Gasteroparesis Study

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Statistical Analysis Plan

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Retrospective Study on *adults with type 1 diabetes on hybrid closed-loop*, two group comparison:

1. Gastroparesis (problem with stomach not emptying food)
2. No gastroparesis
   1. Age, sex, an diabetes duration matched

Hypotheses:

1. Glycemic control will be better in adults with type 1 diabetes and gastroparesis on hybrid closed-loop with a known diagnosis of gastroparesis.
2. Hypoglycemic (below 70) and hyperglycemic (above 180) events will be reduced in adults with type 1 diabetes and gastroparesis on hybrid closed-loop.

Variables:

1. Demographics, diabetes history, medications, complications, pre-meal and post-meal glycemic control, serum glycosylated hemoglobin, total insulin dose, episodes of DKA, hypoglycemia, change in carb ratio
2. Outcomes: A1c, CGM metrics (24-hour mean glucose; day time 6 AM to 9:55 PM and night time 10 PM to 5:55 AM, and glycemic variability-CV, % time spent in hypo (below 70), normal (70-180) and hyper (above 180))
   1. A1c: baseline vs 6 months (change)
   2. CGM: 3 time points
      1. -3 to 0 months
      2. 0 to 3 months
      3. 3 to 6 months
      4. Low and hyperglycemia (normalized by how many days I was worn)

Data Analysis Plan:

1. Give Nicole a template for cleaning data
2. Table 1: Case/Control (gastro/no gastro) columns, rows for:
   1. Baseline characteristics: age, sex, diabetes duration, duration of gastroparesis, mean GCI score, A1c, BMI or weight, avg daily basal (units/Kg), avg daily bolus (units/kg), avg active insulin time (BE SURE THEY ARE BASELINE, NOT MEAN OVER TIME)
   2. Treatment, current symptoms, history of severe hypoglycemia or DKA to be described in the text
   3. Are any repeated measures? (A1c, CGM, etc.)- CGM data are continuous- A1c i believe, is collected only at two time-points- at baseline and 6 months.
   4. T-test/Chi-square/Fisher’s exact test for each row
3. Models:
   1. Primary outcomes- A1c
      1. Change in A1c (6months-baseline) between the groups adjusted for ?age
   2. Secondary outcome:
4. CGM metrics (as described above)- change in CGM metrics ( 6 months- baseline) by groups
   1. -3 to 0 months vs.
   2. 0- 3 months vs.
   3. 3-6 months
5. Change in Insulin: Carb ratio ( baseline to 6 months) between the groups- this is mainly descriptive
6. Change in active insulin time, sensitivity (baseline to 6 months) by groups- again descriptive.
7. Change in basal
8. Change in bolus
9. Change in weight
10. Plots:
    1. Figure 1: A1C
       1. Make this into a boxplot
       2. Viral to check if there is a third timepoint
    2. Figure 2: CGM
       1. 3 panel boxplot:
          1. 24 hour mean glucose
          2. Daytime mean glucose
          3. Nighttime mean glucose
       2. 1 supplementary materials boxplot:
          1. CV of glucose
       3. Still split by gastro/control at pre, post-1 and post-2
    3. Figure 3: % time in hypo/hyper
       1. Boxplot for:
          1. Hypo (by group and period)
          2. Hyper (by group and period)
       2. Need to experiment with this – 2 panel plot? (we don’t need to plot “normal”)