CSII: Longer Catheter Usage Time, a Reasonable Goal

Journal of Diabetes Science and Technology
2016, Vol. 10(4) 989–990
© 2015 Diabetes Technology Society
Reprints and permissions:
sagepub.com/journalsPermissions.nav
DOI: 10.1177/1932296815622647
dst.sagepub.com

Jean-Luc Ardilouze, MD, PhD^{1,2}, Julie Ménard, PhD²,
Fernand Gobeil Jr, PhD^{2,3}, Maude Gagnon-Auger, PhD¹,
Ghislaine Houde, MD^{1,2}, Marie-Hélène Pesant, MD^{1,2},
Rémi Rabasa-Lhoret, MD, PhD^{4,5},
and Jean-Patrice Baillargeon, MD, MSc^{1,2}

Keywords

insulin infusion set, CSII, adverse event, diabetes

Continuous subcutaneous insulin infusions systems (CSII) are commonly used by patients with type 1 diabetes (T1D). A catheter (KT) allows transfer of insulin from the reservoir to the subcutaneous tissue. In clinical practice, KT are replaced every 2 or 3 days. This avoids skin irritation and other adverse events (AEs), including increases in mean blood glucose levels with longer usage. Historically, this commonly held assumption has been that the trade-off is worth it.

Pfützner et al recently reported a study on 22 adult T1D patients, all chronic users of CSII.¹ The 6-month randomized crossover (2 x 3-month) study was conducted prospectively, in a real-world setting. Investigators assessed tolerability of 2-day and 4-day use. The number of KT-related AEs, treatment-related AEs, and other various AEs were significantly higher with 4-day use. With 2-day use, HbA1c improved (7.4 ± 1.2 vs $7.6 \pm 1.2\%$, $P < .05$) and patient treatment satisfaction was higher. According to the authors, these data support the 2- to 3-day replacement recommendation; authors also expressed doubts on the economic benefits of longer KT wear.¹

It seems to us that the Pfützner study data can be interpreted differently. In this type of study, AE frequency is the main issue. However, AE categories were poorly defined, and questionnaires used to record AEs were not validated. The alarming total number of AEs ($n = 2664$) in addition to hyperglycemia ($n = 615$) and hypoglycemia ($n = 888$) implies that CSII is an uneasy method, complicated on average by 1 AE daily. This unexpected deduction contradicts the overall treatment satisfaction reported by participants but is in line with a recent report pointing that AEs related to CSII and especially to KT usage are inappropriately assessed.² Clarity of such studies would be increased if key numbers such as number of participants reporting AEs, KT used, KT changes, frequency of glycemia testing, real failure rate, and so on were reported in standardized fashion. Satisfaction scores (2.1 ± 0.6 vs 2.3 ± 0.6 , $P < .05$) were lower with 4-day use. However, it is doubtful that this statistical difference translates into clinically measurable outcome. This is particularly so because scores were ranked on the positive side of the

spectrum, that is, from 1 (very satisfied) to 6 (not at all satisfied). Finally, the cost-benefit of changing KT every 2 to 3 days or less frequently was not assessed and would require longer and larger trials.

Pfützner et al emphasize 2-day use. An important drawback of frequent KT replacement is the expense incurred by patients and health care systems. The 2 to 3-day replacement regimen however is not an evidence-based practice, with most reports in the scientific literature, including the Pfützner study, emanating from manufacturers themselves.³⁻⁵

Continuous glucose monitoring systems (CGMs) are transitioning from 7-day to 14-day wear. In our opinion, research should attempt to reduce the number of KT-related issues and extend the life of infusion sets in order to match CGMs life. Combining CGMs, algorithm, and insulin delivery system would reduce the number of required sites and be extremely convenient for awaited automated closed-loop insulin delivery.

Abbreviations

AE, adverse event; CGM, continuous glucose monitoring system; CSII, continuous subcutaneous insulin infusions; KT, catheter; T1D, type 1 diabetes.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

¹Endocrinology Division, University of Sherbrooke, Sherbrooke, Quebec

²Research Center of the Centre hospitalier universitaire de Sherbrooke, Sherbrooke, Quebec

³Department of Pharmacology-Physiology, University of Sherbrooke, Sherbrooke, Quebec

⁴Department of Nutrition, University of Montreal, Montreal, Quebec

⁵Institut de recherches cliniques de Montreal, Montreal, Quebec

Corresponding Author:

Jean-Luc Ardilouze, MD, PhD, Endocrinology Division, University of Sherbrooke, 3001 12th Ave N, Sherbrooke, QC, J1H 5N4, Canada.
Email: Jean-Luc.Ardilouze@USherbrooke.ca

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

References

1. Pfützner A, Sachsenheimer D, Grenningloh M, et al. Using insulin infusion sets in CSII for longer than the recommended usage time leads to a high risk for adverse events: results from a prospective randomized crossover study. *J Diabetes Sci Technol*. 2015;9(6):1292-1298.
2. Heinemann L, Fleming GA, Petrie JR, Holl RW, Bergenstal RM, Peters AL. Insulin pump risks and benefits: a clinical appraisal of pump safety standards, adverse event reporting, and research needs: a joint statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group. *Diabetes Care*. 2015;38:716-722.
3. Clausen TS, Kaastrup P, Stallknecht B. Effect of insulin catheter wear-time on subcutaneous adipose tissue blood flow and insulin absorption in humans. *Diabetes Technol Ther*. 2009;11:575-580.
4. Thethi TK, Rao A, Kawji H, et al. Consequences of delayed pump infusion line change in patients with type 1 diabetes mellitus treated with continuous subcutaneous insulin infusion. *J Diabetes Complications*. 2010;24:73-78.
5. Kerr D, Morton J, Whately-Smith C, Everett J, Begley JP. Laboratory-based non-clinical comparison of occlusion rates using three rapid-acting insulin analogs in continuous subcutaneous insulin infusion catheters using low flow rates. *J Diabetes Sci Technol*. 2008;2:450-455.