

Original Article

Application of refractometry to quality assurance monitoring of parenteral nutrition solutions

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Parenteral nutrition (PN) solution contains various concentrations of dextrose, amino acids, lipids, vitamins, electrolytes, and trace elements. Incorrect preparation of PN solution could lead to patient death. In this study we used the refractive index as a quality assurance tool to monitor the preparation of PN solution. Refractive indices of single nutrient components and PN solutions consisting of various concentrations of dextrose, amino acids, electrolytes, and lipids were measured. A mathematical equation and its linear plot were generated then used to predict the refractive index of the PN solution. The best-fit refractive index for PN solution (i.e., the predicted refractive index) = $0.9798 \times (\% \text{ dextrose}) + 1.2889 \times (\% \text{ amino acids}) + 1.1017 \times (\% \text{ lipids}) + 0.9440 \times (\% \text{ sum of the electrolytes}) + 0.5367$ ($r^2 = 0.99$). This equation was validated by comparing the measured refractive indices of 500 clinical PN solutions to their predicted refractive indices. We found that 2 of the 500 prepared samples (0.4%) had less than the predicted refractive index (< 95%). Refractive index can be used as a reliable quality assurance tool for monitoring PN preparation. Such information can be obtained at the bedside and used to confirm the accuracy of the PN solution composition.

Key Words: refractometer, refractive index, quality assurance, nutrition, parenteral nutrition

INTRODUCTION

Parenteral nutrient (PN) solution is composed of various combinations of dextrose, amino acids, lipids, electrolytes, trace elements, vitamins, water, etc. PN is an important adjunctive therapy for a variety of disease states. PN can be used in a variety of settings including hospitals, long-term care and rehabilitation facilities, or at home.

Safe PN for patients is always a high priority for pharmacy professionals who prepare these solutions. Numerous patients have died as a result of receiving infusion of the incorrect PN formula. Dextrose overdose or underdose has been reported.¹⁻³ Quality control of PN solution preparation has become a particularly hot topic in clinical practice.⁴ PN solutions that are in the process of being prepared or at the end of preparation can be checked in several ways.⁵ For example chemical analysis, weighing, or refractive index in accordance with United States Pharmacopeia (USP) standards⁶ and standards of the American Society of Health System Pharmacists.⁷ Studies of documented errors, newly issued practice guidelines, and the introduction of innovative compounding technologies have resulted in improved PN safety.^{8,9}

To assess the compounder's performance, the pharmacy department may determine PN solution contents from the laboratory. However, chemical analysis is time-consuming, expensive, and usually designed for biological, not pharmaceutical systems. The chemical analysis should be validated to meet USP requirements for the components being tested. Measurement of fluid volume delivered from the source container to the final container

is determined by weighing. The total volume delivered is calculated by measuring the actual total bag weight compared with the calculated expected weight. However, only 43.5% of pharmacies use weighting method, and this process evaluates only the accuracy of the total contents and not the individual additives. The refractive index is used by approximately 10% of pharmacies for determining dextrose content. Using the refractive index is useful, but only if pharmacists are trained and get the experience required to obtain consistent and reliable results.⁸ Studies of documented errors, newly issued practice guidelines, and the introduction of innovative compounding technologies have resulted in improved PN safety.^{8,9}

Refractometers are precision optical instruments that measure the degree that light bends as it passes through the interface between two substances of different densities. The refractometer operates on the principle that, as the concentration of a solution increases, its refractive index changes proportionately.^{10,11} The refractive index of a refractometer measurement is remarkably reproducible under varying conditions. The reliability of these physical characteristics can be used to confirm the identity of

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substances, to measure the dietary formula concentrations under different conditions of storage, and preparation. Refractive index also has been widely used to determine the concentrations in multi-component mixtures such as drugs, fruit juices, enteral formula, and PN solutions¹⁰⁻¹⁵ and to confirm the identity of substances in mixtures.¹⁶

In this study, refractive index data were used to develop an equation and generate a linear plot. The linear plot could then be used to predict the refractive index of any combination of dextrose, amino acids, lipids, electrolytes, trace elements, and vitamins in PN solution. In this way, the quality of the PN preparation for clinical application is ensured.

MATERIALS AND METHODS

Parenteral nutrition solution

Our PN solution consisted of the dextrose (31%, TPN-8A and 8B, Biotech, Taoyuan, Taiwan), amino acids (10%, Moriamin-SN, China Chemical & Pharmaceutical, Hsinchu, Taiwan), lipid-in-water emulsion (20%, Lipo-fundin, B. Braun, Melsungen AG, Germany), trace elements (zinc [0.15 mg/mL], copper [0.05 mg/mL], manganese [0.02 mg/mL], chromium [0.0005 mg/mL], iodine [0.0028 mg/mL]; China Chemical & Pharmaceutical, Hsinchu, Taiwan), and vitamins (vitamin A palmitate [10,000 IU/mL], vitamin D₂ [1,000 IU/mL], vitamin E [5 IU/mL], vitamin C [500 mg/mL], vitamin B1 [50 mg/mL], riboflavin [10 mg/mL], vitamins B6 [15 mg/mL], niacinamide [100 mg/mL], and d-pantothenol [25 mg/mL]; Lyo-Povigen, China Chemical & Pharmaceutical, Hsinchu, Taiwan). PN solution also contained electrolytes such as sodium chloride, magnesium sulfate, and calcium gluconate. Various PN solutions were prepared by the Department of Pharmacy, Tri-service General Hospital, Taiwan.

Refractive index of single nutrient solutions

We investigated whether the molar refractivities of single nutrient solutions were additive. Dextrose (0 g/dL, 7.5 g/dL, 15 g/dL, 22.5 g/dL, and 30 g/dL), amino acids (0 g/dL, 2.5 g/dL, 5 g/dL, 7.5 g/dL, and 10 g/dL), lipids (0 g/dL, 5 g/dL, 10 g/dL, 15 g/dL, and 20 g/dL), sodium chloride (0 g/dL, 0.225 g/dL, 0.45 g/dL, 0.675 g/dL, and 0.9 g/dL), potassium chloride (0 g/dL, 0.375 g/dL, 0.75 g/dL, 1.125 g/dL, and 1.5 g/dL), magnesium sulfate (0 g/dL, 0.25 g/dL, 0.5 g/dL, 0.75 g/dL, and 1 g/dL), and calcium gluconate (0 g/dL, 0.25 g/dL, 0.5 g/dL, 0.75 g/dL, and 1 g/dL) were prepared for refractive index measurement. Each sample was measured in triplicate.

Refractive index of mixed nutrient solutions

We investigated whether the molar refractivities of mixed nutrient solutions were additive. PN solutions containing dextrose (0 g/dL, 4 g/dL, 8 g/dL, 12 g/dL, 16 g/dL, or 20 g/dL), amino acids (0 g/dL, 1 g/dL, 2 g/dL, 3 g/dL, 4 g/dL, 5 g/dL, or 6 g/dL), and lipids (0 g/dL or 4 g/dL) were prepared for refractive index measurement (Table 1A, Table 1B). Each sample was measured in triplicate.

Refractive index measurement

The refractive index was measured using a hand-held refractometer, whose scale of 0-32 could be read in 0.2 increments. The refractometer was calibrated with distilled water before each measurement. To measure the solute concentration, one or two drops of the specimen fluid were placed in a designated window.

Predicted refractive index equation

All components of PN solutions were initially considered to determine the refractive index equation. The constant coefficient of the electrolytes was considered to be the sum of coefficients for each of the electrolyte components.

Table 1-A. Measured refractive index of dextrose and amino acids in PN solutions.

Dextrose (g/dL)	Amino acids (g/dL)						
	0	1	2	3	4	5	6
	Refractive index						
0	0.0 ± 0.0	1.5 ± 0.1	2.8 ± 0.1	4.2 ± 0.1	5.6 ± 0.1	6.8 ± 0.1	8.1 ± 0.1
4	4.4 ± 0.1	5.8 ± 0.1	7.1 ± 0.1	8.4 ± 0.1	9.7 ± 0.1	11.0 ± 0.1	12.4 ± 0.1
8	8.8 ± 0.1	10.2 ± 0.1	11.4 ± 0.1	12.8 ± 0.1	14.0 ± 0.1	15.3 ± 0.1	16.4 ± 0.1
12	12.9 ± 0.1	14.1 ± 0.1	15.4 ± 0.1	16.6 ± 0.1	17.9 ± 0.1	19.1 ± 0.1	20.3 ± 0.1
16	16.8 ± 0.1	18.0 ± 0.1	19.2 ± 0.1	20.4 ± 0.1	21.6 ± 0.1		
20	20.6 ± 0.1	21.8 ± 0.1	23.0 ± 0.1	24.2 ± 0.1			

Clinically used range of dextrose (0-20 g/dL) and amino acids (0-6 g/dl) in PN solutions. Results presented are mean ± SD, (n = 3).

Table 1-B. Measured refractive index of dextrose, amino acids, and lipids in PN solutions.

Dextrose (g/dL)	Lipids (4 g/dL)					
	Amino acids (g/dL)					
	0	1	2	3	4	5
	Refractive index					
0	4.9 ± 0.1	6.2 ± 0.1	7.6 ± 0.1	8.9 ± 0.1	10.1 ± 0.1	11.5 ± 0.1
4	9.0 ± 0.1	10.3 ± 0.1	11.7 ± 0.1	13.0 ± 0.1	14.2 ± 0.1	15.5 ± 0.1
8	13.1 ± 0.1	14.3 ± 0.1	15.6 ± 0.1	16.8 ± 0.1	18.0 ± 0.1	19.2 ± 0.1
12	17.1 ± 0.1	18.3 ± 0.1	19.5 ± 0.1	20.7 ± 0.1	21.9 ± 0.1	
16	20.9 ± 0.1	22.1 ± 0.1	23.3 ± 0.1			

Clinically used range of dextrose (0-20 g/dL), amino acids (0-6 g/dl), and lipids (4 g/dL) in PN solutions. Results presented are mean ± SD, (n = 3).

To obtain an equation that accurately predicts refractive index in PN solutions; we included components (having multivariable significance of < 0.05) in a stepwise multivariate regression. A coefficient of discrimination $R^2 = 0.95$ was considered as reflecting a good correlation between the measured and predicted refractive index.

Validation Testing

The refractive indices of PN solutions were calculated using the equation: Predicted refractive index = 0.9798 (SE=0.0027) \times (% dextrose) + 1.2889 (SE=0.0009) \times (% amino acids) + 1.1017 (SE=0.0083) \times (% lipids) + 0.9440 (SE=0.0017) \times (% sum of the electrolytes) + 0.5367 (SE=0.00435) ($r = 0.99978$, $p < 0.001$, $R^2 = 0.99956$). To validate this equation and its linear plot, measured refractive indices were compared to corresponding calculated refractive indices. The measured refractive indices of over 130 pediatric and 370 adult PN solutions were used.

Development of a clinically useful plot from the equation

The equation was $ax + by + cz = d + e$

Where a, b, c, and d = coefficient constants, x = % dextrose, y = % amino acids, z = % total electrolytes, and e = predicted refractive index.

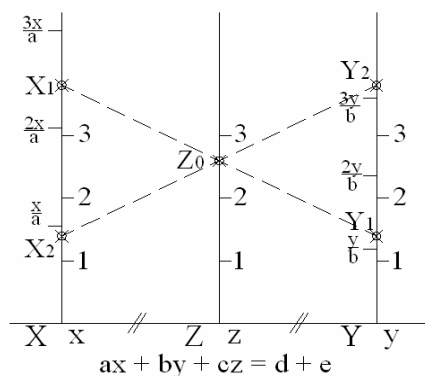
If $X = ax$, $Y = by$, $Z' = cz$, and $D = d + e$,

Then $X + Y + Z' = D$.

And if $Z = (D - Z')/2$,

Then $(X + Y)/2 = Z$.

The following figure shows the equilateral trapezoid geometric relation.¹⁷



For the same Z_0

$$Z_0 = (X_1 + Y_1)/2 = (X_2 + Y_2)/2 = (X_3 + Y_3)/2 = (X_4 + Y_4)/2 = (X_5 + Y_5)/2 = \dots$$

Which is a linear relationship with X and Y.

Then, using a scaling technique whereby

$$x = X/a, y = Y/b, \text{ and } Z = (D - cz)/2$$

$$z = (D - 2Z)/c = D/c - 2/c (Z)$$

Because $D = d + e$, and e = predicted refractive index,

When $x = 0$, $y = 0$, and $z = 0$ that $e = 0$, then $D = d$.

$$z = (d + e) / c - 2/c (Z)$$

$$= \text{offset} - 2/c (Z)$$

$$= Z_0 - 2/c (Z)$$

Two types of PN solutions are used in clinical practice. One contains amino acids, dextrose, and lipids, and the other contains no lipids. When PN solutions contain dextrose, amino acids, and lipids, the predicted refractive index = $0.9798 \times$ (% dextrose) + $1.2889 \times$ (% amino ac-

ids) + $1.1017 \times$ (% lipids) + $0.9440 \times$ (% sum of the electrolytes) + 0.5367 . (Equation 1)

When PN solutions contain dextrose and amino acids, without lipids, lipids are excluded from the equation. In this case, the predicted refractive index = $0.9798 \times$ (% dextrose) + $1.2889 \times$ (% amino acids) + $0.9440 \times$ (% sum of the electrolytes) + 0.5367 . (Equation 2) In this equation, $a = 0.9798$, $b = 1.2889$, $c = 0.9440$, and $d = -0.5367$. Figure 2 shows the result after scaling and substituting $x = X/0.9798$, $y = Y/1.2889$, and $z = -0.5367/0.994 - 2.012 (Z)$ into the trapezoid geometric relationship, the $X = 1.02x$, $Y = 0.78y$, and $Z = e + 2 + 0.5z$.

Statistical analysis

All statistical analysis was performed using Microsoft Excel 2000 and SPSS 11 (SPSS, Chicago, IL, USA) statistical package. Results are presented as the mean \pm S.D. Correlation coefficients following linear regression analysis were used to evaluate the relationship between measured refractive index and predicted refractive index. Statistical significant was defined as $p < 0.05$.

RESULTS

Refractive index of single nutrient solutions

The refractive index of components correlated closely with their molar fraction in solution. The molar refractivities of single nutrients were additive and had minimal variability. A good linear relationship (all $R^2 = 0.99$) between refractive index and a concentration of dextrose, amino acids, lipids, and electrolytes is shown in figure 1. The refraction of vitamins and trace elements in the clinically used concentration range was unreadable (refractive index < 0.2).

Refractive index of multinutrient solutions

Table 1 shows the concentration ranges of dextrose, amino acids, lipids, and electrolytes used to evaluate the limiting form of the equation. Using step by step linear multivariate regression on all components of PN mixtures, the best fit predicted refractive index = $0.9798 \times$ (% dextrose) + $1.2889 \times$ (% amino acids) + $1.1017 \times$ (% lipids) + $0.9440 \times$ (% sum of the electrolytes) + 0.5367 ($r^2 = 0.99$).

Validation of PN solutions composition

Since only two independent variables (% dextrose and % amino acids) can be displayed in a 2-dimensional diagram, we modified the Equation 2 to generate a clinically useful plot to predict refractive index. Equation 2 showed that predicted refractive index = $0.9798 \times$ (% dextrose) + $1.2889 \times$ (% amino acids) + $0.9440 \times$ (% sum of the electrolytes) + 0.5367 . When we substituted the constants ($a = 0.9798$, $b = 1.2889$, $c = 0.9440$, and $d = -0.5367$) from the Equation 2. After scaling and substituting constants into the trapezoid geometric relationship, the $X = 1.02x$, $Y = 0.78y$, and $Z = e + 2 + 0.5z$ were obtained, in here $z =$ % total electrolytes. Therefore, figure 2 could be used to predict the refractive index values of PN solutions containing varied concentrations of dextrose and amino acids.

We validated the correlation between predicted refractive index and the measured refractive index in clinically used PN solutions (figure 3). The predicted refractive

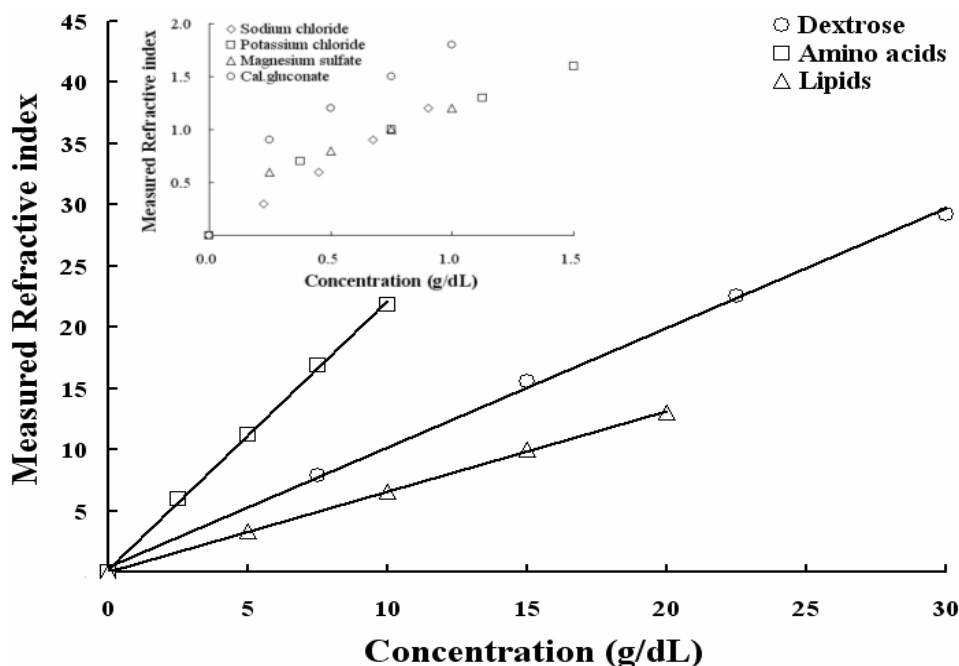


Figure 1. The relationship between refractive index and the concentrations of dextrose, amino acids, lipids, and electrolytes (sodium chloride, potassium chloride, magnesium sulfate, and calcium gluconate).

index value (sample number = 63) determined using this plot was compared to the predicted refractive index. We determined that using the plot of this equation for monitoring PN solutions without lipids consistently predicted the approximate refractive index (figure 3A). Also, a high correlation ($R^2 = 0.99$) was observed between the predicted refractive index value determined by the above equation and the actual refractive index of the clinically used PN solutions (sample number = 500) (figure 3B). A solution was considered acceptable if its refractive index was between 95% and 105% of the estimated refractive index. Of the 500 PN solutions analyzed, only two had refractive indices outside the acceptable range. This was due to an under-dose of amino acids. The variation in refractive index of lipid-containing PN solutions was

acceptable. (within ± 0.4 refractive index units) according to USP allowable manufacturing tolerances for the component ingredients and reader variability in refractometer reading.

DISCUSSION

The refractive index, of a transparent substance, is the ratio of the velocity of light in the air to its velocity in that material under like conditions. A commercial refractometer device typically is less than 20 cm in length, is hand-held, and resembles a spyglass or small telescope. The refractive index measurement represents the obvious line of demarcation between the white and blue fields. Usually the line of demarcation is sharp and clear, but increasing fat content, in the solution, may render the line slightly less distinct. Basically, using the refractive index for bedside monitoring or monitoring PN solution quality in the compounding area is an easy, inexpensive, reliable, and convenient method. The relatively low cost of a hand-held refractometer makes this a practical consideration.

Formulation errors by physicians, compounding errors by pharmacists, and administration errors by nurses are possible. Large errors are the concern in most cases. But in neonates where the tolerance for error is very low because of the patient’s size and weight, all errors are important. O’Neal et al.¹⁸ reported that less than half (48.8%) of respondents used a method of quality assurance in PN preparation at least once daily. The most common reasons for not using a quality assurance method were unknown (27.0%) and inadequate equipment resources (18.0%).

Combeau et al.¹⁹ and Johnson et al.²⁰ evaluated the accuracy of three PN automated compounding systems and the usefulness of end-product laboratory testing of PN solutions. The solutions prepared by the different automatic compounder machines varied significantly. The results showed that measuring the weight of the PN

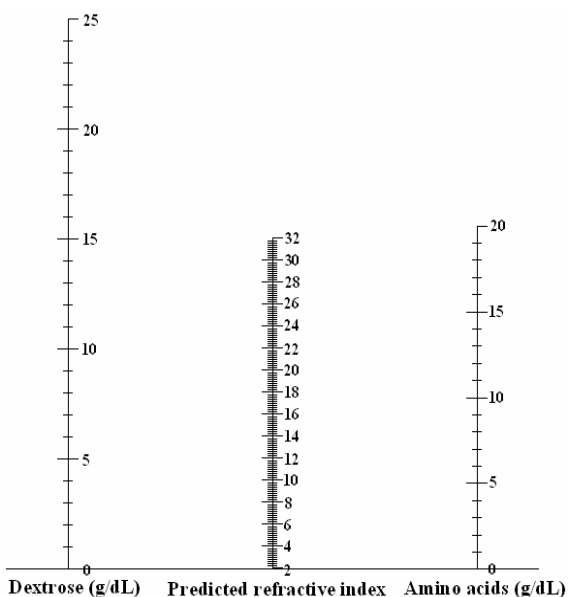


Figure 2. The predicted refractive index values of parenteral nutrition base solutions containing varied concentrations of dextrose and amino acids.

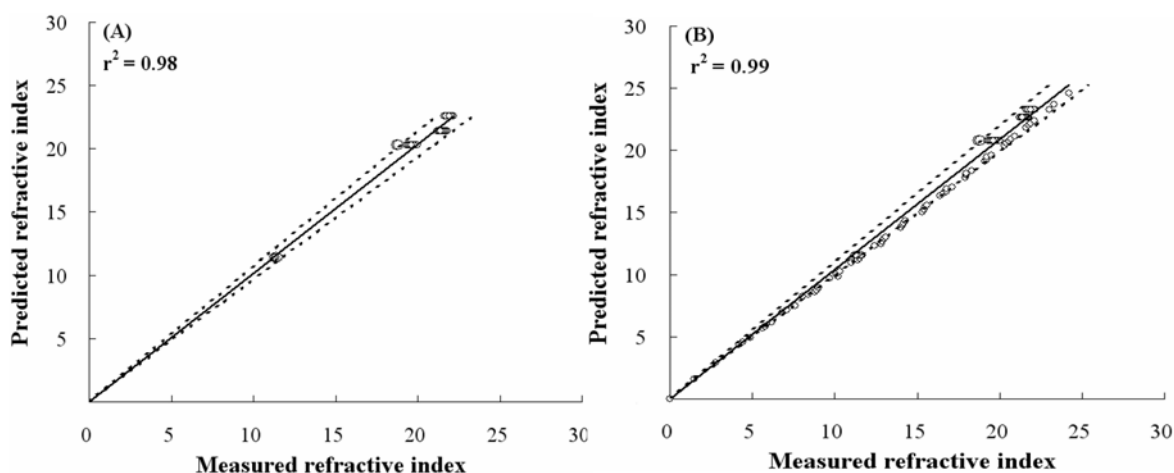


Figure 3. The correlation between predicted refractive index and the measured refractive index in clinically used parenteral nutrition solutions validated the use of the linear plot (A) and equation (B). The predicted refractive index (solid line) and 95-105% quality control limits (area between dotted lines) are also shown in the figure.

solutions results showed that measuring the weight of the PN solutions only is not sufficient to determine the accuracy of the preparation process. The use of refractive index measurements as a quality assurance check for the PN solutions may be extended to quality assurance situations that are deemed critical. Compared with chemical analysis, the refractive index is more convincing. When compared with in process weight testing, the refractive index is more accurate.

The high-alert medications survey findings that 57% of hospital pharmacists and nurses should consider PN solution as a high-alert medication.²¹ In our hospital, after using the hand-held refractometer in the routing PN solution check, the calculation and preparation PN compounding solution error was obviously reduced. This may have resulted from using a quality control tool, which the laboratory technicians used with the working concentration. At the nurse's station, nurses checked the final PN refractive index values and compared them with the predicted refractive index values (Figure 2) before administration. This resulted in zero medication errors reported during the past year. This finding is especially important in the pediatric intensive care unit.

The Institute for Safe Medication Practices describes fatalities that have occurred because medications or solutions were unlabeled in the sterile field. This safety issue along with error-reduction recommended programmed computer alerts and applied auxiliary labels for products, and established nurse/pharmacist double checks for medication cart exchanges, will diminish the trend for staff to be error-prone and will reduce errors.²² Approximately 65% of the hospitals in the United States currently use automated compounding devices for PN admixtures on a daily basis. The barcode system is used to ensure that the correct single solution is used, but the mixed-solution products still have no quality assurance tool to check the final solution.²³ We conclude that the automatic refractive index measurement in automated filling systems would improve the processing and end product testing of PN solutions, reduce the possibility of programming errors, and validate the effectiveness of the system. An equation

can accurately predict the composition of a mixture of dextrose, amino acids, lipids, and trace elements, and a plot can be used to predict the concentrations of dextrose, amino acids, and electrolytes in PN solution. Predicted refractive index is a tool that can be used to provide reasonable quality assurance of PN solutions.

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AUTHOR DISCLOSURES

Wei-Kuo Chang, You-Chen Chao, Ming-Kung Yeh, no conflicts of interest.

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Original Article

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利用屈光計作為監測靜脈營養輸液品質控制工具

靜脈營養(PN)輸液包含不同濃度的葡萄糖，氨基酸，脂肪，維生素，電解質，及微量元素。製備不正確的 PN 輸液，可能導致病人死亡。本研究採用屈光計，作為監測製備的 PN 輸液品質保證工具。屈光值可測出 PN 輸液中不同濃度之葡萄糖、氨基酸、脂肪、電解質。藉由數學統計，尋找最佳線性關係，監測調製後 PN 輸液品質。正確 PN 輸液預測屈光值 = $0.9798 \times (\% \text{葡萄糖濃度}) + 1.2889 \times (\% \text{氨基酸濃度}) + 1.1017 \times (\% \text{脂肪濃度}) + 0.9440 \times (\text{總電解質濃度}) + 0.5367$ ($R^2 = 0.99$)。針對 500 個臨床 PN 輸液，比較預測屈光值與實測屈光值。我們發現 2 個 PN 輸液終製品 (0.4%)，實測屈光值低於預測屈光值 (< 95%)。屈光值可作為 PN 輸液品質保證工具。屈光計可運用於病床邊，監測及確認 PN 輸液調配的準確性。

關鍵字：屈光計、屈光值、品質保證、營養、靜脈營養。