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RESEARCH LETTER

Insulin pump failures are still frequent: a prospective study over 6 years from 2001 to 2007

I. Guilhem · B. Balkau · F. Lecordier · J.-M. Malécot · S. Elbadii · A.-M. Leguerrier · J.-Y. Poirier · C. Derrien · F. Bonnet

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Abbreviation
CSII Continuous subcutaneous insulin infusion

To the Editor: In early studies, the use of continuous subcutaneous insulin infusion (CSII) was associated with an increased rate of diabetic ketoacidosis, caused mainly by infusion system malfunction [1–3]. However, these findings were not confirmed in most subsequent studies [4, 5]. It has been suggested that technological improvements and/or patient and physician vigilance has lowered this risk. Nevertheless, the reliability of pumps has not been re-evaluated during the last two decades.

The aim of this study was to determine the failure rate of pumps from four manufacturers and to assess the clinical consequences in type 1 diabetic patients using new generation insulin pumps.

Between April 2001 and November 2007, we prospectively studied insulin pump failures with 640 consecutive new pumps provided and maintained by the same institution (AIR Bretagne, Rennes, France). The pumps were used in ambulatory CSII treatment by 252 adult type 1 diabetic patients (mean age 40.7±13.1 years; 169 women, 83 men). Patients were given a choice between pumps manufactured by MiniMed Medtronic (MiniMed508, Paradigm) (Northridge, CA, USA) and Roche Disetronic (H-Tron plus, Accu-Chek D-Tronplus, Accu-Chek spirit) (Burgdorf, Switzerland) in 2001 to 2007, and by Smiths Medical (Deltec Cozmo) (St Paul, MN, USA) and Animas (Animas IR 1100, Animas IR 1200) (West Chester, PA, USA) after 2003. The same insulin pump was used by several successive patients once it had been checked and was working correctly. CSII treatment was initiated in an inpatient setting with a specific education programme to prevent and enable correction of CSII malfunctions. A professional healthcare service (on-call 24 h per day) was available to assist pump users. Patients' knowledge was checked by at least four contacts per year and with an annual treatment evaluation in the initiating centre, according to French legislation [6].

We focus on malfunctions directly related to the pump per se and not related to shock or incorrect use, which were treated as censored observations. All pump failures were documented and managed by AIR Bretagne; patients could

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I. Guilhem · J.-M. Malécot · S. Elbadii · A.-M. Leguerrier · J.-Y. Poirier · C. Derrien · F. Bonnet (✉)
Department of Endocrinology, CHU Rennes, Hôpital sud,
16 boulevard de Bulgarie,
35203 Rennes, France
e-mail: fabrice.bonnet@chu-rennes.fr

B. Balkau
INSERM U780,
Villejuif, France

F. Lecordier
AIR Bretagne, ZAC Atalante Villejean,
Rennes, France

F. Bonnet
Université Rennes 1, INSERM U625,
Rennes, France

B. Balkau
University Paris-Sud,
Orsay, France

not contact the manufacturer to exchange the pump directly. Clinical consequences of pump malfunctions were registered: hyperglycaemia (≥13.2 mmol/l), presence of ketones, hypoglycaemia and the need for hospitalisation.

During the study, 232 pumps (36%) broke down after a median time of 15.1 (range 0.1–64.4) months. The rate of pump malfunction was 25 per 100 pump-years. The characteristics of the pumps are shown in Electronic supplementary material [ESM] Table 1. There were 21 minor defects, 103 complete failures (pumps immediately unusable), 66 alarms set off and 42 mechanical malfunctions that required pump replacement, as recommended by the manufacturer (Table 1).

In total, 97 women (57%) and 45 men (54%) experienced a pump failure (χ^2, p=0.63). In univariate analysis, the total duration of CSII during the follow-up (median 58, range 2–79 months) was significantly associated with an increased risk of pump failure (OR 1.04, 95% CI 1.03–1.05; p<0.0001). The age of patients was not related to the risk of pump failure, after adjusting for the duration of CSII (OR 1.00, 95% CI 0.98–1.03; p=0.77).

The pump Kaplan–Meier survival curves (pump malfunction-free) for the four pump manufacturers were significantly different (logrank test, p<0.0001; Fig. 1). As the survival curves did not differ for the models of MiniMed Medtronic, Roche Disetronic and Smiths Medical (ESM Fig. 1), we regrouped the pump models for each of these manufacturers. For Animas, the survival curves differed significantly, and we used only the pump with the better survival curve (Animas IR 1200). Using Cox proportional hazards models to compare the failure rates for manufacturers, MiniMed Medtronic pumps (n=380) had a lower risk of pump failure than Roche Disetronic (n=163) (HR 0.59, 95% CI 0.40–0.88; p=0.009), Smiths Medical (n=54) (HR 0.40 95% CI 0.27–0.59; p<0.0001) or Animas IR1200 (n=31) (HR 0.25, 95% CI 0.14–0.47; p<0.0001) pumps. Roche Disetronic pumps had a lower risk of failure than Smiths Medical (HR 0.52 95% CI 0.32–0.86; p=0.009) or Animas IR1200 (HR 0.42, 95% CI 0.22–0.82; p=0.01) pumps. There was no difference between Smiths Medical and Animas pumps.

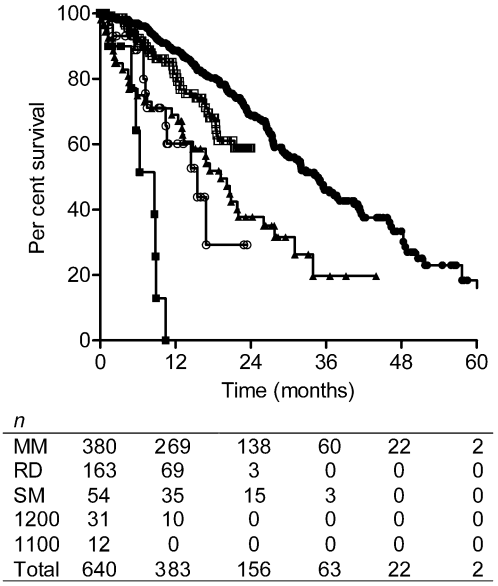

Fig. 1 Survival curves (failure-free) for the different pumps (logrank test; p<0.0001) with the number of pumps at each time (n). The curves were constructed with time 0 at initiation of CSII with a pump, the time of first malfunction, if any, and the time since initiation for censored pumps. The logrank test was used to compare survival curves. MiniMed Medtronic (MM), black circles; Roche Disetronic (RD), white squares; Smiths Medical (SM), black triangles; Animas IR 1200 (1200), white circles; Animas IR 1100 (1100), black squares

Table 1 Types and incidence of insulin pump failures

Type of failure	Number of cases, n (%)	Time before failure (months)	
		Median	Range
Complete pump failure	103 (44)	18.4	0.1–57.6
Keypad inoperative or pump stopped	56	23.4	0.1–51.7
Continuous alarm	19	9.0	1.4–29.6
Failure of display	16	14.4	0.1–46.8
No cartridge detected	8	15.6	10.6–36.6
Software reset	4	11.3	2.7–57.6
Alarm set off	66 (28)	12.8	0.8–64.4
With software reset	10	25.8	7.9–64.4
With probable overdose	1	8.0	
Mechanical defect	42 (18)	16.8	0.2–50.6
Defect in reservoir or battery compartment	26	15.3	0.2–48.6
Button defect	15	31.2	1.3–50.6
Miscellaneous	1	3.8	
Minor defect	21 (9)	11.6	0.5–35.5
Backlight defect	14	9.0	0.5–21.5
Miscellaneous	7	16.5	2.3–35.5
Total	232	15.1	0.1–64.4

For the 232 pump failures, there were no metabolic consequences in 161 cases, hyperglycaemia in 40 (17%) (with the presence of ketones in ten of these cases), one severe instance of hypoglycaemia, possibly due to an overdose by the pump, and consequences were not determined in 30 cases. No hospitalisation was necessary and no patient discontinued CSII therapy after insulin pump failure.

The main finding of this study is that pump failure still occurs frequently, with substantial differences between manufacturers. This study is the first to provide data on the rate of pump failure for new generation devices. The majority of reports on technical features or difficulties with CSII were published before 1990 [1, 2, 7].

Importantly, our findings do not suggest that pump malfunctions are less frequent or even less severe than those observed in early reports: we recorded substantial rates of severe pump failures, with a complete failure in 44% of cases. However, the majority of patients did not experience serious adverse metabolic consequences. We emphasise the importance of patient education and the 24 h on-call service to limit the consequences of pump failures. The advanced security features of modern pumps probably also play a role.

The strengths of the study are the large number of insulin pumps, the prospective follow-up and the fact that all pump users received the same technical education, according to French legislation [6]. The main limitation of our study is the absence of randomised allocation of the different pumps.

These findings show that there are still important technical issues with new generation insulin pumps, more than 25 years after the introduction of CSII. Randomised studies are now needed to further compare the reliability of different models of pumps.

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