

User satisfaction and glycemic outcomes in PwT1D using an innovative micropump: Interim analysis of an observational study

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Aims

This study aims to examine changes in treatment satisfaction and glycemic outcomes in people with type 1 diabetes (PwT1D) transitioning from multiple daily injections (MDI) to continuous subcutaneous insulin infusion (CSII) with an innovative patch micropump (Figure 1).

Methods

- CSII-naïve PwT1D from Spain and Argentina were enrolled in a multi-center, prospective, single-armed study using the Accu-Chek® Solo micropump (Roche Diabetes Care GmbH, Mannheim, Germany; Figure 2).
- The primary outcome was the change from baseline to 13 weeks in the “Impact and satisfaction” scores on the Diabetes Technology Questionnaire (DTQ) in participants from both countries. As a secondary outcome, DTQ scores were also assessed at 1 and 2 years in Argentina.
- HbA1c levels and safety outcomes were also assessed at 13 weeks for both countries, and through 1 and 2 years for Argentina.

The Accu-Chek Solo micropump

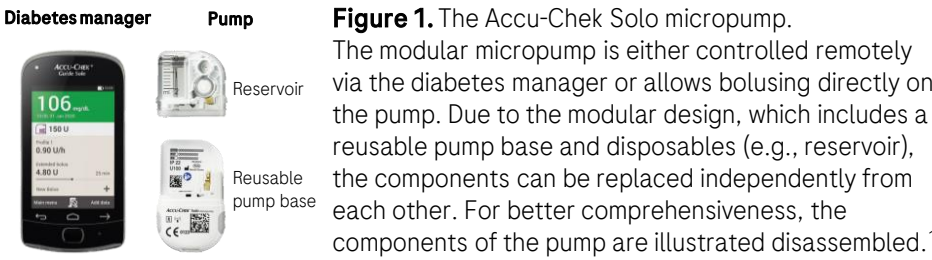


Figure 1. The Accu-Chek Solo micropump. The modular micropump is either controlled remotely via the diabetes manager or allows bolusing directly on the pump. Due to the modular design, which includes a reusable pump base and disposables (e.g., reservoir), the components can be replaced independently from each other. For better comprehensiveness, the components of the pump are illustrated disassembled.¹

Study design

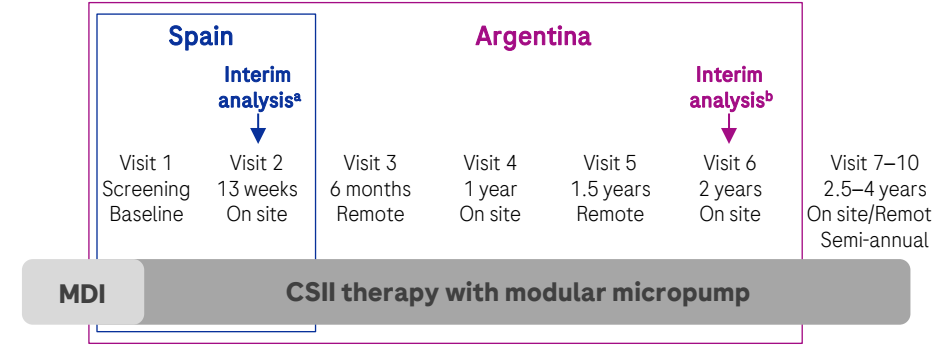


Figure 2. Study design. Participants were screened, and baseline information was collected at Visit 1. Subsequently, participants switched from MDI to CSII using the Accu-Chek Solo micropump. Consecutive visits, alternating between on site and remote, were performed after 13 weeks, as well as semi-annually, beginning with 6 months. ^aData cut-off of May 21, 2024. ^bData cut-off of February 6, 2024.

Results

- A total of 100 CSII-naïve PwT1D from Spain and Argentina were enrolled.
- Demographics of the 100 participants from Spain (n=50) and Argentina (n=50) are depicted in Table 1.
- The mean ($\pm$ standard deviation) change from baseline to 13 weeks in the “Impact and satisfaction” score of the DTQ was 99.3 ± 16.8 ($p=0.0077$) in participants from Spain and 113.4 ± 16.7 ($p<0.0001$) in participants from Argentina (90=non-change score; Figure 3).
- Improvement in satisfaction in participants from Argentina was sustained at 1 year (111.4 ± 14.4 , $p<0.0001$) and at 2 years (107.8 ± 16.1 , $p=0.0005$).
- Overall system satisfaction is depicted in Table 2.
- From baseline to 13 weeks, mean HbA1c decreased from 7.3% to 7.1% ($p=0.2103$) in participants from Spain. In participants from Argentina, it decreased from 8.2% at baseline to 7.9% at 13 weeks ($p=0.0375$), to 7.9% at 1 year ($p=0.0467$), and was 8.0% at 2 years ($p=0.1716$; Figure 4).
- A total of 3 severe hypoglycemic events and 1 case of diabetic ketoacidosis were reported (Figure 4).

Demographics

	Spain (n=50)	Argentina (n=50)
Female sex, n (%)	24 (48.0)	28 (56.0)
Race ^a , n (%)		
White	47 (94.0)	46 (92.0)
Black or African American	3 (6.0)	0
Native American/Alaska Native	0	1 (2.0)
Native American/Alaska Native, white	0	1 (2.0)
Other ^b	0	2 (4.0)
Hispanic, Latino/a, or Spanish origin, yes, n (%)	49 (98.0)	50 (100)
Age, years, mean (SD)	40.74 (11.84)	34.80 (13.47)
Height, cm, mean (SD)	169.26 (8.09)	165.86 (9.32)
Weight, kg, mean (SD)	72.80 (13.34)	70.40 (11.37)
BMI, kg/m ² , mean (SD)	25.33 (3.73)	25.54 (3.25)
Duration of diabetes, years, mean (SD)	18.55 (13.13) ^c	14.88 (11.02)

Table 1. Demographics. ^aSelf-reported. ^bDescriptions specified by participants for the “Other” category included Latin (n=1) and Latino (n=1). ^cn=47. BMI, body mass index; SD, standard deviation.

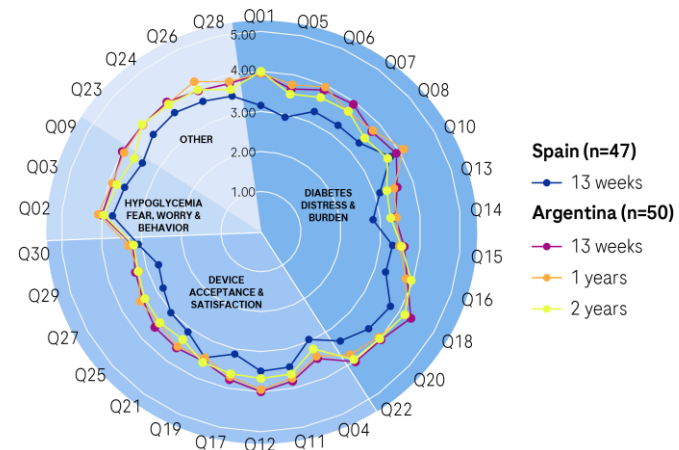
Overall system satisfaction

Question	Spain	Argentina		
	Agree ^a (%) through 13 weeks (n=47)	Agree ^a (%) through 13 weeks (n=50)	Agree ^a (%) through 1 year (n=50)	Agree ^a (%) through 2 years (n=50)
I trust that I can keep my diabetes under control with the insulin pump system	81	86	84	72
On the whole, I think the insulin pump system can be operated intuitively	83	70	66	64
I can operate the system discreetly, without drawing attention to the fact that I have diabetes	75	68	66	66
I hardly notice the insulin pump in everyday life	53	76	68	58
The insulin pump system gives me more flexibility in my everyday activities	77	84	80	72
On the whole, I am satisfied with the insulin pump system	77	88	84	74
I would recommend the insulin pump system	83	88	84	66
Mean of all questions	76	80	76	67

Table 2. Overall system satisfaction of participants, evaluated using a micropump questionnaire created by Roche Diabetes Care, decreased slightly over 2 years of using the Accu-Chek Solo micropump in Argentina; however, a mean of 76% participants at 13 weeks in Spain and 67% at 2 years in Argentina showed a positive reaction (^aagree or agree somewhat).

Diabetes Technology Questionnaire

Figure 3. Change values of the DTQ from baseline through 13 weeks, 1 and 2 years. The mean change scores of the first 30 questions of the DTQ (measuring “Impact and satisfaction”) were clustered according to psychosocial constructs ranging from 1 (much worse) to 5 (much better).² All questions displayed a change score of >2.5 after 13 weeks in participants from Spain and a change in score of >3.0 after 13 weeks, 1 and 2 years for participants from Argentina. Q=question.



Changes in HbA1c and safety reports

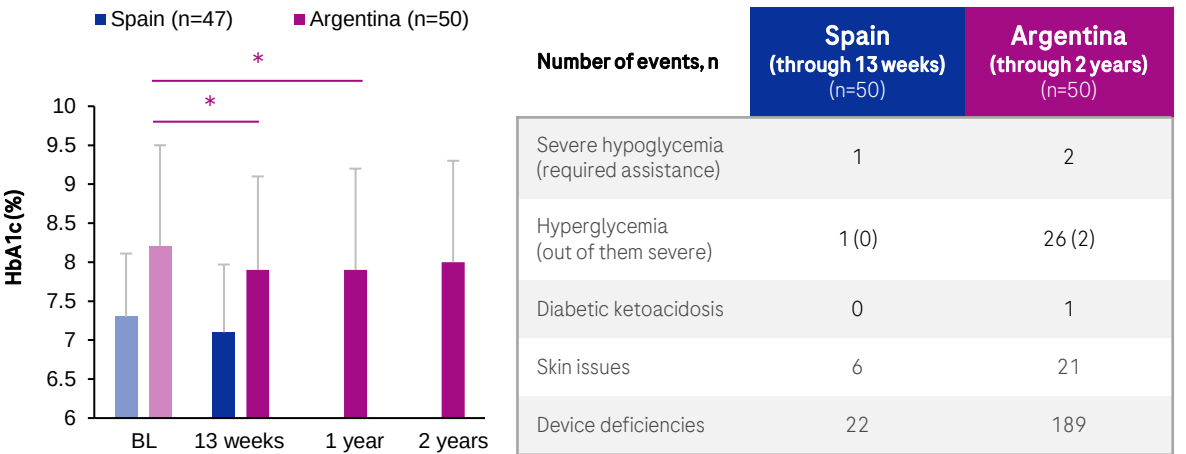


Figure 4. Changes in HbA1c and safety reports. *Indicates $p\leq 0.05$, compared with BL, in a mixed model analysis. BL, baseline.

Conclusion

- PwT1D transitioning from MDI to CSII with the Accu-Chek Solo micropump in Spain and Argentina reported a significant improvement in mean treatment satisfaction at 13 weeks; in the Argentina cohort this improvement was sustained through 2 years.
- In Argentina, a significant reduction in mean HbA1c was observed at 13 weeks and 1 year, with a numerical improvement sustained for up to 2 years.
- In Spain, a numerical improvement in mean HbA1c was observed at 13 weeks.
- Results suggest that the Accu-Chek Solo micropump effectively reduces the burden of diabetes and may improve glycemic control in PwT1D.

References

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Disclosures

BJ, BD, DN, ET, G-RL, SK, and VG are employees of Roche Diabetes Care.

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