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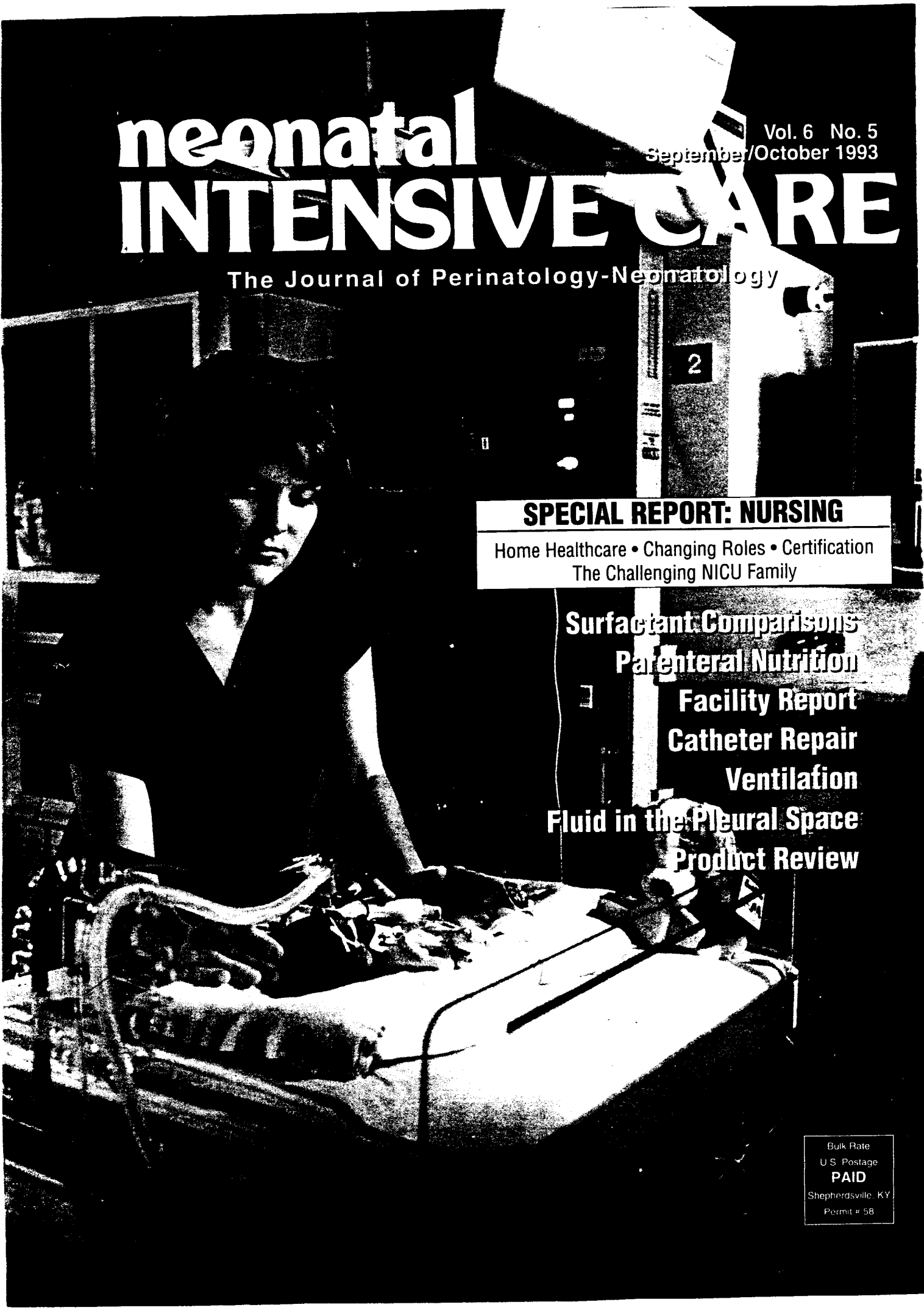

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IS L-CARNITINE STABLE IN PARENTERAL NUTRITION SOLUTIONS PREPARED FOR PRETERM NEONATES?

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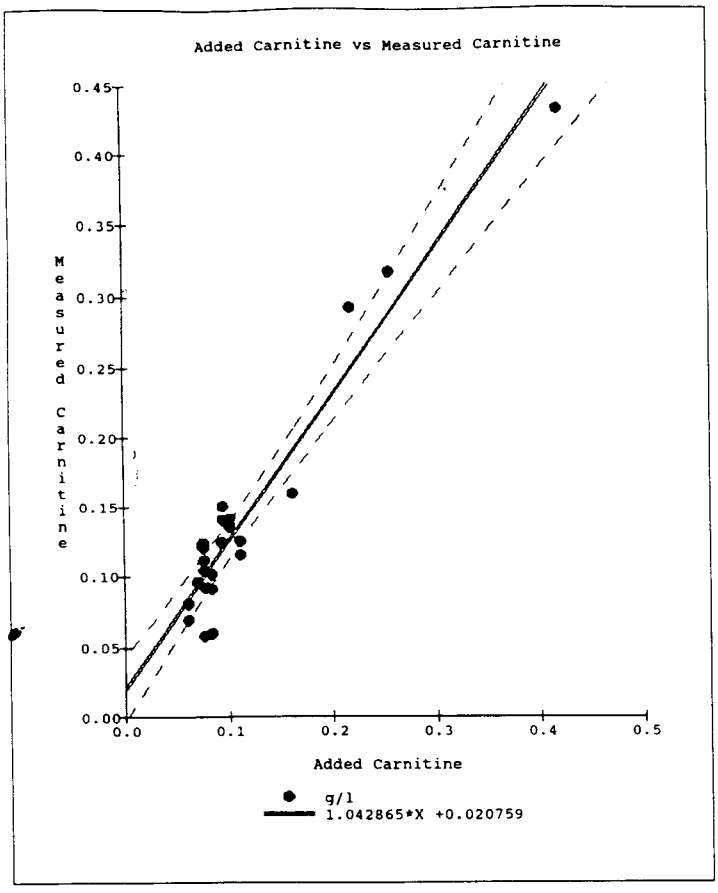
[redacted]

Carnitine is critically important in the metabolism of neonates. Carnitine transports across membranes carboxylic acids that have been activated to the coenzyme A level. Its role in facilitating ß-oxidation has long been recognized as important to the energy status of the neonate. Its role in facilitating the removal of compounds that have accumulated to toxic levels has been recognized more recently as important for normal development of the neonate.

Human milk is an excellent source of carnitine and most commercially available infant formulae have an equally high

Table 1. Nutrient Concentrations in Parenteral Nutrition Solutions Sampled For This Study After Being Administered To Preterm Neonates

Component	Number Of Bags	Mean ± S.D.	Low Value	High Value
Amino Acids (g/l)	24	20.31 ± 8.27	9.67	45.14
Cysteine (g/l)	24	0.95 ± 0.50	0.02	2.26
Dextrose (g/l)	24	112.92 ± 13.98	90.00	150.00
Sodium Chloride (mEg/l)	22	53.64 ± 30.67	10.00	100.00
Sodium Acetate (mEg/l)	15	23.33 ± 10.97	10.00	40.00
Potassium Chloride (mEg/l)	15	10.53 ± 3.78	5.00	20.00
Potassium Acetate (mEg/l)	11	6.82 ± 3.37	5.00	15.00



concentration of carnitine. However the clinician criteria that are indicators for the use of parenteral nutrition are the same criteria that may place the neonate at higher risk for carnitine insufficiency.

During the past decade our laboratory has performed several clinical trials evaluating the use of carnitine supplemented parenteral nutrition solutions in several clinical research studies, with no indication of stability problems. IV carnitine has recently become available commercially, and as neonatologists consider the possible supplementation of parenteral nutrition solutions with carnitine, issues of carnitine stability in the chemical milieu of the types of nutritional solutions currently used for preterm neonates must be addressed.

Bullock et al[1] stored total nutrient admixtures containing TrophoAmine amino acid injection, cysteine, and electrolytes admixed with Intralipid, Nutrilipid, and Liposyn II at 4°C for 24 hours and then at 20-22°C for 24 hours. Evaluation of the emulsion stability using visual assessment, pH determination, and particle size analysis before and after storage indicated that these admixtures were stable.

The neonatal intensive care units in our area routinely combine all components of the parenteral nutrition solution except the fat emulsion in one container and administer the fat emulsion from a separate container via a Y-connector.

Potassium Phosphate (mEg/l)	24	9.29 ± 2.26	5.00	15.00
Magnesium Sulfate (mEg/l)	23	3.83 ± 1.69	0.10	6.00
Calcium Gluconate (mEg/L)	24	24.79 ± 7.59	10.00	35.00
Insulin (units/l)	14	3.43 ± 0.86	1.00	4.00
MVI-PED (ml/l)	24	33.76 ± 27.87	12.82	138.89
Zinc (mcg/l)	24	4242.16 ± 3015.31	1282.05	15277.78
Copper (mcg/l)	24	231.67 ± 160.39	41.67	833.33
Manganese (mcg/l)	24	57.92 ± 40.10	10.42	208.33
Chromium (mcg/l)	24	2.32 ± 1.60	0.42	8.33

Note: All parenteral nutrition solutions contained heparin at 1 unit per ml

We have addressed the question of whether the intravenous carnitine added to the bag containing the amino acids, dextrose, electrolytes, vitamins, and minerals is stable as measured by its bioavailability for an enzyme based assay.

This report describes the results of random sampling of bags of parenteral nutrition solutions supplemented with intravenous carnitine for neonates weighing less than 1500 grams. The parenteral nutrition solution was prepared according to the physician orders for low birth weight neonates, which included Levocarnitine Injectable Solution (1g/5ml) at a dose of 10 mg/kg/day. The nurses recorded the date and time that the bag was hung and the date and time that the bag was taken down to hang a new bag. Before disposal of the used bag, an aliquot of the solution was collected and frozen in the freezer in the NICU (approx -10°C). Frozen samples were transported to the laboratory and stored in a -20°C freezer. The carnitine concentration of each sample collected as the spent bag was being disposed was determined using the radioenzymatic assay.[2]

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A better experimental design would have been to actually measure the solution before it was hung. However, that would have involved a break in the line for sampling which would have added one more possibility for contamination. For this reason, this approach was not implemented. The details of the physicians' orders for parenteral nutrition were copied from the medical record and the concentration ordered was used for comparisons. Extremely small volumes (0.05 ml to 0.1 ml) of the intravenous carnitine product were added manually using a syringe that could only deliver the carnitine stock solution in increments of 0.01 ml.

The quantity of each nutrient required, as well as the total fluid and the rate of administration tolerated, differs among neonates. In addition, as the clinical condition changes for these same neonates, the nutrients added to the bag as well as the concentration of each nutrient can contribute to a high degree of variability among bags of parenteral nutrition solutions used in a neonatal intensive care unit. Table 1 lists the range of concentrations of nutrients ordered for the parenteral nutrition solutions evaluated.

Table 2 lists the carnitine concentrations added and the carnitine concentrations recovered from the bags at the conclusion of their administration. Figure 1 plots the individual data points and shows the line of best fit with 95% confidence intervals. The slope of the line is close to a perfect 1.00 and the correlation coefficient is 0.961701. These data demonstrate that the carnitine was stable and bioavailable for radioenzymatic assay at the conclusion of the administration of the parenteral nutrition solution to the preterm neonates. ■

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Table 2. Carnitine Concentrations Added and Recovered in Parenteral Nutrition Solutions For Neonates

	Number Of Bags	Mean ± S.D.	Low Value	High Value
Carnitine concentration Added (g/l)	24	0.11 ± 0.08	0.06	0.42
Carnitine concentration Recovered (g/l)	24	0.14 ± 0.09	0.06	0.43

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