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Original Investigation

Oral Intradialytic Nutritional Supplement Use and Mortality in Hemodialysis Patients

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Background: Hemodialysis patients have high mortality rates, potentially reflecting underlying comorbid conditions and ongoing catabolism. Intradialytic oral nutritional supplements may reduce this risk.

Study Design: Retrospective propensity-matched cohort.

Setting & Participants: Maintenance hemodialysis patients treated at Dialysis Clinic Inc facilities who were initiated on a nutritional supplement protocol in September to October 2010 were matched using a propensity score to patients at facilities at which the protocol was not used.

Predictors: Prescription of the protocol, whereby hemodialysis patients with serum albumin levels ≤3.5 g/dL would initiate oral protein supplementation during the dialysis procedure. Sensitivity analyses matched on actual supplement intake during the first 3 study months. Covariates included patient and facility characteristics, which were used to develop the propensity scores and adjust multivariable models.

Outcomes: All-cause mortality, ascertained though March 2012.

Results: Of 6,453 eligible patients in 101 eligible hemodialysis facilities, the protocol was prescribed to 2,700, and 1,278 of these were propensity matched to controls. Mean age was 61 ± 15 (SD) years and median dialysis vintage was 34 months. There were 258 deaths among protocol assignees versus 310 among matched controls during a mean follow-up of 14 months. In matched analyses, protocol prescription was associated with a 29% reduction in the hazard of all-cause mortality (HR, 0.71; 95% CI, 0.58-0.86); adjustment had minimal impact on models. In time-dependent models incorporating change in albumin level, protocol status remained significant but was attenuated in models incorporating a 30-day lag. Similar results were seen in sensitivity analyses of 439 patients receiving supplements who were propensity-matched to controls, with 116 deaths among supplement users versus 140 among controls (HR, 0.79; 95% CI, 0.60-1.05), achieving statistical significance in adjusted models.

Limitations: Observational design, potential residual confounding.

Conclusions: Prescription of an oral nutritional supplement protocol and use of oral protein nutritional supplements during hemodialysis are associated with reduced mortality among in-center maintenance hemodialysis patients, an effect likely not mediated by change in serum albumin levels.

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INDEX WORDS: Hemodialysis; nutrition; nutritional supplement; catabolism; mortality; oral nutritional supplement (ONS); serum albumin.

Mortality rates are high among hemodialysis patients, with almost 50% dying within 3 years of initiating kidney replacement therapy.[1] Poor nutritional status is common among patients treated with maintenance dialysis, with prevalence ranging from 18%-75%.[2] Low serum albumin level, which may indicate poor nutritional status and heightened inflammation, is a strong indicator of increased mortality risk.[3-6] This relationship may reflect causality because anorexia and dysgeusia can lead to inadequate protein and calorie intake, resulting in malnutrition and adverse outcomes, particularly in the context of increased nutritional needs that occur in a catabolism milieu. However, nutritional markers, including serum albumin, also reflect underlying inflammation or illness burden.[7,8] In contrast to hypoalbuminemia and weight loss, characteristics suggesting better nutrition or nutritional reserve, such as higher serum creatinine level and higher body mass index (BMI), are associated with improved survival.[3,9,10]

The hemodialysis procedure itself induces a catabolic state.[11-14] In several small studies, oral intradialytic supplement administration appears to ameliorate this catabolic state.[15,16] Recently, Lacson et al[17] addressed this issue in a quality improvement project conducted in patients treated with maintenance hemodialysis at facilities operated by Fresenius

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Medical Care North America. In their protocol, maintenance hemodialysis patients with baseline serum albumin concentrations ≤3.5 g/dL were eligible to receive an oral nutritional supplement (ONS) during each session of thrice-weekly hemodialysis until serum albumin concentration was ≥4 g/dL, at which time the ONS administration would be discontinued. Dividing their population into treated and untreated groups and matching individuals between groups using a propensity score, Lacson et al[17] noted that, among patients receiving nutritional supplements compared with those never receiving an ONS, there was a 34% reduced risk of all-cause mortality in adjusted analyses. Critically, Lacson et al[17] were unable to examine change in serum albumin levels during the study period due to an assay change.

In 2010, Dialysis Clinic Inc (DCI) widely implemented a nutritional supplement protocol, such that when serum albumin concentration was ≤3.5 g/dL, patients were administered 15 g of oral protein during each dialysis session. To evaluate the efficacy of this intervention and explore the relationship between changes in serum albumin levels and outcomes by protocol status, we examined the DCI experience with the nutritional supplement protocol.

Box 1. The Dialysis Clinic Inc Nutritional Supplement Protocol

1. The goal of the protocol is to maintain albumin levels at ≥4.0 g/dL.
2. Start giving Pro-Stat 101 (Medical Nutrition USA), 30 mL, thrice weekly for patients who currently are not receiving a nutritional supplement and also have a serum albumin level ≤3.5 g/dL.
3. The nutritional supplement product may be changed as needed using the clinic-approved list of nutritional supplements.
4. Discontinue giving the nutritional supplement when patient's serum albumin level is ≥4.0 g/dL.
5. Restart giving the nutritional supplement when serum albumin level is ≤3.5 g/dL.
6. For in-center patients, the nutritional supplement should be given either before or during dialysis treatment.
7. For home patients, the nutritional supplement should be supplied to patient to take at home 3×/wk.

METHODS

Study Population

DCI is a large not-for-profit dialysis provider that operates approximately 210 dialysis facilities across the United States. DCI promoted the nutritional supplement protocol to facility medical directors in September to October 2010, such that nephrologists could include their patients in the DCI protocol, which called for patients to receive a liquid supplement containing 15 g of protein at each in-center hemodialysis session if their serum albumin concentration was ≤3.5 g/dL. Patients were maintained on the protein ONS until they achieved an albumin level ≥4.0 g/dL and resumed the protocol if albumin level again declined to ≤3.5 g/dL. The protocol did not address use of an ONS outside the hemodialysis unit (Box 1).

Given provider patterns, patients for whom the protocol was prescribed typically were clustered within facilities; accordingly, dialysis facilities were classified as adopters or nonadopters. Facilities were considered adopters if the protocol was prescribed for ≥10% of patients. For analyses, protocol users were drawn only from facilities that adopted the protocol in September or October 2010, whereas, to avoid contaminating the control group, patients for whom the protocol was not prescribed were drawn only from facilities that had not adopted the protocol by the end of covariate ascertainment (July 31, 2011). Patients treated in facilities adopting the protocol between November 2010 and July 2011 were excluded from analyses. The baseline period for both the protocol group and controls was September or October 2010. Patients eligible for inclusion in this study needed to have had at least 7 in-center hemodialysis treatments in September or October 2010. Children and individuals treated with home dialysis were excluded. The study was approved by the Tufts Institutional Review Board.

Covariates

Patient-level data were collected from DCI's medical information system, DARWIN, including laboratory results, which were assayed at a central laboratory in Nashville, TN. Serum albumin was assayed using a bromocresol green method. Baseline laboratory values were the first laboratory assessment from the baseline month (either September or October 2010), with normalized protein catabolic rate (nPCR) calculated using pre- and postdialysis urea nitrogen levels from a single session. Predialysis blood pressure (BP) was the average for the baseline month, and weight was estimated dry weight averaged for the month. We defined vascular access by the type used during the baseline month. If more than one access was used, the type used for the majority of treatments in the following month informed the primary access. Missed treatments and recent hospitalization data reflect occurrences between August 1 and September 30, 2010. Facility-level data were extracted from the DCI medical information system, with the exception of the standardized mortality ratio (SMR), which was derived from the *2010 Dialysis Facility Report* for individual dialysis facilities prepared by the University of Michigan Kidney Epidemiology and Cost Center (publicly available at and downloaded for individual facilities from http://projects.propublica.org/dialysis/). For most facilities, the SMR was the average value from 2006-2009, although for newer units, as little as 1 year was used. Other facility characteristics were based on data from August 2010. Missing data for covariates were imputed with flexible additive imputation models using the transcan function in the Hmisc package in R version 2.14.1 statistical software (R Foundation for Statistical Computing). Extreme values (eg, single-pool Kt/V > 3 and hemoglobin level >20 or <5 g/dL) were set to missing and imputed.

Outcomes

The primary study outcome was all-cause mortality, captured through the DCI medical information system. Patients were censored at the time of transplantation, modality change, or transfer to a non-DCI dialysis facility. Withdrawal from dialysis therapy was classified as death with a date of death assigned at 7 days after the last dialysis session. Mortality was ascertained through March 2012.

Statistical Analyses

Primary analyses matched individuals for whom the nutritional supplement protocol was prescribed who received dialysis in facilities with ≥10% of participants treated with the protocol to individuals for whom the protocol was not prescribed who received dialysis in facilities with <10% of patients treated with it. We used logistic regression to create a propensity score for protocol prescription based both on patient- and facility-level

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