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Original Article

Treatment Retention and Hemoglobin Response During Darbepoetin Alfa and Recombinant Human Erythropoietin Beta Therapy in Children With CKD-Related Anemia: A Secondary Analysis of a Randomized Trial

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ABSTRACT

Background: Erythropoiesis-stimulating agents are widely used for CKD-related anemia in children, but pediatric evidence regarding longer-term treatment retention remains limited. This secondary analysis evaluated treatment retention and hemoglobin response during darbepoetin alfa and recombinant human erythropoietin beta therapy. **Methods & Materials:** Data were analyzed from a multicenter, open-label, active-controlled randomized trial involving children aged 1–18 years with CKD-related anemia conducted at the Department of Pediatric Nephrology, Bangladesh Institute of Child Health and Dhaka Shishu (Children) Hospital, and the Department of Pediatric Nephrology, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh, from October 2019 to September 2020. Participants received either darbepoetin alfa or recombinant human erythropoietin beta and were evaluated over 48 weeks. Treatment retention was defined as continuation of the assigned ESA through the 48-week evaluation. Hemoglobin response was assessed using the reported aggregate association between mean hemoglobin concentration and treatment duration. **Results:** A total of 44 children were included, comprising 19 receiving darbepoetin alfa and 25 receiving recombinant human erythropoietin beta. Overall, 33 of 44 children (75.0%) continued the assigned ESA through 48 weeks. Retention was observed in 15 of 19 children (78.9%) receiving darbepoetin alfa and 18 of 25 (72.0%) receiving recombinant human erythropoietin beta. Eleven children (25.0%) discontinued treatment. Inadequate ESA response requiring transfusion accounted for 5 discontinuations, iron-related hypersensitivity associated with transfusion for 3, and missed or delayed dosing for more than 16 weeks for 3. Mean hemoglobin concentration showed a strong positive association with treatment duration in both groups, with r=0.845 (p=0.004) for darbepoetin alfa and r=0.801 (p=0.001) for recombinant human erythropoietin beta. **Conclusion:** Approximately three-quarters of children remained on their assigned ESA through 48 weeks, and higher mean hemoglobin concentrations were observed at later treatment time points with both regimens. No conclusion regarding comparative superiority can be made from these findings.

Keywords: *Chronic kidney disease; pediatric anemia; darbepoetin alfa; recombinant human erythropoietin beta; treatment retention*

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INTRODUCTION

Anemia is a major complication of chronic kidney disease (CKD) in children, and its frequency increases as kidney function declines [1-3]. Across European epidemiological studies, the incidence of pediatric CKD stages 3–5 has been reported at approximately 11–12 cases per million age-related population, while prevalence estimates have generally ranged from approximately 56 to 75 cases per million [4]. Congenital anomalies of the kidney and urinary tract (CAKUT) constitute a major cause of childhood CKD, although the relative contribution of congenital, hereditary, and acquired disorders varies across geographic regions [4-6]. In a South Asian cohort reported by Amanullah et al., CAKUT accounted for 49% of CKD among 229 children in Pakistan, and anemia was found in 81.4% of children with CKD stages 3–5 compared with 32.5% of those with earlier-stage disease [7]. Similarly, in a recent cohort of hospitalized children with CKD stages 3–5, anemia was reported in 37.1% of stage 3, 70.4% of stage 4, 100% of stage 5 non-dialysis, and 90.0% of stage 5 dialysis patients [8]. These findings indicate that anemia becomes progressively more prominent in advanced pediatric CKD and remains particularly important among children approaching or receiving kidney replacement therapy. Reduced renal erythropoietin production remains central to CKD-related anemia, although iron deficiency, inflammation, impaired iron utilization, dialysis-associated blood loss, nutritional factors, and other metabolic abnormalities may also contribute to inadequate hemoglobin correction. In the study conducted by Yeşilbaş et al., inflammatory markers were increased in children with non-dialysis CKD despite the absence of a significant increase in circulating hepcidin, illustrating the complexity of iron regulation in this population [9]. Moreover, in a retrospective pediatric hemodialysis cohort reported by Ambarsari et al., maintenance intravenous iron therapy was associated with a lower risk of anemia among children receiving erythropoiesis-stimulating agents (ESAs), with a relative risk of 0.42 [10]. ESAs therefore remain an important component of anemia management in pediatric CKD. In the systematic review conducted by Bruce et al., 58 publications representing 54 pediatric cohorts were identified, including 38 studies of recombinant human erythropoietin, 11 of darbepoetin alfa, and 3 of continuous erythropoietin receptor activator. Although the different ESA preparations were generally effective in improving or maintaining hemoglobin, considerable variability was observed in dosing schedules, treatment response, and adverse outcomes. Conventional recombinant human erythropoietin has traditionally required relatively frequent administration, whereas the longer half-life of darbepoetin alfa permits less frequent dosing [11]. In the prospective study reported by André et al., 54 children were enrolled and 39 were included in the final analysis [12]. Among these children, 26 (66.7%) achieved a hemoglobin concentration above 11 g/dL during darbepoetin therapy, while extended dosing intervals were feasible in selected patients. Longer-term experience was also described in the prospective registry by Schaefer et al., in which 319

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children receiving darbepoetin alfa were analyzed for up to 2 years; mean baseline hemoglobin was 11.1 g/dL, and 48 (15.0%) children received at least one red blood cell transfusion during follow-up [13]. However, maintenance of target hemoglobin remains difficult in routine pediatric dialysis practice. In the study conducted by Khalil et al., only 18.2–35.7% of children receiving maintenance hemodialysis achieved the specified hemoglobin target during quarterly assessments, despite ESA and intravenous iron treatment [14]. Comparative pediatric evidence between darbepoetin alfa and conventional recombinant human erythropoietin remains limited. In the systematic review and meta-analysis conducted by Bertazza Partigiani et al., seven studies were included, while direct comparative analyses involved 208 children [15]. No significant difference in hemoglobin improvement was observed between darbepoetin alfa and epoetin alfa after approximately 21–28 weeks, with a pooled mean difference of 0.15 g/dL. However, most comparative evidence has focused on short-term hematologic efficacy, and considerably less information has been reported regarding longer-term continuation of assigned ESA therapy. In a contemporary UK and US chart review reported by Mountcastle et al., 7 of 50 children discontinued their index ESA during follow-up, while darbepoetin alfa was the most frequently used ESA [16]. So, the present secondary analysis was undertaken to describe treatment retention and hemoglobin response during darbepoetin alfa and recombinant human erythropoietin beta therapy in children with CKD-related anemia over a 48-week treatment period.

METHODS & MATERIALS

This secondary analysis used data from a multicenter, open-label, active-controlled randomized trial comparing darbepoetin alfa with recombinant human erythropoietin beta for CKD-related anemia in children treated at the Department of Pediatric Nephrology, Bangladesh Institute of Child Health and Dhaka Shishu (Children) Hospital, and the Department of Pediatric Nephrology, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh, between October 2019 and September 2020. Children aged 1 to 18 years with dialysis-independent CKD stages G3b to G5 or dialysis-dependent CKD stage G5d receiving maintenance hemodialysis were eligible if hemoglobin was 8 to <11 g/dL, transferrin saturation was >20%, and serum ferritin was >100 ng/mL in dialysis-independent participants or >200 ng/mL in dialysis-dependent participants. Major exclusion criteria included severe anemia requiring transfusion, hemoglobin >11 g/dL, estimated glomerular filtration rate ≥60 mL/min/1.73 m², recent transfusion, active infection or inflammatory disease, hematologic or bleeding disorders, uncontrolled hypertension, severe hyperparathyroidism, poor adherence to iron supplementation, recent ESA exposure, or refusal of consent. Participants received subcutaneous darbepoetin alfa at the protocol-specified regimen or subcutaneous rHuEPO beta at 100 IU/kg three times weekly, together with nutritional support, iron, and folic acid; ESA doses were adjusted according to hemoglobin concentration, rate of hemoglobin rise, dose, and clinical status, with a target hemoglobin of 11 to 12 g/dL. Treatment retention was defined as continuation of the assigned ESA regimen through the 48-week evaluation, while discontinuation was categorized according to missed or delayed dosing, inadequate ESA response requiring transfusion, or iron-related hypersensitivity associated with transfusion. Hemoglobin response was assessed from the reported aggregate relationship between mean hemoglobin concentration and duration of ESA therapy in each treatment group, while CKD etiology was summarized descriptively. Frequencies and percentages were used for treatment retention and discontinuation. Pearson correlation coefficients and corresponding p values were used to describe the association between mean hemoglobin concentration and treatment duration. Because participant-level time-to-event and repeated hemoglobin data were unavailable for this secondary analysis, Kaplan-Meier estimates, confidence intervals, between-group survival comparisons, and longitudinal models were not independently recalculated. Analyses reported from the parent trial were performed using SPSS version 23.0, with $p < 0.05$ considered statistically significant.

RESULTS

A total of 44 children were included, of whom 19 received darbepoetin alfa and 25 received recombinant human erythropoietin beta. Overall, 33 children (75.0%) continued treatment through the 48-week evaluation, including 15 of 19 (78.9%) in the darbepoetin alfa group and 18 of 25 (72.0%) in the recombinant human erythropoietin beta group. Eleven children (25.0%) discontinued treatment before 48 weeks, including 4 (21.1%) in the darbepoetin alfa group and 7 (28.0%) in the recombinant human erythropoietin beta group. Among the 11 discontinuations, 5 were due to inadequate ESA response requiring blood transfusion, 3 were associated with iron-related hypersensitivity requiring transfusion, and 3 resulted from missed or delayed dosing for more than 16 weeks. Thus, 8 of the 11 children who discontinued treatment required blood transfusion in association with treatment discontinuation (*Table I*).

Table I
Treatment status through the 48-week evaluation.

Treatment status or reason	Darbepoetin alfa, n = 19	rHuEPO beta, n = 25	Overall, N = 44
Continued through 48-week evaluation	15 (78.9%)	18 (72.0%)	33 (75.0%)
Discontinued before 48-week evaluation	4 (21.1%)	7 (28.0%)	11 (25.0%)
Missed or delayed dosing for >16 weeks	2 (10.5%)	1 (4.0%)	3 (6.8%)
Inadequate ESA response requiring transfusion	2 (10.5%)	3 (12.0%)	5 (11.4%)
Iron-related hypersensitivity with transfusion requirement	0 (0.0%)	3 (12.0%)	3 (6.8%)

Note. Percentages for discontinuation categories were calculated using the corresponding treatment-group denominator. ESA = erythropoiesis-stimulating agent; rHuEPO = recombinant human erythropoietin beta.

Mean hemoglobin concentration showed a strong positive association with duration of ESA therapy in both treatment groups. In children receiving darbepoetin alfa, the correlation between mean hemoglobin concentration and treatment duration was $r = 0.845$ ($p = 0.004$). A similarly strong positive correlation was observed in the recombinant human erythropoietin beta group, with $r = 0.801$ ($p = 0.001$). These findings indicate that higher mean hemoglobin concentrations were observed with increasing duration of ESA therapy in both treatment groups **(***Table II***).**

Table II
Correlation between mean hemoglobin concentration and duration of ESA therapy.

Treatment group	Pearson correlation coefficient, r	p value
Darbepoetin alfa	0.845	0.004
rHuEPO beta	0.801	0.001

Note. ESA = erythropoiesis-stimulating agent; rHuEPO = recombinant human erythropoietin beta.

Obstructive uropathy, including posterior urethral valve, was the most frequently reported underlying CKD etiology, accounting for 57% of the cohort. Glomerulonephritis accounted for 17%, followed by neurogenic bladder in 14%, hypoplastic kidney in 10%, and atypical hemolytic uremic syndrome in 2% (*Table III*). Among children with glomerulonephritis, focal segmental glomerulosclerosis was the most common subtype, accounting for 43%, followed by C1q nephropathy in 29%, while mesangial proliferative glomerulonephritis and other chronic glomerulonephritis each accounted for 14%.

Table III
Underlying etiologies of chronic kidney disease.

CKD etiology	Proportion
Obstructive uropathy, including posterior urethral valve	57%
Glomerulonephritis, all subtypes	17%
Neurogenic bladder	14%
Hypoplastic kidney	10%
Atypical hemolytic uremic syndrome	2%

Note. CKD = chronic kidney disease.

DISCUSSION

The present study showed that treatment with the assigned erythropoiesis-stimulating agent was continued through the 48-week evaluation by 33 (75.0%) of the 44 children with CKD-related anemia. Treatment was continued by 15 of 19 (78.9%) children receiving darbepoetin alfa and 18 of 25 (72.0%) receiving recombinant human erythropoietin beta. Thus, continuation was observed in approximately three-quarters of the overall cohort during the extended treatment period. Although the proportion was numerically higher with darbepoetin alfa, no formal between-group comparison was undertaken, and this difference should therefore remain descriptive. Direct pediatric evidence concerning long-term retention on these two ESA regimens remains limited. In the contemporary chart review reported by Mountcastle et al., permanent discontinuation of the index ESA was documented in 7 (14.0%) of 50 children during follow-up [16]. However, different definitions of discontinuation, heterogeneous ESA exposure, transplantation during follow-up, and the observational design prevent direct numerical comparison with the present findings. Therefore, the current 48-week retention data provide additional descriptive information on continuation of assigned ESA therapy in children with CKD-related anemia. Among the 11 (25.0%) children who discontinued treatment, inadequate ESA response requiring blood transfusion accounted for 5 cases, iron-related hypersensitivity associated with transfusion accounted for 3 cases, and missed or delayed dosing for more than 16 weeks accounted for 3 cases. In total, 8 of the 11 discontinued children required blood transfusion in association with treatment discontinuation. Difficulty in maintaining adequate hematologic control despite ESA treatment has also been demonstrated in other pediatric CKD populations. In the study conducted by Khalil et al., only 18.2–35.7% of children receiving maintenance hemodialysis achieved the specified hemoglobin target of 11–12 g/dL during quarterly assessments, although ESA and intravenous iron treatment were being provided [14]. These observations indicate that incomplete hemoglobin control remains clinically relevant during pediatric dialysis treatment. However, failure to remain within a target hemoglobin range should not be considered equivalent to the transfusion-requiring inadequate ESA response observed in the present study. Iron availability also remains an important component of the hematologic response to ESA therapy. In the retrospective cohort reported by Ambarsari et al., anemia developed in 7 of 21 children receiving maintenance intravenous iron compared with 16 of 20 children who did not receive maintenance iron, with a relative risk of 0.42 [10]. Thus, an association between adequate iron support and maintenance of hemoglobin was demonstrated during ESA treatment. In the present study, iron status was addressed before enrollment, and iron supplementation was continued during ESA therapy. Nevertheless, three treatment discontinuations were associated with iron-related hypersensitivity and transfusion requirement. Because the specific intravenous iron preparation responsible for these events cannot be compared directly with preparations evaluated in the available pediatric studies, no external adverse-event rate can appropriately be applied to these findings. A positive relationship between mean hemoglobin concentration and treatment duration was observed with both ESA regimens. The reported correlation was r=0.845 (p=0.004) during darbepoetin alfa therapy and r=0.801 (p=0.001) during recombinant human erythropoietin beta therapy. These findings are consistent with the established hematologic activity of ESAs in pediatric CKD. In the systematic review conducted by Bruce et al., 58 publications representing 54 pediatric cohorts were evaluated, including 38 studies of recombinant human erythropoietin and 11 studies of darbepoetin alfa, and hematologic efficacy was demonstrated across the evaluated ESA preparations [11]. Considerable heterogeneity in dosing, study design, and treatment response was also identified. Therefore, the positive hemoglobin findings of the present study are consistent with the broader pediatric ESA literature, while variation in individual treatment response remains expected. Evidence specifically supporting the hematologic effect of darbepoetin alfa was reported in the prospective study conducted by André et al [12]. Among 39 children included in the final analysis, hemoglobin increased in 29 (74.0%) during six months of darbepoetin therapy, and 26 (66.7%) had a hemoglobin concentration of at least 11 g/dL at month 6. Mean hemoglobin increased from 9.5 to 11.7 g/dL among ESA-naïve children and from 11.1 to 11.5 g/dL among children switched from recombinant human erythropoietin. Longer-term experience was reported by Schaefer et al., in which 319 children receiving darbepoetin alfa were analyzed during follow-up of up to two years [13]. Mean baseline hemoglobin was 11.1 g/dL, and hemoglobin concentrations were generally maintained during treatment. These observations support the capacity of darbepoetin alfa to correct or maintain hemoglobin in pediatric CKD across different treatment settings. Comparative

evidence should be interpreted more cautiously. In the systematic review and meta-analysis conducted by Bertazza Partigiani et al., direct comparative analyses included 208 children, and no significant difference in hemoglobin improvement was found between darbepoetin alfa and epoetin alfa after approximately 21–28 weeks; the pooled mean difference was 0.15 g/dL (95% CI, −0.22 to 0.52) [15]. Importantly, epoetin alfa rather than recombinant human erythropoietin beta represented the conventional ESA comparator in that direct analysis. Therefore, those findings provide supportive class-level evidence but do not establish equivalence between the specific regimens evaluated in the present study. Similarly, the correlation coefficients observed here should not be compared numerically as indicators of superior hemoglobin response. Because they were derived from aggregate mean hemoglobin values over treatment duration rather than participant-level repeated measurements, they demonstrate that higher mean hemoglobin values occurred at later treatment time points, but they do not estimate individual longitudinal response or a treatment-by-time difference between the two groups. Overall, the present findings extend the available pediatric evidence by describing both continuation of assigned ESA therapy over 48 weeks and the accompanying aggregate hemoglobin response. Previous studies have largely concentrated on hematologic efficacy, target hemoglobin achievement, dosing, safety, or shorter treatment intervals, while directly comparable pediatric data on prolonged treatment retention remain scarce. The observed continuation of therapy in 75.0% of the cohort therefore represents a clinically relevant descriptive finding, while the reported positive hemoglobin correlations provide complementary evidence of hematologic response during both darbepoetin alfa and recombinant human erythropoietin beta therapy.

LIMITATIONS

This secondary analysis was limited by the small sample size and the availability of aggregate rather than participant-level longitudinal data, which prevented independent time-to-event analysis and individual-level modeling of hemoglobin response. In addition, the open-label design of the parent trial and the absence of formal between-group testing for treatment retention limit comparative interpretation of the findings.

CONCLUSION

Treatment with the assigned ESA was retained through 48 weeks by 75.0% of children with CKD-related anemia, with continuation observed in 78.9% of those receiving darbepoetin alfa and 72.0% receiving recombinant human erythropoietin beta. Mean hemoglobin concentration showed a strong positive association with treatment duration in both groups. These findings support sustained use and hematologic response with both ESA regimens, although the available data do not establish superiority of either treatment.

RECOMMENDATION

The two forms of ESA can be utilized in the treatment of anemia in children suffering from CKD, with hemoglobin, iron, and compliance being monitored on a regular basis. Large and well-powered comparative studies would be needed to establish their efficacy.

FUNDING

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CONFLICT OF INTEREST

None declared.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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