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Combined Intra-Arterial and Intravitreal Chemotherapy in Retinoblastoma: A Systematic Review and Meta-Analysis

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ABSTRACT

Introduction: Intra-arterial chemotherapy for retinoblastoma has been widely implemented as a primary or secondary treatment choice, yet its efficacy alone is limited in cases with extensive vitreous seed. The effect of intravitreal chemotherapy combined with intra-arterial chemotherapy on tumor control rates and globe salvage is still uncertain. The objective of this review was to explore the effectiveness and safety of intra-arterial plus intravitreal chemotherapy in retinoblastoma.
Methods: A comprehensive search strategy was implemented across three electronic databases (PubMed, Scopus, and Cochrane) for relevant studies from inception until June 2024.
Results: Six studies involving 471 eyes were included in the analysis,. Only three studies were comparative. The level of heterogeneity varied across each reported outcomes. The pooled globe salvage rate was 66% (311/471 eyes, 0.78 [95% CI: 0.55, 0.91]). The overall tumor control rate was 83.5% (304/364 eyes, 0.86 [95% CI: 0.74, 0.93]). Metastatic disease occurred in 3 of 471 eyes (0.63%, 0.015 [95% CI: 0.006, 0.036]).
Conclusion: The pooled evidence from this meta-analysis supports the efficacy and favorable safety profile of combined intra-arterial and intravitreal chemotherapy in treating retinoblastoma. Further research with extended follow-up period are needed to validate these findings.
Keywords: chemotherapy, intra-arterial, intravitreal, retinoblastoma

ABSTRAK

Pendahuluan: Kemoterapi intra-arterial untuk retinoblastoma banyak digunakan sebagai pilihan terapi primer atau sekunder. Efektivitas kombinasi kemoterapi intravitreal dengan kemoterapi intra-arterial terhadap tingkat kontrol tumor dan preservasi mata masih belum pasti. Tinjauan ini bertujuan untuk mengevaluasi keamanan dan efektivitas kemoterapi intra-arterial plus intravitreal pada retinoblastoma.
Metode: Penelusuran studi melalui PubMED, Scopus, dan Cochrane dilakukan hingga Juni 2024 untuk studi yang melaporkan luaran dan komplikasi kemoterapi intra-arterial dan intravitreal pada retinoblastoma.
Hasil: Sebanyak 6 studi yang melibatkan 471 mata memenuhi kriteria inklusi. Hanya tiga studi yang bersifat komparatif. Tingkat heterogenitas bervariasi pada setiap hasil yang dilaporkan. Tingkat preservasi mata keseluruhan adalah 66% (311/471 mata, 0.78 [95% CI: 0.55, 0.91]). Tingkat kontrol tumor keseluruhan adalah 83,5% (304/364 mata, 0.86 [95% CI: 0.74, 0.93]). Penyakit metastatik terjadi pada 3 dari 471 mata (0,63%, 0.015 [95% CI: 0.006, 0.036]).
Kesimpulan: Meta-analisis kami menunjukkan bahwa kombinasi kemoterapi intra-arterial dan intravitreal efektif dan aman untuk pengobatan retinoblastoma. Studi kohort jangka panjang diperlukan untuk memperkuat temuan studi ini.
Kata kunci: kemoterapi, intra-arterial, intravitreal, retinoblastoma

INTRODUCTION

The most common malignant intraocular tumor in children, retinoblastoma (Rb), is caused by mutations in the RB1 gene located on chromosome 13q14.2.[1] Each year, around 8,000 new cases of retinoblastoma are diagnosed worldwide, affecting approximately 1 per 17,000 live births.[2] The standard treatments for intraocular retinoblastoma include chemotherapy, enucleation, external beam radiation, and focal treatments such as laser therapy, cryotherapy, and brachytherapy.[1,3] However, intra-arterial and intravitreal chemotherapy have emerged as promising therapeutic modalities for refractory or advanced retinoblastoma.[4]

Intra-arterial chemotherapy (IAC) delivers chemotherapic agents through direct injection into the ophthalmic artery, increasing drug concentration within the eye and minimizing systemic exposure.[5] While IAC has been widely recognized as a primary treatment for retinoblastoma, the outcome of IAC and systemic chemotherapy is compromised by the inadequate blood supply to vitreous seeds.[6] Limited drug penetration due to the blood-retinal barrier and the vitreous' lack of blood vessels makes vitreous seeding management difficult.[7] The injection of chemotherapy directly into the vitreous cavity has gained popularity for its role in managing vitreous seeds.[8,9] The combination of IAC with IVitC is primarily indicated in cases of persistent active vitreous seeding following IAC, which is more common in advanced stages.[10] Combining IAC with IVitC improves outcomes and significantly reduces enucleation rates compared to IAC alone.[11] Although IVitC shows potential for globe salvage, there is still a lack of evidence on the role of IVitC in achieving tumor control and preventing metastatic disease when combined with IAC. Tumor control was defined as positive clinical response after treatment, characterized by regression of the tumor and clinical disappearance of seeding.[12]

Given the broad adoption of IVitC in the IAC era, its significant contribution to globe preservation rates should not be underestimated. The objective of this review is to investigate the therapeutic benefits and safety profile of combining IVitC with IAC in the management of retinoblastoma.

METHODS

Eligibility Criteria

Studies were included based on the following criteria: (1) randomized controlled trial (RCT), non-RCT or observational studies, (2) subjects were retinoblastoma patients, (3) reported at least one ocular outcome (globe salvage, ocular complications, tumor control, systemic complications, metastatic disease). Studies not published in English and studies with inaccessible full-text articles were excluded.

Literature Search Strategy

This systematic review was conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. We searched PubMed, Scopus, and Cochrane with the terms “intra-arterial chemotherapy”, “IAC”, “intravitreal chemotherapy”, “IVitC”, and “retinoblastoma”. Furthermore, manual screening of the reference lists from included studies was also performed to identify further relevant studies. The last search was performed on June 27, 2024. Further details on the literature search can be seen in Figure 1.

Selection Process

All title/abstracts identified in electronic databases were screened independently by 2 reviewers (JD, LC) using the inclusion and exclusion criteria. Two reviewers (JD,

LC) proceeded with a full-text review of screened articles. Disagreements were resolved through discussion between reviewers.

Data Extraction

The extracted data in general included author, year, study design, sample size, grade of Rb, laterality, number of sessions, and follow-up duration. The main outcomes included globe salvage and enucleation rates, ocular complications, systemic complications, and metastasis/death.

Bias Assessment

The methodological quality of non-randomized controlled trials (non-RCTs) were assessed using the Methodological Index for Non-Randomized Studies (MINORS) by two authors.

Statistical Analysis

The cumulative incidence and 95% confidence interval of eyes achieving globe salvage and undergoing enucleation were calculated for each cohort. Given that most included studies were single-arm trials, a meta-analysis of proportions was performed to generate pooled outcome estimates. The heterogeneity across studies was assessed using the I^2 test. Heterogeneity was considered substantial if I^2>50%. R and RStudio (Posit, Boston, USA) were used for all statistical analysis.

RESULT

Search Results

A total of 210 studies were identified through electronic database search. There were 85 studies remained for further assessment after duplicates were removed. Following the exclusion of non-English and irrelevant articles, 14 studies were considered eligible for full-text review. After full-text review, six studies were deemed eligible for inclusion, consisting 471 eyes, published between 2017 and 2022. Three of the studies were retrospective single-arm cohort, whereas three was a comparative study. Only five studies were included in meta-analysis for a specific outcome as the remaining study did not report the necessary data. The details of included studies are summarized in Table 1.

Globe Salvage

Globe salvage rates of 58% to 100% were reported in six studies including a total of 471 eyes. Global salvage rate was 66% (311/471) for patients treated with IAC and IVitC. Pooled results with 5 studies on the overall rate of proportion of eyes that achieved globe salvage were illustrated in forest plot (Figure 2), and we obtained an overall positive result of 0.784 (95% CI: 0.553 to 0.914). Enucleation was done in 158 of the 471 eyes (33.5%). The overall summary proportion of eyes that were enucleated was 0.216 (95% CI: 0.086-0.447; Figure 2).

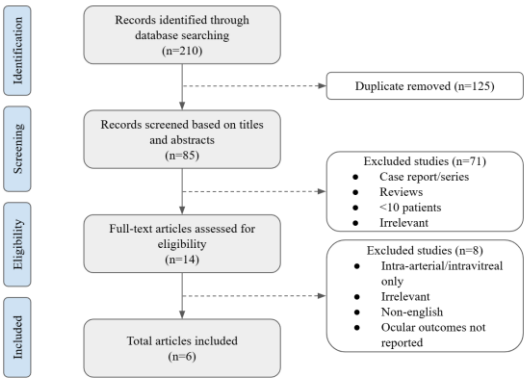

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) shows literature selection process.

Study Quality

The mean MINORS scores of all included studies (range: 9–19) indicate moderate to good overall study quality, which is largely due to the retrospective design and absence of blinding. This limitation affects the interpretation of our pooled estimates, as observed treatment effects may be confounded by heterogeneity.

Table 1. Characteristics of included studies.

Author	Year of Publication	Country	Design Study	Follow-up duration, mean (median, range) months	Number of patients	Number of eyes	Age, mean, (median, range), months	Retinoblastoma classification (no of eyes)	No. of IAC infusions, mean (median, range)	No. of IVitC infusions, mean (median, range)	IAC regimen, doses (mg)	IVitC regimen, doses (µg/mL)	Unilateral (%)	Primary (%)
Dalvin, et al.	2018	USA	Retrospective cohort	27 (21, 2–63)	20	20	50 (36, 5–278)	D (13) E (7)	3.4 (3, 1-8)	6 (6, 2-14)	M ± T	M ± T	100	100
Mirzayev, et al.	2020	Turkey	Retrospective cohort	59.3 (61, 10-98)	7	7	14.3 (11, 1-56)	B (2) D (2) E (3)	2.2 (1-3)	2.5 (1-4)	M (5-7.5) ± T (0.3-0.8)	M (25/0.05) ± T (20 /0.05)	N/A	0
Liang, et al.	2020	China	Retrospective cohort	27 (29, 7-36)	30	30	(30, 12-84)	N/A	3.2 (3-4)	6 (1-14)	M (3-6), T (1-2), C (30-60)	M (30/0.1)	100	100
Gonzalez, et al.	2021	Colombia	Retrospective cohort	(29, 16-59)	N/A	100	(8.7, 4.53-18.55)	A (1) B (10) C (27) D (51) E (11)	(5, 3-7)	(5, 4-8)	M (3-7.5) ± T (1), C (20-30)	M (20-30), T (10-20), C (4)	38.8	43
Naseripour, et al.	2023	Iran	Retrospective cohort	(15, 2.25-29.5)	201	293	24.2	A (8) B (64) C (32) D (56) E (129)	N/A	N/A	M (3.5-5) ± T (0.5-1), C (25)	M (25/0.1) or T (20 /0.1)	54	60 (unilateral); 25 (bilateral)
Francis, et al.	2017	USA	Retrospective cohort	18.1	21	21	(43.9)	D (11) E (10)	2.9	4.8	M (3-7.5), T (0.5-2), C (30-70)	M (30) T (20)	85.7	52.3

IAC = Intra-arterial Chemotherapy; IVitC = Intravitreal Chemotherapy; M = Melphalan; T = Topotecan; C = Carboplatin; N/A = Not Available

Table 2. Treatment outcomes

Study	Globe Salvage, no. of eyes (%)	Enucleation Rate, no. of eyes (%)	Tumor Control, no. of eyes (%)	Intraocular Complications, no. of eyes (%)	Systemic Complications, %	Metastasis, no. of eyes (%)
Dalvin, et al.	13 (65)	7 (35)	16 (80)	N/A	N/A	0
Mirzayev, et al.	5 (71.4)	2 (28.6)	N/A	N/A	N/A	0
Liang, et al.	28 (93.3)	2 (6.67)	29 (96.6)	19 (63)	0	0
Gonzalez, et al.	73 (73)	25 (25)	N/A	42 (42)	17 (17)	1 (1)
Naseripour, et al.	171 (58)	122 (42)	239 (82)	N/A	N/A	3 (2)
Francis, et al.	21 (100)	0	20 (95.2)	N/A	N/A	0

N/A = Not Available

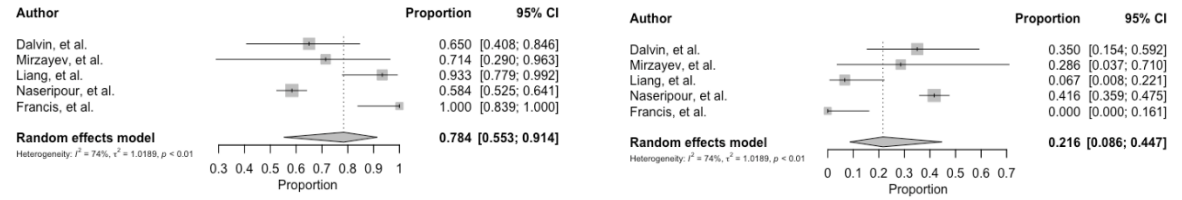

Figure 2. The pooled proportion of eyes with globe salvage (left) and treated with enucleation (right).

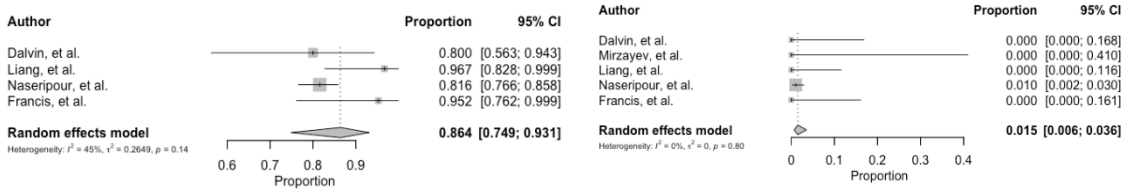

Figure 3. Forest plot depicting tumor control following IAC and IVitC (left) and proportion of metastasis (right).

Tumor Control

Four studies reported tumor control rate of 80% to 96.6% (Table 2). The overall tumor control rate was 83.5% (304/364 eyes; Figure 3)

Ocular Complications

Two studies reported ocular complications following IAC and IVitC (Table 1). The most common ocular complications reported by Liang et al. were retinal pigment epithelium (RPE) atrophy (43%), followed by lens opacity (23%), vitreous hemorrhage (17%), neovascular glaucoma (6%), and rhegmatogenous retinal detachment (3%). As reported by Gonzalez et al., the most common ocular complications observed were choroidal

vascular occlusion (20%), ophthalmic artery spasm (6%), retinal hemorrhage (5%), vitreous hemorrhage (4%), optical neuropathy (2%), and venous retinal branch occlusion (1%).

Systemic complications

In the study of Gonzalez et al., neutropenia was observed in 5 eyes (5.9%), femoral artery thrombosis in 2 eyes (2.4%), cerebral artery thrombosis in 1 eye (1.2%), bronchospasm in 1 eye (1.2%), and contrast media allergies in 8 eyes (9.4%).

Metastasis

Most patients in these studies did not have metastasis following IAC and IVitC. Metastatic disease occurred in 3 out of 471 eyes (0.63%). The pooled proportion of metastasis, as estimated using a random-effects model, was 0.015 (95% CI: 0.006–0.036; Figure 3).

DISCUSSION

To the best of our knowledge, this is the first meta-analysis to evaluate the efficacy of combined intra-arterial and intravitreal chemotherapy for retinoblastoma, unlike previous studies that mainly focused on intra-arterial and intravenous chemotherapy as first-line treatment. Our pooled analysis of 6 studies involving a total of 471 eyes highlights the potential benefits of combining intra-arterial and intravitreal chemotherapy for the treatment of retinoblastoma patients. Globe salvage was achieved in 64.4% of all eyes (37.5% rate of enucleation) overall in our pooled analysis. The efficacy of IAC in globe salvage appears to vary based on disease stage, consistent with a 5-year study by Shields et al. According to their study, 100% of cases in groups B and C achieved globe preservation, which decreased to 94% in group D (and was much lower at 36% in group E) showing a lesser rate in advance disease.[13] Furthermore, Shields et al. showed a significant decrease in enucleation rates of IVitC group vs. pre-IVitC period (2012-2015) in group E eyes (75% vs. 27%, P = 0.039) and all groups (44% vs. 15%, P = 0.012).[14] Another study by Naseripour et al. confirmed that the combination of these two chemotherapy approaches led to improved outcomes in advanced cases diagnosed after 2008 compared to those treated earlier (2001–2007).[15] Indonesia's National Retinoblastoma Protocol (PNPK) recommends intravitreal melphalan for vitreous seeding and combination therapy (IVitC + IAC/IVC + laser) for complex cases with preretinal tumors.[16] Our findings support this integrated approach for optimal tumor control. As demonstrated by this analysis, the majority of studies included patients with advanced retinoblastoma. Our analysis furthermore highlights that combining both modalities may offer superior therapeutic outcomes for patients diagnosed with advanced retinoblastoma.

One of the most important indicators of treatment effectiveness for retinoblastoma is tumor control rate. In this study, tumor control was achieved in 83.5% of cases. This aligns with previous research by Shields et al. which concluded that the use of both IAC and IVitC results in significantly better tumor control.[17] This suggests that the addition of IVitC effectively addresses vitreous seeding, a known limitation of IAC monotherapy. Before the introduction of IVitC in the IAC era, systemic chemotherapy often failed to adequately control vitreous seeding, resulting in enucleation in most cases.[3] Intravitreal injection is an ideal approach for vitreous disease, because it minimizes drug loss by bypassing ocular barriers and systemic breakdown. Chemotherapy can now be administered safely through IVitC by modifying the technique to include injection with anti-reflux technique at a pars plana site free of tumor.[18] The ability of IVitC to directly target vitreous seeds likely

contributes to improved disease control, further reducing the likelihood of tumor recurrence and progression. Thereby, our analysis reinforces the efficacy of combining IAC with IVitC in achieving superior tumor control, particularly in cases complicated by vitreous involvement. However, the results should be interpreted with caution due to significant clinical heterogeneity. This variability may reflect disparities in retinoblastoma staging across studies, with some focusing exclusively on advanced disease. The lack of standardized treatment protocol across studies, such as chemotherapeutic agents, dosing regimens, and administration intervals may independently affect treatment outcomes. Additionally, inconsistency of follow-up durations limit the assessment of long-term efficacy and safety.

While combination treatments in cancer may be more effective, but it may also come with more side effects. The high intraocular drug concentration achieved with intra-arterial chemotherapy increased the risk for local adverse events.[19] On the other hand, intravitreal chemotherapy raises concerns about the risk of extraocular tumor dissemination and metastasic spread. However, Smith et al. suggests that the risk is minimal (around 0.7% of treated eyes) and can be eliminated with appropriate precautions.[20] As observed from our analysis, most studies focused on globe preservation and preventing enucleation, but did not provide detailed reports on ocular and systemic complications. The most commonly reported ocular complications in our review were retinal pigment epithelium (RPE) atrophy, lens opacity, choroidal vascular occlusion and vitreous hemorrhage. This result is in accordance with a previous study by Shields et al. which also identified similar complications following IAC and IVitC treatments.[17] The most commonly ocular side effects of IVitC reported by Smith et al. include vitreous hemorrhage, cataract, iris and choroidal atrophy, uveitis, retinal detachment, retinal toxicity, and phthisis bulbi.[20] Despite the risk of extraocular spread, IVitC appears to have a favorable safety profile. Among 261 patients who received standard-dose intravitreal melphalan, only 8 (3%) developed substantial toxicity.[20] Moreover, Francis et al. reported that the toxicity in the IAC plus intravitreal chemotherapy group was not significantly worse than in the IAC-only group.[21] The most common systemic complications were contrast media allergies and neutropenia. None of the studies reported a need for transfusion. Of the neutropenia cases, three were severe (grade 4), one was moderate (grade 3), and one was mild (grade 2).

Preserving the eye may not be beneficial in advanced stages if the risk of metastatic spread is high.[22] Choosing enucleation in these cases might be a safer and more effective strategy. In view of our analysis, metastasis was uncommon among the majority of patients after receiving IAC and IVitC, occuring in only 3 out of 471 eyes (0.63%). This finding was similar to the 2016 study by Shields et al., who reported no metastasis or death when using combination of IAC and IVitC, improving the chances of globe preservation beyond prior limits, especially in the presence of vitreous seeding.[17]

There are some limitations in this study. First, most of the included studies were observational and non-randomized cohort, which may impact the strength of our conclusions and introduce potential selection bias. Secondly, while several other chemotherapeutic modalities were included in the studies, we made efforts to focus specifically on IAC and IVitC. Third, three out of six studies were non-comparative, which prevented us from conducting a pairwise comparative meta-analysis between IAC with combination therapy. One study were ineligible for

meta-analysis because it did not provide subgroup analysis of the outcome. Lastly, due to insufficient reporting, we were unable to perform a detailed subgroup analysis based on retinoblastoma grouping, which limits our ability to assess the efficacy across disease stages. However, this study yields pooled estimates for globe salvage and enucleation rate which can provide guidance for therapeutic intervention.

CONCLUSION

In summary, our systematic review demonstrates the efficacy and safety of combined intra-arterial and intravitreal chemotherapy in treating retinoblastoma. The use of dual-modal therapy should be considered when treating advanced retinoblastoma, which previously led to enucleation due to persistent vitreous seed. Further prospective studies with stratification by retinoblastoma group are needed to optimize treatment protocols based on disease severity.

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