JDI Journal of Diabetes Investigation Open access
Official Journal of the Asian Association for the Study of Diabetes
ORIGINAL ARTICLE

Safety of the batteries and power units used in insulin pumps: A pilot cross-sectional study by the Association for the Study of Innovative Diabetes Treatment in Japan

Takashi Murata[1]*, Shinsuke Nirengi[2], Naoki Sakane[2], Akio Kuroda[3], Yushi Hirota[4], Munehide Matsuhisa[3], Mitsuyoshi Namba[5], Tetsuro Kobayashi[6] for The Association for the Study of Innovative Diabetes Treatment in Japan (ASINDTJ)

[1]Diabetes Center, NHO Kyoto Medical Center, [2]Division of Preventive Medicine, Clinical Research Institute, NHO Kyoto Medical Center, Kyoto, [3]Diabetes Therapeutics and Research Center, Institute of Advanced Medical Sciences, Tokushima University, Tokushima, [4]Division of Diabetes and Endocrinology, Department of Internal Medicine, Kobe University Graduate School of Medicine, [5]Hyogo College of Medicine College Hospital, Hyogo, and [6]Division of Immunology and Molecular Medicine, Okinaka Memorial Institute for Medical Research, Tokyo, Japan

Keywords
Battery, Continuous subcutaneous insulin infusion, Insulin pump

***Correspondence**
Takashi Murata
Tel.: +81-75-641-9161
Fax: +81-75-643-4325
E-mail address:
murata-tky@umin.net

J Diabetes Investig 2018; 9: 903–907

doi: 10.1111/jdi.12765

ABSTRACT

Aims/Introduction: We investigated the safety of the batteries and power units used in insulin pumps in Japan.

Materials and Methods: A self-administered questionnaire was sent to the 201 members of the Association for Innovative Diabetes Treatment in Japan.

Results: A total of 56 members responded, and among the 1,499 active devices, 66 had episodes of trouble related to the batteries and power units. The ratio of reported troubles to the number of insulin pumps was significantly higher in insulin pumps with a continuous glucose monitoring sensor compared with insulin pumps without a continuous glucose monitoring sensor (odds ratio 2.82, $P < 0.05$). The cause and the consequences varied. The brands of the batteries varied; alkaline batteries purchased at drug stores and other shops accounted for 19.7%. Termination of battery life within 72 h of use was reported most frequently (50.0%), suspension of the insulin pump (21.2%) and leakage of the battery fluid (4.5%) followed. A total of 53.2% of the reported insulin pumps needed to be replaced, and 37.1% of them recovered after replacement of the battery.

Conclusions: As trouble related to the batteries and power units of insulin pumps was frequent, practical guidance should be provided to respective patients regarding the use of reliable batteries, and to be well prepared for unexpected insulin pump failure.

INTRODUCTION

Insulin pump therapy, or continuous subcutaneous insulin infusion, consists of an infusion set with an insulin reservoir, a tube and a cannula, pumping mechanism, computer chip, screen, casing, and battery. The prevalence of insulin pump therapy for patients with type 1 diabetes mellitus is increasing in many countries. Rapid-acting insulin analog is used in the insulin pump, and it is infused subcutaneously to mimic physiological insulin secretion[1]. Pharmacokinetic studies showed that the rapid-acting insulin analog acts within 15 min, peaks in 1 h and disappears within 4 h after subcutaneous injection[2]. Insulin infusion failure is a critical problem in insulin pump therapy because of a small amount of subcutaneous residual insulin[3,4]. Once the insulin infusion is accidentally stopped, patients start to develop diabetic ketoacidosis within 5–6 h[5]. Therefore, it is very important that insulin infusion is maintained during insulin pump therapy. We sometimes experience diabetic ketoacidosis caused by insulin pump malfunctions, such as the obstruction of the infusion set or the dislocation of the cannula from the skin, and, as the majority of type 1 diabetes mellitus patients require insulin to maintain their lives, the loss of function of insulin pumps can become a fatal problem[6]. However, the incidence and the causes of battery and power unit failure during insulin pump therapy have been rarely published to

Received 4 August 2017; revised 2 October 2017; accepted 16 October 2017

date. Batteries sold at drug stores and other shops are cheap, and sometimes the manufacturers are not identifiable. Therefore, the Association for Innovative Diabetes Treatment in Japan (ASINDTJ) decided to investigate the prevalence of trouble regarding batteries and power units used in insulin pumps.

METHODS

Study design and participants

A multicenter, cross-sectional survey regarding the safety of batteries and power units used in insulin pumps was carried out among ASINDTJ members. The questionnaire used for the survey was designed by the authors, and underwent content and construct validation by the organizers of the association. A self-administered questionnaire was mailed to all the 201 members (physicians 85.6%, registered nurses 3.5%, pharmacists 3.0%, laboratory technicians 3.0%, registered dieticians 2.0%, other occupations 3.0%) across Japan in 2016. The following variables were assessed: type of insulin pump, number of battery and power unit problems, combination of continuous glucose monitoring (CGM; yes/no), year of the problem, type of battery, cause of the problem and actions required to resolve the troubles.

Statistical analysis

All statistical analysis was carried out using R (R Foundation for Statistical Computing, Vienna, Austria)[7]. We reported data for categorical variables, such as percentages, odds ratios and 95% confidence intervals (CI). We compared the characteristics of insulin pumps with or without a CGM sensor using Fisher's exact test. *P*-values of <0.05 were considered significant.

Ethics

As the present study was strictly limited to information about insulin pumps and contains no information about the patients wearing them, ASINDTJ decided that this study did not need to be approved by an ethics committee.

RESULTS

A total of 56 members of the ASINDTJ responded to the questionnaire. As of 1 September 2016, MiniMed 620G, Paradigm 722 and Paradigm 712 (Medtronic MiniMed, Inc., Northridge, CA, USA) were mainly used in Japan, and a small number of TOP-8100 and TOP-8200 (TOP Corporation, Tokyo, Japan) were used (Table S1). Just 14.3% of the respondents supplied the batteries for insulin pumps to patients. Among them, 12.5% purchased the batteries at a medical institution, and 87.5% were provided batteries by the sales representatives involved in the leasing contract of the insulin pumps. Regarding the supplier of the batteries, 62.5% wished that the batteries be included in the leasing contract of the insulin pumps. Regarding reasons, 80% expected the supply of appropriate batteries, 65.7% thought pump users would not have to purchase the batteries themselves and 60% expected the possibility of using poor quality batteries would be reduced (multiple answers were accepted).

A total of 24 ASINDTJ members reported troubles occurring in the batteries and power units, and the reports on MiniMed 620G with CGM sensor were most common (Table 1). There were 44 cases out of 639 insulin pumps with a CGM sensor ([1] in Table 1), and 22 cases out of 860 insulin pumps without a CGM sensor ([2]–[7] in Table 1). The ratio of reports regarding problems related to the batteries and the power units to the number of insulin pumps was significantly higher in insulin pumps with a CGM sensor compared with insulin pumps without a CGM sensor (odds ratio 2.82, 95% CI 1.67–4.75, $P < 0.05$). The reported problems were mainly in 2015 and 2016, and many of the problems occurred in the MiniMed 620G with a CGM sensor (Table S2).

The brands of the batteries varied; and alkaline batteries purchased at drug stores, hundred-yen stores, volume-sales electronics retailers and DIY stores accounted for 19.7% of the report (Tables 2 and S3). Regarding the types of trouble related to the batteries and the power units, termination of the battery life within 72 h of use was reported most frequently (50.0%), suspension of the insulin pump (21.2%) and leakage of the battery fluid (4.5%) followed (Tables 3 and S4). An error message generated by the MiniMed 620G with a CGM sensor, 'Error 25' (power error detected), was reported most frequently (Tables 4 and S5). Regarding the actions required to resolve the trouble, 53.2% of the reported insulin pumps needed to be replaced, 37.1% of them recovered after replacement of the battery and 9.7% of them recovered by following the manufacturer's instructions, including telephone support (Table S6).

DISCUSSION

In the present study, the rate of trouble related to the batteries and power units used in insulin pumps was approximately 5% among all active devices. The ratio of reports related to the batteries and power units of the insulin pumps to their total number was significantly higher in insulin pumps with a CGM sensor (sensor-augmented pumps) compared with insulin pumps without a CGM sensor.

The reported troubles occurred mainly in 2015 and 2016, and this might be related to the fact that sensor-augmented pumps became commercially available in Japan from February 2015.

As this survey does not include information regarding the numbers, periods, manufacturers and brands of the batteries used in pumps without the batteries and the power unit problem, the rate of occurrence is unclear. However, considering the generally accepted idea that the batteries used in insulin pumps should be reliable, it might be better to recommend that insulin pump users choose batteries from well-known manufacturers rather than those of unidentified manufacturers.

It is important to note that approximately 20% of the report resulted in the suspension of the insulin pumps, which could potentially have caused severe adverse events including

Table 1 | Models of insulin pumps with reports of trouble

Model	No. reports	No. active devices	Rate (%)
(1) MiniMed 620G with CGM sensor	44	639	6.9
(2) MiniMed 620G without CGM sensor	4	207	1.9
(3) Paradigm 722	14	568	2.5
(4) Paradigm 712	3	64	4.7
(5) TOP-8200	0	4	0.0
(6) TOP-8100	0	2	0.0
(7) Others	1	15	6.7
Total	66	1,499	4.4

(1) Insulin pumps with continuous glucose monitoring (CGM) sensor. (2)–(7) Insulin pumps without CGM sensor.

Table 2 | Details of the batteries in the reported trouble cases

Type of battery	Brand and product name of the battery	*n*	Rate (%)
(1) Lithium battery	Energizer	2	3.0
	Panasonic	7	10.6
(2) Alkali battery	Panasonic Evolta	13	19.7
	Panasonic except Evolta	7	10.6
	Panasonic (unknown product name)	4	6.1
	Fujitsu Premium	1	1.5
	Maxell Voltage	1	1.5
	Toshiba Alkali1	3	4.5
	Batteries purchased at drug store, hundred-yen store, volume-sales electronics retailer and DIY store	13	19.7
	Unknown	2	3.0
(3) Rechargeable battery	Panasonic Rechargeable Evolta	1	1.5
	Unknown	1	1.5
(4) Unclassifiable battery	Unknown	13	19.7
Total		68	100

Table 3 | Types of trouble related to the batteries and the power units

	n	Rate (%)
(1) Termination of battery life within 72 h of use	33	50.0
(2) Suspension of the insulin pump	14	21.2
(3) Leakage of the battery fluid	3	4.5
(4) Usage of inappropriate batteries	1	1.5
(5) Others	15	22.7
Total	66	100

Table 4 | Types of error message (MiniMed 620G with continuous glucose monitoring sensor)

	n	Rate (%)
(1) Power error detected (Error 25)	17	38.6
(2) Insert battery (Delivery stopped)	2	4.5
(3) Low battery (Replace battery soon)	15	34.1
(4) Replace battery now (Delivery stopped)	4	9.1
(5) Replace battery (Battery life less than 30 min)	2	4.5
(6) Battery not compatible	0	0.0
(7) Battery failed (Insert a new battery)	1	2.3
(8) Pump error (Delivery stopped)	1	2.3
(9) Others	4	9.1
Total	46	100

hyperglycemia, diabetic ketoacidosis or death in absolutely insulin-dependent patients if appropriate actions, such as changing the batteries or injecting insulin using alternative devices, had not been taken within an adequate time to resolve the trouble. It is also important to note that approximately 5% of the reports resulted in the leakage of battery fluid inside the insulin pumps, which could potentially lead to a complete loss of function of the devices including the alarm function.

Batteries are not the only cause of power unit-related problems. For example, approximately 40% of the error messages generated by MiniMed 620G with a CGM sensor were 'Error 25.' This 'Error 25' is caused by the interference of the software operating the pump, and indicates drainage of the internal rechargeable battery due to the disturbance in its charging process. Some of the early termination of battery life might be related to the software that diagnoses the decline of battery power. As MiniMed 620G pumps were designed and built in the USA, it is not clear which battery available in Japan is really suited to use with the device. Medtronic started to sell alkaline batteries manufactured by Energizer (St. Louis, MO, USA) as the recommended battery to use with its pumps from January 2017 in Japan. Further evaluation is required to specify other recommendable batteries from different manufacturers.

The reason why almost half of the insulin pumps with battery and power unit problems needed to be replaced in the present study is unclear. Medtronic disclosed that it replaces insulin pumps with multiple episodes of 'Error 25.' Medtronic has updated the software version of the MiniMed 620G from 2.6B to 2.9B to reduce 'Error 25'; however, the effect is unknown at this moment.

From the present study, we would like to propose that battery- and the power unit-related problems are frequent events. It is worth noting the special background of insulin pump prescription in Japan. Unlike in the USA, insulin pumps are leased to patients from medical institutions due to the monthly health insurance reimbursement system. The majority of the insulin pumps are subleased from medical institutions, to which insulin pumps are leased by the representative sales companies. Some of the insulin pumps are purchased by the institutions and

leased to the patients, but this is a minority. When governmental regulations regarding the health insurance reimbursement of insulin pump therapy are strictly interpreted, medical institutions need to supply all the consumables to the patients. This means not only the infusion sets, but also batteries need to be provided to the patients; however, the reality is that only a limited number of medical institutions are executing this, as shown in the present study.

There are several previous studies that surveyed insulin pump failure; however, detailed information related to batteries and power units is limited. A prospective study carried out in France reported that there were 26 cases of 'defect in reservoir or battery compartment' among 42 mechanical defects, accounting for 18% of the 232 entire insulin pump failures including complete pump failure, alarm set off and minor defect[8]. A cross-sectional study using a self-report questionnaire completed by patients in the UK reported 'battery compartment problem' accounted for 11% of the insulin pump malfunction[9]. However, in these studies, it was unclear how much of the battery compartment problem was related to the batteries themselves rather than the problem of the insulin pump enclosure. A prospective study of pediatric and adolescent patients in Australia and New Zealand surveying various adverse events including pump malfunctions, set/site related, severe hypoglycemia and cutaneous problems reported adverse events up to 40 out of 100 person-years, of which 'battery issue' accounted for 6%; that is, frequency of 2.4 out of 100 person-years[10]. Another prospective study carried out in France reported that the incidence rate of insulin pump malfunctions was 33 out of 100 pump-years, and mechanical defect accounted for 35% of the reported malfunctions; however, the proportion of the trouble related to batteries and power units was not described[11]. In the present study, 53.2% of the insulin pumps with problems in the batteries or power units needed to be replaced. A retrospective study carried out in Italy reported that 0.165 insulin pump replacements per patient-year were experienced in children and adolescents with type 1 diabetes, and Animas VIBE (Animas Corporation, West Chester, PA, USA) and MiniMed VEO (Medtronic MiniMed, Inc., Northridge, CA, USA), both with CGM connectivity, were the most replaced in this survey, but the difference between sensor-augmented pumps and insulin pumps without a CGM sensor did not reach statistical significance[12].

A limitation of the present study was its cross-sectional observational design, lacking information about the frequency of troubles and patient background, together with a low response rate (27.9%). There is the possibility of missed reports that can affect the number of incidents, because the self-administered questionnaire was not sent to the patients directly, and the actual number of incidents might be much larger than that described in this report. A prospective study regarding the safety of the batteries and power units used in insulin pumps would be valuable to further clarify the frequency of such problems.

As the troubles related to the batteries and power units of insulin pumps were frequent, practical guidance should be provided to respective patients to use reliable batteries, and to be well prepared for unexpected insulin pump failure. As some of the insulin pumps recovered after following the manufacturer's instructions, reminding patients to keep the telephone number of the manufacturer's telephone support at hand might be helpful. If the electricity supply to the insulin pump is completely lost, the alarm function could no longer be activated. Executing self-monitoring of blood glucose four times a day or more, a standard procedure required for safe continuous subcutaneous insulin infusion, might help in finding insulin pump failure in such situations. Once insulin pump failure occurs, injecting insulin with insulin pens is important to prevent hyperglycemia and diabetic ketoacidosis. So far, the safety of the battery and power units used in insulin pumps has not been widely discussed. However, we believe that this is a very important issue related to the safety and the effectiveness of continuous subcutaneous insulin infusion.

ACKNOWLEDGMENTS

This study was supported by ASINDTJ. An abstract in Japanese was presented at the 16th ASINDTJ annual meeting (26 November 2016, Yokohama, Japan), and a short review in Japanese was published in Nihonijishinpo (29 April 2017). The authors thank all the ASINDTJ members who cooperated with this study, especially Dr Hideichi Makino for valuable discussion.

DISCLOSURE

The author(s) declare the following potential conflicts of interest to the research, authorship and/or publication of this article. Takashi Murata discloses the following relationships: lecture fees from Novo Nordisk, Eli Lilly, Sanofi, Arkray, MSD and Sumitomo Dainippon; and grants paid to the institution as study physician by Novo Nordisk, Sanofi, Kissei, Ono and, Astellas. Naoki Sakane discloses the following relationships: lecture fees from Novo Nordisk, Eli Lilly and Sanofi. Akio Kuroda discloses the following relationships: lecture fees from Eli Lilly and Sanofi. Yushi Hirota discloses the following relationships: lecture fees from Novo Nordisk, Eli Lilly, Sanofi, Medtronic and Abbott. Munehide Matsuhisa discloses the following relationships: lecture fees from Mitsubishi Tanabe, Eli Lilly, Astellas, Novo Nordisk, Sanofi and Novartis; and research grants from Daiichi Sankyo, Astellas, Mitsubishi Tanabe, Boehringer Ingelheim and Tokushima Data Service. Mitsuyoshi Namba discloses the following relationships: lecture fees from Sanwakagakukenkyusho, Sanofi, Novo Nordisk, Astra Zeneca, Novartis, Eli Lilly, Mitsubishi Tanabe and Kowa; and research grants from Arkray, Astellas, Novo Nordisk, Sanwakagakukenkyusho, Kyowa Hakko Kirin, Kowa, Ono, Daiichi Sankyo, Teijin, Mitsubishi Tanabe, Boehringer Ingelheim, Takeda, Sanofi, Sumitomo Dainippon, Astra Zeneca and Pfizer. Tetsuro Kobayashi discloses the following relationships: lecture fees from Sanofi. Shinsuke Nirengi declares no conflict of interest.

REFERENCES

1. Pickup JC. Insulin-pump therapy for type 1 diabetes mellitus. *N Engl J Med* 2012; 26: 1616–1624.
2. Torlone E, Fanelli C, Rambotti AM, *et al*. Pharmacokinetics, pharmacodynamics, and glucose counterregulation following subcutaneous injection of the monomeric insulin analogue (Lys(B28), Pro(B29)) in IDDM. *Diabetologia* 1994; 37: 713–720.
3. Ross PL, Milburn J, Reith DM, *et al*. Clinical review: Insulin pump-associated adverse events in adults and children. *Acta Diabetol* 2015; 52: 1017–1024.
4. Ross P, Gray AR, Milburn J, *et al*. Insulin pump-associated adverse events are common, but not associated with glycemic control, socio-economic status, or pump/infusion set type. *Acta Diabetol* 2016; 53: 991–998.
5. Attia N, Jones TW, Holcombe J, *et al*. Comparison of human regular and lispro insulins after interruption of continuous subcutaneous insulin infusion and in the treatment of acutely decompensated IDDM. *Diabetes Care* 1998; 21: 817–821.
6. Cope JU, Morrison AE, Samuels-Reid J. Adolescent use of insulin and patient-controlled analgesia pump technology: A 10-year Food and Drug Administration retrospective study of adverse events. *Pediatrics* 2008; 121: e1133–e1138.
7. Kanda Y. Investigation of the freely available easy-to-use software 'EZR' for medical statistics. *Bone Marrow Transplant* 2013; 48: 452–458.
8. Guilhem I, Balkau B, Lecordier F, *et al*. Insulin pump failures are still frequent: A prospective study over 6 years from 2001 to 2007. *Diabetologia* 2009; 52: 2662–2664.
9. Pickup JC, Yemane N, Brackenridge A, *et al*. Nonmetabolic complications of continuous subcutaneous insulin infusion: A patient survey. *Diabetes Technol Ther*. 2014; 16: 145–149.
10. Wheeler BJ, Heels K, Donaghue KC, *et al*. Insulin pump-associated adverse events in children and adolescents–a prospective study. *Diabetes Technol Ther*. 2014; 16: 558–562.
11. Guenego A, Bouzillé G, Breitel S, *et al*. Insulin Pump Failures: Has There Been an Improvement? Update of a Prospective Observational Study. *Diabetes Technol Ther*. 2016; 18: 820–824.
12. Rabbone I, Minuto N, Bonfanti R, *et al*. Insulin pump failures in Italian children with Type 1 diabetes: Retrospective 1-year cohort study. *Diabet Med* 2017; 34: 621–624.

SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Table S1 | Number of insulin pumps and their models.
Table S2 | Years in which the reported trouble occurred.
Table S3 | Details of the batteries in the reported trouble cases.
Table S4 | Types of trouble related to the batteries and the power units.
Table S5 | Types of error message.
Table S6 | Actions required to resolve the trouble.