ANALYSIS AND DEVELOPMENT OF A MEAL DETECTION ALGORITHM FOR THE ARTIFICIAL PANCREAS

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Introduction

Type 1 diabetes is a disease where no insulin is produced in the body, making it necessary for subjects to continuously monitor blood glucose levels and inject insulin several times a day. The artificial pancreas uses a closed-loop system that consists of a combination of monitoring (subcutaneous sensing, finger stick, and insulin insertion) and computer programming (algorithms using MATLAB) to be able to detect the change in continuous glucose monitor (CGM) levels and a response for the event.[5] Meal detection in particular poses a problem due to rapid increase in blood glucose and the risk of hyperglycemia. The challenge that faces meal detection is being able to respond within an appropriate time and with the correct amount of insulin to compensate for the meal.[1] The previous developments of the artificial pancreas have all used meal announcement to compensate for a meal.[2-4] The Doyle group is one of the few groups working on the development of an artificial pancreas without the need for a meal announcement, creating a fully automatic system.[6] To aid in responding to meal, an algorithm is being developed that uses different parameters to assist in identifying when a meal has been consumed alerts the system of a meal and inform the controller to respond to the meal in order to maintain the ideal glucose levels of 80-140 mg/dL. Using data from recent clinical trials, the response of the controller without meal detection to the meal was analyzed by qualitatively identifying an increase in insulin delivery due to a post-prandial rise in glucose to assist in the development of the artificial pancreas.

Methods

Segmenting Meals

Data from recent clinical trials that were administered at Sansum Diabetes Research Institute were taken and cut into smaller segments of data.

- One hour before and six hours after the meal
- Trends of BG and insulin levels analyzed
- 24 meals total
- 12 patients (breakfast and dinner) monitored

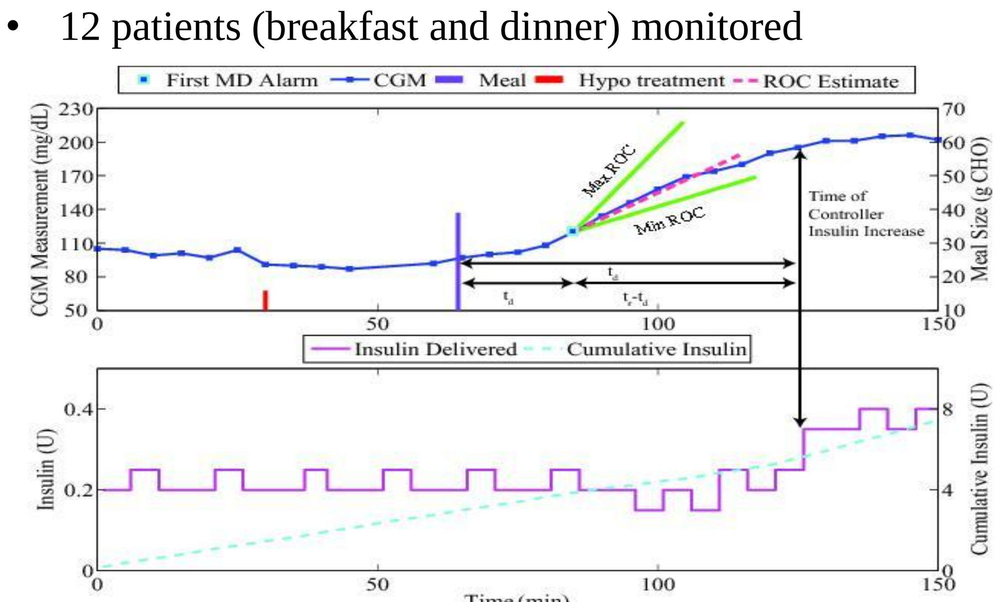


Figure 1: Basic meal detection Algorithm Parameters

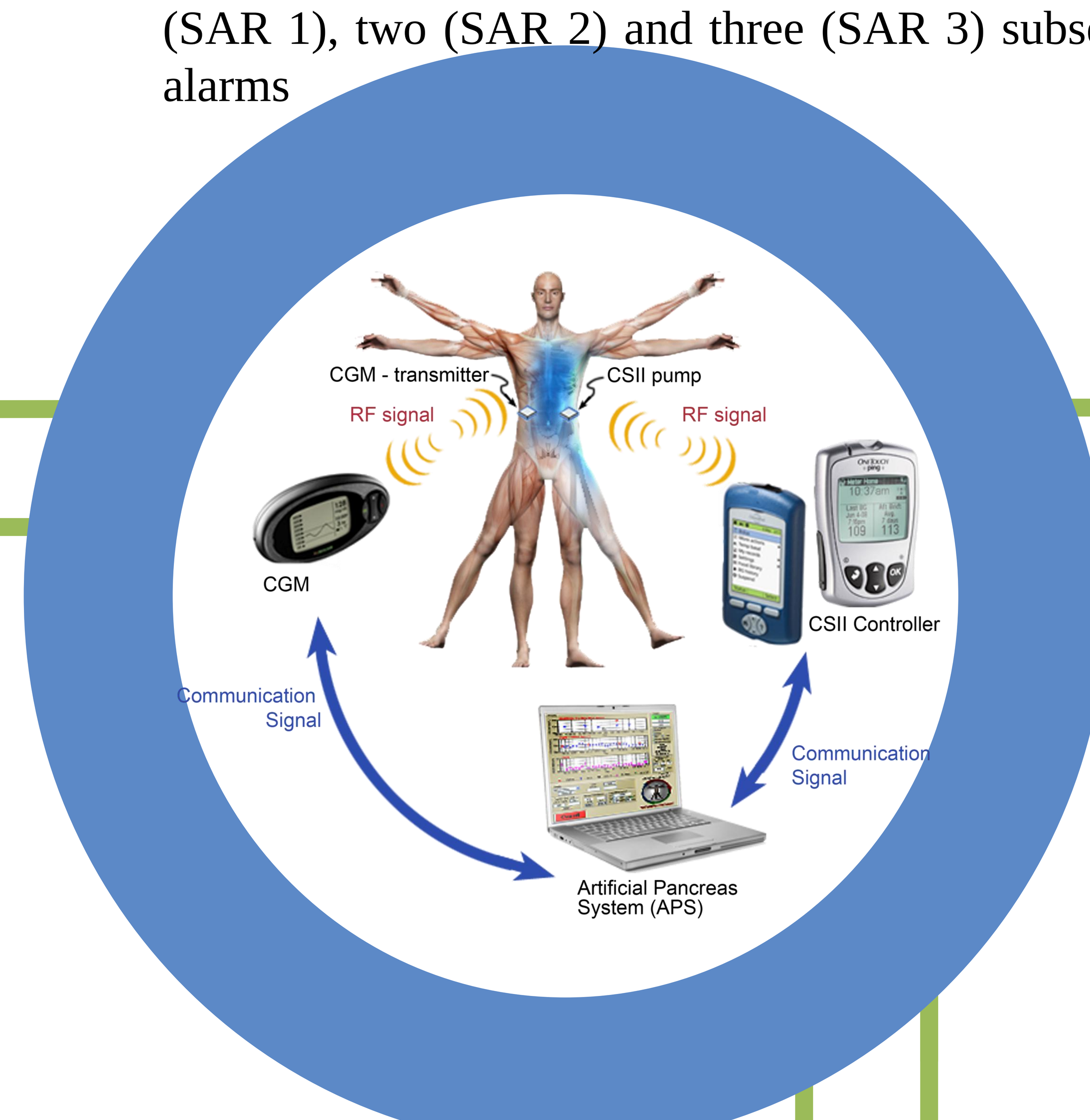
Running the Basic Meal Algorithm

- CGM levels taken from last five minutes
- Predicted slope is determined
- Algorithm uses parameters for alarming a meal
  - Rate of change must be within given min. and max.
  - Number of subsequent alarms (SAR) needed to detect meals.
  - Data must be monotonically increasing to alarm
  - BG level must be above the threshold (110 mg/dL)
- CGM rate of change min. and max. between 1.8 and 3 mg/dL/min. would flag the meal
- Algorithm was executed with the parameters of one (SAR 1), two (SAR 2) and three (SAR 3) subsequent alarms

Calculating the Meal Detection and Response

Ideal number of alarms was determined using the average time difference between the alarm to the meal and the insulin to the meal

- True positives and false negatives were calculated to observe accuracy
  - True positives- alarms detected the meal
  - False positive- alarms for a nonexistent meal
  - False negative- does not alarm when there is a meal
  - Time of meal to the alarm, and time of insulin increase is calculated
- Time of meal to the alarm (t_d) and time of insulin increase (t_r) is calculated and analyzed



Results

The Faster Meal Detector

Of the three algorithms that were executed, SAR 1 was the best for detecting a meal early. SAR 1 had the same number of false positives as SAR 2 and SAR 3.

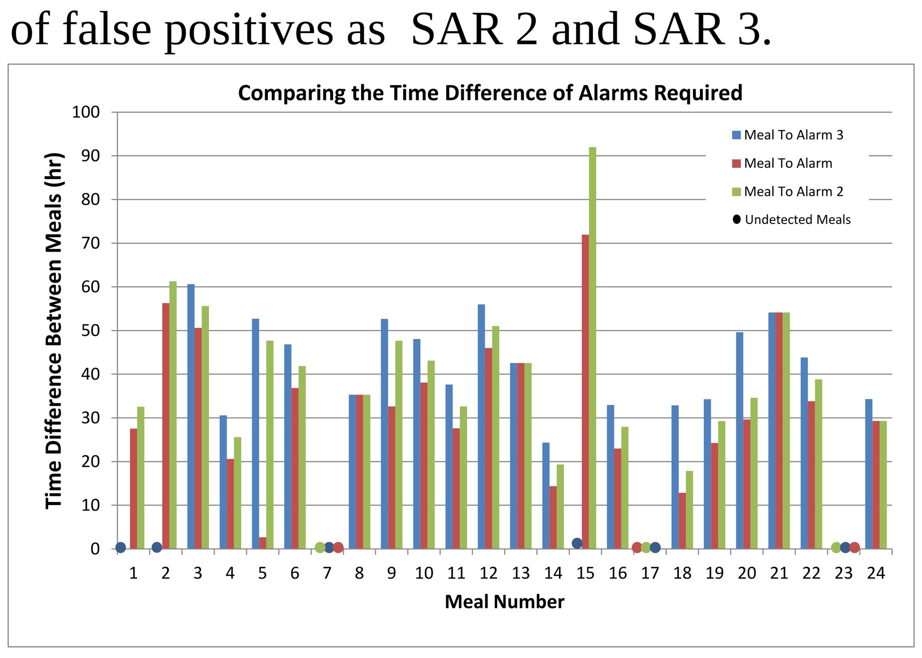


Figure 2: Time difference of meal to alarm for each algorithm

The three alarms are indicated in *Figure 3*. The alarms for Meal 14 have a delayed reaction of 14, 19 and 24 minutes after the meal

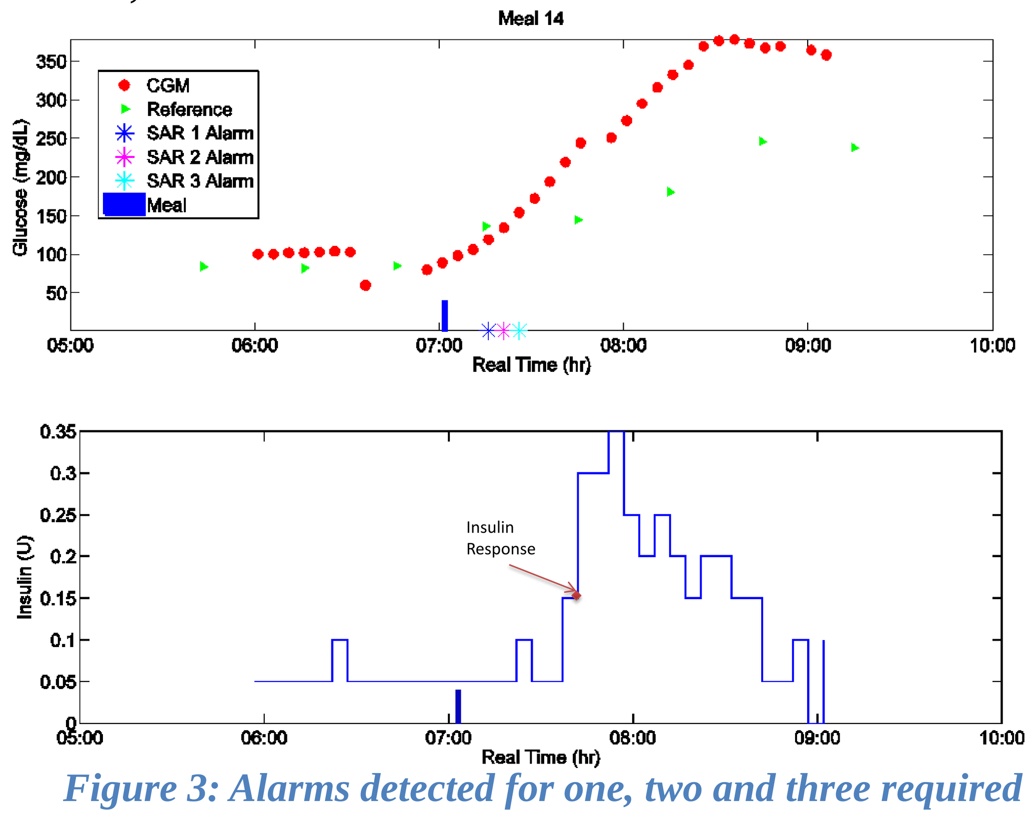


Figure 3: Alarms detected for one, two and three required in the algorithm.

Table 1: Error Results for Alarm Parameters

Alarms Required	SAR 1	SAR 2	SAR 3
True Positive Ratio	0.875	0.875	0.75
# of False Positives	1 (Meal 23)	1 (Meal 23)	1(Meal 23)
Average Time for 1st Alarm (t_d)	34 min.	41 min.	43min
Average Time for Insulin Delivery (t_r)	46 min	47 min	40 min
Average Time Difference (t_r-t_d)	11 min	6 min	-3min

Summary

- SAR 1 is the better alarm for detecting a meal faster.
  - Did not jeopardize the user as predicted with false positives.
- False positives deem a further risk for the algorithm that only requires one alarm
  - Only necessary for one point to be within the range
  - Other two algorithms require two or three subsequent alarms to be certain of a meal (causing lags)
  - Can cause unnecessary bolus of insulin
  - Risk of reaching hypoglycemic levels in blood glucose.
- False Negative
  - Does not detect a meal
  - SAR 3 is least favorable
    - Five errors (one false positive and three false negatives).
    - Two meal errors were the same as the other two algorithms
    - Insulin increase would beat the alarm

From the data collected, the algorithm requiring only one alarm seems to function as the best detector for a meal, however because the data was for a small sample more analysis must be done the determine the number of alarms necessary and tune other parameters.

Future Work

The next goal is to determine the best alarm quantitatively using MATLAB. Further analysis of the alarm parameters will be researched using a Receiver Operating Characteristic curve. The curve will compare the false positives with the true positives and determining what the best number of alarms should be, as well as inspecting both the amount of and shape of the insulin curve.

Acknowledgments

I would like to thank my mentor Rebecca Harvey for advising me, EUREKA for funding my research this summer and National Institutes of Health for providing financial support for this research.

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