

## ORIGINAL ARTICLE

# Characteristics of people with type 1 diabetes who use technology in their treatment and who use frequently the technical assistance teleconsultation service



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## Abstract

**Introduction:** Technical issues related to continuous subcutaneous insulin infusion (CSII), associated or not with continuous glucose monitoring (SAP), are handled by tele-technical assistance from the manufacturer. We analyze the characteristics of the most demanding patients of technical teleassistance.

**Material and methods:** Patients with type 1 diabetes (T1D) in treatment with CSII or SAP, who made use of technical teleassistance from 01/01/2017 to 02/28/2021 (2298 consultations) were included. We selected the group of patients who made  $\geq 10$  calls (90th percentile, P90) and the one who made a single call (10th percentile, P10). The number and most frequent reasons for consultation, clinical characteristics and HbA<sub>1c</sub> were collected and both groups were compared.

**Results:** 51 patients (P90) made a total of 876 calls (38.1% of calls), 32 used SAP. The most frequent reason for consultation was related to continuous glucose monitoring (36.8%). 51 (P10) made 51 calls (2.2%), 3 used SAP. The most frequent reason for consultation was related to device damage (25.5%). The most demanding patients used SAP more frequently (62.7 vs. 5.9%,  $P < .001$ ), had been in advanced treatment for less time ( $7.1 \pm 5.5$  vs.  $12.1 \pm 6.2$  years,  $P < .001$ ) and their HbA<sub>1c</sub> was lower ( $7.2 \pm 0.9$  vs  $7.6 \pm 0.8\%$ ).

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**Conclusions:** Most of the calls to the technical teleassistance service for ISCI/SAP devices come from a more demanding group of people with T1D. The greatest demand is concentrated in patients who use SAP, with a shorter time of use of advanced therapy and a better degree of glucose control.

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## PALABRAS CLAVE

Diabetes tipo 1;  
Infusión subcutánea  
continua de insulina;  
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continua de glucosa;  
Bomba-sensor;  
Tele-asistencia  
técnica

## Características de las personas con diabetes tipo 1 que utilizan tecnología en su tratamiento y son más solicitantes del servicio de teleconsulta de asistencia técnica

### Resumen

**Introducción:** Las incidencias técnicas relacionadas con infusores subcutáneos continuos de insulina (ISCI), asociados o no a monitorización continua de glucosa (SAP), son atendidas mediante tele-consulta técnica del fabricante. Analizamos las características de los pacientes más solicitantes del servicio de teleconsulta técnica.

**Material y métodos:** Se incluyeron pacientes con Diabetes tipo 1 (DT1) en tratamiento con ISCI o SAP, que solicitaron tele-asistencia técnica del 01/01/2017 al 28/02/2021 (2298 consultas). Seleccionamos el grupo de pacientes que realizaron  $\geq 10$  llamadas (percentil 90, P90) y el que realizó una única llamada (percentil 10, P10). Se recogieron el número y motivos más frecuentes de consulta, las características clínicas y HbA<sub>1c</sub> y se compararon ambos grupos.

**Resultados:** 51 pacientes (P90) realizaron un total de 876 llamadas (38,1% de llamadas), 32 utilizaban SAP. El motivo más frecuente de consulta estaba relacionado con la monitorización continua de la glucosa (36,8%). 51 (P10) realizaron 51 llamadas (2,2%), 3 utilizaban SAP. El motivo más frecuente de consulta estaba relacionado con daños en el dispositivo (25,5%). Los pacientes más solicitantes de teleconsultas usaban más frecuentemente SAP (62,7 vs 5,9%,  $P < ,001$ ), llevaban menos tiempo en tratamiento avanzado ( $7,1 \pm 5,5$  vs  $12,1 \pm 6,2$  años,  $P < ,001$ ) y su HbA<sub>1c</sub> era inferior ( $7,2 \pm 0,9$  vs  $7,6 \pm 0,8$ %).

**Conclusiones:** Mayoritariamente las llamadas al servicio de tele-asistencia técnica de dispositivos ISCI/SAP proviene de un grupo de personas más solicitantes. La mayor demanda se concentra en pacientes usuarios de SAP, con un menor tiempo de uso de la terapia y un mejor grado de control de la DT1.

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## Introduction

In patients with type 1 diabetes (DM1) in whom multiple dose insulin (MDI) therapy does not achieve the expected blood glucose or quality-of-life goals, the introduction of continuous subcutaneous insulin infusion (CSII) treatment under a specific structured educational programme for self-care and self-management, in addition to improving blood glucose control, is associated with a positive and lasting user experience on the part of the patients.<sup>1</sup> The use of continuous glucose monitoring (CGM) associated with MDI or CSII (sensor-augmented pump [SAP]) has also proven to be effective and safe in these patients.<sup>2,3</sup> In the recently published SED 1 study, it was found that around 21% and 25% of patients with DM1 in Spain use CSII and/or CGM, respectively, as part of their treatment.<sup>4</sup> In fact, both therapies have universal public funding throughout Spain and CGM is part of the treatment of the vast majority of patients with DM1, regardless of the insulin administration method used.<sup>5-8</sup>

Manufacturers and distributors of medical devices in Spain have to comply not only with European legislation

(directives and regulation), but also with the requirements set out in the Spanish Royal Decree of 2009 (RD1591/2009).<sup>9</sup> Their obligations include having an incident surveillance system in operation, which they are responsible for managing, taking any necessary corrective measures, having a proven quality system and assigning a qualified person to liaise with the authorities who is responsible for ensuring compliance with the requirements established by legislation, regulations and Royal Decree. With medical devices used by patients (CSII, CGM and SAP, in our case), technical issues are common, and these need to be effectively resolved as quickly as possible. Such incidents are usually dealt with and resolved by the manufacturer's or distributor's technical telecare service, which provides continuous support 24 h a day, 365 days a year, and is easily accessible to both users and healthcare professionals.<sup>10</sup> As mentioned above, recording incidents and providing an appropriate response are obligations for manufacturers and distributors of medical devices in Spain and the European Union. These records are shared with the institutions and healthcare professionals who care for people with DM1 and have enabled us to verify the great variation in how often these services are used by patients.

**Table 1** Characteristics of the study population.

	P90 group n = 51	P10 group n = 51	P-value
SAP users (%)	62.7	5.9	<.001
Gender (% female)	72.5	49.0	.025
Age (years)	48.6 ± 12.4	47.5 ± 13.9	.660
Time since onset of DM1 (years)	29.6 ± 11.4	29.8 ± 11.4	.950
Duration of treatment with CSII (years)	7.1 ± 5.5	12.1 ± 6.2	<.001
HbA <sub>1c</sub> (%)	7.2 ± 0.9	7.6 ± 0.8	.023

Values expressed as mean ± standard deviation or percentage.

P90 group: 90th percentile of calls ( $\geq 10$  calls during the study period); P10 group: 10th percentile of calls (one call during the study period); SAP: continuous subcutaneous insulin infusion + continuous glucose monitoring (*sensor-augmented-pump*).

The aim of this study was to analyse the characteristics of the patients with DM1 who are on advanced blood glucose control therapy and use CSII or SAP who most often use the technical support telecare service, and compare them to those who use it less.

## Material and methods

This was a cross-sectional study that included data from patients with DM1 who were on CSII/SAP treatment from a referral diabetes unit in a tertiary hospital who made use of the Medtronic technical telecare service (Medtronic Ibérica, Madrid, Spain) from 1 January 2017 to 28 February 2021. At that time there were 479 patients at our centre's diabetes unit registered as CSII therapy users, 136 (28.4%) of whom used a SAP device. All the devices used belong to the manufacturer and distributor Medtronic, which informs us on a monthly basis of each and every reason patients request telecare.

During the period studied, there were 2298 consultations to the technical telecare service. Of the 479 active patients on treatment with CSII/SAP, we selected the group of patients who made 10 or more calls (90th percentile of calls) and the group of patients who made a single call (10th percentile of calls) during the stated period. We collected the clinical characteristics for the members of both groups, along with the total number and the most common reasons for consultation, and the degree of metabolic control in the last year as measured by HbA<sub>1c</sub>.

Results are expressed as mean ± standard deviation or as a percentage. The differences between the two groups were analysed using Student's *t*-test for unpaired data. The percentages were compared using Fisher's exact test. Statistical analysis was carried out using the statistical package SPSS version 25.0 (SPSS Inc., Chicago IL, USA).

## Results

The characteristics of the study population are shown in [Table 1](#).

### 90th percentile of calls ( $\geq 10$ calls during the study period; P90)

In total, 51 patients made a total of 876 calls; that is, 10.6% of the total number of patients on advanced blood glu-

cose control therapy made 38.1% of the total telecare calls. Thirty-two of these 51 patients used SAP. The most common reasons for consultation were: 1) CGM-related consultations (322/876 calls; 36.8% of all calls); 2) inquiries about the characteristics of the system (88/876; 10.0% of all calls); and 3) damage or malfunction of the CSII device clip (86/876; 9.8% of all calls).

### 10th percentile of calls (one call during the study period; P10)

Overall, 51 patients made a total of 51 calls (51 calls out of 2298, 2.2% of all calls). The most common reasons for consultation were: 1) damage to the device (13/51 calls; 25.5% of all calls); 2) damage or malfunction of the CSII device clip (13/51 calls; 25.5% of all calls); and 3) damage to the battery compartment cover (7/51 calls; 13.7% of all calls).

As can be seen in [Table 1](#), the patients consulting most frequently are mostly SAP users and mainly female. It should be pointed out that 60% of SAP users in our diabetes unit are female. We found no differences in the age of the two groups, but we did find differences in the duration of use of the advanced therapy. The patients in P10, who needed less support, had been using advanced therapy for longer. Blood glucose control measured by HbA<sub>1c</sub> was 0.8% better in the P90 group.

## Discussion

Assessing the data provided by the technical support telecare service of a CSII/SAP manufacturer and provider, a large percentage of the calls was made by a concentrated group of people who consult more often than others and are mainly users of SAP therapy.

Because of the potential risks involved with the use of medical devices, the public authorities group them into different classes based on the vulnerability of the human body.<sup>9</sup> Different conformity assessment procedures are applied according to each class, such that for lower risk products, performing the assessment is the sole responsibility of the manufacturers, while the other classes require the involvement of a notified body. The degree of intervention and the thoroughness of the assessment are in line with the degree of risk attached to the product. As mentioned earlier, in the case at hand, the manufacturers/distributors of CSII, CGM and SAP devices are obliged to have an incident

surveillance system for which they have to take responsibility and fully respond to. Despite the large number of DM1 patients treated with these devices, there are very few articles in the literature detailing the most common causes of device failure, and very few explaining why people call the technical support telecare services and describing their characteristics.<sup>10–12</sup>

If we add the years since the publication in this same journal of our data on the experiences and management in real life of CSII treatment in the adult population with DM1, it can be seen that the clinical characteristics of the population included in this study are very similar, both in the P90 group and in the P10 group.<sup>1</sup> As our results show, 10% of all patients made almost 40% of all calls during the period analysed. The reason for consultation in four out of 10 cases had to do with CGM (for example, connection failures, updating, signal loss, etc.) and this explains the fact that two thirds of the patients who consulted the most used SAP devices. In addition, compared to the group of patients who consulted less, the patients in the P90 group had been using the device for less time and their HbA<sub>1c</sub> was significantly lower. The differences found in the gender of the two groups are related to the fact that in our population in general, females are more likely to use SAP devices. The patients who seek telecare the least, in contrast, are users of CSII devices, and in their case the most common reason for calling involved damage to the infusion device in different locations, both significant and cosmetic (for example, cracks in the casing or rupture of the retention ring of the insulin reservoir). Damage to the CSII device clip (for example pocket, trousers or other clothing) as a reason for calling was common in both groups of patients and is an occurrence well recognised by the healthcare professionals looking after patients with DM1 who use these therapies. It is to be hoped, and really expected, that the continuous analysis of all this information by the manufacturer and the implementation of the corrective measures and pertinent improvements in the devices will lead to fewer calls to the telecare service. For the healthcare professionals who look after these patients, being aware of the above information should help and enhance educational aspects in the most common areas and time periods in which calls are made and for the profile of patients most often seeking support.

The main limitation of our study is the fact that it was carried out in a single diabetes unit with extensive experience in using these treatments and devices. In addition, it is limited to the use of devices from a single manufacturer and distributor. That makes it difficult to generalise our results. In our study, we define more and less requesting of support using P90 and P10, respectively. We do not have any data on the patients included in the programme who made no calls during the stated period. Our study's main strength is the fact that the information comes from almost 500 patients and 2300 calls rigorously collected over a period of four years.

To sum up, a high percentage of all calls to the technical support telecare service run by the manufacturer and distributor of CSII and SAP devices for treating DM1 came from one group of people consulting more often. The largest

number of calls for support was from patients who are SAP users, who have been using the therapy for less time and have better control of their DM1.

## Conflicts of interest

The authors have no conflicts of interest to declare in relation to the writing of this article.

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