It is definitely a game changer

Closed loop technology in the home experienced by adults with type 1 diabetes

Hendrieckx C 1, Speight J 1, 2, Poole LA 1, 3, Sharifi A 1, Loh M 4, Forsburg JC 1, Traylor S 1, 4, Jenkins AJ 4, Kumareswaran K 1, Macsiacl RJ 1, Ward GM 4, Colman PG 1, Bach LA 5, Kyong A 6, Kurtz N 7, Grossman B 8, Roy A 9, O’Neal DN 1

1 The Australian Centre for Behavioural Research in Diabetses, Diabetes Victoria, Melbourne, Australia; 2 School of Psychology, Deakin University, Burwood, Victoria, Australia; 3 Department of Medicine, St Vincent’s Hospital Melbourne, Victoria, Australia; 4 Department of Endocrinology and Diabetes, The Alfred Hospital, Melbourne, Australia; 5 Department of Endocrinology & Diabetes, St Vincent’s Hospital Melbourne, Victoria, Australia; 6 Diabetes and Endocrinology, Melbourne Health, Royal Melbourne Hospital, Parkville, Australia; 7 Department of Sleep Medicine, St Vincent’s Hospital Melbourne, Victoria, Australia; 8 Medtronic, Northridge, United States

Background

Closed loop (CL) technology (artificial pancreas) has the potential to prevent hypoglycaemia and reduce glycaemic variability in type 1 diabetes (T1D). Maximum benefits of this technology will depend largely on uninterrupted and appropriate use by the person with T1D. Treatment preference, acceptability and perceived benefits/costs of T1D will therefore be key factors for implementation. Surveys of people with T1D suggest that some may perceive new CL technology as intrusive and burdensome, whilst others may desire it to ease the intellectual burden and continuous vigilance necessary in maintaining optimal glycaemic control. With few exceptions 5 of studies of CL to date have focused almost entirely upon glycaemic outcomes rather than psychosocial experience. Only one qualitative study has focused on adults’ experience of CL with/without CGMS. Although all participants reported technical issues during at least one CL night, they were positive that with future fine-tuning of the algorithms and the accuracy of the sensor, the CL has the potential to significantly improve their diabetes care and their quality of life.

Method

Study Design

We conducted semi-structured interviews with 10 adults with T1D between April 2014 and March 2015 after they had completed four nights of CL in the home setting. Impaired awareness of hypoglycaemia was an exclusion criterion. Interview topics included overall experiences with CL over four nights, effect of CL on glycaemic levels, effect of CL on hypoglycaemia; understanding of algorithms; potential concerns about using CL in comparison with current management (CSII) or with without CGMS. During the interviews, two 10-point scales were used to assess: ease of using CL, and 2 confidence in accuracy of CL, with higher scores indicating greater ease/confidence.

Participants

Participant characteristics are shown in Table 1. All routinely managed their T1D with an insulin pump (CSII) and three used Continuous Glucose Monitoring System (CGMS); though all had experienced of CGMS.

Table 1: Participants’ characteristics at baseline

<table>
<thead>
<tr>
<th>Age</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-32</td>
<td>6</td>
</tr>
<tr>
<td>33-42</td>
<td>7</td>
</tr>
<tr>
<td>43-52</td>
<td>7</td>
</tr>
</tbody>
</table>

Diabetes duration: years

<table>
<thead>
<tr>
<th>No</th>
<th>(5-6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
<td>10</td>
</tr>
<tr>
<td>57-67</td>
<td>2</td>
</tr>
</tbody>
</table>

Usual CGMS: 10 (100)

Usual CGMS use: 3 (30)

Theme

Impact of CL on overnight glycaemic levels

Example Participant Quote

‘Flat-line’ overnight

“...I was surprised how stable I kept my BG’s #1”

Probable diabetes, but generally well controlled by diet, exercise and medications. #3

Alarm system on CL is not working as expected.

“You have to be very careful and pay attention to the alarms.”

Target range

“...they let it flat line for however long it takes to go down to 9 and then it flat lines and then it is not in alarm.” #10

“...it doesn’t get lower than 10 although it’s just one number and one you’re not really sure if that is really low or not.” #10

Personal control and diabetes control

“...I was really surprised how, particularly in bringing your sugar levels up just by reducing the insulin I was quite impressed about how that worked.” #9

“...I was quite surprised how, particularly in bringing your sugar levels up just by reducing the insulin I was quite impressed about how that worked.” #9

“...I was quite impressed about how that worked.” #9

“...I was quite impressed about how that worked.” #9

Results

All participants experienced the CL system as ‘easy to use’ (score range 7.5-10), but all recognised that their previous experience with CSII/CGMS was very helpful in preparing them for the technology. Themes emerging from the interviews are shown in the center table.

1. Impact of CL on overnight glycaemic levels. Participants reported stable overnight glycaemic levels, though four did not perceive this to be any different from what they achieved with CGMS/CSII. For one participant, stable glycaemic levels were never in the middle of the target zone, for another it was at the higher end.

2. Personal control and diabetes control. Participants experienced that CL controlled their glucose levels overnight without feeling they were losing personal control.

3. Impact of CL on sleep. Participants reported improved sleep in the home setting as they observed how the CL system tracked their glucose levels, preventing hypoglycaemia.

4. Benefits of CL compared to current treatment (CSII with/without CGMS). Although all participants reported technical issues during at least one CL night, they were positive that with future fine-tuning of the algorithms and the accuracy of the sensor, the CL has the potential to significantly improve their diabetes care and their quality of life.

Conclusions

Participants gave a very positive evaluation of CL used overnight in the home setting.

All most achieved stable overnight glycaemic levels but the greatest perceived benefit of CL over current CSII (and CGMS) is the proactive and accurate response to falling glucose levels, preventing hypoglycaemia.

All that noted improvements to the technology (sensors and algorithms) are needed to increase its accuracy and reliability.

References


This qualitative study explored participants’ experiences after four nights of Home Closed Loop (CL) Insulin Delivery System use vs. Sensor Augmented Pump Therapy with Low-Glucose Suspend (SAPT-LGS) in a randomised cross-over trial. Ten adults (≥18 years) completed the trial between April 2014 and March 2015; median age 37.5 years (range 32-62) and diabetes duration 31 years (range 8-36); five were women. Semi-structured interviews were conducted on day five, after four consecutive nights of CL at home. Interviews were audio-recorded, with transcriptions imported into NVivo 10 for thematic analysis. A coding framework was developed to identify the main themes and subthemes.

When asked about the four nights’ CL experience, the most common observation was the ‘flat-line’, showing stable overnight glucose levels. Although most reported technical glitches during one or more nights, few safety concerns were raised. If any, these related to feeling unsure whether the system would respond in time to falling glucose. However, confidence increased when they observed how the CL stopped insulin delivery when their glucose was trending down, how (when switching to CL at night) the CL dealt with high glucose levels. Compared with their current insulin pumps (and, for some, sensors), participants reported the following benefits: less decision making, resulting in fewer human errors; fewer alarms, as the CL kept glucose levels within target overnight; not having to cope with the consequences of hypo- and hyperglycaemia (e.g. feeling sick post event), due to less glucose variability. Participants found the CL was easy to use, but they noted that this might be different for people who are less ‘tech savvy’.

In conclusion, participants gave a very positive evaluation of the CL in the home. They were impressed with how well the CL system responded to their glucose levels, although they noted that further improvement of the technology will enhance the user’s experience.

Presented at: 75th Scientific Sessions of the American Diabetes Association (5-9 June 2015, Boston USA)

Enquiries: chendrieckx@acbrd.org.au