Gasteroparesis Study

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# Statistical Methods

Throughout the results, the three periods will be abbreviated as: + Pre: Months -3 to 0 pre-670G + Post-1: Months 0 to 3 post-670G + Post-2: Months 3 to 6 post-670G

Demographics and clinical characteristics were summarized using median and interquartile range (IQR) or count and proportion (%). Changes in variables of interest between any two periods were calculated as differences. Comparisons between groups were performed using Wilcoxon rank sum tests or Fisher’s exact tests, due to the small sample size. Wilcoxon signed rank tests were used to compare changes between two periods within a group. Linear regression was used to test for an association between the change (pre-670G minus post-670G) in A1C (outcome) with Group (gastroparesis versus control), adjusting for age.

# Summary Statistics

**Table 1: Clinical Characteristics, by Group**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All (n=14) | Gastroparesis (n=5) | Control (n=9) | P Value |
| **Age (years)** | 49.5 (45.5, 53.75) | 49 (45, 54) | 50 (47, 53) | 1 |
| **Gender**\*\* |  |  |  | 1 |
| FEMALE | 6 (43%) | 2 (40%) | 4 (44%) |  |
| MALE | 8 (57%) | 3 (60%) | 5 (56%) |  |
| **Years with Diabetes** | 32 (21, 37.5) | 31 (23, 35) | 33 (21, 38) | 1 |
| **Mean Weight over Pre and Post2** | 167.5 (142.75, 199.5) | 165 (139.5, 170) | 197.5 (152.5, 200) | 0.6993 |
| **Mean Basal over Pre and Post2** | 21.5 (13.75, 31) | 22.5 (19.5, 29) | 20.5 (12, 31.5) | 0.6064 |
| **Mean Daily Bolus over Pre and Post2** | 16 (11.75, 27.38) | 18.5 (13.5, 24) | 12.5 (11.5, 28.5) | 0.7383 |
| **Mean Active Insulin Hours over Pre and Post2** | 3.5 (3.16, 3.59) | 3.5 (3.12, 3.62) | 3.5 (3.25, 3.5) | 1 |
| **Mean Carb Ratio** | 10.17 (9.36, 12.38) | 10.2 (10.08, 12.5) | 10.15 (9.15, 12) | 0.8981 |

Table 1 compares basic demographics and clinical characteristics between the Gastroparesis and Control groups. The two groups were similar in all variables.

**Table 2: Clinical Characteristics, Gastroparesis Group**

|  |  |
| --- | --- |
| Characteristic | All (n=5) |
| **Years from Dx of Gastroparesis to 1st CGM placement** | 4.25 (3.69, 5.87) |
| **Median GCI Score: Pre** | 2.5 (1.5, 3.25) |
| **Median GCI Score: Post2** | 3 (1.5, 3.5) |

The median time from diagnosis of gastroparesis to the 670G placement was 4.2 years. There was not a significant difference between GCI scores pre versus post (2.5 vs. 3; p=1).

**Table 3: CGM Amount of Wear**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All (n=14) | Gastroparesis (n=5) | Control (n=9) | P Value |
| **Total Sensor Readings, Pre** | 8325 (4992.25, 17093.5) | 8145 (5467, 8552) | 8505 (4834, 25836) | 0.5185 |
| **Total Sensor Readings, Post-1** | 10028 (6918, 15584.5) | 8892 (6641, 10272) | 13369 (7749, 23639) | 0.3636 |
| **Total Sensor Readings, Post-2** | 27071 (19018.75, 30687.5) | 25768 (8724, 27417) | 28015 (25312, 51389) | 0.1898 |
| **Total Sensor Readings, overall** | 50548.5 (32064.25, 80184) | 37345 (26168, 42203) | 74598 (57468, 87932) | 0.029 |
| **Pre period length, days** | 47.46 (34.48, 100.18) | 34.42 (30.43, 34.65) | 82.93 (58.28, 116.42) | 0.012 |
| **Post-1 period length, days** | 38.86 (26.68, 76.87) | 33.7 (25.59, 39.78) | 72.94 (29.93, 97.64) | 0.2977 |
| **Post-2 period length, days**\* | 247.34 (134.25, 294.43) | 265.67 (121.54, 456.52) | 229.01 (172.39, 273.48) | 0.7972 |
| **Total length, days**\* | 353.6 (315.8, 488.42) | 309.98 (177.02, 532.05) | 368.62 (335.03, 471.47) | 0.6993 |
| **Pre average sensor readings per day** | 236.93 (138.43, 266.19) | 273.54 (236.6, 281.05) | 186.89 (102.56, 243.9) | 0.0829 |
| **Post-1 average sensor readings per day** | 257.54 (244.17, 259.32) | 259.62 (259.48, 263.88) | 250.34 (239.31, 257.14) | 0.002 |
| **Post-2 average sensor readings per day** | 146.5 (97.17, 246.29) | 96.99 (8.09, 236.49) | 189.03 (98.15, 249.56) | 0.3636 |
| **Overall average sensor readings per day** | 210.07 (155.94, 247.3) | 214.47 (166.18, 256.55) | 205.67 (152.52, 243.28) | 0.5185 |

Table 3 describes the amount of CGM data we have for each period and each group.

# Primary Outcome: A1C

**Table 3a: A1C Summary Statistics**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All (n=14) | Gastroparesis (n=5) | Control (n=9) | P Value |
| **A1C, Pre** | 7.55 (7.32, 7.77) | 7.3 (7, 7.5) | 7.7 (7.4, 7.9) | 0.0522 |
| **A1C, Post2** | 7.15 (6.73, 7.2) | 7.1 (7, 7.2) | 7.2 (6.7, 7.9) | 0.7863 |
| **Mean A1C over Pre and Post2** | 7.3 (7.08, 7.6) | 7.15 (7, 7.35) | 7.45 (7.2, 7.75) | 0.1611 |
| **Change in A1c (pre-post2)** | 0.35 (0.3, 0.65) | 0.3 (0.3, 0.3) | 0.5 (0.3, 0.9) | 0.2003 |

A1C levels in the control group were slightly higher compared to the gastroparesis group in the Pre period. There was not a significant difference between groups in A1c levels during Post-2, or in the change between Post-2 versus Pre.

There was a significant difference overall between Pre and Post-2 A1C values (7.55 vs. 7.15p=0.02). Within subjects with Gastroparesis, there was not a significant difference between Pre and Post-2 A1C (7.3 vs. 7.1; p=0.1). Within control subjects, there also was not a significant difference between Pre and Post-2 A1C (7.7 vs. 7.2;p=0.06).

**Table 3b: A1C Model: Outcome Pre A1C minus Post-2 A1C**

|  |  |  |
| --- | --- | --- |
| Predictor | Estimate (95% CI) | P Value |
| - Control | 0.28 (-0.39, 0.95) | 0.3731 |
| Age (years) | -0.01 (-0.07, 0.05) | 0.7639 |

After adjusting for age, Group was not significantly associated with the change in A1C from Pre to Post-2 (p=0.3731)

# Secondary Outcome: CGM

**Table 4a: CGM Summary Statistics**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All (n=14) | Gastroparesis (n=5) | Control (n=9) | P Value |
| **24-Hour Mean Glucose, Pre** | 170.8 (159.7, 190.9) | 167.6 (157.8, 191.6) | 173.8 (161.2, 188.7) | 0.6064 |
| **24-Hour Mean Glucose, Post-1** | 157.2 (149.5, 160.6) | 156.7 (153.2, 159.2) | 157.2 (148.3, 163.1) | 0.4376 |
| **24-Hour Mean Glucose, Post-2** | 155 (147.6, 163.1) | 150 (148.9, 156.2) | 159 (147.1, 168) | 0.2977 |
| **Daytime Mean Glucose, Pre** | 168.6 (160, 193.3) | 167.7 (159.1, 192.3) | 169.6 (161.5, 193.7) | 0.6993 |
| **Daytime Mean Glucose, Post-1** | 161.5 (155.2, 168.2) | 159.8 (157.7, 161.3) | 163.2 (154.3, 168.5) | 0.4376 |
| **Daytime Mean Glucose, Post-2** | 155.8 (150.7, 169.5) | 153.6 (150.6, 156) | 164.8 (151, 171.6) | 0.4376 |
| **Nighttime Mean Glucose, Pre** | 168.4 (156.2, 186.5) | 167.2 (154.2, 170.3) | 169.7 (162.1, 190.3) | 0.6064 |
| **Nighttime Mean Glucose, Post-1** | 145.3 (139, 149.3) | 137.8 (133.2, 145.7) | 145.7 (142.6, 150.5) | 0.3636 |
| **Nighttime Mean Glucose, Post-2** | 146.8 (137.9, 152) | 132.7 (131, 148.6) | 149.3 (141.7, 152.3) | 0.2398 |
| **Glucose Variability (cv), Pre** | 0.4 (0.3, 0.4) | 0.3 (0.3, 0.4) | 0.4 (0.3, 0.4) | 0.3636 |
| **Glucose Variability (cv), Post-1** | 0.3 (0.3, 0.4) | 0.3 (0.3, 0.4) | 0.3 (0.3, 0.4) | 0.3636 |
| **Glucose Variability (cv), Post-2** | 0.4 (0.3, 0.4) | 0.3 (0.3, 0.4) | 0.4 (0.3, 0.4) | 0.4376 |

Table 4a reports the median (IQR) of various CGM summary measurements. None of the CGM measures showed significant differences between patients with gastroparesis and controls.

Overall 24-hour mean glucose was significantly different between Pre and Post-1 (p=410^{-4}), as well as between Post-1 and Post-2 (p=0.2958). Within the control group, 24-hour mean glucose was also different between Pre and Post-1 (p=0.004), and between Post-1 and Post-2 (p=0.57). Within the gastroparesis group, 24-hour mean glucose measurements did not differ between any period.

Daytime mean glucose was significantly different between Pre and Post-1 (p=410^{-4}), and between Post-1 and Post-2 (p=0.2166). Within the control group, daytime mean glucose was also different between Pre and Post-1 (p=0.008), and between Post-1 and Post-2 (p=0.301). Within the gastroparesis group, none of the SD glucose measurements differed between period.

Nighttime mean glucose was significantly different between Pre and Post-1 (p=910^{-4}), and between Post-1 and Post-2 (p=0.9032). Within the control group, daytime mean glucose was also different between Pre and Post-1 (p=0.004), and between Post-1 and Post-2 (p=0.652). Within the gastroparesis group, none of the SD glucose measurements differed between period.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All (n=14) | Gastroparesis (n=5) | Control (n=9) | P Value |
| **% of time in hypo (<70), Pre** | 1.9 (1.3, 2.8) | 1.6 (0.1, 4) | 2.1 (1.4, 2.8) | 0.8981 |
| **% of time in hypo (<70), Post-1** | 2.4 (1.3, 3.1) | 2.6 (2.2, 3) | 1.7 (1.2, 3.1) | 0.8981 |
| **% of time in hypo (<70), Post-2** | 1.8 (1.1, 3.2) | 2.2 (1.3, 3.2) | 1.2 (1.1, 3) | 0.7972 |
| **Percent of time in normal (70-180), Pre** | 55.9 (44.5, 60.9) | 55.4 (43.7, 60.7) | 56.3 (46.6, 60.9) | 0.8981 |
| **Percent of time in normal (70-180), Post-1** | 68.4 (66.5, 74.1) | 69.5 (66.2, 78.1) | 68 (67.4, 73.3) | 0.6064 |
| **Percent of time in normal (70-180), Post-2** | 68.7 (66.3, 76.2) | 73.4 (67.6, 80.2) | 67.4 (63.9, 74.4) | 0.2398 |
| **Percent of time in hyper (>180), Pre** | 41.7 (34.1, 54.7) | 41.6 (33.6, 56.9) | 41.7 (35.4, 52.5) | 1 |
| **Percent of time in hyper (>180), Post-1** | 29.2 (23.5, 31.5) | 28.8 (22.2, 31.6) | 29.4 (24.4, 31.5) | 0.6064 |
| **Percent of time in hyper (>180), Post-2** | 28.7 (21.8, 32.5) | 25.6 (20.5, 29.8) | 30.4 (22.2, 35.6) | 0.1898 |

**Table 4b: CGM Changes**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All (n=14) | Gastroparesis (n=5) | Control (n=9) | P Value |
| **24-Hour Mean Glucose Change (Pre-Post1)** | 11.9 (5.7, 30.9) | 10.8 (8.7, 32.5) | 12.9 (4.7, 26.3) | 0.8981 |
| **24-Hour Mean Glucose Change (Post1-Post2)** | 1.7 (-1.3, 3.9) | 3.9 (1, 4.2) | 0.4 (-1.8, 3.3) | 0.3636 |
| **24-Hour Mean Glucose Change (Pre-Post2)** | 14.3 (3.9, 31.8) | 17.5 (2.1, 33.5) | 13.4 (9.3, 26.7) | 0.7972 |
| **Daytime Mean Glucose Change (Pre-Post1)** | 10.6 (4, 28.6) | 10 (6.4, 32) | 11.3 (3.6, 18.4) | 0.7972 |
| **Daytime Mean Glucose Change (Post1-Post2)** | 2.5 (-1.4, 4.3) | 3.8 (0.2, 4.1) | 2.2 (-1.6, 4.3) | 0.7972 |
| **Daytime Mean Glucose Change (Pre-Post2)** | 15.3 (5.6, 28.4) | 17.1 (5.5, 32.2) | 15 (5.8, 16) | 0.7972 |
| **Nighttime Mean Glucose Change (Pre-Post1)** | 19.6 (11.5, 43.3) | 21.5 (6.2, 37.2) | 19.5 (12.8, 45.4) | 0.8981 |
| **Nighttime Mean Glucose Change (Post1-Post2)** | -2.2 (-3.4, 3.9) | 2.1 (-2.9, 3.7) | -2.5 (-7.9, 4) | 0.6064 |
| **Nighttime Mean Glucose Change (Pre-Post2)** | 16.2 (8.6, 49.2) | 18.6 (3.2, 39.3) | 13.9 (8.7, 52.4) | 0.8981 |
| **CV Change (Pre-Post1)** | 0 (0, 0.1) | 0 (0, 0) | 0 (0, 0.1) | 0.7972 |
| **CV Change (Post1-Post2)** | 0 (0, 0) | 0 (0, 0) | 0 (0, 0) | 0.6993 |
| **CV Change (Pre-Post2)** | 0 (0, 0) | 0 (0, 0.1) | 0 (0, 0) | 0.6064 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All (n=14) | Gastroparesis (n=5) | Control (n=9) | P Value |
| **% Time in Hypo, Change (Pre-Post1)** | 0.1 (-0.5, 1.1) | -0.1 (-1, 1.8) | 0.2 (-0.4, 0.4) | 1 |
| **% Time in Hypo, Change (Post1-Post2)** | 0.3 (-0.1, 0.4) | 0.2 (-0.2, 0.4) | 0.4 (0, 0.5) | 0.7972 |
| **% Time in Hypo, Change (Pre-Post2)** | 0.2 (-0.1, 0.8) | 0.1 (-0.6, 2.6) | 0.3 (0, 0.5) | 1 |
| **% Time in Normal, Change (Pre-Post1)** | -12.4 (-21.5, -5.6) | -14.1 (-21.5, -5.5) | -12.4 (-21.4, -6) | 0.6993 |
| **% Time in Normal, Change (Post1-Post2)** | -1 (-2, 1.3) | -1.4 (-2.1, -1) | -0.9 (-1.7, 1.6) | 0.6993 |
| **% Time in Normal, Change (Pre-Post2)** | -11.9 (-23, -7.3) | -18 (-22.6, -6.9) | -10.3 (-23.1, -8.4) | 0.8981 |
| **% Time in Hyper, Change (Pre-Post1)** | 11.2 (5.9, 24.1) | 12.8 (5.7, 24.3) | 11 (6.5, 23.6) | 0.7972 |
| **% Time in Hyper, Change (Post1-Post2)** | 1.3 (-1.5, 1.7) | 1.7 (1.3, 1.8) | 1.1 (-1.7, 1.6) | 0.6064 |
| **% Time in Hyper, Change (Pre-Post2)** | 10.9 (4.9, 24.8) | 16 (3.8, 25.6) | 8.7 (8.1, 24.8) | 0.6993 |

**Table 5: Other Changes**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All (n=14) | Gastroparesis (n=5) | Control (n=9) | P Value |
| **Change in Carb Ratio** | 2.4 (1.5, 3.2) | 3 (0.4, 3.1) | 2.1 (1.5, 3.9) | 0.6888 |
| **Change in Active Insulin Time** | 60 (33.8, 82.5) | 45 (30, 60) | 60 (60, 90) | 0.4111 |
| **Change in Weight (Pre-Post-2)** | -0.5 (-3.5, 7.2) | -2 (-2, 5) | 0 (-4, 8) | 1 |
| **Change in Daily Basal (pre minus post)** | 1 (-1.8, 2.8) | 1 (-1, 4) | 1 (-2, 2) | 0.9463 |
| **Change in Daily Bolus (pre minus post)** | -3 (-5, -1.2) | -1 (-5, 3) | -3 (-13, -3) | 0.1786 |