Technology

Insulin pump reliability: A picture emerges

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When introduced to the UK in the 1980s, pump therapy soon fell into disrepute owing to a perceived increased risk of diabetic ketoacidosis (DKA), in some cases fatal, associated with pump failure. As insulin pump therapy has established itself as an effective way of optimising intensive insulin therapy, the apparent reliability of modern insulin pumps could be taken for granted. Certainly, the evidence no longer indicates that pump therapy is associated with an increased risk of DKA.

Pump failure, however, still occurs and minimising the risk of adverse outcomes when this does happen is dependent on effective blood glucose monitoring and regularly reinforcing advice on how to respond to pump failure.

Three of the papers summarised alongside highlight some common themes. Ross and colleagues report from four centres in New Zealand, with 83 adult and 92 paediatric pump users responding to their survey covering the year 2014, 86% of whom were using an Animas pump. Rabbone and colleagues report data obtained from 1574 paediatric pump users in 40 Italian centres using an electronic record form covering 2013. 29.2% were using the Animas Vibe pump and 34.4% the Medtronic Veo. Guenego and colleagues report from a single French centre on 350 new pumps provided to 174 patients from 2008 to 2013, comparing their findings to a previous survey from 2001 to 2007. 69% of these pumps were Medtronic and 21% Animas.

Ross et al looked broadly at adverse events related to pumps, with 3.42 reported per 100 person-years. Of these adverse events, 17 (9.8%) resulted in hospitalisation. Sixteen of these were due to DKA or elevated ketones, but 13 of these 16 were related to infusion set or site problems, not pump failure. Guenego et al reported 33 malfunctions per 100 pump-years. Of these malfunctions, 19% were classified as severe pump failures – either complete failure or an alarm indicating that the pump should be replaced. Of these severe failures, 13% resulted in episodes of hyperglycaemia, equivalent to 0.471 per 100 person-years, but no cases of ketosis or hospitalisation.

Guenego et al reported 33 replacement pumps needed per 100 pump-years – equivalent to the malfunction rate. This appears to reflect a different support system in France, where national policy requires that pump users do not contact manufacturers for technical support. Instead a non-profit organisation provides 24/7 technical support, reviewing all malfunctions and returning the offending pump to the manufacturer for replacement. This appears to result in a high replacement rate and a short pump life, with a median survival time of 26 months (interquartile range, 16–39). Complete failures occurred earlier, with a median life of 13.5 months for these pumps. Pump failures were more likely for female users and those under 40.

Pump replacement rates in the other studies were remarkably similar – 16.1 per 100 person-years in New Zealand and 16.5 per 100 person-years in Italy. Accidental pump damage was responsible for 28.6% of replacements in New Zealand and 28.5% in Italy. In Italy, the mean lifetime of the device was 2.92±2.07 years, 62.3% of pump failures occurred after at least 2 years, and the Animas Vibe and Medtronic Veo more commonly failed than other pumps. None of the studies found any relationship between pump failures and duration of diabetes or metabolic control.

These studies highlight that pump failures are not uncommon, but, in these centres, they were very rarely associated with any adverse clinical effect. The importance of education, and re-education, to ensure users are alert to the possibility of pump failure, how to identify it and what action to take if it occurs, is paramount. The French centre with no serious clinical sequelae from pump failures has a 24/7 on-call medical service. Centres should consider how best to support those on any intensive insulin regimen when it fails to control blood glucose levels adequately. Finally, regular review of the functioning components of the pump should be a routine aspect of pump care, and users should be specifically advised to inspect these components after any impact or contact with water. ■

Acta Diabetol

Adverse events in CSII are common

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! Factor	✓✓✓✓

1 Data on insulin pump-associated adverse events (AEs) are limited. These investigators conducted a retrospective survey-based study to describe the incidence, characteristics and potential predictors of AEs in adults and children with T1D.

2 Adults and families of children with pumps were recruited from four centres across New Zealand. Participants completed a questionnaire, which relied on self-reported data, based on their experience in the previous 12 months.

3 Responses were obtained from 174 (64%) of the 270 eligible participants. At least one AE was reported by 84% of individuals, with an overall incidence of 3.42 per person per year. Serious AEs requiring hospitalisation occurred in 9.8% of participants. All but one case were for high ketones or diabetic ketoacidosis.

4 The most commonly reported AEs were related to set or site problems (53% of respondents), followed by cutaneous complications (43%) and pump malfunction (38%).

5 A number of potential associations with AEs were explored, but few predictors were found. However, longer duration of pumping and age <18 years were both associated with fewer AEs.

6 Insulin pump-associated AEs were common for both adult and paediatric users, although the severity of reported AEs varied considerably.

7 AEs should be anticipated, as they are common and clinically important. User and health professional education to foresee problems is vital, along with vigilance towards glucose monitoring and infusion set changes.

Ross P, Gray AR, et al (2016) Insulin pump-associated adverse events are common, but not associated with glycemic control, socio-economic status, or pump/infusion set type. *Acta Diabetol* **53**: 991–8

Diabet Med

Insulin pump failures in children: Rates and reasons

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! Factor	✓✓✓✓

1 This study evaluated the rate of insulin pump replacement due to failure or malfunction in a large cohort of Italian children and adolescents with T1D under the age of 19 years.

2 Data was collected from 40 paediatric diabetes centres using a standardised electronic case report form during the year 2013. The form included data on participant age, disease duration, date of pump therapy initiation, pump model, pump replacement and related adverse clinical events.

3 In total, 1574 (13.9%) of 11 311 children and adolescents were using an insulin pump. During 2013, 332 pumps were replaced owing to failure/malfunction (56%), accidental damage (22%) or warranty expiration (22%). The rate of replacement, excluding warranty expiration, was 0.165 per person-year.

4 The mean lifetime of a device was 2.92±2.07 years. Most pump failures (62.3%) occurred ≥2 years after initiation of pump therapy, suggesting that user inexperience was not to blame. An increased risk of failure was noted in the newer, more sophisticated pump models.

5 No relationship was found between metabolic control and pump failure. The few metabolic severe adverse events recorded might have been related to other causes.

6 As the number of technologically advanced pumps being used increases, real-life studies of pump failures are crucial in providing information on pump safety.

Rabbone I, Minuto N, Bonfanti R et al (2016) Insulin pump failures in Italian children with Type 1 diabetes: retrospective 1-year cohort study. *Diabet Med* 25 Nov [Epub ahead of print]

Diabetes Technol Ther

Are we seeing fewer insulin pump failures?

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! Factor	✓✓✓✓

1 This prospective observational study assessed the rate and clinical consequences of insulin pump failures recorded by a centre in France from 2008 to 2013. A previous study had been conducted from 2001 to 2007.

2 Malfunctions that were directly related to the pump (not the infusion set) were independently managed by a single not-for-profit association.

3 During the inclusion phase, 350 new pumps were acquired. Malfunctions occurred in 239 (68%) pumps at an incidence rate of 33 per 100 pump-years. There were 28 (12%) complete failures, 17 (7%) alarm failures, 83 (35%) mechanical defects and 105 (44%) minor defects. There were no significant differences in survival curves according to pump brand and model.

4 Six episodes of hyperglycaemia occurred after a severe pump failure (n=45), representing 0.47 events per 100 person-years. No cases of ketosis, hypoglycaemia or hospitalisation were recorded in relation to severe pump failure.

5 In multivariate analysis, only user age of <40 years at pump initiation was associated with a higher risk of pump malfunction. Mean HbA_{1c} levels were similar in users who had and had not experienced pump defects.

6 While pump malfunctions remain common, fewer complete failures were reported than in the earlier study. This may be due to improved quality or the centre's strategy of systematic screening and replacement in case of mechanical defects.

Guenego A, Bouzillé G, Breitel S et al (2016) Insulin pump failures: has there been an improvement? Update of a prospective observational study. *Diabetes Technol Ther* **18**: 820–4

J Diabetes Sci Technol

Early detection of infusion set failure

Readability	✓✓✓
Applicability to practice	✓✓✓✓
WOW! Factor	✓✓✓✓

1 Insulin infusion set failure in type 1 diabetes can result in prolonged hyperglycaemia or diabetic ketoacidosis. Such failures are often characterised by variable and unpredictable patterns of increasing glucose levels despite increased insulin infusion.

2 These investigators set out to develop a novel algorithm designed to alert the user to the onset of infusion set failure based upon continuous glucose sensor values and insulin delivered from a pump.

3 The algorithm was calibrated from 12 weeks of infusion set use without failures recorded by four participants in ambulatory conditions. It was validated using data from an additional 18 weeks from nine participants with and without failures. For each dataset, infusion sets were worn for 7 days (or until failure).

4 On retrospective analysis, the algorithm identified failures 2.52±1.91 days ahead of the actual event as recorded by the clinical team. The algorithm achieved 50% sensitivity, 66% specificity and 55% accuracy.

5 If the failure alarm had been activated by the algorithm in real time and been acted upon, a 29% reduction in time spent in hyperglycaemia (>10 mmol/L) would have been achieved (from 82.7±40.9 hours/week/person to 58.8±31.1 hours/week/person).

6 This method requires uninterrupted continuous glucose monitoring data to detect trends accurately. However, the authors hope that, after further validation, the algorithm could be implemented as an additional safeguard in future fully automated closed-loop systems.

Cescon M, DeSalvo DJ, Ly TT et al (2016) Early detection of infusion set failure during insulin pump therapy in type 1 diabetes. *J Diabetes Sci Technol* **10**: 1268–76

"As the number of technologically advanced pumps being used increases, real-life studies of pump failures are crucial in providing information on pump safety."