottawa Scale (NOS) to assess the quality of the included literature. The assessment included three aspects: selection of study subjects (0–4 points), comparability (0–2 points), and exposure or outcome assessment (0–3 points). The maximum NOS score was 9 points. Scores of 6 or higher were considered high-quality studies, while scores below 4 were considered low-quality. The two reviewers agreed on over 80% of the literature quality assessment items. In case of disagreement, discussions were held or consultations with experts were conducted to resolve the issue. All included literature scored 6–8 points.

Data extraction

Two reviewers independently extracted the data, verified consistency and accuracy, and then entered it into a computer database. The extracted literature content included: first author, publication journal, year of publication, number of cases in each group in each study, average age, treatment regimen, efficacy, and adverse reactions.

Observation indicators

Objective response (ORR), progression-free survival (PFS), overall survival (OS), and grade 3 or higher adverse effects (AE). The Lugano 2014 criteria were used to evaluate the efficacy. ORR was defined as the proportion of patients who achieved complete remission (CR) and partial remission (PR) among all patients eligible for efficacy assessment. PFS was defined as the time from the start of treatment to the first recurrence, progression, death, or last follow-up for any reason. OS was defined as the time from the start of treatment to death or last follow-up for any reason. Adverse reactions were assessed according to the Common Terminology Criteria for Adverse Events (CTCAE).

Statistical analysis

RevMan 5.4 software was used for meta-analysis of the data. If statistical heterogeneity existed among studies ($I2 > 50\%$, $P < 0.1$), the random-effects model was used for meta-analysis. If homogeneity existed among studies ($I2 \leq 50\%$, $P \geq 0.1$), the fixed-effects model was used for meta-analysis. Mean difference (MD) and its 95% CI were used to evaluate quantitative data, and relative risk (RR)

was used to analyze count data. $P < 0.05$ indicated statistically significant differences. Funnel plots were used to assess publication bias.

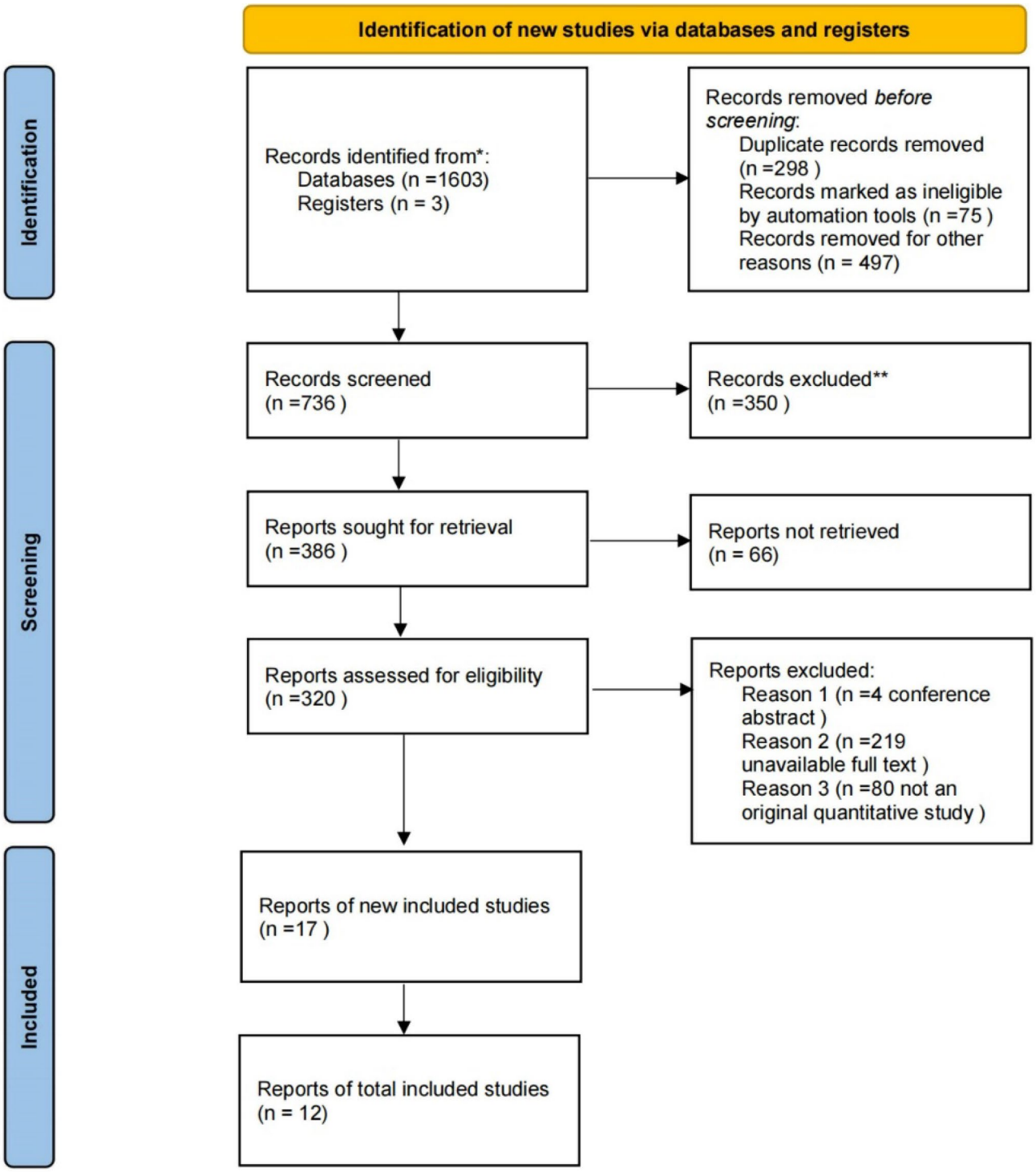

Fig. 1 Literature screening process

Results

Study characteristics

A total of 1603 articles were retrieved (PubMed 664, Embase 907, Cochrane Central Database 20, Clinical Trials 3, Wan Fang 9), and after removing duplicate articles, reviews, conference abstracts, etc., the literature was screened by reading titles and abstracts, and finally 12 articles were included after reading the full text (Fig. 1), with a total of 410 patients. Data on interventions and outcomes were extracted independently using a pre-tested data extraction table. Based on whether chemotherapy or radiotherapy was received or not (subgroup 1), and whether new drugs were combined with treatment or not (subgroup 2), the included studies were divided into two groups (Table 1). Subgroup 1 enrolls studies comparing traditional therapy versus no therapy, and subgroup 2 enrolls patients comparing new drugs versus conventional therapy. Subgroup 1 used traditional regimens (EPOCH regimen, CHOP-like regimens, and/or local radiotherapy) in 152 cases, and the control group (untreated) in 30 cases. Subgroup 2 used traditional regimens (EPOCH regimen, CHOP-like regimens, and/or local radiotherapy) in 115 cases, and combined new drugs (bortezomib, lenalidomide, or CART) in 44 cases. For those patients who only receiving palliative therapies, the reasons include: older age at diagnosis or poor PS, or due to the presence of co-morbidities that contributed to poor performance

Table 1 Grouping of the included literature

	Study	Published year	Sample size	Research design	Jadad score	New drugs
Subgroup1	Jorge Castillo [14]	2008	112	restrospective study	3	
	Yusuke Koizumi [21]	2016	24	restrospective study	4	
	Ariela Noy [23]	2016	12	RCT	3	
	Brenda Mai [20]	2020	21	restrospective study	3	
	A. H. Rudresha [24]	2020	13	restrospective study	3	
	Jayachandran Perumal Kalaiyarasi [25]	2020	25	restrospective study	3	
	Nadine Rapiti [22]	2022	26	restrospective study	3	
Subgroup2	Christopher Dittus [15]	2018	8	restrospective study	4	Bortezomib
	Fu Weijia [17]	2020	15	restrospective study	4	Bortezomib/Ixazomib/Lenalidomide
	Rehan Jessa [19]	2022	42	restrospective study	4	Bortezomib/Rituximab/ASCT
	Brian T. Hess [31]	2023	80	restrospective study	3	ASCT
	Ning Dong [18]	2023	32	restrospective study	3	Bortezomib/Rituximab/ASCT/HSCT /CAR-T

Table 2 Patient outcomes

Group	Study	Follow-up(month)	PFS(month)	OS(month)	Mortality rate
Subgroup1	Jorge Castillo [14]	19	NA	15	29/55(53%)
	Yusuke Koizumi [21]	15	13	15	NA
	Ariela Noy [23]	73 weeks (40–165)	NA	11.6 (2–63 s)	NA
	Brenda Mai [20]	19 (< 1–112)	NA	4.7	9/16(75%)
	A. H. Rudresha [24]	33	NA	9	6/13(46%)
	Jayachandran Perumal Kalaiyarasi [25]	26.9(0.3–34.1)	5.9	12.4	NA
	Nadine Rapiti [22]	78	8(1–97)	16 (1–111)	NA
Subgroup2	Christopher Dittus [15]	48	10.8(0.73–77.8)	10.8(0.73–77.8)	NA
	Fu Weijia [17]	30.3(4.8–61.1)	6.8(2.5–11.1)	17.9(5.6–30.2)	8/15(53%)
	Rehan Jessa [19]	96	8	15	NA
	Brian T. Hess [31]	34(1–196)	72% (95% CI 62, 83)	79% (95% CI 70, 89)	NA
	Ning Dong [18]	77.6	6.7 (3.4, 8.3) vs. NR (NA)	14.7 (10.2, 33.7) vs. 89.1 (56.7, NA)	NA

and overall function, or not tolerate the chemotherapy, and some patients with HIV + and having been received anti-retroviral therapy (ART) alone. All the outcomes are showed in Table 2.

Bias risk assessment using Cochrane bias risk assessment criteria showed that NOS was used to evaluate bias risk (Figs. 2, 3)

Efficacy comparison (Fig. 4)

Among patients eligible for efficacy assessment, the objective response rate (ORR) was higher in the combined new drug group than in the traditional treatment group [56.8% (25/44) vs. 70.2% (66/94); OR = 2.18, 95%CI 1.58–2.78, $P = 0.002$]. Heterogeneity among study results was I = 95%.

Survival comparison (Figs. 5, 6)

Four studies used HR to assess OS and PFS. Compared with the traditional regimen, the overall survival rate in the combined new drug group was better (HR = 1.81, 95%CI 0.44–7.46, $P = 0.41$), and the progression-free survival rate in the combined new drug group was better (HR = 2.22, 95%CI 1.71–2.90, $P < 0.001$).

Adverse events (Fig. 7)

Among 159 patients eligible for assessment, there was no significant difference in grade 3–4 adverse events (HR = 0.85, 95%CI 0.27–2.71, $P < 0.78$) between the two groups.

Bias analysis (Fig. 8)

The included studies may have publication bias due to the original data, and the local areas may be irregular, but there was no significant publication bias overall.

Discussion

This META analysis included 11 retrospective studies and 1 RCT, comparing the efficacy, survival, and safety of novel drug combinations with traditional regimens in 410 newly diagnosed PBL patients. So far, there are no systematic reviews about comparison between new and traditional therapies before, which are curial for clinical practice. The results showed that, comparing with the traditional regimen, the new drugs combination regimen significantly improved ORR and PFS in newly diagnosed PBL, with the similar OS and adverse reactions. The new drugs include bortezomib, rituximab, lenalidomide, hematopoietic stem cell transplantation (autologous and allogeneic), and CAR-T therapy. Among the above treatment regims, bortezomib is the most widely used and has showed significant efficacy. In recent years, stem cell transplantation and CART therapy have also achieved certain efficacy in PBL, but more data research is needed to explore the remote outcomes.

PBL was first discovered in 1997 by Delecluse et al. [5]. The pathogenesis of PBL is currently unclear and may be related to viral infection [6, 7]. PBL originates from plasmablasts, which are activated B cells that have undergone somatic hypermutation and class switch recombination [8]. According to relevant literature [9–12], the median overall survival of PBL patients is 15 months, and the 3-year OS rate is 25%.

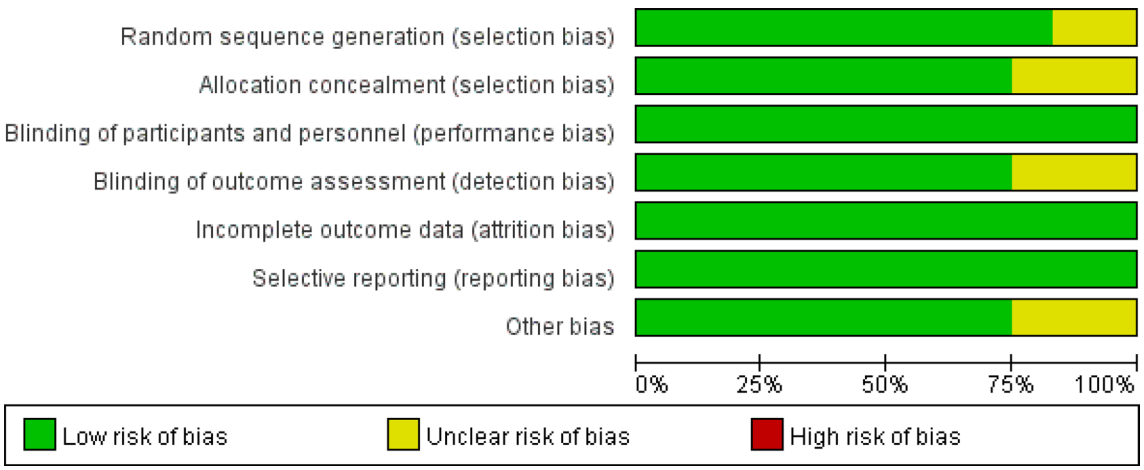

Fig. 2 Risk of bias assessment of included literature 1

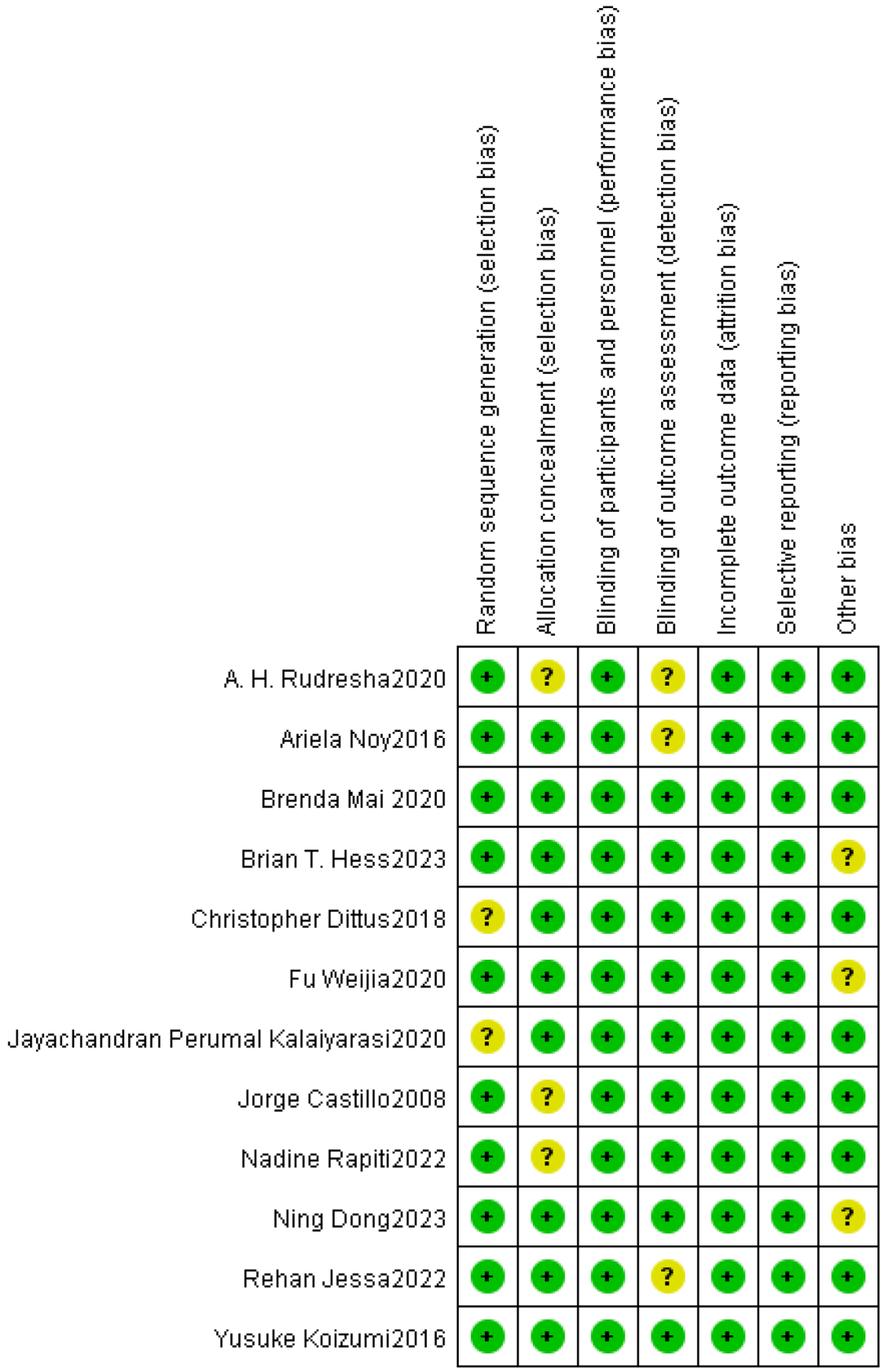

Fig. 3 Risk of bias assessment of included literature 2

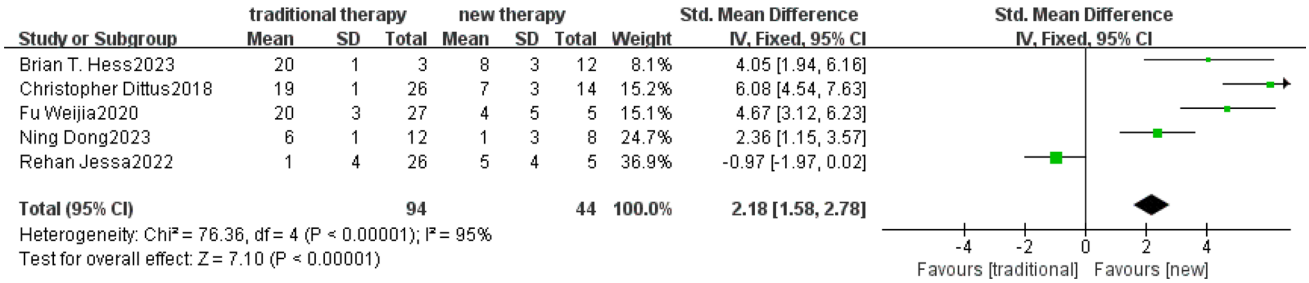

Fig. 4 Objective response rate (ORR) in the combination drug group versus the conventional therapy group

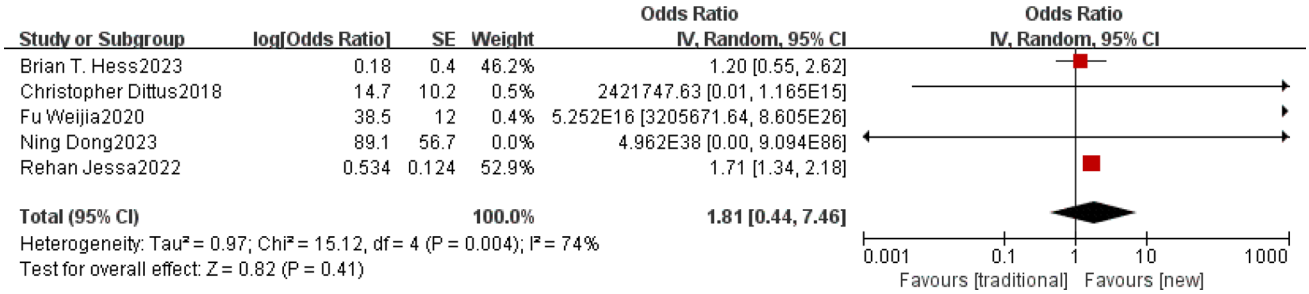

Fig. 5 Overall survival (OS) compared between the combination drug group and the conventional treatment group

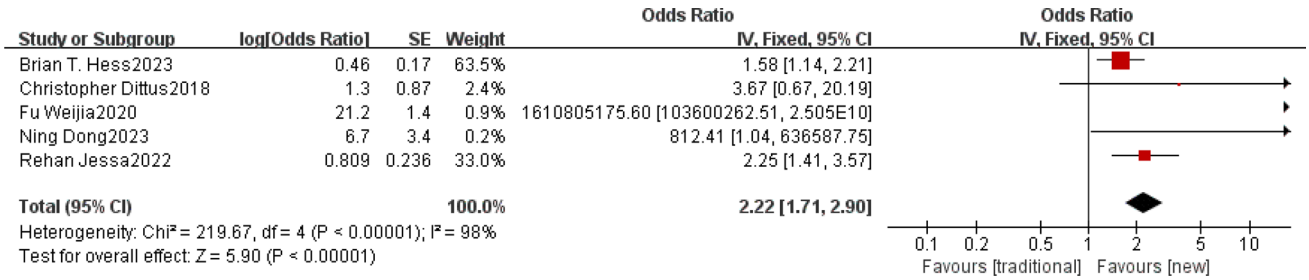

Fig. 6 Comparison of progression-free survival (PFS) between the combination drug group and the conventional treatment group

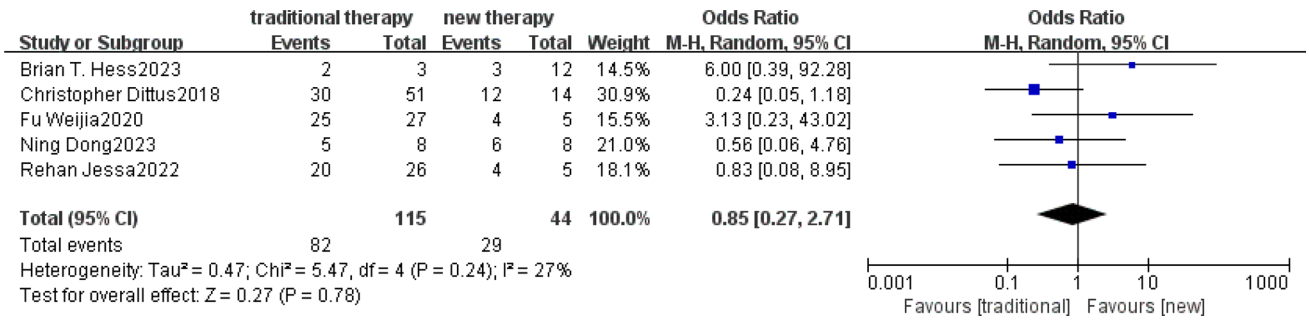

Fig. 7 Comparison of grade 3–4 adverse events (AEs) between the combination drug group and the conventional treatment group

Barta et al. [13] studied 93 cases of HIV-related PBL and found that the EPOCH regimen showed significant advantages in CR, PFS, and OS compared to the CHOP regimen. Castillo JJ et al. [14] used EPOCH combined with bortezomib in 16 newly diagnosed PBL patients, with 15 achieving CR and 1 achieving PR. A multicenter study in

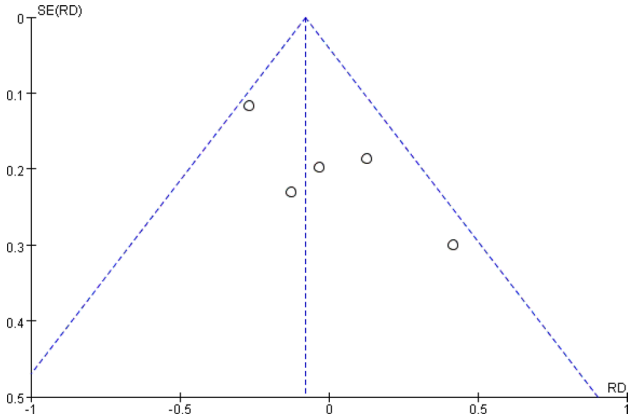

Fig. 8 Bias analysis of the combined new drug group and the conventional treatment group

the United States showed [1] that consolidation radiotherapy after chemotherapy in early PBL can improve outcomes, with chemotherapy combined with radiotherapy showing significantly improved 3-year PFS (85% vs. 65%) and OS (96% vs. 71%) compared to chemotherapy alone. Cattaneo C et al. [16] followed 24 newly diagnosed PBL patients for 10 years, and 67% of PBL patients underwent autologous hematopoietic stem cell transplantation (ASCT) after first-line therapy, with 50% achieving CR, 17% achieving PR, and a 2-year recurrence rate of 30%.

In 2024, Ramirez-Gamero et al. [1] reviewed the diagnosis, risk stratification, and treatment of plasma cell lymphoma, recommending EPOCH ± bortezomib for PBL patients, with the option of combining local radiotherapy and ASCT for high-risk patients.

This META analysis systematically analyzed the data and concluded that chemotherapy regimens combining bortezomib, such as V-EPOCH or V-CHOP, for newly diagnosed PBL, including 1 case in the study by Fuweijia et al. [17] that achieved CR with combined bortezomib and lenalidomide in the first-line treatment and 1 case that achieved remission again with bortezomib combined with ixazomib when the disease recurred. Compared with traditional treatment regimens, combined chemotherapy regimens based on bortezomib significantly improved ORR and PFS in newly diagnosed PBL, which is consistent with previous reports. In addition, 1 patient in the study by Fuweijia et al. [17], 8 patients by Brian T et al. [1], 9 patients by NingDong et al. [18], and 3 patients by RehanJ et al. [19] underwent ASCT, and 29 patients by Brian T et al. [1] and 10 patients by NingDong et al. [18] underwent local radiotherapy, further improving efficacy. Therefore, we speculate that the treatment regimen of bortezomib combined with EPOCH or CHOP regimens, combined with local radiotherapy according to the situation, and ASCT for some high-risk patients is a more appropriate option for newly diagnosed PBL.

Adverse events are another important factor that needs to be considered in clinical practice. The combination treatment of PBL with new drugs has adverse reactions, such as neurotoxicity. The results of this META analysis are consistent with known reports related to adverse reactions. The results of this META analysis show that the new drug does not increase the incidence of adverse events.

Among the included studies, only one study compared the outcomes of PBL patients with HIV positive and negative. Other studies included only HIV positive group or negative patients, or did not provide comparative descriptions, so this study is lack of the comparison of efficacy between HIV-positive and negative patients, which may add bias to results.

As 30% of PBL express CD30, and brentuximab vedotin has a targeted therapeutic effect on CD30, some researchers have explored targeted therapy for PBL. Holderness et al. [26] reported 1 case of a patient with CLL who partially transformed to PBL, and the disease progressed after chemotherapy and radiotherapy. The patient received brentuximab vedotin treatment, and the tumor size significantly reduced. Studies have shown [27, 28] that PD-1 and PD-L1 are also overexpressed and have biological activity in PBL. One case [29] of early relapsed elderly PBL patient achieved CR with pembrolizumab plus radiotherapy.

CAR-T therapy for PBL is another research direction. Raghunandan et al. [30] reported a case of a young patient who developed PBL after receiving immunotherapy and anti-CD19 CAR-T therapy for acute lymphoblastic leukemia. For PBL, the patient received bortezomib and chemotherapy, followed by allogeneic stem cell transplantation. When PBL relapsed, combined chemotherapy regimens containing daratumumab were ineffective, and the patient remained in CR for 14 months after CAR-T therapy.

The exploration directions for PBL also include newly developed drugs for DLBCL or multiple myeloma, including venetoclax, selinexor, elotuzumab, CELMODS, and PGRCD5 bispecific antibodies.

Conclusion

The results of this META analysis suggest that the use of new drugs, especially bortezomib, in the treatment of newly diagnosed PBL may improve patient efficacy and survival, with similar adverse reactions to traditional regimens. However, this study has certain limitations: all included patients were newly diagnosed PBL, most were retrospective case analyses, and there was not enough data for finer classification. Further analysis is needed for newly diagnosed, relapsed/refractory, age, stage, etc., and the impact on the prognosis of PBL patients still needs further exploration.

Author contributions Bingling Guo Data curation,Writing – original draft-Equal Xi Quan Data curation-Equal, Investigation-Equal Zailin Yang Writing – review & editing-Equal Jieping Li Writing – original draft-Equal, Writing – review & editing-Equal Yao Liu Project administration-Equal, Writing – review & editing-Equal.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Conflict of interest The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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