Effects of Oral Nutritional Supplements on Clinical Outcomes and Nutritional Markers in Hemodialysis Patients Qualifying with Serum Albumin 3.6 or 3.7 g/dL

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Introduction

- Use of oral nutritional supplements (ONS) has been shown to improve clinical outcomes in dialysis patients with serum albumin ≤ 3.5 g/dL.[1-3]
  - There is evidence that patients with albumin 3.6 or 3.7 g/dL are also at increased risk for death.[4]
- Here we performed a retrospective evaluation of a pilot program to provide ONS to to hemodialysis patients with albumin 3.6 or 3.7 g/dL.

Objective

To assess the effects of providing ONS to dialysis patients with serum albumin 3.6 or 3.7 g/dL on clinical outcomes and nutritional markers

Methods

Data Sources and ONS Pilot Program

- Data for this analysis were derived from electronic health records.
- The pilot program provided ONS to patients with serum albumin concentrations of 3.6 or 3.7 g/dL between May and July 2017.

Patients and Exposure

- Patients included in this analysis were ≥18 years, receiving in-center hemodialysis 3 times per week, had a qualifying albumin measurement of 3.6 or 3.7 g/dL, and had not received ONS in the 60 days prior to qualifying albumin measurement.
- ONS patients were those who were treated at a facility participating in the pilot, had a qualifying albumin measurement, and subsequently received at least 1 dose of ONS.
- Eligible control patients were those who were treated at a non-pilot facility and had a qualifying albumin measurement of 3.6 or 3.7 g/dL.

Matching

- ONS patients were matched 1:1 to control patients based on calendar month and propensity scores for age, sex, vascular access, diabetes status, Charlson comorbidity index score, race, etiology, pre-dialysis weight in the prior 30 days, dialysis vintage, and were hard matched on both qualifying albumin and the preceding albumin measurement.
- Patient demographics and characteristics were considered as of index date and compared by calculating standardized differences.

Outcomes and Statistical Analysis

- Index date for matched exposure pairs was considered as the date of first receipt of ONS by the ONS patient.
- Patients were followed forward in time from index date until 30 October 2017 or censoring. Outcomes considered were:
  - Mortality
  - All-cause hospitalization
  - Missed dialysis treatments
  - Nutrional markers (albumin, normalized protein catabolic rate [nPCR], and creatinine).
- Outcomes for ONS and control patients were compared using generalized linear models.

Results

Table 1. Baseline Patient Characteristics

		Control N = 2902	ONS N = 2902	Standardized Difference (%)
Age, years	mean ± SD	62.2 ± 13.5	62.3 ± 13.8	+0.7
Female, n (%)		1328 (45.8)	1225 (42.2)	-7.3
Vintage, months	mean ± SD	61.9 ± 52.8	58.9 ± 51.5	-5.8
Body mass index, kg/m^2	mean ± SD	30.2 ± 8.0	29.5 ± 7.9	-8.8
Race, n (%)				
White		924 (31.8)	962 (33.2)	+3.0
Black		1135 (39.1)	1025 (35.3)	-7.9
Hispanic		574 (19.8)	622 (21.4)	+4.0
Asian		120 (4.1)	161 (5.6)	+7.0
Other/unknown		149 (5.1)	132 (4.6)	-2.3
Etiology, n (%)				
Diabetes		1217 (41.9)	1229 (42.4)	+1.0
Hypertension		818 (28.2)	796 (27.4)	-1.8
Other		867 (29.9)	877 (30.2)	+0.7
Vascular access type, n (%)				
Arteriovenous fistula		2132 (73.5)	2115 (72.9)	-1.4
Arteriovenous graft		549 (18.9)	566 (19.5)	+1.5
Central venous catheter		221 (7.6)	221 (7.6)	0
CCI	mean ± SD	5.4 ± 1.7	5.3 ± 1.7	-5.9
Diabetes, n (%)		2119 (73.0)	2068 (71.3)	-3.8
Prior Transplant, n (%)		118 (4.1)	103 (3.6)	-2.6
Hospitalization in Prior Month, n (%)		274 (9.4)	291 (10.0)	+2.0
nPCR, g/kg/day	mean ± SD	1.0 ± 0.3	1.0 ± 0.3	0
Phosphorus, mg/dL	mean ± SD	5.4 ± 1.6	5.3 ± 1.6	-6.3
Alkaline phosphatase, IU/L	mean ± SD	103.2 ± 69.2	103.9 ± 76.1	+1.0
Hemoglobin, g/dL	mean ± SD	10.8 ± 1.2	10.7 ± 1.2	-8.3
Serum ferritin, ng/mL	mean ± SD	792 ± 375	800 ± 412	+2.0
TSAT, %	mean ± SD	30.9 ± 13.4	30.9 ± 13.4	0.0
Qualifying serum albumin, n (%)				
3.6 g/dL		984 (33.9)	984 (33.9)	NA [a]
3.7 g/dL		1918 (66.1)	1918 (66.1)	
Prior serum albumin, n (%)				
3.7 g/dL		559 (19.3)	559 (19.3)	NA [a]
3.8 g/dL		1017 (35.0)	1017 (35.0)	
3.9 g/dL		735 (25.3)	735 (25.3)	
4.0 g/dL		348 (12.0)	348 (12.0)	
4.1 g/dL		161 (5.6)	161 (5.6)	
4.2 g/dL		65 (2.2)	65 (2.2)	
≥ 4.3 g/dL		17 (0.6)	17 (0.6)	

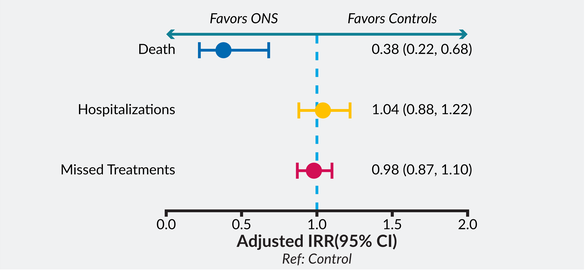
[a] Not applicable, variable was matched exactly

Abbreviations: nPCR, normalized protein catabolic rate; TSAT, saturated transferrin; SD, standard deviation.

Patient Characteristics

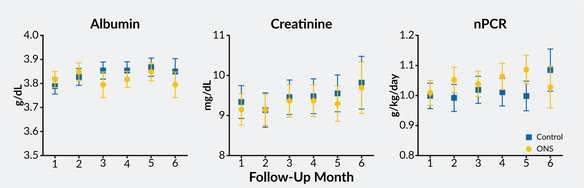
- During the study period, there were 2902 eligible ONS patients who were matched to an equivalent number of control patients.
- There were no significant differences in patient demographics and characteristics between ONS and control patients, indicating that the groups were well matched.

Figure 2. Clinical Outcomes



Adjusted for sex, race, body mass index, diabetes, and hospitalizations in prior month.
Abbreviations: CI, confidence interval; IRR, incidence rate ratio; Ref, referent.

Figure 3. Nutritional Markers



Presented are mean monthly values and 95% confidence intervals adjusted for sex, race, body mass index, diabetes, and hospitalizations in prior month.
Abbreviations: nPCR, normalized protein catabolic rate.

Clinical Outcomes

- Comparisons of clinical outcomes among ONS and matched control patients are presented in Figure 2.
  - After adjustment for case mix, there was a significantly lower death rate among ONS patients relative to controls (0.07 vs 0.12 events per patient-year [PPY]; adjusted incidence rate ratio [aIRR] = 0.38; 95% confidence interval [CI] = 0.22-0.68).
  - No significant differences were observed in hospitalizations (1.37 vs 1.16 admissions PPY; aIRR = 1.04; 95% CI = 0.88-1.12) or missed dialysis treatments (11.2 vs 11.4 events PPY; aIRR = 0.98; 95% CI = 0.87-1.10).

Nutritional Markers

- Longitudinal values for albumin, creatinine, and nPCR over 6 months of follow-up are presented in Figure 3.
  - There were no significant differences in any markers of nutritional status between ONS and control patients.

Conclusions

- In patients with albumin 3.6 or 3.7 g/dL, receipt of ONS was associated with significantly lower risk of death.
- There were no significant differences in hospitalizations, missed treatments, or markers of nutritional status between ONS and control patients.
  - The lack of observed effects may be due in part to survivor bias whereby patients in the ONS group, who might otherwise have died, survived and remained in the analysis through follow-up.
- These findings indicate that provision of ONS to dialysis patients with albumin 3.6-3.7 g/dL could be beneficial in reducing mortality.
- Dialysis providers should consider expanding ONS programs to include patients with albumin 3.6-3.7 g/dL.

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