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ORIGINAL ARTICLE

Transition of continuous subcutaneous insulin infusion systems in a very short time frame as a consequence of a public tender process

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KEYWORDS

Continuous
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Abstract

Aim: The procurement of pumps/supplies through a tender process is common practice among public services. A report is presented on the feasibility and safety of the transition from one continuous subcutaneous insulin infusion (CSII) system to another within a very short time frame (4-weeks) as the consequence of a public tender.

Methods: The program consisted of: Session-1 was a system start-up training session. Patient satisfaction was evaluated. Session-2 consisted of a call from technical staff 72 h after Session-1 to provide support regarding the programming or the change of infusion set. Session-3 was a training session regarding the use of therapy management software. During and 2 months after Session-2, clinical events, technical issues, and training reinforcement incidents were registered. HbA1c data were collected retrospectively.

Results: A total of 219 patients were enrolled. During the second week, 81% of patients were transferred to the new system. Patient overall satisfaction scored 9.4/10 (none <7). There were 30 training reinforcement events and 7 technical issues, with all 37 of them being sorted out over the telephone. There were 31 additional clinical events (infusion set issues). Twenty-four were considered mild, and were solved by phone technical support. Medical assistance was needed in six (five unexpected hyperglycemia, one ketosis). There was only one severe event (ketoacidosis requiring hospitalization). HbA1c did not deteriorate during the transition process. One hundred twenty-eight patients attended the therapy management software training.

Conclusions: With the assistance of a specific program, a complete switch to a new insulin pump in a large population of patients with T1D in the context of a public tender in a very short time was carried out safely and without deterioration of metabolic control.

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PALABRAS CLAVE

Infusión subcutánea continua de insulina; Diabetes mellitus tipo 1; Recambio; Concurso público

Recambio de dispositivos de infusión subcutánea continua de insulina en un periodo breve en el contexto de un concurso público**Resumen**

Introducción: El sistema público de salud financia la utilización de infusores subcutáneos de insulina (ISCI) como tratamiento no convencional en pacientes con diabetes mellitus tipo 1 (DT1). En este contexto, y con el fin de mejorar la eficiencia, es frecuente que los centros encargados de este tipo de terapia utilicen procedimientos de licitación. Nuestro objetivo fue evaluar la eficacia y la seguridad de un proceso de recambio de dispositivos ISCI a llevar a cabo en un breve periodo (4 semanas) en un procedimiento de concurso público.

Pacientes y métodos: El proceso de recambio incluyó 3 sesiones precedidas por la presentación y la justificación del mismo: sesión 1: adiestramiento en la utilización del nuevo dispositivo ISCI y administración de una encuesta de satisfacción; sesión 2: contacto telefónico de soporte a las 72 h de iniciado el programa a la búsqueda de incidencias, y sesión 3: a los 3 meses, sesión de refuerzo/consolidación de los conocimientos y adiestramiento en el uso de programa informático de gestión del tratamiento. Durante 2 meses se recogieron todas las incidencias clínicas y técnicas. Retrospectivamente, se obtuvo la HbA_{1c} más cercana al inicio y la primera una vez finalizado el programa.

Resultados: Se efectuó el recambio en 219 pacientes, el 81% de los recambios se efectuó en las 2 primeras semanas. En la encuesta de satisfacción realizada se obtuvo una puntuación media de 9,4 sobre 10. Se efectuaron un total de 30 llamadas telefónicas extra con el fin de reforzar aspectos educativos y en 7 ocasiones se atendieron incidencias técnicas que fueron resueltas de manera inmediata. Veinticuatro de 31 eventos clínicos registrados fueron considerados de carácter leve. Seis de ellos fueron moderados (5 hiperglucemias simples/1 cetosis). Un evento fue catalogado como grave (cetoacidosis diabética). Todos los eventos se relacionaron con el equipo de infusión (recambio) y en todos se resolvieron de manera satisfactoria. La HbA_{1c} tras el recambio no cambió significativamente. Ciento veintiocho pacientes acudieron al adiestramiento en el uso del programa informático de gestión del tratamiento.

Conclusiones: En el contexto de un proceso de licitación y bajo un programa diseñado específicamente, el recambio de dispositivos ISCI puede realizarse de manera segura y sin deterioro alguno en el control metabólico en un considerable número de pacientes y en un corto periodo.

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Introduction

Continuous subcutaneous insulin infusion (CSII), also known as insulin pump therapy, represents an alternative to multiple doses of insulin (MDI) when this conventional intensive insulin therapy is unable to achieve the major metabolic goals of type 1 diabetes (T1D) treatment, HbA_{1c} as close as possible to normal levels without an unacceptable incidence of hypoglycemia.¹ Thus far, meta-analyses indicate that CSII has demonstrated beneficial effects in reducing the number of episodes of severe hypoglycemia, as well as, diminishing HbA_{1c} by 0.3–1.2% depending on the meta-analysis.^{2–4}

There is a huge difference in cost between MDI and CSII therapies. Data regarding the cost-effectiveness of CSII compared with MDI in the delivery of intensive insulin therapy for the treatment of T1D, although positive, are still scarce.⁵ In this context, national health services and centers that provide CSII therapy employ specific guidelines and indications, including the most suitable target groups of subjects, to sustain the cost of CSII therapy implementation. In addition to this, they may consider procuring pump therapy

through a tender process that involves various manufacturers of insulin pump devices.^{1,6–8}

We aimed to describe the feasibility and safety of the transition from one CSII device to another in a very short time frame as the consequence of a public tender.

Materials and methods

The tender was performed following the local regulatory requirements and all the patients using CSII received information about it. After the resolution of the tender and previously to the start of the transition process, all patients were fully informed about the procedure by the medical team.

The CSII replacement process was based on three main pillars: a properly coordinated human team, a structured and specific training program and a procedure result assessment. The human team was composed of a training group (Medtronic qualified technical personnel), a logistical team (Medtronic) and a medical team (Diabetes Unit, Endocrinology and Nutrition Department, University Hospital Clinic of Barcelona). During the entire procedure, 24 h technical

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