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Literature Review

Literature Review: Effectiveness of Roxadustat Administration in the Management of Anemia in Patients with Chronic Kidney Disease

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Abstract

Background: Chronic kidney disease (CKD) is a global health burden with high morbidity and mortality. Anemia is a common complication that worsens quality of life, increases cardiovascular risk, and reduces survival. Roxadustat, an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), represents a novel therapy by stimulating endogenous erythropoietin, lowering hepcidin, and improving iron metabolism. **Objective:** To evaluate the effectiveness and safety of roxadustat in managing anemia among CKD patients. **Methods:** A literature review was performed through PubMed, Google Scholar, and ScienceDirect. Six studies, including randomized controlled trials, retrospective cohorts, and real-world registry data, were analyzed. **Results:** Roxadustat consistently increased hemoglobin and maintained it within therapeutic targets in both dialysis and non-dialysis patients. It improved iron utilization, reduced intravenous iron needs, and showed favorable lipid effects. The safety profile was generally comparable to erythropoiesis-stimulating agents, with no significant increase in cardiovascular or infectious adverse events. **Conclusion:** Evidence indicates that roxadustat is an effective, safe, and practical treatment for anemia in CKD. Its ability to optimize hemoglobin control, enhance iron metabolism, and maintain safety supports its potential as an alternative to conventional therapy.

Keywords: Roxadustat; Anemia; Chronic Kidney Disease.

Introduction

Chronic kidney disease (CKD) is a clinical syndrome that occurs as a result of a gradual and persistent decline in kidney function. CKD can be caused by multifactorial conditions lasting for three months or more and is characterized by a glomerular filtration rate (GFR) of less than 60 mL/min/1.73 m² accompanied by signs of kidney damage. These manifestations may include albuminuria, abnormal urinary sediment, abnormal kidney structure, renal tubular disorders, or a history of kidney transplantation[1]. CKD is one of the non-communicable diseases with high morbidity and mortality.

Globally, the incidence of CKD reached 697.5 million cases in 2017. In the Global Burden of Disease (GBD) study, 79 of 195 countries had more than one million CKD cases[2]. This number decreased in 2021 to 674 million cases, with mortality reaching 1.5 million deaths. However, the burden remained higher than that of other common chronic diseases, such as diabetes mellitus, cardiovascular disease, chronic respiratory disease, and osteoarthritis[3]. Deaths due to CKD

are projected to increase to between 2.2 million and 4 million cases by 2040[4].

Data from the 2018 Basic Health Research (Riskesdas) showed that the prevalence of CKD in Indonesia was 3.8%. Meanwhile, the 2023 Indonesian Health Survey (SKI) report by the Health Development Policy Agency (BKPK) recorded a decrease to 1.8%. Nevertheless, the proportion of CKD patients diagnosed by physicians who underwent hemodialysis among those aged ≥15 years increased, particularly among younger age groups. The 25–34-year age group accounted for the highest proportion, at 31.4%[5]. This finding indicates a shift in the disease burden toward the productive-age population.

CKD can cause various signs and symptoms, including pallor, cognitive changes, respiratory disorders, gastrointestinal symptoms, changes in kidney shape and urine production, hematuria, integumentary symptoms, and peripheral edema[6]. In advanced conditions, CKD may lead to several complications, one of which is anemia[7]. Anemia is defined as a decrease in hemoglobin (Hb) concentration in the blood, which plays an important role in oxygen transport. According to Kidney Disease: Improving Global Outcomes (KDIGO), anemia occurs when hemoglobin concentration is <13.0 g/dL in men and <12.0 g/dL in women[8].

The prevalence of anemia among CKD patients is estimated at 42% and increases progressively with CKD stage. In fact, approximately 80% of patients with stage 5 CKD experience anemia[9]. Anemia in CKD is caused by reduced erythropoietin production, impaired iron metabolism due to chronic inflammation, and dysregulation of hypoxia-inducible factor (HIF)[10]. Uremia, vitamin deficiency, bleeding, and hemodialysis also contribute as additional mechanisms[11]. Anemia worsens cardiovascular and clinical outcomes, reduces quality of life, and increases morbidity and mortality among CKD patients[12].

The main management of CKD patients with anemia involves the administration of erythropoiesis-stimulating agents (ESAs) and oral or intravenous iron supplementation[13]. Blood transfusion is also a therapeutic option for CKD patients with severe anemia[14]. A new class of therapeutic agents, namely hypoxia-inducible factor prolyl hydroxylase inhibitors (HIF-PHIs), has recently emerged for the treatment of anemia in CKD. HIF-PHIs work by stabilizing HIF, which induces endogenous erythropoietin production and subsequently promotes erythropoiesis[15]. In addition, HIF-PHIs reduce hepcidin levels and regulate iron metabolism[16].

Roxadustat (FG-4592) is an oral HIF-PHI that has been developed globally[17]. After phase 3 clinical trials, roxadustat received approval as an oral therapy for anemia in China[18]. Roxadustat has also been approved for marketing in Japan, Chile, South Korea, and the European Union[19]. Roxadustat has promising potential as an alternative therapeutic option for managing anemia in CKD patients, including in Indonesia. This literature review comprehensively examines scientific evidence from previous studies regarding the effectiveness of roxadustat in the management of anemia among CKD patients, with the aim of improving understanding of its clinical use.

Materials and Methods

Study Design

This study employed a narrative literature review design to evaluate the effectiveness of roxadustat in managing anemia in patients with chronic kidney disease (CKD). This approach allows for a comprehensive synthesis of evidence from various types of studies, including randomized controlled trials, cohort studies, and real-world registry data.

Sample

The sample consisted of scientific articles examining the effectiveness of roxadustat for anemia management in patients with chronic kidney disease (CKD). Eligible studies were published in English or Indonesian between 2020 and 2025, available in full text with open access, and employed clinical trial, randomized controlled trial, cohort, or observational designs. Studies were required to evaluate the therapeutic effects of roxadustat on anemia in CKD patients. Articles such as editorials, opinion papers, non-systematic reviews, conference abstracts, and studies not directly related to the research topic were excluded to ensure the inclusion of high-quality and relevant evidence for the literature review.

Data Collection Technique

Articles were collected through electronic searches using accredited scientific databases, including PubMed, Google Scholar, and ScienceDirect. The keywords used in the search were "Roxadustat" and "Chronic Kidney Disease." The selection process was conducted in several stages: initial screening based on titles and abstracts to eliminate irrelevant articles or those outside the publication period; full-text review to assess eligibility and completeness of information; and final selection, which resulted in 6 articles that were analyzed in this literature review.

Data Analysis Technique

Data from the selected articles were extracted into summary tables including author and year of publication, study methods, study duration, patient population, intervention and control groups, and conclusions regarding the effectiveness of roxadustat. A narrative analysis was then conducted to synthesize the information and provide a comprehensive overview of the effectiveness and safety of roxadustat in managing anemia among CKD patients. The findings from this synthesis were used to identify consistent trends, gaps in the current evidence, and potential implications for clinical practice.

Ethical Consideration

This study is a secondary literature review using previously published articles that are publicly accessible. Therefore, it did not involve direct participation of human or animal subjects and did not require ethical approval. Nevertheless, the study adhered to principles of academic integrity, proper citation, and respect for the intellectual property of the original authors.

Results

The initial literature search identified 3,505 articles related to the study keywords. During the title and abstract screening, 565 articles were excluded because they were published more than five years ago, while 2,925 additional articles did not meet the predefined inclusion criteria, resulting in the exclusion of 3,490 records. The remaining 15 articles underwent full-text assessment for eligibility. After a detailed review, 9 articles were excluded because they provided incomplete findings or were not directly relevant to the study objectives. Consequently, 6 articles fulfilled all inclusion criteria and were included in the final analysis. These selected studies formed the evidence base for this literature review and were synthesized to identify key findings, compare methodologies, and summarize current evidence related to the research topic. The characteristics of the included studies are presented in the following table.

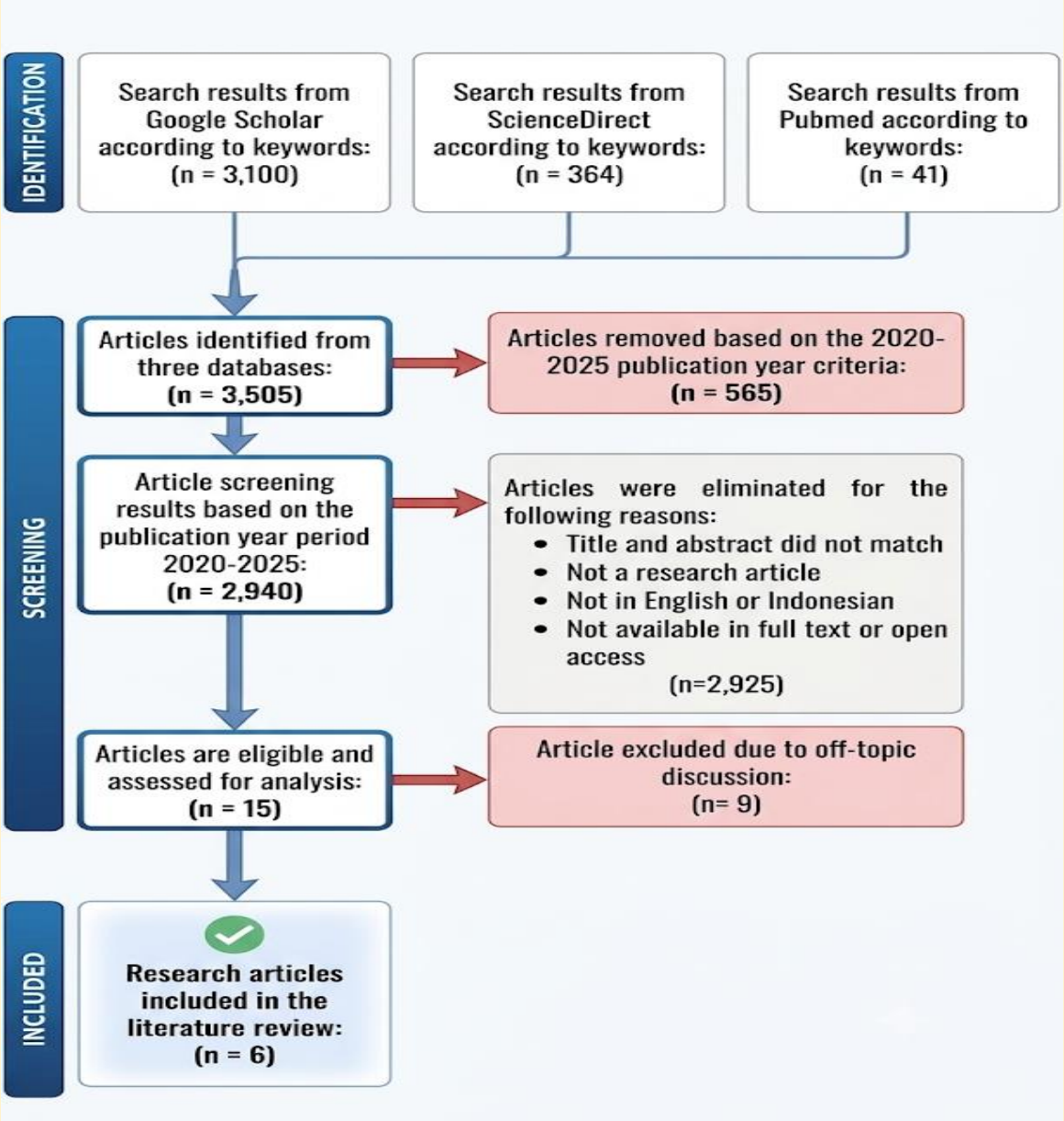

Figure 1. Literature Search Flow Diagram

Table 1. Literature Review Analysis Results

Author (Year)	Method (Duration)	Population	Intervention	Comparator	Study Results
Coyne et al. (2021)	Phase 3 multicenter RCT for 52 weeks.	922 patients aged ≥18 years with stage 3–5 CKD who were not undergoing dialysis and had anemia.	Oral roxadustat tablets, 70 or 100 mg according to body weight, three times weekly (n = 616).	Placebo three times weekly (n = 306).	Roxadustat increased Hb by 2.00 g/dL, whereas placebo increased Hb by 0.16 g/dL. Hb response at week 24 was achieved by 86% of patients in the roxadustat group and 6.6% in the placebo group, with an odds ratio of 77.6 ($p < 0.0001$). TEAEs and TESAEs were balanced.
Barratt et al. (2021)	Phase 3 multicenter	616 patients aged ≥18 years with	Oral roxadustat tablets, 70 or	Darbepoetin alfa	Hb response at week 24 was achieved by 89.5% of patients

Author (Year)	Method (Duration)	Population	Intervention	Comparator	Study Results
	RCT for 104 weeks.	stage 3–5 CKD who were not undergoing dialysis and had anemia.	100 mg according to body weight, three times weekly (n = 323).	administered subcutaneously or intravenously (n = 293).	in the roxadustat group and 78.0% in the darbepoetin group, with a difference of +11.5%. Roxadustat reduced LDL and intravenous iron requirements. Safety was comparable.
Fishbane et al. (2022)	Phase 3 multicenter RCT for 52 weeks.	2,133 CKD patients aged ≥18 years who had undergone hemodialysis or peritoneal dialysis for ≥2 weeks and had anemia.	Oral roxadustat tablets, 70–200 mg, three times weekly (n = 1,068).	Parenteral epoetin alfa according to local prescribing practice (n = 1,065).	The mean Hb increase from week 28 to week 52 was 0.77 g/dL in the roxadustat group and 0.68 g/dL in the epoetin alfa group, with a difference of 0.09 g/dL and p = 0.036. The roxadustat group showed reductions in LDL, serum hepcidin, and ferritin. AEs and SAEs were comparable between groups.
Yang et al. (2022)	Multicenter RCT for 12 weeks.	100 adult patients with end-stage CKD who had undergone peritoneal dialysis for >3 months.	Standard-dose oral roxadustat, initial dose 100 mg or 120 mg according to body weight, three times weekly, equivalent to 1.5–2 mg/kg (n = 50).	Low-dose oral roxadustat, initial dose 50 mg, 70 mg, 90 mg, or 110 mg according to body weight, three times weekly, equivalent to 1–1.4 mg/kg (n = 50).	There was no significant difference between the two treatment groups. The proportion of patients achieving the target Hb level after 12 weeks was 52% in the low-dose group and 62% in the standard-dose group. The change in Hb level at week 12 was 5.0 g/L in the standard-dose group and 6.0 g/L in the low-dose group (p = 0.581).
Jin et al. (2022)	Single-center retrospective cohort study for 24 weeks.	790 CKD patients with anemia at Zhejiang Provincial People's Hospital.	Oral roxadustat capsules, 100 or 120 mg according to body weight, three times weekly (n = 95).	rhEPO administered subcutaneously once or twice weekly (n = 695).	Roxadustat increased Hb more rapidly and to a greater extent at weeks 4, 12, and 24. At week 24, the Hb increase in the roxadustat group was 2.00 g/dL. The proportion of patients achieving the target Hb level after 24 weeks in the roxadustat group was 52.6%.
Du et al. (2025)	Prospective phase 4 multicenter study for 52 weeks.	2,021 CKD patients with anemia, including non-dialysis patients and patients undergoing hemodialysis or peritoneal dialysis.	Oral roxadustat 70, 100, or 120 mg according to body weight and dialysis/non-dialysis status, three times weekly (n = 2,021).	No comparator.	Roxadustat increased mean Hb by 14.2 g/L at weeks 24–36 and 14.3 g/L at weeks 36–52. The proportions of patients achieving Hb ≥100 g/L at weeks 24–36 and 36–52 were 83.3% and 86.1%, respectively.

Discussion

As shown in Table 1, this literature review examined six articles discussing the effectiveness of roxadustat in the management of anemia among CKD patients. Most of the analyzed studies were multicenter phase 3 randomized controlled trials (RCTs), one was a single-center retrospective cohort study, and one was a real-world registry-based study. Three large studies, namely ANDES, DOLOMITES, and ROCKIES, were conducted multinationally in North America, Europe, and East Asia. Meanwhile, the ROXSTAR Registry study, Yang et al., and Jin et al. were conducted in China.

The study populations included CKD patients in various clinical conditions, including patients who had not yet undergone dialysis, patients who had recently initiated dialysis therapy, and patients who were already receiving hemodialysis or peritoneal dialysis. Study duration ranged from 24 to 104 weeks, providing an overview of the short- and medium-term effectiveness of roxadustat therapy in CKD patients. The reviewed articles evaluated oral roxadustat administered at doses adjusted according to body weight or hemoglobin response and compared it with placebo or conventional ESAs such as epoetin alfa and darbepoetin. One study compared the effectiveness of different roxadustat doses. Overall, most studies reported consistent findings that roxadustat had comparable or superior effectiveness to conventional ESAs. Additional benefits of roxadustat were also observed across various CKD patient populations.

The ANDES study conducted by Coyne et al. (2021)[20] showed that roxadustat significantly increased hemoglobin levels in non-dialysis CKD patients compared with placebo. The mean difference in hemoglobin increase between the two groups from week 28 to week 52 was 1.85 g/dL. This effect remained consistent even in patients with high C-reactive protein (CRP) levels, with an increase of 1.90 g/dL. These findings indicate that the effectiveness of roxadustat is not affected by inflammatory conditions, suggesting that it may be a therapeutic option for patients with chronic inflammation, who generally show a lower response to conventional ESAs and require higher doses to achieve target hemoglobin levels.

The study also reported that the proportion of patients in the roxadustat group who achieved a hemoglobin response without rescue therapy during the first 24 weeks reached 86.0%, compared with only 6.6% in the placebo group. In this study, treatment-emergent adverse events (TEAEs) were reported in 92.3% of patients receiving roxadustat and 89.5% of patients receiving placebo. Meanwhile, treatment-emergent serious adverse events (TESAEs) were 3.8 and 2.9, respectively. These data indicate that although most patients experienced TEAEs, the overall safety profile of roxadustat was comparable to placebo in terms of the type and frequency of reported adverse events. This supports the acceptable tolerability of roxadustat in CKD patients.

Similar findings were reported in the DOLOMITES study by Barratt et al. (2021)[21], which compared the effectiveness of roxadustat with darbepoetin alfa in non-dialysis CKD patients. This study demonstrated the non-inferiority of roxadustat to darbepoetin alfa. The proportion of patients achieving the target hemoglobin level at week 24 was higher in the roxadustat group at 89.5%, compared with 78.0% in the darbepoetin alfa group. Hemoglobin levels were maintained for up to 104 weeks. The roxadustat group also showed superiority over darbepoetin alfa in terms of a better metabolic profile, including reduced LDL levels from weeks 12 to 28 and reduced need for intravenous iron from weeks 1 to 36.

In terms of safety, roxadustat had outcomes comparable to darbepoetin alfa. TEAEs occurred in 91.6% of patients in the roxadustat group and 92.5% in the darbepoetin alfa group, with an overall incidence difference of less than 5%. Cardiovascular risk analysis showed a more favorable trend in the roxadustat group, with a hazard ratio (HR) of 0.81 for major adverse cardiovascular events (MACE) and 0.90 for MACE+. Although these results did not reach statistical significance (p = 0.339 and p = 0.583), overall they indicate that roxadustat has an acceptable safety profile and does not significantly increase cardiovascular risk compared with standard therapy.

The effectiveness of roxadustat was also confirmed in CKD patients undergoing dialysis therapy. The ROCKIES study by Fishbane et al. (2022)[22] reported the non-inferiority of roxadustat to epoetin alfa. This was demonstrated by comparable mean changes in hemoglobin from week 28 to week 52 between roxadustat (0.77 g/dL) and epoetin alfa (0.68 g/dL), which is a standard therapy. In terms of safety, the proportion of patients experiencing at least one adverse event (AE) in the roxadustat and epoetin alfa groups was 85.0% and 84.5%, respectively. Similar percentages were also found for patients with at least one serious adverse event (SAE), namely 57.6% and 57.5%. This study also reported additional advantages in the roxadustat group. Roxadustat produced a greater mean reduction in serum hepcidin by 28.21 ng/mL and a more significant decrease in ferritin levels. In addition, serum iron increased and was maintained for 52 weeks.

The study by Yang et al. (2022)[23] involving CKD patients undergoing peritoneal dialysis demonstrated that both treatment groups consistently increased hemoglobin levels, indicating that stimulation of erythropoiesis through activation of hypoxia-inducible factor remained effective even when the dose was reduced. At week 12, 52% of patients in the low-dose group achieved the hemoglobin target, compared with 62% in the standard-dose group. This result had a p-value of 0.31, indicating no statistically significant difference. The increase in hemoglobin levels also did not differ significantly between the low-dose group (6.0 g/L) and the standard-dose group (5.0 g/L). A retrospective study by Jin et al. (2022)[24] compared the effectiveness of oral roxadustat and subcutaneous recombinant erythropoietin (rhEPO) in CKD patients with anemia over 24 weeks.

At several time points, the study showed that roxadustat produced a more significant increase in hemoglobin (Hb) levels. After 4 weeks of therapy, the mean Hb level in the roxadustat group reached 96 g/L, an increase of 10 g/L from baseline, whereas the rhEPO group only reached 87 g/L, with an increase of 6 g/L. At week 12, Hb levels in the roxadustat group increased to 105 g/L, with a change of 15 g/L, higher than the rhEPO group, which reached 94 g/L with an increase of 11 g/L. This trend continued until week 24, with Hb levels of 105 g/L in the roxadustat group (increase of 17 g/L) and 97 g/L in the rhEPO group (increase of 14 g/L). At that week, the roxadustat group had a higher proportion of patients achieving the target Hb level of 100–120 g/L than the rhEPO group, at 52.6% and 41.4%, respectively.

The findings of the ROXSTAR registry study by Du et al. (2025)[25] further strengthen the results of other studies based on real-world clinical practice. This study showed a stable and meaningful increase in Hb levels, with a mean increase of 14.2 g/L at weeks 24–36 and 14.3 g/L at weeks 36–52. A total of 83.3% of patients achieved Hb ≥100 g/L at weeks 24–36, increasing to 86.1% at weeks 36–52. The most significant increase in Hb levels occurred in the non-dialysis patient group. Among dialysis patients, the increase in Hb was greater in the peritoneal dialysis group than in the

hemodialysis group. Roxadustat was also confirmed to be safe, with a relatively low incidence of drug-related adverse events (10.8%). In addition, no deaths were directly attributed to therapy. These findings indicate that roxadustat has the potential to become a promising alternative therapy for anemia due to CKD in real-world clinical practice, both in dialysis and non-dialysis populations.

Conclusion

Overall, evidence from the six main studies reviewed in this article confirms that roxadustat, as an oral HIF-PHI, is effective in managing anemia among CKD patients across various populations, including non-dialysis, hemodialysis, and peritoneal dialysis patients. In addition, roxadustat provides several advantages compared with conventional ESA therapy, such as improving iron utilization, reducing hepcidin levels, and improving lipid profiles through LDL reduction. Roxadustat has a safety profile comparable to ESAs and has the potential to become a promising alternative therapy.

This review has several limitations that should be considered. Most clinical evidence included in this analysis was derived from Western populations (Europe and North America) and East Asian populations (China), so it may not fully represent population variations in other regions. Further studies involving more diverse populations and long-term evaluation of clinical outcomes are needed to strengthen the evidence and support the integration of roxadustat as a standard therapy in the management of anemia among CKD patients.

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Conflict of Interest Statement

The author(s) declare no commercial, financial, or personal conflicts of interest related to this research. All authors approved the final manuscript and consented to its publication in *Healthy Tadulako Journal*.

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