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Insulin pump failures in Italian children with Type 1 diabetes: retrospective 1-year cohort study

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What's new?

- Insulin pump failure/malfunction and consequent replacement rate in a large cohort of Italian children with Type 1 diabetes are comparable with previously reported data.
- Insulin pump failure/malfunction is higher in more sophisticated pump models.
- No relationship between metabolic control and insulin pump failure has been confirmed on a much larger cohort than previously described.

Abstract

Aims Insulin pump failure and/or malfunction requiring replacement have not been thoroughly investigated. This study evaluated pump replacement in children and adolescents with Type 1 diabetes using insulin pump therapy.

Methods Data were collected for all participants younger than 19 years, starting insulin pump therapy before 31 December 2013. For each child, age, disease duration, date of insulin pump therapy initiation, insulin pump model, failure/malfunction/replacement yes/no and reason were considered for the year 2013.

Results Data were returned by 40 of 43 paediatric centres belonging to the Diabetes Study Group of the Italian Society of Paediatric Endocrinology and Diabetology. In total, 1574 of 11 311 (13.9%) children and adolescents with Type 1 diabetes were using an insulin pump: 29.2% Animas VIBE™, 9.4% Medtronic MiniMed 715/515™, 34.3% Medtronic MiniMed VEO™, 24.3% Accu-Check Spirit Combo™ and 2.8% other models. In 2013, 0.165 insulin pump replacements per patient-year (11.8% due to pump failure/malfunction and 4.7% due to accidental damage) were recorded. Animas VIBE™ (22.1%) and Medtronic MiniMed VEO™ (17.7%) were the most replaced.

Conclusions In a large cohort of Italian children and adolescents with Type 1 diabetes, insulin pump failure/malfunction and consequent replacement are aligned with rates previously reported and higher in more sophisticated pump models.

Introduction

By harnessing technology, continuous subcutaneous insulin infusion provides an improvement in metabolic control and quality of life for people with diabetes [1–3]. A Position Statement to improve pump technologies using a more rigorous, standardized approach to safety, has recently been published [4]. This statement suggests a benefit from

collecting data about all adverse events related to insulin pump use, especially after its worldwide increased use [5–7]. As with other countries, recent reports have shown that Italy saw a fourfold increase in pump users from 2005 to 2013 [8,9].

Metabolic and non-metabolic complications can occur during pump therapy. The risks of diabetic ketoacidosis and severe hypoglycaemia have been described previously [10]. Few data are available about non-metabolic complications: Pickup *et al*. observed a pump malfunction rate of 48%, without considering replacement [11]; Wheeler *et al*. reported a pump replacement rate of 23% in a population of 230 children and adolescents [12]; Guilhem *et al*. found a pump malfunction rate of 25 per 100 pump-years [13]; and Ross *et al*. reported total adverse events, not only pump replacements, in over 40% of pump users/year [14].

The aim of this study was to evaluate the rate of insulin pump replacement due to failure/malfunction in a large cohort of Italian children and adolescents aged < 19 years with Type 1 diabetes during 2013.

Methods

A standardized electronic case report form was sent to 43 paediatric diabetes centres belonging to the Diabetes Study Group of the Italian Society of Paediatric Endocrinology and Diabetology. Pump therapy was regularly administered in all these centres, which include 26 tertiary centres according to Sweet criteria [15].

The electronic case report form included data pertaining to the centre and to children receiving therapy up to 31 December 2013: ID, gender, date of birth, date of Type 1 diabetes onset, date of pump initiation, pump manufacturer and model, infusion set and insulin used, continuous glucose monitoring usage, frequency of sensor use and catheter and infusion set change as days/month, and HbA_{1c} as mean values for 2013.

Data regarding 2013 up to 31 December concerning pump replacement (yes/no, reason for pump failure or accidental damage or replacement following warranty expiration) and related clinical adverse events, diabetic ketoacidosis and severe hypoglycaemia, defined according to International Society of Paediatric and Adolescent Diabetes guidelines [16,17], were collected in the first 6 months of 2014.

HbA_{1c} was measured using a DCA-2000 Analyser (Siemens/Bayer, Italy) or high-performance liquid chromatography, standardized according to the National Glycohemoglobin Standardization Program.

In Italy all pumps are funded by the National Health System.

The study was approved by the local research ethics committee and conducted according to the Declaration of Helsinki. Participants and their parents provided written informed consent.

Data are presented as median with first and third quartile. A non-parametric Mann–Whitney *U*-test was used to compare quantitative variables between two groups when not normally distributed. The Shapiro–Wilk test was used to evaluate the normality of the distributions. Differences in frequencies were analysed by the chi-square test. Data were analysed using STATISTICA™ (version 9, StatSoft Corporation, Tulsa, OK, USA). All the tests were two-tailed and $P < 0.05$ was considered significant.

Results

Electronic case report forms for each participant using continuous subcutaneous insulin infusion were returned by 40 of 43 centres (93%), for a total of 1574 of 11,311 children and adolescents with Type 1 diabetes, aged 0–18 years (13.9%, 95% confidence interval (95% CI): 13.3 to 14.6%, 92.5% followed at tertiary care centres) using insulin pump therapy. Their clinical and metabolic data are shown in Table 1.

During 2013, 332 pump replacements (0.21 replacements per patient-year) were recorded. The reasons for replacement were: pump failure/malfunction not due to accidental damage (186/332; 56%), accidental damage (73/332; 22%) and replacements for warranty expiration (73/332; 22%). This means that the real rate of pump replacement due to failure/malfunction, excluding warranty expiration, in our large cohort sample is 0.165 replacements per patient-year (259/1574), 11.8% for pump failure/malfunction and 4.7% for accidental damage, The mean lifetime of each device was 2.92 ± 2.07 years. In 15.7% of the cases, pump failure occurred in the first year of pump therapy; in 62.3% pump failure occurred after at least 2 years of pump therapy.

The age group in which pump replacement for failure appeared more frequent was the 6–10-year-olds, followed by the 1–5-year-old group and the 11–18-year-old group (20.1% vs. 18.4% vs. 15.1%, although this did not reach statistical significance, chi-square test, $P = 0.076$).

No relationship was observed between pump replacement for malfunction or accidental damage and type and duration of catheter used, or with type of centre (tertiary vs. primary/secondary). However, in tertiary centres, the percentage of pump replacements was higher, but did not reach statistical significance (chi-square test, $P = 0.06$).

Table 2 shows the replacement rate by the insulin pump model. Animas VIBE™ and Medtronic Minimed Veo™ showed the highest rate of pump replacement (chi-square test, $P = 0.0003$).

A sensor-augmented pump was used in 28.7% of participants (451/1574 with a mean of 14.9 ± 9.6 days/month). The sensor was used more frequently ($P < 0.0001$) and for longer periods (> 20 days/month, $P < 0.005$) in children < 6 years when compared with other age groups .

Pump replacement was more frequent in sensor-augmented pump users, but without reaching statistical significance when compared with conventional pump users (chi-square test, $P = 0.05$). When considering the two most frequently replaced pump models (Animas VIBE™ and MedtronicMinimed VEO™), no significant differences in the number of pump failures were found between sensor-augmented and conventional pump users.

No relationship between metabolic control and insulin pump failure was found. In the cohort of children who required pump replacement, one severe hypoglycaemic episode (0.3 episodes/100 participants/year) and seven cases of diabetic ketoacidosis (2.1 episodes/100 participants/year) were declared and no discontinuation occurred.

Discussion

Among 13.9% of children and adolescents with Type 1 diabetes using insulin pump therapy in Italy in 2013, we found a rate of insulin pump failure (0.165 failure per patient-year) similar to that reported in previous papers involving pump replacements [12,13,18] and lower than that in other studies which evaluated malfunction without replacement [11–14]. Furthermore, Animas VIBE™ and Medtronic Minimed Veo™ were the most frequently replaced models for failure/malfunction.

Although retrospective data collection was performed, in Italy the need for pump replacement must be evaluated by the diabetologist, and a formal request by the latter must be made to the regional health agency. The need for such a procedure makes our data collection less subject to data loss. Only pump replacement was evaluated because it was easier to recall and verify.

Interestingly, most pump replacements occurred after 2 years from initiation of continuous subcutaneous insulin infusion (62.3%), suggesting that pump failure or malfunction are not related to user error due to inexperience in pump use.

Only one-third of participants in the study used continuous glucose monitoring consistently, especially pre-schoolers, and they used a sensor for > 20 days/month. This is probably due to the parent's desire to improve the quality of life of their child and a greater fear of hypoglycaemia, which has been reported in this age group [19,20]. In our data, the use of sensors does not seen to affect the risk of pump failure.

Ross *et al*. [18] recently found no association between adverse events and pump type. However, in our study, the risk of pump failure seems to increase in the newer and more sophisticated pump models.

The increased frequency of insulin pump failure in 6–10 year-old group is comparable with previously reported data [12].

Finally, no relationship was found between metabolic control and insulin pump failure, as previously suggested [18]. We can hypothesize that the few metabolic severe adverse events in our study might be related to causes other than pump failure requiring replacement.

In conclusion, insulin pumps are an established part of Type 1 diabetes treatment. Pump use is growing and is likely to continue to expand. Insulin pump replacement in a large cohort of Italian children and adolescents with Type 1 diabetes is similar to that reported previously and more frequent in sophisticated pump models. With the ever-growing circulation of new technologically advanced pumps, the assessment of pump failure rates under real-life conditions is fundamental because it provides crucial information on pump safety in real-life use.

Funding sources

None.

Competing interests

None declared.

Author contributions

IR and NM conceived the study, developed study design and wrote the paper; RB, MM, FC, VC, GdA, APF, DI, GI, FL, RS, ST, ST, and SZ provided database and performed data quality control, contributed in interpretation of results and to discussion; AP conducted statistical analysis and contributed to interpretation of results; AES collected database, contributed to the discussion of the results and to write the manuscript.

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Table 1 Clinical characteristics of 1574/11 311 (13.9%) children and adolescents with Type 1 diabetes using an insulin pump in Italy during 2013

Number (%)	1574 of 11 311 (13.9)
Gender (male/female) (, %)	49.9 /M; 50.1 F
Mean age (, years)	12.9 [9.4– to 15.3]
Diabetes duration (, years)	2.6 [1.2– to 5.1]
Pump therapy duration (, years)	3.1 [2.2– to 4.0]
Pump model (, *n*/%) (%)	
Animas Vibe™	460 (29.2)
Medtronic Veo™	540 (34.3)
Medtronic 515/715™	148 (9.4)
AccuCheck Spirit Combo™	382 (24.3)
Others (including Omnipod™)	44 (2.8)
Animas Vibe™	460 (29.2)
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AccuCheck Spirit Combo™	382 (24.3)
Others (including Omnipod™)	44 (2.8)
Insulin analogue type, *(n*/%) (%)	
Aspart	819 (53.9)
Lispro	526 (34.6)
Glulisine	174 (11.5)
Aspart	819 (53.9)

Lispro	526 (34.6)
Glulisine	174 (11.5)
HbA_{1c} as mean of year 2013 (, mmol/mol)	60 [53– to 65]
%	7.6 [7.0 to 8.1]
HbA_{1c} as mean of 2013, %	7.6 [7.0–8.1]
Frequency of infusion set replacement (, days)	3.0 [2.8– to 3.2]
Sensor augmented pump use (, *n*/%) (%)	451 (28.6)
Sensor usage (, days/ per month)	12.9 [7.2– to 18.6]

Data are presented as absolute numbers and percentages (categorical data) or as median values with the first and third quartiles [quantitative data].

Table 2 - Pump replacement rate according to the insulin pump model .

Total pump models, *n* (%)	259/ of 1,574 (16.5)
Animas Vibe™, *n* (%)	102/ of 460 (22.1)*
Medtronic Veo™, *n* (%)	96/ of 540 (17.7)*
Medtronic 515/715™, *n* (%)	16/ of 148 (10.8)
AccuCheck Spirit Combo™, *n* (%)	41/ of 382 (10.7)
Others (including Omnipod™) , *n* (%)	4 /of 44 (9.1)

* Highest rate of pump replacement (chi-square test, $P = 0.0003$).