Abstract

Introduction: Aluminum (Al) is a toxic element which may contaminate pharmaceutical products used as individual components to prepare total parenteral nutrition mixtures (TPN). Objectives: 1) to determine Al levels in the individual components used to prepare TPN mixtures; 2) to compare detected Al levels with those imposed by international regulations (FDA); 3) to calculate the total amount of Al administered to adult and children receiving those typical TPN mixtures. Methods: Al was determined by Inductively Coupled Plasma- Atomic Emission Spectrometry (ICP-OES) (Perkin Elmer OPTIMA 5100 DV) in 44 individual products, from different labs and lots, belonging to 16 components available in Argentina: dextrose and amino acids for adult formulas and for pediatric formulas: lípids; potassium chloride; sodium chloride, magnesium sulfate; sodium phosphate; calcium gluconate; sodium glycerophosphate, zinc sulfate; multitrace elements; steril water (ampoules and great volume presentations). Results: Al levels were detected in 43 of the 44 the studied components, except sterile water. The components of large volume presented between 249 y 1,580 g Al/ L, between 4 and 180 times FDA established levels (25 g Al/ L). Small volume components presented Al levels between 85 y 4,909 g/ L, not declared in labels. Conclusions: The highest amounts of Al were detected in calcium gluconate, sodium phosphate and multitrace elements. 2) Usually prescribed TPN mixtures would have higher Al levels than those accepted by FDA regulation; 3) The highest aluminum concentration was provided by dextrose, amino acids and lipids in adult TPN mixtures. In neonate TPN mixtures, Al highest amounts were provided by dextrose and calcium gluconate. The calculated concentration of Al in TPN mixtures was higher than those stipulated by international regulation (5 g Al/kg (body weight)/ d). It would be advisable for manufacturers to declare the content of aluminum in the label, with the aim of avoiding toxicities which would compromise the critical patients’ evolution.

Keywords

Aluminum, Individual products for parenteral nutrition, Parenteral nutrition mixtures, International regulations (FDA), Argentine legislation.