An accurate flow controlling device to administer simultaneously different parenteral nutrition solutions

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ABSTRACT An easily operable, disposable flow controlling device is presented which enables a simultaneous administration of different sterilized parenteral nutrition solutions at a constant flow rate obtained by gravity drip infusion. The device contains safety mechanisms for preventing air embolism and inverse blood flow.

KEY WORDS Parenteral nutrition, infusion flow controlling device

Introduction

Instead of administering a concentrated dextrose solution and subsequently a concentrated amino acid solution for parenteral nutrition (PN), it is attractive to administer a homogeneous mixture of both component solutions to a patient. In such a mixture of two or more different component solutions the final concentration of each nutrient will be lower than in the corresponding original solution. Consequently the incidence of unwanted side effects such as nausea, vomiting, hyper- or hypoglycemia, which are related to the high concentration of the constituents will be reduced. Simultaneous administration of all nutrients also favors an improved nitrogen balance as compared to a consecutive procedure (1). It is possible to compound a complete mixture from component solutions before the administration. The interaction between amino acids and dextrose referred to as the Maillard reaction (2) prohibits the heat sterilization of such a mixture. As a consequence these mixtures should be compounded under aseptic precautions. This aseptic compounding is a time consuming and therefore expensive process with a potential risk of contamination. In addition such extemporaneously compounded PN mixtures have a limited shelf life.

Not only is the simultaneous administration of all nutrients favorable but a constant flow rate is another basic principle of PN (3). Conventional control mechanisms of delivery systems using gravity drip infusion are not sufficiently reliable to guarantee a constant flow rate (4–6). A common flow regulator in fixed position offers a constant resistance to the flowing fluid. When the fluid level in the container diminishes, a decrease of flow will be the result. Consequently, this technique necessitates repeated adjustment of the flow rate during infusion.

Ideally, a PN delivery system should be simple to handle and allow the simultaneous infusion of sterilized dextrose, amino acids, and additives at a constant flow rate obtained at gravity drip excluding the necessity of any mechanical support. Recently a new disposable flow controlling device (Isoflux, van Leer

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Description of the flow controlling device

The upper part of the device (Fig. 1) its size being 50x30x10 mm, contains three inlets (a, b, c) to which one to three fluid containers (A, B) can be connected. The flow controlling device either equipped with steel needles or plastic spikes is adaptable to the different types of commercially available plastic bags. The connecting tube between the device and the indwelling vena cava catheter contains a drip chamber (p) and a Y-connector for administration of other solutions (q). Depending on the position of the oval shaped flow setting valve (f) at the lower part of the device a flow rate between approximately 8 and 400 ml/h can be selected. A diagram of the device is shown in Figure 2. The device contains two silicone rubber diaphragms (d, e). In its relaxed position the upper diaphragm closes the orifice (1). Each inlet orifice a, b, or c can be closed by inserting a nonsterile plug (h into f, Figs. 1 and 2). By connecting a fluid container to an inlet (for instance b) the weight of the fluid column forces the upper diaphragm to a deflected position.

After passing the 15 μ filter (k), permeable for viscous solutions and Intralipid but impermeable for blood, the fluid reaches unhindered the left side and, via the flow setting valve (f), the right side of the lower diaphragm (e). The fluid force at the left side of this diaphragm is greater than at the right side, resulting in a deflection of the diaphragm to the right and in a greater or lesser closing of the outlet orifice. By altering the radius of its deflection the lower diaphragm automatically adapts to variations in liquid level in the container. Since the infusion flow remains constant as long as a sufficient difference in pressure is maintained in the device itself, a fluid column height of at least 80 cm above the level of the injection site is necessary.

Methods

Experiments on effluence of anhydrous dextrose in water solutions with concentrations varying from 10 to 40% (w/v) and Intralipid 10% (w/v) via the flow controlling device were performed in vitro. The other observations were made on routine PN via tunneled vena cava catheters. Three different solutions in 1-L bags were administered to all patients, one bag containing anhydrous dextrose in water 20% (w/v) with vitamins, the second anhydrous dextrose in water 15% (w/v) with minerals, and the third an amino acid solution 8% (w/v). The Isoflux administration set was compared with a W-type administration set including a conventional roller clamp for flow control. In a W-type administration set the three tubes attached to the PN containing bags are joined by two Y-connectors prior to the drip chamber.

After initially having set the fluid flow by the lever...
stuck to the flow setting valve (f) accurate counting of the drip rate (drops/min) at fixed intervals was performed. Assessment of drop volume was not carried out, because in most instances drop volume slightly increases with rising drip rate (7). During the infusions the flow rate was not readjusted and in some infusions the weight drop of the three bags was measured using spring balances.

Results

The drip rate during the in vitro effluence experiments of the tested solutions did not exceed 8% of the set rate. The variation in drip rate in six experiments using the Isoflux system during an PN infusion period of 10 h and in eight similar experiments during an administration period of 24 h is presented in Figure 3. These results show that the set drip rate is accurately kept constant within narrow limits during both infusion periods. An example of the satisfactory simultaneous emptying of the three PN containing bags is presented in Figure 4. On the other hand, an unstable flow necessitating repeated flow adjustments was the result when the same PN solutions were administered to the same patients using the W-type administration set.

Since its introduction this new flow controlling device has been used at more than 3000 occasions for the administration of three different PN solutions. The outcome of all these PN infusions was always the same: a very constant flow rate during all infusions without unwanted side effects.

Discussion

In general, infusion pumps are successfully used to achieve a constant administration of PN solutions (3, 8–11). Jeejeebhoy et al. (12) used a pneumatic pressure system for this purpose. Both energy-dependent pump and pneumatic systems do not simplify PN delivery systems. The Isoflux administration set provides a constant infusion rate at gravity drip. Since flow readjustment during the infusion period is not required, the system markedly relieves the duties of the personnel responsible for the administration of the PN solutions. This phenomenon makes the system especially attractive for patients on home PN, where PN administration mainly takes place during the evening and night. Furthermore, this flow controlling device enables the simultaneous administration of different sterilized solutions making superfluous the use of expensive aseptic compounded PN mixtures.

Two mechanisms increase the safety of the device. First, a one way valve, located just prior to the connecting point (Fig. 1, q) with the vena cava catheter, which prevents inverse blood flow. Second, when the containers have emptied, the upper diaphragm (Fig. 2, d) returns to the relaxed position closing the orifice 1 (Fig. 2) and thus abandoning the risk of air embolism.

A disadvantage of the Isoflux administration set is that only bags empty simultaneously. Bottles, however, empty consecutively because of a different resistance induced by the individually varying air-inlet tubes in each of the bottles. Therefore, we administer fat emulsions in bottles, for instance Intralipid, via the Y-connector q (Fig. 1) before or after the infusion of the PN bags.

In the Netherlands a daily exchange of an
Isoflux administration set financially counterbalances the investments required for the purchase of infusion pumps and labor and material costs related to appropriate aseptic mixing of PN solutions.

References