Cycling Parenteral Nutrition from 24 to 12 hours in 1 Step is Safe in Patients Requiring Long-Term Therapy Sandra I. Austhof, Robert DeChicco, Mandy L. Corrigan, Rex A. Speerhas, Gail Cresci, Sreenija Suryadevara, Achuthan Sourianarayanane, Arthi Kumaravel, Rocio Lopez, Ezra Steiger

Abstract Body: Introduction: Cycling parenteral nutrition (PN) over 12 hours is the preferred administration method in long-term patients as it allows time off the infusion. Potential adverse events (AEs) associated with cycling PN are rebound hypoglycemia due to the rapid discontinuation of dextrose infusion associated with weaning, along with hyperglycemia and respiratory distress, due to the increase in the rate of dextrose and fluid infusion, respectively. The study aim was to test the prediction that patients without diabetes mellitus (DM) or major organ dysfunction requiring long term PN could be cycled from 24 hours to 12 hours in 1 step without increasing the risk of PN-related AEs compared to the standard 2-step process. Methods: Cleveland Clinic inpatients followed by the Nutrition Support Team (NST) who were receiving PN at goal calories infused over 24 hr without severe electrolyte or blood sugar abnormalities and awaiting discharge on PN cycled over 12 hr were consented for study participation. The study was approved by the Institutional Review Board. Patients with DM or major organ dysfunction were excluded. Patients were randomly assigned to a 1-Step "fast track" protocol (i.e., cycled from 24 to 12 hr in 1 day) or 2-Step "standard" protocol (i.e., cycled from 24 to 12 hr in 2 days). Data was collected upon study entry and daily until 1 day after a 12 hour cycle was achieved or until the patient was removed from the study. The type and prevalence of PN-related AEs were documented and graded as mild or serious. AEs were defined as hypo- or hyperglycemia, new onset or worsening dyspnea, tachycardia, tachypnea, lower extremity or sacral edema, pulmonary edema or abdominal ascites. Determination whether the AE was PN-related was made by a NST physician and an independent physician. Differences of opinion regarding the AE etiology were resolved by further review and discussion until a consensus was reached. A univariable analysis was performed to assess differences between the groups. Student's t-tests were used to compare continuous factors (i.e., age and BMI) between subjects. Pearson's chi-square tests were performed for categorical variables (i.e., gender). An interim analysis was done to rule out large discrepancies in AEs between the groups which would place patients at undue risk. Results: 49 patients were enrolled and data from 40 patients (1-Step N=23; 2-Step N=17) were analyzed. The mean age was 51.4 yr and 64% of subjects were male. The most prevalent AE was mild hyperglycemia (blood glucose 200-400 mg/dL) occurring in 39.1% of patients in the 1-Step and 41.2% in the 2-Step group (p=0.13). Hypoglycemia (blood glucose <70 mg/dL) occurred in 4.3% of patients in the 1-Step and 17.6% in the 2-Step group (p=0.26). No occurrences of new onset or worsening dyspnea, tachycardia, tachypnea, lower extremity or sacral edema, pulmonary edema or abdominal ascites were seen in either group. Overall, there was no significant difference in the prevalence of mild AEs between the groups (43.5% in 1-Step vs 52.9% in 2-Step, P=0.25). No serious AEs were observed in either group. Conclusions: Mild hyperglycemia was the most commonly occurring AE when cycling PN patients from 24 to 12 hr with no significant difference between a 1-Step versus 2-Step protocol. No serious AEs were observed in either group. These preliminary data suggest despite mild hyperglycemia, 1-Step cycling is as safe as 2-Step cycling in patients without DM or major organ dysfunction requiring long-term PN. Fast track cycling could potentially facilitate hospital discharge, resulting in decreased healthcare costs and improved patient satisfaction.