Use of Fuzzy Logic Controller (FLC) in a Closed Loop Artificial Pancreas

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Introduction

With currently available technologies, it is difficult to prevent hyper- and hypoglycemia in patients with type 1 diabetes. Artificial Pancreas Systems (APS) which connect existing glucose sensing and insulin delivery devices with computer algorithms offer a promising direction for improved glycemic control. Here we evaluate an APS controller algorithm based on Fuzzy Logic which does not rely on predictive models nor require meal announcement or boluses. The fuzzy logic controller (FLC) calculates doses using only the patient’s total daily insulin and three previous 5-min CGMS readings.

Methods

A FLC was used to deliver insulin to adult patients with type 1 diabetes (age range: 18-35 yrs, mean age: 23.6 yrs, HbA1c range: 6.4-8.6%, mean HbA1c: 7.7%). This was done through the APS system developed by UC Santa Barbara and Sansum Diabetes Research Institute using an OmniPod pump and Dexcom Seven Plus sensors. There were 4 periods of 6 hrs corresponding to the aims beginning at 8 pm. There was no pre-meal priming boluses, nurse or physician data entry or modifications. The controller is fully automated and was initialized using only the patient’s Total Daily Insulin.

Results

<table>
<thead>
<tr>
<th>ID</th>
<th>PF</th>
<th>Avg BG</th>
<th>Max BG</th>
<th>Min BG</th>
<th>Time &gt; 200</th>
<th>Time &lt; 70</th>
<th>Time 70-200</th>
</tr>
</thead>
<tbody>
<tr>
<td>102</td>
<td>4</td>
<td>176</td>
<td>303</td>
<td>90</td>
<td>28%</td>
<td>0%</td>
<td>72%</td>
</tr>
<tr>
<td>103</td>
<td>4</td>
<td>156</td>
<td>304</td>
<td>66</td>
<td>18%</td>
<td>1%</td>
<td>81%</td>
</tr>
<tr>
<td>Avg</td>
<td>4</td>
<td>166</td>
<td>303</td>
<td>78</td>
<td>23%</td>
<td>0.5%</td>
<td>76.5%</td>
</tr>
</tbody>
</table>

Eight out of ten patients who completed the study had average blood glucose values of 169 mg/dL (range 151-206mg/dL) and were within an ideal BG range (70-200mg/dL) for 73% of the 24-hour study period. Two patients experienced hypoglycemia due to FLC initialization errors. The study of patient 112 was stopped after 18 hours because of sensor failure. Avg. LBGI and HBGI values were 0.47 & 7.79 respectively.

Secondary analyses of the FLC performance in four, 6-hour subsets of the entire study period to evaluate:

- Correction of hyperglycemia (8pm-2am): 170 mg/dL
- Fasting and diurnal variation (2am-8am): 131 mg/dL
- Small meal (30 gram CHO) (8am-2pm): 182 mg/dL
- Moderate meal (60 gram CHO) (2pm-8pm): 202 mg/dL

Conclusion

FLC presents a promising approach to Artificial Pancreas Systems that warrants further study.

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Objective

In this early feasibility/safety study, we evaluated the FLC in the setting of bed rest in the CRC. Two carbohydrate-controlled meals were given (30g breakfast, 60 gram lunch) without meal announcement or pre-meal bolus. Multiple endpoints related to the frequency and severity of hyper- and hypoglycemia were assessed.

BG & Dose History (Typ. Patient)

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