Insulin Pump Therapy in Children with Type 1 Diabetes: The Dark Side of the Moon

Andrea E. Scaramuzza, M.D., Marta Dell'Acqua, R.N., Maddalena Macedoni, M.D., and Gian Vincenzo Zuccotti, M.D.

It is well established that insulin pump therapy [continuous subcutaneous insulin infusion (CSII)] has several advantages when compared with multiple daily injections (MDI) of insulin, especially the sensor-augmented pump.[1] However, we do not know whether the improvement in technology is accompanied by a high or low frequency of pump breakdowns or pump malfunctions (PM) and whether this has an impact on metabolic control.

During a survey, we extrapolated the answers concerning malfunctions of the pump itself or the infusion set. Patients were divided into two groups according to the presence or absence of PM. Age, disease duration, last glycated hemoglobin (HbA1c), mean HbA1c of the whole period using CSII, last insulin requirement, last body mass index z-score, and severe hypoglycemia and diabetic ketoacidosis were compared in the two groups of children with type 1 diabetes.

The use of a bolus calculator, the number of boluses made with the bolus calculator, the use of different type of boluses, the use of temporary basal, and the number of self-monitoring of blood glucose were also evaluated.

The primary end point was the change in HbA1c between patients with or without PM.

Among the 280 patients at our center, 130 (46%) were using CSII, of which 41 (32%) had used it for 3 years or more (range, 3–8.7 years; mean ± standard deviation, 5.3 ± 1.5 years). Pump malfunctions were recorded in 19/41 patients (46.3%), including battery or drive mechanism failure (n = 9, 47.4%), pump breakdown (n = 4, 21%), or others, including one theft (n = 6, 32.7%).

Interestingly, after analyzing data of the two groups (malfunction or not), we found a significantly higher HbA1c in the malfunction group, while no difference was observed for any other factor analyzed (**Table 1**). In addition, in the group without PM, there were significantly more patients with HbA1c < 7.5% (58 mmol/mol; International Society for Pediatric and Adolescent Diabetes recommendations) than those who had had PM (50% versus 21%; p = .004 by chi-square test). Moreover, although various types of infusion set defects have been reported in 27/41 patients (65.9%), this does not seem to affect glycemic control, neither at the last visit or as a mean of the whole period using CSII (p = .75 and p = .56, respectively).

Author Affiliation: Department of Pediatrics, Pediatric Diabetology Unit, University of Milano, Luigi Sacco Hospital, Milano, Italy

Abbreviations: (CSII) continuous subcutaneous insulin infusion, (HbA1c) glycated hemoglobin, (MDI) multiple daily injections, (PM) pump malfunctions

Keywords: childhood, continuous subcutaneous insulin infusion, insulin pump therapy, insulin therapy, pump malfunction, type 1 diabetes

Corresponding Author: Andrea Scaramuzza, M.D., Unit of Pediatric Diabetology, Metabolic Disease and Nutrition, Department of Pediatrics, University of Milano - Luigi Sacco Hospital, Via Giovanni Battista Grassi 74, 20157 Milano, Italy; email address scaramuzza.andrea@hsacco.it

Table 1.
Clinical Characteristics of the 41 Children with Type 1 Diabetes Using an Insulin Pump for More Than 3 Years, According to Pump Malfunction (n = 19) or Not (n = 22)[a]

	No PM (-)	PM (+)	Significance
Age, years	15.4 ± 4.3	15.8 ± 3.5	0.73
Disease duration, years	7.7 ± 5.0	9.5 ± 4.3	0.63
Body mass index z-score	0.10 ± 1.00	0.04 ± 0.89	0.86
Insulin requirement, U/kg/day	0.73 ± 0.23	0.84 ± 0.26	0.17
HbA1c,% (mmol/l)	7.63 ± 0.93 (60 ± 13)	8.05 ± 1.11 (64 ± 11)	0.04
Mean HbA1c, % (mmol/mol)	7.36 ± 0.63 (57 ± 17)	8.13 ± 1.11 (65 ± 11)	0.01
Basal rate, %	49 ± 9	45 ± 12	0.19
Boluses, %	51 ± 9	55 ± 12	0.19
Special functions,[b] yes/no	10/12	9/10	0.25
Self-monitoring of blood glucose, number	4.83 ± 1.68	4.79 ± 1.59	0.67
Severe hypoglycemia, episodes/100 patients/year[c]	3.2 ± 0.6	3.4 ± 0.4	0.74
Diabetic ketoacidosis, episodes/100 patients/year[d]	1.1 ± 0.1	0.9 ± 0.1	0.57

[a] Data are expressed as mean ± standard deviation and compared by mean of Students' t-test or chi-square test when appropriate.
[b] We considered special function "yes" only when special functions were used daily or more than 5 days per week.
[c] Severe hypoglycemia was defined as an episode absolutely requiring assistance from another person and preferably accompanied by a confirmatory blood glucose value <50 mg/dl (<2.8 mmol/liter).
[d] Diabetic ketoacidosis was defined as blood glucose >250 mg/dl (>13.9 mmol/liter) with either low serum bicarbonate (<15 mEq/liter) or low pH (<7.3) and either ketonemia or ketonuria and requiring treatment within a health care facility.

The high number of pump and set failures, similar to that reported elsewhere,[2–4] did not affect the increase of acute complications, probably because current insulin pumps already incorporate systems to detect some types of fault.

To the best of our knowledge, no one has investigated the possible relationship between PM and impairment in metabolic control, as observed here. In our opinion, it is not a problem due to an acute lack of insulin, the breakdown of the insulin pump, or the delay in patients' support (in Italy, pump companies offer a 24/7 assistance service, and in each case, the replacement of the pump occurred in less than 36 h and patients were instructed to use MDI in the meantime), but rather a possible distrust of the machine. It is as if the patients who experienced PM have a lesser confidence in the instrument and its technology.

Ours is just a pilot (and in some way not planned) experience that needs to be confirmed in larger groups of patients. In the meantime, this aspect should be a warning for companies that make insulin pumps. Having a Ferrari (a smart pump) may be pointless if you are afraid of being left on foot.

If anyone is interested, we are available to run a multicenter study about the relationship between PM and glycemic control.

Acknowledgment:

We thank all children with type 1 diabetes and their families who participated in the survey for their collaboration.

References:

1. Yeh HC, Brown TT, Maruthur N, Ranasinghe P, Berger Z, Suh YD, Wilson LM, Haberl EB, Brick J, Bass EB, Golden SH. Comparative effectiveness and safety of methods of insulin delivery and glucose monitoring for diabetes mellitus: a systematic review and meta-analysis. Ann Intern Med. 2012;157(5):336–47.
2. Mecklenburg RS, Guinn TS, Sannar CA, Blumenstein BA. Malfunction of continuous subcutaneous insulin infusion systems: a one-year prospective study of 127 patients. Diabetes Care. 1986;9(4):351–5.
3. Guilhem I, Leguerrier AM, Lecordier F, Poirier JY, Maugendre D. Technical risks with subcutaneous insulin infusion. Diabetes Metab. 2006;32(3):279–84.
4. Paul N, Kohno T, Klonoff DC. A review of the security of insulin pump infusion systems. J Diabetes Sci Technol. 2011;5(6):1557–62.