A STUDY OF PEDIATRIC (≥ 12 < 18 YEARS OLD) IN-CENTER HEMODIALYSIS PATIENTS: RESULTS FROM THE 2000 END STAGE RENAL DISEASE (ESRD) CLINICAL PERFORMANCE MEASURES PROJECT

Supplemental Report #1

2000 ESRD Clinical Performance Measures Project

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INTRODUCTION

The purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of ESRD services in the assessment of care provided to ESRD patients and to stimulate improvement in that care. Annually, a national sample of adult (aged ≥ 18 years) in-center hemodialysis (HD) patients is randomly selected for inclusion in this Project. For the first time, this Project's 2000 data collection effort obtained clinical information on all pediatric in-center HD patients in the U.S. aged 12 years up to but not including 18 years old (hereinafter referred to as 12-18 years old).

This supplemental report describes the demographic characteristics of in-center HD patients 12-18 years old in the U.S. It also describes several parameters of dialysis care including dialysis adequacy, vascular access, management of anemia and serum albumin values.

METHODS

All in-center HD patients aged 12-18 years old identified by the 18 ESRD Networks as alive and receiving HD on December 31, 1999 were selected for inclusion in this data collection effort.

Data Collection

During May 2000, a three-page data collection form was sent to each facility that had one or more HD patients 12-18 years old dialyzing at that facility. Clinical information in the patients' medical records was abstracted for each patient who was receiving in-center HD during the months of October, November, and December,1999. Patient characteristic information collected included: gender, age, race, Hispanic ethnicity, years on dialysis, and primary cause of ESRD. The parameters of care examined included adequacy of dialysis, vascular access information, management of anemia, and assessment of serum albumin.

Clinical information used to assess the quality of care provided to these patients included the following: patient height and weight, pre- and post-dialysis blood urea nitrogen (BUN) values, dialysis session length to calculate Kt/V values, dialyzer KUf values, reported urea reduction ratios (URRs) and reported Kt/V values, type of vascular access, blood pump flow rates, monitoring of the access site for stenosis, hemoglobin (Hgb) values, prescribed Epoetin dose and route of administration, iron use and route of administration, transferrin saturation values, serum ferritin concentrations, and serum albumin values.

Completed forms were returned to the appropriate Network office where data were reviewed and entered into a computerized database (Visual FoxPro). The data were forwarded to HCFA for aggregation and analysis.

Data Analysis

For this Report, a patient had to meet the following criteria to remain in the sample for analysis: a data collection form with at least one monthly hemoglobin value, at least one paired pre- and post-dialysis BUN value, and at least one serum albumin value over the three month study period. This case definition was identical to the one that has been used for the adult (≥ 18 years old) in-center HD sample over the course of the Project period (1993-2000). All available reported monthly values were utilized in calculating mean and median values. Kt/V values were calculated according to the Daugirdis II formula.[1]

Due to the small numbers of persons in racial categories other than Black and White, analyses by race were limited to these two racial groups. Associations by age group compared patients 12-15 years old to patients 16-18 years old. Causes of ESRD were categorized as congenital/urological vs. other identified causes combined (FSGS, glomerulonephritis, SLE, hypertension or cystic disease) for some analyses. Associations of clinical data with patient characteristics were tested by Chi square, hierarchical ANOVA, and two-tailed student's t-test analyses, with a p-value < 0.05 considered to be significant. Multivariate logistic regression analysis was conducted to determine significant associations of patient characteristics with mean blood pump flow rates.

The data analyses were conducted utilizing Epi Info, v. 6.04[2] and SPSS for Windows, v. 8.0.[3]

RESULTS

486 patients between 12-18 years old were identified as receiving in-center HD as of December 31, 1999. 433 patients (89%)of this group met the case definition and were included in the sample for analysis. Selected characteristics of the patients in the sample for analysis are shown in Table 1. A higher percent of patients 12-15 years old had congenital/

Table 1: *Selected patient characteristics*

Characteristic	n	(%)
TOTAL	**433**	**(100)**
GENDER		
Males	232	(54)
Females	200	(46)
RACE		
American Indian/Alaska Native	6	(1)
Asian/Pacific Islander	18	(4)
Black	182	(42)
White	212	(49)
Other/Unknown	15	(3)
ETHNICITY		
Hispanic	92	(21)
Non-Hispanic	326	(75)
Other/Unknown	15	(3)
AGE (years)		
Mean (± SD)	15.8	(± 1.6)
Median	16.2	
12-15	203	(47)
16-18	229	(53)
PRIMARY CAUSE OF ESRD		
Congenital/Urological	106	(24)
FSGS	74	(17)
Glomerulonephritis	73	(17)
SLE	25	(6)
Hypertension	14	(3)
Cystic disease	8	(2)
Other/Unknown	133	(31)
DURATION OF DIALYSIS (years)		
Mean (± SD)	2.9	(± 3.6)
Median	1.3	
< 0.5	93	(22)
0.5-0.9	88	(20)
1.0-1.9	81	(19)
2.0+	170	(39)

* Note: Percents may not add up to 100% due to rounding

urological causes of ESRD compared to patients 16-18 years old (43% vs. 29%, $p< 0.05$) and were Hispanic (27% vs. 17%, $p< 0.05$). There were no significant differences in years on dialysis by gender, race, ethnicity, or age group. Patients with congenital/urological causes of ESRD had a significantly longer duration of dialysis compared to patients with other identified causes of ESRD combined (3.4 yrs vs. 2.5 yrs, $p < 0.05$).

Selected clinical measures of interest are depicted in Table 2.

Dialysis Adequacy

79% of patients had a mean calculated delivered Kt/V ≥ 1.2; 75% of patients had a mean calculated delivered URR ≥ 65%. Females had a significantly higher mean calculated Kt/V value compared to males (1.55 vs. 1.40, $p <0.001$) (Figure 1). Patients with congenital/urological causes of ESRD had a significantly higher mean calculated Kt/V value compared to patients with other identified causes of ESRD combined (1.55 vs. 1.43, $p< 0.05$). Blacks had significantly lower mean calculated Kt/V values compared to Whites (1.41 vs. 1.50, $p < 0.05$), as did patients dialyzing less than six months compared to patients dialyzing two years or longer (1.30 vs. 1.58, $p< 0.001$). A similar pattern was noted for adequacy of dialysis assessed by calculated delivered URR. There were no significant differences in delivered adequacy of dialysis as measured by Kt/V by ethnicity or age group, however, Hispanics had a significantly higher mean calculated delivered URR compared to non-Hispanics (71.4% vs. 69.1%, $p<0.05$).

Figure 1: *Distribution of mean calculated Kt/V values, by gender*

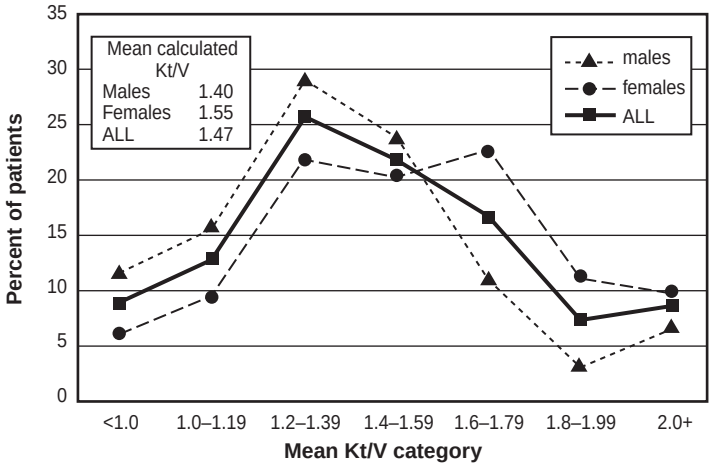


Table 2: *Selected Clinical Measures of Interest*

Clinical Measure[a]			Clinical Measure[a]		
ADEQUACY OF DIALYSIS			IRON MANAGEMENT		
Calculated Kt/V			Transferrin saturation (%)		
Mean (± SD)	1.47	(± 0.38)	Mean (± SD)	27.7	(± 14.8)
Median	1.44		Median	25.0	
mean Kt/V ≥ 1.2	305	(79)	Mean transferrin saturation ≥ 20%	254	(70)
Calculated URR			Serum ferritin concentration (ng/mL)		
Mean (± SD)	69.6	(± 8.8)	Mean (± SD)	298.2	(± 320.8)
Median	69.9		Median	186.9	
mean URR ≥ 65%	325	(75)	Mean serum ferritin ≥ 100 ng/mL	256	(68)
Dialysis session length (minutes)			Patients with relative iron deficiency[b]	45	(10)
Mean (± SD)	206.8	(± 28.8)	Patients prescribed iron	317	(73)
Median	210.0		Within this group:		
Blood pump flow rate (mL/minute)			Prescribed IV	228	(72)
Mean (± SD)	299.2	(± 84.1)	Prescribed PO	122	(38)
Median	300.0				
VASCULAR ACCESS			SERUM ALBUMIN		
Type of access			BCG[c]		
AV fistula	157	(37)	Mean (± SD)	3.85	(± 0.51)
AV graft	94	(22)	Median	3.93	
Catheter	171	(41)	BCP[d]		
Catheter in use ≥ 90 days	101	(24)	Mean (± SD)	3.62	(± 0.52)
			Median	3.62	
ANEMIA MANAGEMENT			Mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP)	354	(83)
Hemoglobin (gm/dL)			Mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP)	195	(46)
Mean (± SD)	10.99	(± 1.6)			
Median	11.2				
Mean Hgb ≥ 11 gm/dL	240	(55)			
Mean Hgb 11-12.9 gm/dL	210	(49)			
Mean Hgb < 9 gm/dL	49	(11)			
Mean Hgb < 10 gm/dL	99	(23)			
Patients prescribed Epoetin	418	(97)			
Within this group:					
prescribed IV	374	(89)			
prescribed SC	45	(11)			
Epoetin dose (units/kg/dose)					
IV					
Mean (± SD)	93.3	(± 65.5)			
Median	74.4				
SC					
Mean (± SD)	73.3	(± 53.1)			
Median	58.7				

[a] continuous variables displayed as the mean (± SD) and median values; categorical variables displayed as number and percent of available values

[b] relative iron deficiency defined for this report as a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/dL

[c] BCG = bromcresol green laboratory method

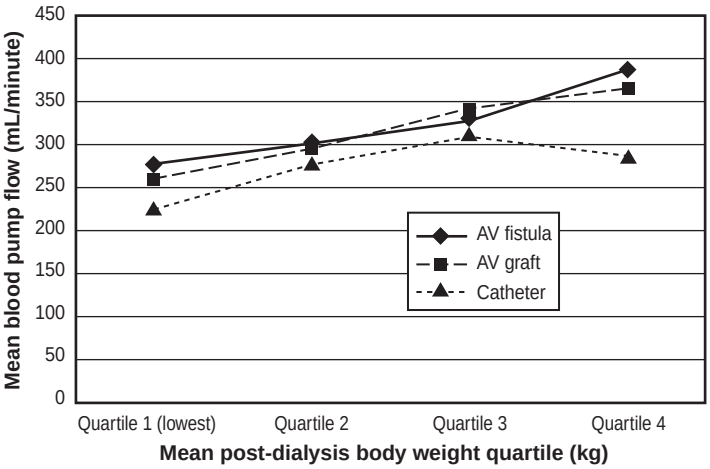
[d] BCP = bromcresol purple laboratory method

Significantly longer dialysis session lengths were noted for Blacks compared to Whites (210 vs. 204 minutes, p< 0.05), males compared to females (209 vs. 204 minutes, p< 0.05), for patients dialyzing two or more years compared to patients dialyzing less than six months (211 vs. 202 minutes, p< 0.05) and for patients in the highest quartile of post-dialysis body weight compared to those in the lowest quartile (214 vs. 205 minutes, p< 0.05).

Mean blood pump flow rates were significantly different by age group, cause of ESRD, and patient weight. Patients 12-15 years old had significantly lower mean blood pump flow rates compared to patients 16-18 years old (276 vs. 319 mL/minutes, p< 0.001). Patients with congenital/urological causes of ESRD had significantly lower mean blood pump flow rates compared to patients with other causes of ESRD combined (276 vs. 310 mL/minute, p< 0.01).

Post-dialysis body weight was significantly associated with mean blood pump flow rates for all access types (Figure 2). Multivariate logistic regression analysis, with mean blood pump flow rate ≥ 300 mL/minute (the median value) as the outcome variable of interest was conducted. Patient characteristic variables entered into the model included gender, race (Black vs. White only), age (years), cause of ESRD (congenital/urological vs. other causes combined), and post-dialysis weight (kg). Only patient weight and age remained as significant predictors of a mean blood pump flow rate ≥ 300 mL/minute in the final model.

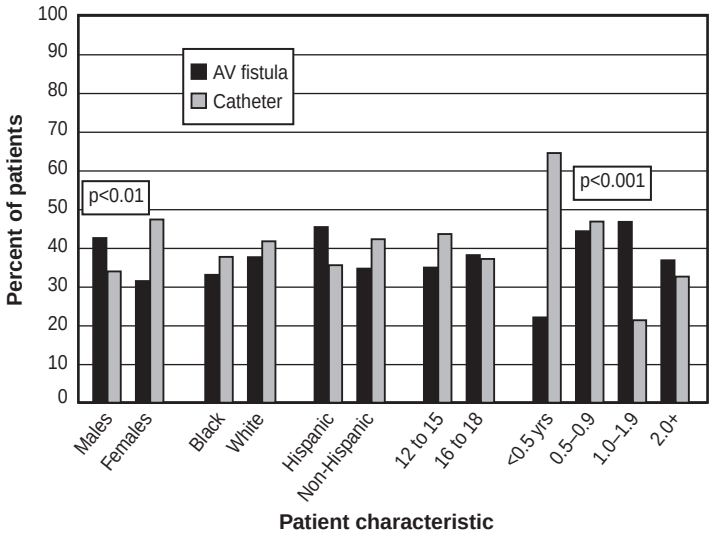
Figure 2: *Mean blood pump flow by quartile body weight and access type*



Vascular Access

Significant differences in the type of vascular access reportedly used on the last HD session during October-December 1999 were associated with gender and years on dialysis (Figure 3). A larger percentage of males compared to females had an AV fistula as their type of vascular access (43% vs. 31%, p< 0.01). A higher percentage of patients dialyzing less than six months compared to patients dialyzing longer had a catheter as their vascular access (66% vs. 33%, p< 0.001).

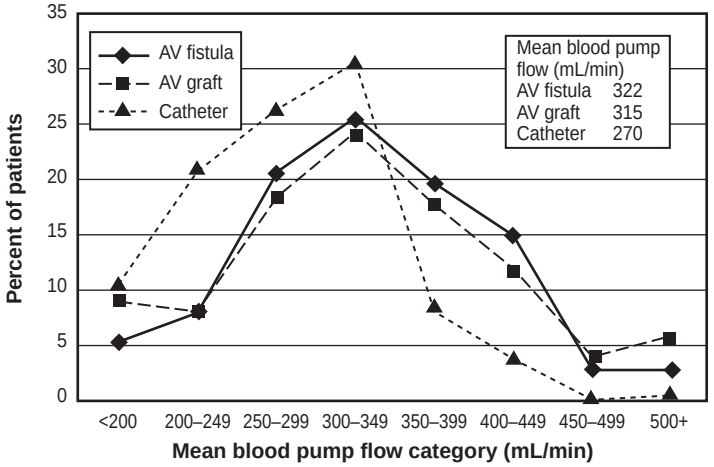
Figure 3: *Type of vascular access by selected patient characteristics*



A larger percentage of patients dialyzed with an AV fistula or an AV graft had a mean calculated Kt/V value ≥ 1.2 compared to patients dialyzed with a catheter (84% and 86% vs. 72%, respectively, p< 0.05).

The distributions of mean blood pump flow rates by access type are shown in Figure 4. Mean blood pump flow rates were significantly lower for catheters compared to either AV fistulae or AV grafts (270 vs. 322 and 315 mL/minute, respectively, p< 0.001).

Figure 4: *Distribution of mean blood pump flow rates (mL/minute) by vascular access type*



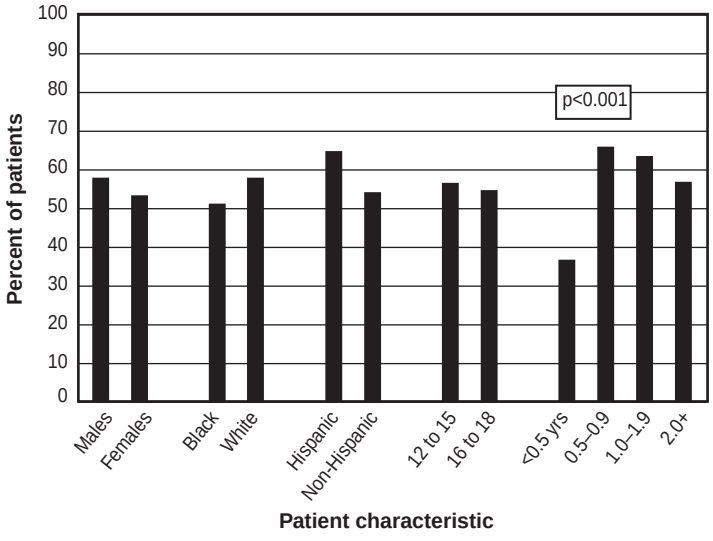
171 (41%) patients had a catheter as their current access. Within this subset of patients, 63% had no fistula or graft surgically created at this time, 14% had a fistula or graft maturing (not ready to cannulate), and 7% had a temporary interruption of the fistula or graft due to clotting or revisions. 3% of patients were not candidates for fistula or graft placement as all sites had been exhausted, and 13% had a catheter as their access for other reasons not further described.

36% of patients (90/251) with an AV fistula or an AV graft had their access routinely monitored for stenosis. Within this subset of patients, 61% were monitored with dynamic venous pressure, 11% with static venous pressure, 10% with Color-Flow Doppler, 9% with the Dilution Technique, and 19% had "Other" types of monitoring (groups not mutually exclusive).

Anemia Management

The mean (SD) hemoglobin for the patients in the sample for analysis was 10.99 gm/dL (± 1.6). 55% of patients had a mean hemoglobin ≥ 11 gm/dL; 49% had a mean hemoglobin 11-12.9 gm/dL. 11% of patients had a mean hemoglobin < 9 gm/dL; 23% had a mean hemoglobin < 10 gm/dL. The percent of patients with mean hemoglobin ≥ 11 gm/dL by selected patient characteristics is shown in Figure 5. A smaller percentage of patients dialyzing less than six months compared to patients dialyzing longer met this threshold (37% vs. 61%, p< 0.001).

Figure 5: *Percent of patients with mean hemoglobin ≥ 11 gm/dL by selected patient characteristics*



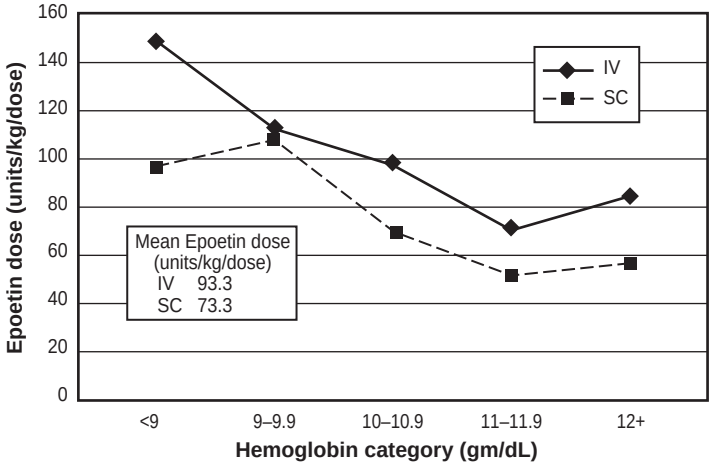
The mean (SD) Epoetin dose for patients prescribed Epoetin by the intravenous (IV) route was 93.3 units/kg/dose (± 65.5), by the subcutaneous (SC) route, 73.3 units/kg/dose (± 53.1). Mean Epoetin doses were lower by the SC route compared to the IV route across all hemoglobin categories. (Figure 6) For both routes of administration, Epoetin doses tended to decrease with increasing mean hemoglobin values. Within the group of patients prescribed Epoetin IV, females were prescribed significantly higher doses compared to males (103.3 vs. 84.1 units/kg/dose, p< 0.01), as were patients dialyzing two or more years compared to patients dialyzing less than six months (105.3 vs. 90.7 units/kg/dose, p< 0.05). Further analysis was not conducted on the group of patients prescribed Epoetin SC due to the small number of patients in this group (n=45).

The mean (SD) transferrin saturation for patients in the sample for analysis was 27.7% (± 14.8). 70% of patients had a mean transferrin saturation ≥ 20%. There were no significant differences in mean transferrin saturation values or in the percent of patients with mean transferrin saturation ≥ 20% by gender, race, ethnicity, age group, duration of dialysis, or cause of ESRD.

The mean (SD) serum ferritin concentration was 298.2 ng/mL (± 320.8). 68% of patients had a mean serum ferritin concentration ≥ 100 ng/mL. A larger percentage of Blacks compared to Whites had a mean serum ferritin concentration ≥ 100 ng/mL (74% vs. 63%, p< 0.05), as did patients dialyzing two or more years compared to patients dialyzing less than six months (77% vs. 51%, p< 0.01).

10% of patients (n=45) had relative iron deficiency, defined for this report as having both a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL. Patients with relative iron deficiency had significantly lower mean hemoglobin values compared to other patients (10.6 gm/dL vs. 11.1 gm/dL, p< 0.05).

Figure 6: *Mean Epoetin dose (units/kg/dose) by hemoglobin category*



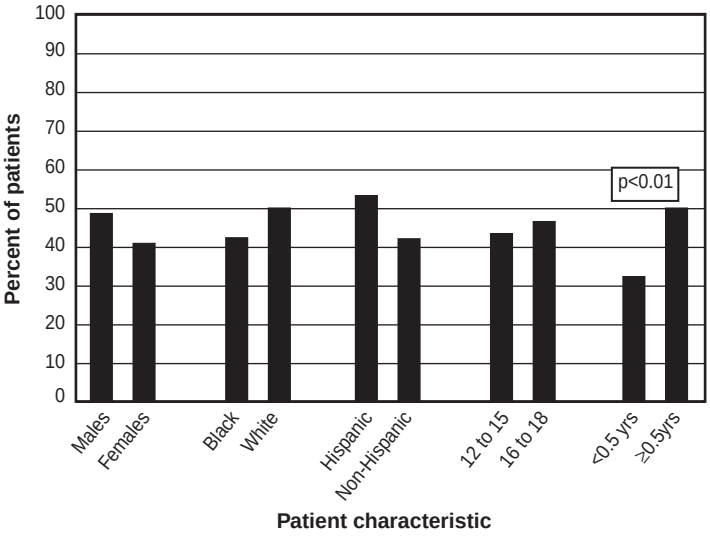
317 (73%) patients were prescribed some iron, either IV or orally at least once during the three month study period. Within this subset of patients, 72% were prescribed iron by the IV route and 38% were prescribed iron orally (groups not mutually exclusive). The mean hemoglobin was higher in the group of patients who received IV iron at least once during the study period compared to those patients who did not receive IV iron (11.1 gm/dL vs. 10.8 gm/dL, $p< 0.05$).

Iron prescription practice did not appear to vary by the patient's iron stores status. 77% of patients with a mean transferrin saturation value < 20% were prescribed some iron during the study period; 53% were prescribed IV iron. 69% of patients with a mean serum ferritin concentration < 100 ng/mL were prescribed some iron during the study period; 39% by the IV route. 67% of patients with both a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL were prescribed some iron during the study period; 38% by the IV route.

Serum Albumin

The mean serum albumin for patients with values determined by the bromcresol green (BCG) laboratory method (n=339) was 3.85 gm/dL (± 0.51); by the bromcresol purple (BCP) method (n=90), 3.62 gm/dL (± 0.52). 83% of patients had a mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP); 46% had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP). A lower percentage of patients dialyzing less than six months compared to those dialyzing six months or longer had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) (32% vs. 49%, $p< 0.01$) (Figure 7).

Figure 7: *Percent of patients with mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP)* by selected patient characteristics*



* BCG = bromcresol green laboratory method
BCP = bromcresol purple laboratory method

KEY OBSERVATIONS

- The etiology of ESRD in pediatric patients on hemodialysis is different than that of adult ESRD patients, with 24% having congenital/urologic causes for their renal failure.

- 79% of patients had a mean calculated delivered Kt/V ≥ 1.2, and females had a significantly higher mean calculated Kt/V compared to males.

- Mean blood pump flow rates were significantly different by age group, cause of ESRD and patient weight. However, after multivariate analysis, only weight and age remained as significant predictors of a mean blood pump flow rate ≥ 300 mL/minute.

- 41% of patients had a catheter as their current access, and this type of access was associated with lower blood pump flow rates and lower Kt/V values compared to patients with AV fistulae or grafts as their current access. Female patients and those on dialysis for less than six months were more likely to have a catheter as their current access.

- The mean hemoglobin was 10.99 gm/dL and 55% of patients had a mean hemoglobin ≥ 11 gm/dL.

- 10% of patients had relative iron deficiency, defined for this report as having both a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL, and these patients had significantly lower mean hemoglobin values compared to other patients.

- 46% of patients had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP). Only 32% of patients dialyzing less than six months compared to 49% of patients dialyzing six months or longer had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP)

NEXT STEPS

Further analyses of these data will be conducted to more fully understand where opportunities for improvement in patient care exist.

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