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ERYTHROPOIESIS-STIMULATING AGENT THERAPY IN HEMODIALYSIS FOR KIDNEY DISEASE RELATED ANEMIA: A SYSTEMATIC REVIEW

Terapi Agen Perangsang Eritropoiesis pada Pasien Hemodialisis dengan Anemia Akibat Penyakit Ginjal: Tinjauan Sistematis

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ABSTRAK

Anemia merupakan komplikasi umum pada pasien penyakit ginjal kronik (PGK) yang menjalani hemodialisis dan berdampak pada kualitas hidup serta prognosis. Tinjauan sistematis ini dilakukan berdasarkan kerangka Arksey dan O'Malley serta panduan PRISMA untuk mengevaluasi efektivitas dan keamanan erythropoiesis-stimulating agents (ESA) konvensional. Dari 539 artikel yang teridentifikasi pada periode 2015–2025, sebanyak 9 studi memenuhi kriteria inklusi. Sebagian besar ESA terbukti efektif meningkatkan hemoglobin (Hb) ke kisaran target 10–12 g/dL, meskipun terdapat variasi antar agen. Epoetin alfa menunjukkan peningkatan Hb yang lebih besar (2,3 g/dL) dibanding epoetin beta (1,2 g/dL), dengan efek samping ringan seperti pusing dan pruritus. Darbepoetin alfa mencapai proporsi pasien tertinggi yang berada dalam target Hb (88–90%), meskipun pada sebagian kasus ditemukan hipertensi dan komplikasi akses vaskular. C.E.R.A. menawarkan keuntungan interval dosis bulanan dan stabilitas Hb, namun hanya 55,9% pasien yang mencapai target Hb. Kejadian efek samping serius dengan C.E.R.A. relatif rendah (12%) dan sebagian besar terkait komorbiditas pasien. Kesimpulannya, terapi ESA efektif dalam mengoreksi anemia pada pasien PGK dengan hemodialisis, tetapi perbedaan efektivitas dan keamanan antar agen menekankan pentingnya pemilihan yang terindividualisasi. Epoetin alfa lebih sesuai untuk koreksi Hb yang cepat, darbepoetin alfa unggul dalam pencapaian target Hb, sementara C.E.R.A. bermanfaat pada pasien yang memerlukan regimen sederhana dengan penyesuaian dosis minimal. Pemilihan terapi ESA perlu mempertimbangkan kondisi klinis, komorbiditas, kepatuhan pasien, serta kapasitas sistem pelayanan kesehatan untuk mengoptimalkan luaran.

Kata kunci: *anemia, efektivitas, erythropoiesis-stimulating agents, hemodialisis, keamanan*

ABSTRACT

Anemia is a common complication of chronic kidney disease (CKD) in patients undergoing hemodialysis, with significant impact on quality of life and prognosis. This systematic review, conducted in line with Arksey and O'Malley's framework and PRISMA guidelines, evaluated the effectiveness and safety of erythropoiesis-stimulating agents (ESAs). From 539 articles identified between 2015 and 2025, nine studies met the inclusion criteria. Most ESAs effectively increased hemoglobin (Hb) to the recommended target of 10–12 g/dL, though differences were observed across agents. Epoetin alfa produced a greater mean Hb increase (2.3 g/dL) compared to epoetin beta (1.2 g/dL), with both generally associated with mild adverse events such as dizziness and pruritus. Darbepoetin alfa achieved the highest proportion of patients within target Hb (88–90%),

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though occasional cases of hypertension and vascular complications were reported. C.E.R.A. offered the advantage of once-monthly dosing and stable Hb levels, but the proportion of patients achieving target Hb was lower (55.9%). Serious adverse events with C.E.R.A. were relatively low (12%) and mostly attributable to comorbidities. In conclusion, conventional ESA therapy is effective in correcting anemia among CKD patients on hemodialysis, but variations in efficacy and safety highlight the need for individualized selection. Epoetin alfa may be preferred for rapid Hb correction, darbepoetin alfa for higher target attainment, and C.E.R.A. for simplified regimens requiring fewer dose adjustments. Tailoring ESA therapy to patient comorbidities, adherence, and healthcare system resources is essential to optimize outcomes.

Keywords: anemia, effectiveness, erythropoiesis-stimulating agents, hemodialysis, safety

INTRODUCTION

Chronic Kidney Disease (CKD) is characterized by structural or functional abnormalities of the kidneys persisting for more than three months, often leading to reduced estimated Glomerular Filtration Rate (eGFR) and complications such as fluid overload, electrolyte disturbances, hypertension, cardiovascular disease, and anemia [1]. Anemia is highly prevalent in CKD, affecting up to 85.33% of patients in stages 3–5 and being more severe in those with end-stage renal disease (ESRD) on hemodialysis. It results mainly from reduced erythropoietin production, shortened red blood cell lifespan, iron deficiency, and impaired utilization [2]. The World Health Organization defines anemia as Hb <12 g/dL in women and <13 g/dL in men [3].

According to the 2023 Indonesia Health Survey (SKI), the national prevalence of CKD was 0.18%, and 235 per 1,000,000 population underwent hemodialysis in the same year, indicating a growing healthcare burden [4]. Anemia remains highly prevalent, affecting 84.5% of CKD patients on hemodialysis [5]. Collectively, these data underscore the considerable clinical and economic burden of CKD-related anemia in Indonesia.

The introduction of erythropoiesis-stimulating agents (ESAs) in the late 1980s reduced dependence on blood transfusions, which were previously required for patients with Hb levels of 5–6 g/dL and carried risks of iron overload, sensitization, and infection. Currently available ESAs include short-acting epoetin alfa and epoetin beta, the long-acting darbepoetin alfa, and the continuous erythropoietin receptor activator (C.E.R.A., methoxy polyethylene glycol-epoetin beta) [1,6]. According to the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines, initiation of ESA therapy is recommended in CKD patients when Hb levels fall below 10 g/dL, with careful consideration of iron status, comorbidities, and the risks of adverse events [1].

In Indonesia, epoetin alfa and epoetin beta are the only ESAs reimbursed by the National Health Insurance (JKN), making them the mainstay therapy [7]. However, recent cohort studies associate high-dose ESA use with increased risks of adverse outcomes and mortality, highlighting the need for cautious, individualized treatment [8].

Despite extensive global research, no systematic review has specifically compared the effectiveness and safety of different ESA generations in Indonesian hemodialysis patients. This review addresses that gap by synthesizing available evidence to inform clinical practice and policy.

METHODS

Focus and Search Strategy

This systematic review aimed to evaluate the effectiveness and safety of erythropoiesis-stimulating agents (ESAs) in managing anemia among patients with chronic kidney disease (CKD) undergoing hemodialysis. A comprehensive literature search was conducted from January 3 to March 31, 2025, using keywords such as

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"effectiveness," "safety," "erythropoiesis-stimulating agent," "anemia," "CKD," "hemodialysis," and "end-stage renal disease." Relevant articles were identified through international databases (Scopus, ScienceDirect, PubMed, and Google Scholar) and national databases (Garuda and Neliti). The literature search identified 539 records, of which 9 studies met the eligibility criteria and were included in the final review. The selection process followed the PRISMA guidelines and is summarized in Figure 1.

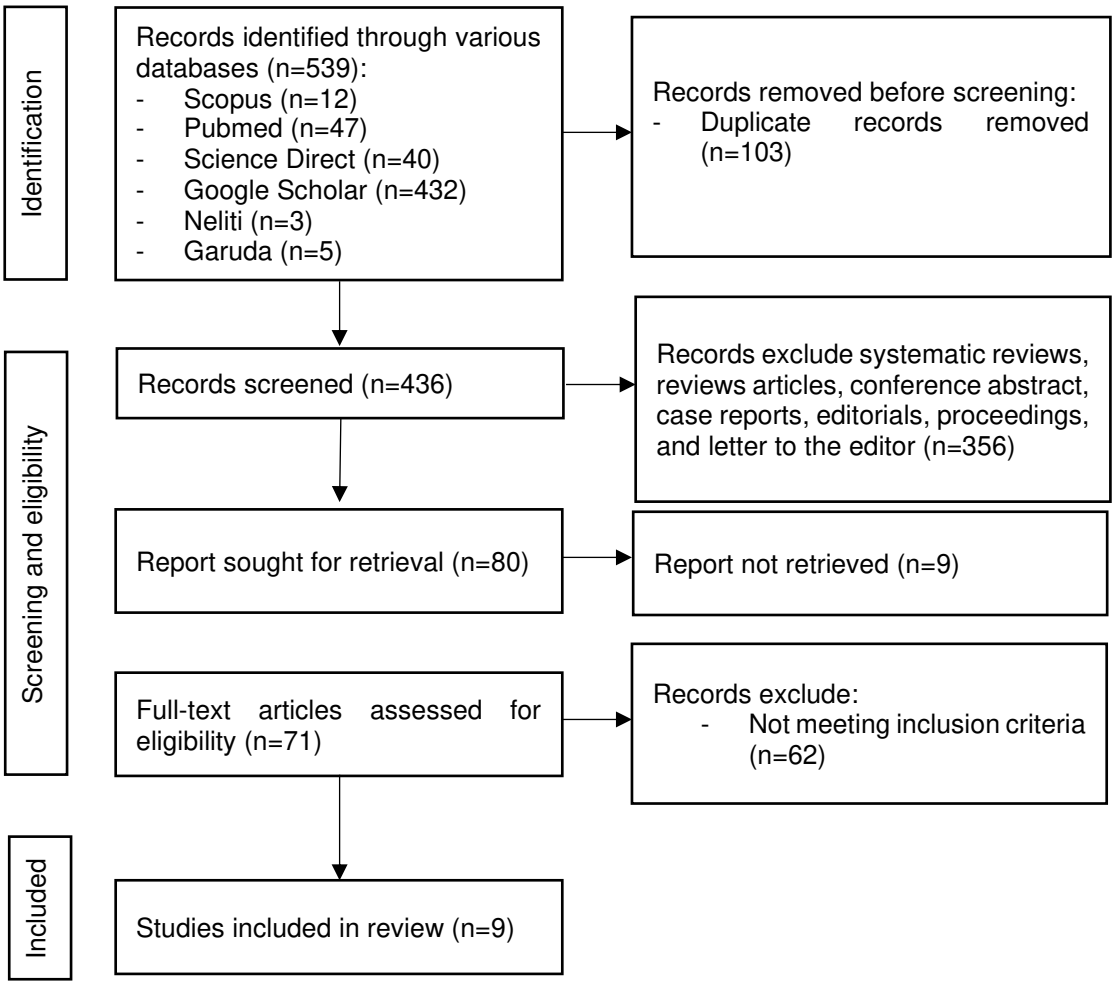

Figure 1. PRISMA Method for Search Strategy Source. Processed by Author (2025)

Eligibility Criteria

The eligibility criteria were based on the PICO framework (Population, Intervention, Comparison, and Outcome). The population (P) included adult patients (≥18 years) with anemia due to CKD undergoing hemodialysis. The intervention (I) was ESA therapy. The comparison (C) included either comparisons among different ESAs or between ESA and alternative therapies. The outcome (O) assessed the effectiveness and safety of ESA therapy.

Inclusion criteria were: articles published between 2015 and 2025, reporting primary research (randomized controlled trials or observational studies), indexed in one of the five selected databases, and involving CKD stage 4 or 5 patients on hemodialysis for ≥3 months. Studies evaluating a single ESA or comparisons between ESAs were eligible. Exclusion criteria were articles in languages other than English and Indonesian, as well as systematic reviews, reviews, conference abstracts, case reports, editorials, proceedings, and letters to the editor.

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A total of nine studies were included in this review. Although some trials primarily evaluated novel agents such as roxadustat, daprodustat, or pegmolesatide, these studies were retained because they provided comparative data on conventional ESAs (epoetin alfa, epoetin beta, darbepoetin alfa, and CERA). Thus, conventional ESA outcomes were extracted and synthesized for the purpose of this review.

Data Extraction

Data extraction was performed independently by two reviewers using a standardized form. Extracted data included study design, sample size, patient characteristics, ESA type and dosing, comparator(s), outcomes (hemoglobin changes, proportion achieving target Hb, and incidence of adverse events), and main findings. Any discrepancies were resolved through discussion, and if consensus could not be reached, the third reviewer acted as an adjudicator.

Quality Assessment

The methodological quality of included studies was assessed using the Newcastle–Ottawa Scale (NOS) for observational studies and the Cochrane RoB 2 tool for randomized controlled trials.

Data Synthesis

Due to heterogeneity in study design, interventions, comparators, and reported outcomes, a narrative synthesis approach was adopted. Meta-analysis was not feasible.

RESULT

This review included nine clinical studies conducted in Japan, Qatar, China, North Macedonia, Indonesia, and the United States, encompassing randomized controlled trials, observational cohorts, and quasi-experimental designs. Short-acting ESAs such as epoetin alfa and epoetin beta demonstrated good efficacy in increasing hemoglobin (Hb) levels but required more frequent dosing adjustments. In contrast, long-acting agents such as darbepoetin alfa and CERA (methoxy polyethylene glycol-epoetin beta) offered the advantage of extended dosing intervals, though some were associated with a higher incidence of hypertension and vascular complications.

Across the included studies, most ESAs successfully maintained Hb within the recommended range of 10–12 g/dL. However, safety outcomes varied: epoetin was linked to mild adverse events such as dizziness and pruritus, while darbepoetin and CERA were occasionally associated with vascular access complications or cardiovascular events. Notably, CERA demonstrated favorable safety and efficacy, with a greater proportion of patients achieving stable Hb compared to short-acting ESAs. A summary of the included studies is presented in Table 1. This table outlines key study characteristics, including author, year, study design, sample size, and sampling methods. These details provide context for interpreting the findings on the efficacy and safety of ESA therapy in patients with CKD undergoing hemodialysis.

Table 1. Characteristics of the Studies Included in the Systematic Review

No	Author, Year and Tittle	Study Design, Sample Size, and Sampling Method
1.	Al-Ali et al. (2015) [8] *Erythropoietin-stimulating agents in the management of anemia of end-stage renal disease patients on regular hemodialysis: A prospective randomized comparative study from Qatar*	Prospective, randomized, multicenter study in Qatar comparing epoetin alfa/beta, darbepoetin alfa, and CERA in 327 hemodialysis patients. Patients were randomized to one of the three ESA regimens and followed for 40 weeks.
2.	Winkelmayer et al. (2015) [9] *Longer-term outcomes of darbepoetin alfa versus epoetin alfa in patients with ESRD initiating*	Registry-based, retrospective cohort study mimicking a cluster-randomized trial. Included 19,932 incident hemodialysis patients from 984 US facilities (492 matched facility pairs) assigned to darbepoetin alfa or

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No	Author, Year and Tittle	Study Design, Sample Size, and Sampling Method
	hemodialysis: A quasi-experimental cohort study	epoetin alfa based on facility-level ESA use between 2003 and 2010.
3.	Akizawa et al. (2020) [10] Efficacy and safety of daprodustat compared with darbepoetin alfa in Japanese hemodialysis patients with anemia: A randomized, double-blind, phase 3 trial	Randomized, double-blind, phase 3 active-controlled trial in Japan involving 271 hemodialysis patients with CKD-related anemia. Patients previously receiving ESAs were randomized 1:1 to oral daprodustat or darbepoetin alfa.
4.	Kacarska et al. (2020) [10] *Safety and Efficacy of Methoxy Polyethylene Glycol-epoetin Beta in Anemia Treatment in Patients on Hemodialysis: a Macedonian Experience*	Observational, prospective, single-arm study in 8 dialysis centers in North Macedonia. A total of 184 CKD patients on hemodialysis were followed monthly for 12 months. Consecutive sampling was assumed based on routine clinical enrollment.
5.	Gunawan Widodo et al. (2021) [11] *Comparison Of The Effectiveness And Safety Of Anemia Epoetin Alfa With Epoetin Beta In hemodialysis Routine Patients At Haji Hospital Surabaya*	Quasi-experimental, non-equivalent control group study at RSU Haji Surabaya involving 50 hemodialysis patients with anemia. Patients were assigned to epoetin alfa (n=25) or epoetin beta (n=25) groups. Data collection used a combination of retrospective and prospective methods, with total sampling applied.
6.	Singh A et al. (2022) [12] *Efficacy and Safety of Daprodustat for Treatment of Anemia of Chronic Kidney Disease in Incident Dialysis Patients: A Randomized Clinical Trial*	Prospective, randomized, open-label, multicenter phase 3 trial involving 312 patients with advanced CKD initiating or recently started on dialysis. Patients were randomized 1:1 to daprodustat or darbepoetin alfa across 90 centers in 14 countries.
7.	Fishbane S et al. (2022) [13] *Roxadustat Versus Epoetin Alfa for Treating Anemia in Patients with Chronic Kidney Disease on Dialysis: Results from the Randomized Phase 3 ROCKIES Study*	Open-label, randomized, phase 3 trial involving 2133 dialysis-dependent CKD patients with anemia. Patients were randomized 1:1 to receive roxadustat or epoetin alfa across multiple clinical centers using local practice protocols.
8.	Nurfina Dian K. et al. (2023) [14] *Clinical Profile and Outcomes of Anemia Therapy in Chronic Kidney Disease Patients Undergoing Hemodialysis at PKU Muhammadiyah Hospital Yogyakarta*	Retrospective observational cohort study at RS PKU Muhammadiyah Yogyakarta involving 113 CKD stage 4–5 patients undergoing routine hemodialysis. Patients received either epoetin alfa or beta for at least 3 months. Data were collected from medical records using total sampling.
9.	Zhang et al. (2023) [15] *Pegmolesatide for the treatment of anemia in patients undergoing dialysis: a randomized clinical trial*	Randomized, open-label, phase 3 non-inferiority trial conducted at 43 dialysis centers in China. A total of 372 dialysis patients aged 18–70 years were randomized in a 2:1 ratio to receive pegmolesatide (n=248) or epoetin alfa (n=124), with 347 patients included in the per-protocol analysis.

The synthesized findings are outlined in Table 2, highlighting the comparative effectiveness and safety of different ESAs in hemodialysis patients. Key aspects include hemoglobin response, target achievement, clinical notes on effectiveness, safety profiles, and head-to-head comparisons across agents.

Table 2. Summary of Effectiveness and Safety Outcomes of ESAs in Hemodialysis Patients

No	ESA Type	Key Studies (n)	Effectiveness (Mean Hb Change / Target Achievement)	Clinical Notes on Effectiveness	Safety Profile (Common AEs)	Comparative Findings
1.	Epoetin alfa	4 (Winkelmayer 2015 [9]; Gunawan 2021	↑ Hb 2.3 g/dL (vs 1.2 with epoetin beta); Target Hb 10–12	More effective than epoetin beta;	Mild AEs: dizziness, pruritus,	Superior efficacy vs epoetin beta;

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No	ESA Type	Key Studies (n)	Effectiveness (Mean Hb Change / Target Achievement)	Clinical Notes on Effectiveness	Safety Profile (Common AEs)	Comparative Findings
		[10]; Fishbane 2022 [11]; Nurfina 2023 [12])	g/dL consistently achieved	comparable to roxadustat; stable Hb vs pegmolesatide	cough, fever; no major CV events	non-inferior to roxadustat; slightly less stable Hb vs pegmolesatide
2.	Epoetin beta	3 (Winkelmayer 2015 [9]; Gunawan 2021; [10] Nurfina 2023 [12])	↑ Hb 1.2 g/dL; Comparable Hb rise with epoetin alfa in some studies	Less robust Hb improvement than epoetin alfa	Similar AEs (dizziness, pruritus, GI upset)	Inferior to epoetin alfa; no clear advantage
3.	Darbepoetin alfa	4 (Al-Ali 2015 [13]; Akizawa 2020 [14]; Singh 2022 [15]; Fishbane 2022 [11])	↑ Hb 1.5 g/dL (mean 10.6–10.8 g/dL)	Longer dosing interval; stable Hb maintenance	Hypertension, vascular access events, rare bleeding	Comparable to epoetin alfa; non-inferior to daprodustat
4.	CERA (Methoxy-PEG epoetin beta)	2 (Al-Ali 2015 [13]; Kacarska 2020 [16])	↑ Hb 1.5 g/dL (mean 11-12 g/L); Target Hb achievement at 28 weeks	Fewer dose adjustments; convenient once-monthly dosing	CV events (rare), some mortality linked to comorbidities	More convenient vs short-acting ESAs

Abbreviations: ESA = erythropoiesis-stimulating agent; Hb = hemoglobin; AE = adverse event; CV = cardiovascular; CERA = continuous erythropoietin receptor activator.

Building upon the synthesized findings in Table 2, the proportion of patients achieving the target hemoglobin range (10–12 g/dL) with different ESA therapies is further illustrated in Figure 2. This visualization allows for a clearer comparison of treatment response rates across agents.

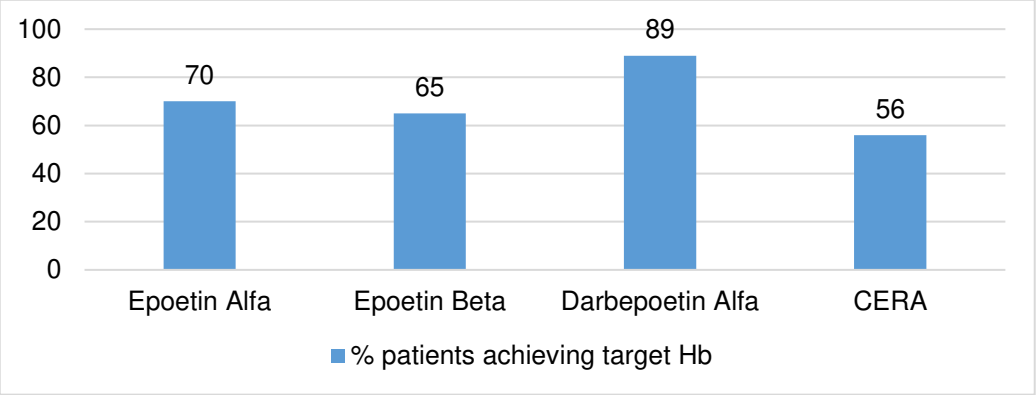

Figure 2. Proportion of Patients Achieving Target Hemoglobin (10–12 g/dL) with Different ESA Therapies

As shown in Figure 2, the proportion of patients achieving target hemoglobin (10–12 g/dL) varied across ESA types. Darbepoetin alfa demonstrated the highest achievement rate (89%), followed by epoetin alfa (70%) and epoetin beta (65%), while C.E.R.A. showed the lowest proportion (56%). These findings indicate variability in treatment response depending on the type of ESA administered.

DISCUSSION

This systematic review confirms the effectiveness of ESAs in correcting anemia among CKD patients undergoing hemodialysis, with most agents maintaining Hb within

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the target range of 10–12 g/dL. However, variability in outcomes across ESA types deserves closer examination. As illustrated in Figure 2, the proportion of patients achieving target hemoglobin differed among ESA types, with darbepoetin alfa demonstrating the highest attainment (89%), followed by epoetin alfa (70%) and epoetin beta (65%), while C.E.R.A. showed the lowest proportion (56%). This variability reflects pharmacokinetic differences between agents and indicates that not all ESAs provide the same likelihood of achieving treatment goals.

Short-acting ESAs such as epoetin alfa generally demonstrated greater Hb increases compared to epoetin beta, consistent with their higher receptor binding affinity and shorter half-life that necessitates more frequent dosing adjustments. In contrast, long-acting ESAs such as darbepoetin alfa and C.E.R.A. provided improved Hb stability and dosing convenience, reflecting their extended half-lives and different glycosylation patterns. Beyond pharmacology, patient-specific factors also play a critical role. Chronic inflammation and cardiovascular comorbidities may impair erythropoietic response, while disturbances in iron metabolism particularly elevated hepcidin can blunt ESA effectiveness. These aspects highlight the need for integrated management, including careful monitoring of iron indices and comorbidity control, rather than relying solely on Hb targets.

Safety profiles also varied across ESA types. While epoetin alfa and beta were generally associated with mild adverse events such as dizziness, pruritus, and fever, darbepoetin alfa and C.E.R.A. were more frequently linked to hypertension and vascular access complications. Nevertheless, the overall incidence of serious adverse events was low. These findings suggest that the choice of ESA should not only be based on efficacy but also consider patient comorbidities, risk of cardiovascular complications, and potential adherence challenges.

The strengths of this review include the synthesis of evidence from randomized controlled trials, quasi-experimental studies, and observational cohorts across multiple regions, providing a broad overview of ESA use in clinical practice. However, several limitations must be acknowledged. Considerable heterogeneity exists in study design, patient populations, dosing regimens, and outcome measures, which complicates direct comparisons. Potential publication bias should also be considered, as most available studies report favorable outcomes. Furthermore, the limited number of studies from Southeast Asia constrains the applicability of findings to local health systems. Importantly, economic evaluations remain scarce, despite their importance for guiding reimbursement policies and resource allocation in low- and middle-income countries.

These findings carry important implications for clinical guidelines and policy. In Indonesia, short-acting ESAs remain the mainstay therapy due to reimbursement by the national health insurance system, yet their frequent dosing may reduce adherence. Long-acting ESAs such as darbepoetin alfa and C.E.R.A. offer practical advantages in terms of dosing convenience and Hb stability, and may be especially beneficial for patients with low adherence or in healthcare facilities with limited capacity for frequent dose adjustments. Policymakers should therefore consider incorporating comparative evidence on ESA safety and efficacy into national guidelines, while supporting large-scale, region-specific prospective studies and cost-effectiveness analyses. Such measures would strengthen individualized ESA therapy and ensure more efficient resource use in CKD management.

CONCLUSION

ESA therapy is effective for managing anemia in CKD patients undergoing hemodialysis, though differences in efficacy and safety exist across agents. Epoetin alfa demonstrates greater hemoglobin improvement compared to epoetin beta, while darbepoetin alfa achieves the highest proportion of patients reaching the target Hb range (10–12 g/dL). C.E.R.A. offers the advantage of once-monthly dosing and stable Hb

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levels, although with slightly lower target attainment. In terms of safety, epoetin formulations are mainly associated with mild adverse events such as dizziness and pruritus, while darbepoetin alfa and C.E.R.A. are more frequently linked to hypertension and vascular complications, though serious adverse events remain uncommon.

In practice, the choice of ESA should be individualized. In resource-limited settings such as Indonesia, short-acting ESAs remain the most accessible option due to reimbursement by national health insurance. However, long-acting agents may be preferable for patients with poor adherence or limited access to frequent monitoring. Future studies should prioritize region-specific cost-effectiveness and safety evaluations to guide clinical decision-making, and further explore the potential role of novel agents within local healthcare systems.

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