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ORIGINAL ARTICLE

Design and development of a manual pump for bolus enteral nutrition☆

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Abstract
Introduction: Enteral nutrition (EN) is based on administration of liquid solutions into the gastrointestinal tract using a tube. After identifying unsolved practical difficulties in administration of EN using volume syringes, a new device to overcome such technical difficulties was proposed.
Material and methods: Specific technologies (CAD, 3D printing) were used in collaboration with the PRODINTEC Foundation (Gijón, Asturias). Clarke Modet, a law firm specialized in intellectual property, provided legal advice on formulas for legal protection of the invention.
Results and discussion: The resulting device is a manual pump for infusion of EN to patients that solves previously identified problems and is highly functional and compact. It would allow for comfortable and safe administration of solutions. Integration of a bottle into the device itself and pump dimensions facilitate transport and patient mobility. According to the described configuration, this invention has many advantages over the previously known procedures, such as a simpler administration within the field of intermittent EN, improving the standard nutritional support technique, which in this case is use of volume syringes. This would facilitate the work of caregivers while promoting patient self-care and autonomy. The pump was accredited novelty of design, inventive activity and industrial exploitation potential by the European Patent Office (EPO), to which a patent has been requested.

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PALABRAS CLAVE
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Diseño enteral

Diseño y desarrollo de una bomba manual para la nutrición enteral en bolos

Resumen
Introducción: La nutrición enteral (NE) se basa en la administración de soluciones líquidas en el aparato digestivo mediante el uso de una sonda. Tras identificar dificultades prácticas no resueltas en la administración de NE por bolos mediante jeringa de volumen, se planteó un nuevo dispositivo que superara estas dificultades técnicas.
Material y métodos: Para su diseño se utilizaron tecnologías específicas (CAD, impresión 3D) en colaboración con la Fundación PRODINTEC (Gijón, Asturias). Mediante el asesoramiento legal de Clarke Modet, especialistas en derecho intelectual, se buscaron fórmulas para la protección de la invención.
Resultados y discusión: El dispositivo obtenido se corresponde a una bomba manual para la infusión de NE a los pacientes. Solventa problemas previamente identificados, siendo altamente funcional y compacto. Permitiría una administración, de forma cómoda y segura, de soluciones líquidas. La integración de una botella en el propio dispositivo y su dimensionamiento facilitan su transporte y favorecen la movilidad del paciente. De acuerdo con la configuración descrita, la presente invención presenta múltiples ventajas respecto a las técnicas previamente conocidas, como simplificar las técnicas de administración dentro del campo de la NE intermitente, mejorando la técnica de aporte nutricional de referencia, que en este caso es el uso de jeringas de volumen, facilitando la labor de los cuidadores y al mismo tiempo promoviendo los autocuidados y la autonomía de los pacientes. Fue acreditada novedad de diseño, actividad inventiva y capacidad de explotación industrial, pendiente de concesión de una patente mundial por la Oficina Europea de Patentes.

Introduction

Enteral nutrition (EN) is a form of artificial nutrition based on the administration of liquid formulations in the gastrointestinal tract with the help of a tube. The proximal extremity of the tube is located outside the patient and is accessible for manipulation, while the distal extremity is positioned in the stomach, duodenum or jejunum, where it delivers the required nutrients.[1] Enteral nutrition is indicated in patients that have problems in ensuring adequate nutrition through active oral intake, but who have a functioning digestive apparatus.

The method of administration of the nutritional formula is a fundamental clinical decision. One route or other will be chosen depending on the type of needs and the characteristics of the patient. A nasogastric tube is usually chosen if EN is expected to be of short duration, while a gastrostomy may be considered if prolonged administration is expected. While EN is usually started in the hospital setting, it is commonly maintained in the home of the patient (home enteral nutrition [HEN]).

Enteral nutrition can be administered on a continuous basis, intermittently (bolus dosing) or both. Different strategies are used depending on the method of administration, e.g., gravity drip, volume syringes or electronic infusion pumps.[2] Electronic pumps for nutrition are commonly used in the in-hospital EN setting and allow automatization with great safety,[3] though there are also serious inconveniences. In effect, these are complex devices equipped with pressure and flow sensors, and require electrical energy in order to be operated, programming for use, and adequate and exhaustive maintenance. They are, moreover, bulky and heavy – a fact that considerably complicates transport and handling. These features result in a serious loss of autonomy for both the patients and their caregivers. Lastly, their access and use is further limited by the high cost of these systems.

On the other hand, volume syringes are the most commonly used option in the ambulatory setting, with bolus dosing designed to simulate human mealtimes. Their use in intermittent EN also poses technical difficulties and some risks, fundamentally related to incorrect administration of the nutritional formula. The correct application of the technique requires an adequate flow in order to avoid complications associated with volume overload in the digestive tract, which results in abdominal pain, vomiting, nausea and reflux (gastroesophageal or through the ostomy) as the most common problems associated with this type of administration.[4,5]

Nutrient supply in the form of boluses delivered with a syringe requires enormous dedication on the part of the caregivers and results in a considerable loss of patient autonomy. This is further worsened by the fact that many of these patients present associated diseases that complicate motor function, such as Parkinson's disease, Alzheimer, myasthenia gravis, Guillain-Barré, amyotrophic lateral sclerosis or the sequelae of previous cerebrovascular events.

Innovation in the development of medical devices arises from the experience and inventive capacity of healthcare professionals, combining clinical practice, intimate knowledge of disease, and the inherent need to provide answers to problems that arise on a daily basis. It was the identification