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Persistent low albumin and temporary vascular access in pediatric patients with systemic lupus erythematosus on hemodialysis

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Abstract

Pediatric patients with systemic lupus erythematosus (SLE) often present with significant kidney disease. In a previous cross-sectional analysis, we showed that pediatric patients with end-stage renal disease (ESRD) secondary to SLE have lower serum albumin levels and less permanent vascular access for hemodialysis (HD) compared to pediatric patients on HD secondary to other causes. The goal of this longitudinal study was to determine if there was an improvement in these targets over time. To this end, we performed a longitudinal analysis of patients receiving HD in the ESRD Clinical Performance Measures Project 2000–2004 study years, comparing achievement of clinical targets between pediatric patients with SLE and pediatric patients with other causes of ESRD. In the longitudinal follow-up, pediatric patients with SLE were less likely to reach target albumin levels than other children with ESRD maintained on HD [odds ratio (OR) 0.18, 95% confidence interval (CI) 0.09, 0.35] and were less likely to have arteriovenous fistulas or grafts than other pediatric patients (OR 0.45, 95% CI 0.23, 0.89). Pediatric patients with SLE maintained on HD are at particularly high risk for failing to meet some clinical targets that have been associated with improved long-term outcomes in other populations. This is true even as they remain on dialysis over time.

Keywords

Albumin; Dialysis; Pediatrics; Systemic lupus erythematosus; Vascular access

Introduction

Systemic lupus erythematosus (SLE) is an autoimmune disease that affects an estimated five to ten children of every 100,000 in the USA [1]. Pediatric patients with SLE often present with significant organ involvement, including kidney disease. In up to 30% of children with SLE, kidney disease progresses to end-stage renal disease (ESRD) and subsequent need for dialysis and/or transplantation [2–5].

The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) has established clinical practice guidelines and recommendations to guide and improve the care provided to patients with ESRD. Achievement of these threshold levels has been associated with reduced morbidity and mortality in children and adults on dialysis in the USA [6–17].

In a previous cross-sectional study exploring whether pediatric patients (ped pts) with ESRD secondary to SLE maintained on hemodialysis (HD) were able to meet recommended threshold values, we demonstrated that ped pts with SLE were less likely to meet albumin levels $\geq 3.5/3.2$ g/dL [bromocresol green (BCG)/purple (BCP) method] and were more likely to have vascular catheters rather than arteriovenous fistulas or grafts (AVF/AVG) for HD access compared to ped pts with ESRD due to other causes [18]. There was no significant difference in hemoglobin levels or single-pooled Kt/V urea levels (where K is clearance, t is time, and V is patient's total body water) between ped pts with ESRD secondary to SLE maintained on HD and patients with other causes of ESRD. The goal of the longitudinal study reported here was to determine if there was improvement in the achievement of target values over time in ped pts with SLE who remained on HD compared to children with ESRD secondary to other causes.

Material and methods

Methods

We performed a longitudinal study of ped pts with SLE receiving HD included in the ESRD Clinical Performance Measures (CPM) Project 2000–2004 study years. The patients were compared to ped pts with other underlying causes of ESRD maintained on HD those same years.

End-stage renal disease CPM

In order to provide oversight of dialysis care in the USA, the Center for Medicare and Medicaid Services (CMS) established the ESRD CPM Project. The ESRD CPM Project works with 18 ESRD network organizations to collect demographic and clinical data on patients with ESRD maintained on dialysis [19]. This data collection process has included clinical parameters, such as anemia management, dialysis adequacy, vascular access, and serum albumin levels. In 2000, the ESRD CPM Project began collecting data on pediatric HD patients in the USA aged 12 years to less than 18 years. In the ESRD CPM 2002 Project year, patients aged 0 through 11 years were also included in this analysis. Data were submitted for all ped pts identified by the 18 ESRD networks as alive and receiving in-center HD during the yearly data collection period (the preceding October, November, and December for each project year in 2000–2004). The minimum clinical data required for inclusion in a given study year included at least one monthly predialysis hemoglobin and serum albumin level, and predialysis and postdialysis blood urea nitrogen levels.

Patients with data submitted for two or more consecutive study years were included in the longitudinal cohort. Patients who had data submitted for non-consecutive study years had only data from the first study year included in the analysis and were not included in the longitudinal cohort.

Clinical parameters assessed in this analysis included serum albumin level, hemoglobin, and dialysis access. Patients were dichotomized as either reaching or not reaching threshold values for these parameters, which were based on goals or targets specified in KDOQI for adult and/or pediatric ESRD patients [serum albumin levels $\geq 3.5/3.2$ g/dL (BCG/BCP), serum hemoglobin levels ≥ 11 g/dL, and presence of functioning AVF or AVG].

Data analysis

All available data were used to calculate means. The causes of ESRD were dichotomized into SLE (ICD 9 code: 710.0) versus all other (focal segmental glomerulosclerosis, congenital and/or urological, glomerulonephritis, hypertension, cystic disease, and patients reported as “unknown” diagnoses). In addition, a second group of ped pts with glomerulonephritis only (vasculitis, Henoch–Schönlein purpura, Wegner's granulomatosis, polyarteritis nodosa,

Buerger's disease, hemolytic–uremic syndrome, acute glomerulonephritis, chronic glomerulonephritis, and idiopathic glomerulonephritis) was included in the analyses as these patients may also be receiving immunosuppressive regimens that may affect reaching threshold values.

In this analysis, we wished to determine whether patients maintained on HD for more than one consecutive CPM Project study year were able to meet recommended guidelines over time and if improvement in meeting targets occurred. Longitudinal analysis techniques, such as generalized estimating equations, provide a statistically powerful method for incorporating individual level outcomes and covariates. These techniques permit the estimation of individual mean effects and individual change over time as well as population mean effects over the entire study period; they require no assumptions on the stability of population characteristics over time.

We used the generalized estimating equation, logit link, and unspecified correlation structure to fit the longitudinal data involving repeated measurements on the same subject. This analysis allowed us to account for intra-subject correlations among repeated measures on the same subject. Initially, simple longitudinal logistic regression models were fit with the dependent variable, with target values of albumin, hemoglobin, and AVF/AVG. In addition to the diagnosis of SLE, other independent variables in the simple regression included potential confounders, such as age, race, gender, body mass index (BMI), and achievement of threshold values for the other clinical parameters. In order to have the most parsimonious multiple longitudinal regression model, SLE diagnosis and only the statistically significant simple regression variables were included in the analysis. A priori variables included in the longitudinal analysis included SLE diagnosis and other recommended threshold values. *P* values of less than 0.05 were considered to be significant. Data were analyzed using STATA, ver. 9 (Stata Corporation, College Station, TX).

Results

A total of 98 unique ped pts with SLE receiving HD had data submitted for at least one study year during the 2000–2004 CPM Project study years: 69 patients had data for 1 year only, 19 patients for 2 consecutive years, eight for 3 consecutive years, one for 4 years, and one for 5 years. During these same study years, 1822 unique ped pts with other causes of ESRD receiving HD were identified. Of these, 1233 patients had data for 1 year only, 391 for 2 consecutive years, 146 for 3 consecutive years, 34 for 4 consecutive years, and 18 for 5 consecutive years. The longitudinal cohort consisted of patients followed for 2 or more consecutive study years, resulting in 29 patients with SLE and 589 patients with other causes of ESRD. In a separate longitudinal analysis, ped pts with SLE were compared to a second control group of 701 patients with glomerulonephritis; 489 patients had data for 1 year only, 138 patients for 2 consecutive years, 61 for 3 consecutive years, nine for 4 years, and four for 5 years. Demographic information on these patients is presented in Table 1. The SLE patients were older in each CPM Project year, and there was a predominance of females. There was no significant difference in mean height or body mass index (BMI). In terms of ethnicity, there was an increased percentage of Black race patients in the SLE group.

The mean serum albumin and hemoglobin levels in patients over time in the CPM Project years are shown in Fig. 1. As a group, patients with ESRD on HD secondary to SLE had lower serum albumin levels over time compared to the other patients. There was no significant difference in hemoglobin levels over time between groups. Table 2 shows the percentage of patients with data from 1, 2, or 3 consecutive years who achieved threshold levels of serum albumin, hemoglobin, AVF/AVG, and *Kt/V* (years 4 and 5 data are not presented because there was only one SLE patient in these categories). Fewer patients with ESRD secondary to SLE reached

threshold levels of serum albumin or had AVF/AVG placement compared to patients with other diagnoses.

In order to account for the intra-individual correlation associated with outcomes, we next performed longitudinal logistic regression to determine if there was improvement in the achievement of threshold values over time. Longitudinal logistic regression analyses examining predictors of achieving albumin levels $\geq 3.5/3.2$ g/dL (BCG/BCP method)] are presented in Table 3. Pediatric patients with SLE were less likely to reach target albumin levels than other children with ESRD maintained on HD [odds ratio (OR) 0.18, 95% confidence interval (CI) 0.09–0.35]. Other significant predictors of not achieving albumin threshold levels over time included mean serum hemoglobin <11 g/dL and presence of vascular catheter for HD access.

In the adjusted analysis, ped pts with SLE showed no statistical difference in achieving hemoglobin levels compared to other children with ESRD maintained on HD (OR 0.87, 95% CI 0.48–1.58). Significant predictors of not achieving hemoglobin threshold values in all patients over time included younger age, higher BMI, albumin levels $<3.5/3.2$ g/dL (BCG/BCP method), and presence of vascular catheter for HD access.

In the longitudinal follow-up, ped pts with SLE were less likely to have AVF/AVG than other pediatric patients (OR 0.45, 95% CI 0.23–0.89). Other significant variables associated with failing to achieve AVF/AVG included female gender, hemoglobin target <11 g/dL, and albumin target $<3.5/3.2$ g/dL (BCG/BCP method).

In order to evaluate patients with SLE to a similar control group with potentially inflammatory kidney disease, we compared ped pts with SLE to patients with glomerulonephritis. In the adjusted analysis, ped pts with SLE were still less likely to meet the recommended albumin levels (OR 0.26, 95% CI 0.13–0.52) (Table 4). While there was a difference in achievement of AVF/AVG between SLE patients and others with glomerulonephritis in the simple regression, this difference was not statistically significant after adjustment for other potential confounders.

Discussion

Pediatric patients with SLE comprise 5% of the total pediatric chronic HD population in the USA. To our knowledge, this is the first report describing changes in threshold laboratory and clinical values over time in children with ESRD secondary to SLE who are maintained on HD. Our results demonstrate that this population is at particularly high risk for failing to achieve a number of clinical targets that have been associated with adverse outcomes in adult and pediatric patients maintained on HD.

In this analysis, ped pts with SLE were more likely to have low albumin levels than other ped pts maintained on HD identified in the ESRD CPM Project, including those with glomerulonephritis. Unfortunately, over time, the percentage of ped pts with SLE and low serum albumin levels continued to be high, and this is of great concern. There may be multiple reasons for a low serum albumin level in ped pts with SLE. Pediatric patients with SLE often present with multiple organ system involvement, leading to a significant inflammatory milieu that may dampen albumin production. Additionally, ped pts with SLE may have elevated levels of acute-phase proteins, such as C-reactive protein. Serum albumin concentrations have been shown to inversely correlate with serum levels of acute-phase proteins and an elevated C-reactive protein has been associated with protein malnutrition, perhaps by interfering with protein absorption or utilization [12,15,20–22]. Immunosuppressive medications that are metabolized in the liver may cause a diminished appetite, leading to decreased intake of protein.

These patients may also have improved serum albumin levels due to a declining residual renal function and less proteinuria.

Although hospitalization and mortality cannot be determined from the data in the ESRD CPM Project, further evaluation of the impact of low albumin is warranted. In other ESRD populations, low serum albumin has been associated with increased mortality and increased hospitalization rates [11–13,15,20,22–25]. In a study by Wong and colleagues, a 1 g/dL decrease in serum albumin was associated with a 54% higher risk of death, independent of other factors in ped pts initiating dialysis [24]. Low serum albumin in ESRD patients has also been associated with increased number of hospitalized days as well as increased susceptibility to infections [11,22].

In this analysis, we also showed that ped pts with ESRD secondary to SLE maintained on HD were less likely than their non-SLE counterparts to achieve creation of AVF/AVG, despite the known advantages of these types of vascular access. Although there was improvement in the odds of AVF/AVG placement over time in both groups, the number of patients who have AVF/AVG is very low, especially during the first year in the CPM Project. This may be secondary to bias of pediatric nephrologists. However, this low AVF/AVG creation is not justified by known outcome data, especially in face of the high age in both patient groups.

In the ped pts with SLE, the factors most strongly associated with failing to place AVF/AVG were also failing to meet hemoglobin and albumin targets, suggesting that these patients had more active disease. There are many reasons why ped pts with SLE may be less likely to have AVF/AVG than other children with ESRD. It may be more difficult to create and/or maintain AVF/AVGs in ped pts with SLE as they may have concomitant antiphospholipid syndrome, i.e. a hypercoagulable state. The presence of antiphospholipid antibodies has been associated with thrombosis of vascular grafts in adult patients with SLE [26,27]. Early on in their course, ped pts with SLE may also require more frequent intravenous catheters for the delivery of medications. This may ultimately render their vessels unusable for the creation of an AVF/AVG when they reach ESRD. Interestingly, patients with SLE were not significantly different than others in terms of hemoglobin and Kt/V levels over time. Although vascular catheters may be associated with adequate dialysis and Kt/V levels, lower serum albumin levels were still observed. This may be secondary to increased infectious complications compared to AVFs or AVGs. We speculate that such infections, either directly, or indirectly contribute to an inflammatory milieu and may result in lower serum albumin levels.

This analysis is limited by the small sample size of the SLE cohort due to the fact that SLE underlying ESRD in children is uncommon. Also, SLE patients often present with ESRD at an older age compared with other diagnoses, and, even if they remained on HD, the data would not have been included in the ESRD CPM Project after they were older than 18 years. The potential for survival bias also exists. Pediatric patients with SLE who are sicker may have died, leaving a healthier population in this cohort. We were also unable to account for dilution of laboratory results due to limitations of the dataset. It would have been interesting if the trends in patients followed for the entire study period could have been evaluated; however, because of the small sample size, this was not possible. Instead, we focused on longitudinal analysis of the entire cohort. Despite these limitations, this study reports on one of the most complete and largest databases of ped pts with SLE and ESRD.

In this study, we show that ped pts with SLE maintained on HD are at particularly high risk for failing to meet a number of the clinical targets that have been associated with improved long-term outcomes in other populations. This is true even as they remain on dialysis over time. In particular, they are less likely to meet albumin targets compared to other children. It is possible that early physician intervention could impact and improve the low albumin in ped

pts with SLE through newer therapies targeting inflammatory cytokines or nutritional supplementation. Given the improved clinical outcomes associated with AVF/AVG, barriers to conversion to these types of vascular access should be studied in pediatric SLE patients. Future prospective studies should examine the obstacles to vascular access placement pre-ESRD and the association of vascular access type with morbidity and mortality in this specific population.

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Fig. 1.

Trends in serum albumin and hemoglobin levels over consecutive Clinical Performance Measure (CPM) Project years. *Note* Serum albumin levels were lower initially and there was no significant improvement over time in the patients with SLE maintained on HD compared to patients with other causes of ESRD. There was no significant difference in serum hemoglobin levels initially and over time between pediatric patients with SLE and other patients. *SLE* Systemic lupus erythematosus, *HD* hemodialysis, *ESRD* end stage renal disease

Characteristics of pediatric patients receiving hemodialysis for two or more consecutive Clinical Performance Measures Project study years

Table 1

Patient characteristics	SLE (n=29)	Other diagnoses (n=589)	GN (n=212)	P (SLE vs. other)	P (SLE vs. GN)
Mean age, years (SD)	16.1 (1.6)	14.8 (3.7)	15.6 (2.6)	0.0003	0.001
Female (%)	80	43	51	<0.0001	<0.0001
Black race (%)	75	48	54	<0.0001	<0.0001
Dialysis vintage ≤6 months (%)	61	39	32	<0.0001	<0.0001

SLE, Systemic lupus erythematosus; GN, glomerulonephritis

Table 2

Percentage of patients achieving recommended threshold levels

Clinical parameters	SLE patients			Other patients		
	Consecutive CPM study years					
	1 (n=69)	2 (n=19)	3 (n=8)	1 (n=1233)	2 (n=391)	3 (n=146)
Serum albumin $\geq 3.5/3.2$ g/dL, BCG/BCP (%)	55	50	54	77	86	86
Serum hemoglobin ≥ 11 g/dL (%)	50	63	50	59	64	68
Presence of AVF/AVG (%)	16	37	46	38	53	60
Mean Kt/V ≥ 1.2	80	84	100	80	84	84

BCG/BCP, Bromocresol green/purple; AVF/AVG, arteriovenous fistulas/grafts; Kt/V , quantification of hemodialysis and peritoneal dialysis treatment adequacy

Table 3

Longitudinal logistic regression comparing the odds of achieving threshold values in patients with SLE to patients with ESRD secondary to other diagnoses

Clinical parameters	Unadjusted odds ratio	95% Confidence interval	Adjusted odds ratio	95% Confidence interval
Albumin $\geq 3.5/3.2$ g/dL (BCG/BCP method)	0.16	0.09–0.28	0.18 ^a	0.09–0.35
Hemoglobin ≥ 11 g/dL	0.60	0.35–1.04	0.87 ^b	0.48–1.58
AVF/AVG vs. vascular catheter	0.48	0.23–0.91	0.45 ^c	0.23–0.89
Mean $Kt/V \geq 1.2$	0.59	0.19–1.86	0.45 ^d	0.14–1.48

ESRD, End-stage renal disease; HD, hemodialysis; BMI, body mass index

^a Adjusted for significant covariates in simple regression: age, gender, race, serum hemoglobin, vascular access for HD

^b Adjusted for significant covariates in simple regression: age, BMI, epotein dose, transferrin saturation, serum albumin, vascular access for HD

^c Adjusted for significant covariates in simple regression: age, gender, serum hemoglobin, serum albumin

^d Adjusted for significant covariates in simple regression: gender, race, serum hemoglobin, serum albumin

Table 4

Longitudinal logistic regression comparing the odds of achieving threshold values in patients with SLE to those with glomerulonephritis

Clinical parameters	Unadjusted odds ratio	95% Confidence interval	Adjusted odds ratio	95% Confidence interval
Albumin $\geq 3.5/3.2$ g/dL (BCG/BCP method)	0.19	0.11–0.36	0.26 ^a	0.13–0.52
Hemoglobin ≥ 11 g/dL	0.46	0.26–0.81	0.76 ^b	0.40–1.45
AVF/AVG vs. vascular catheter	0.42	0.22–0.81	0.52 ^c	0.25–1.07
Mean $Kt/V \geq 1.2$	0.75	0.23–2.48	0.43 ^d	0.12–1.62

^a Adjusted for significant covariates in simple regression: age, gender, race, serum hemoglobin, vascular access for HD

^b Adjusted for significant covariates in simple regression: age, serum albumin, vascular access for HD

^c Adjusted for significant covariates in simple regression: age, gender, serum hemoglobin, serum albumin

^d Adjusted for significant covariates in simple regression: gender, race, serum hemoglobin, serum albumin