Latino Program - Gerard Gonzalez

Kristen Campbell

jULY 9, 2019

#Statistical Methods There were a total of 75 participants and 16 controls in the data with differing numbers of visits during baseline, year 1, year 2 and year 3. Only those who were followed at least 3 years were included in this analysis. Baseline visit was indicated by clinician. Visits were categorized into 12 visit windows Â±1.5 months around target visit times (three month intervals after baseline). Up to 3 years of data were analyzed. If there was more than one visit in a window, the visit nearest to the target was selected. The last visit of each year was utilized for descriptive statistics and analyses.

If a participant was less than 12 years of age during year 1 and transitioned to greater than or equal to 12 years of age during that year, the participant was considered less than 12 years old during the entirety of year 1. If a participant was less than 12 years old during year 2 and transitioned to greater than or equal to 12 years old during that year, the participant was considered less than 12 years old during the entirety of year 2. The same was done for year 3 age categories. The checks per day variable was only reported for patients who were never on CGM during a given year. Descriptive statistics were obtained for A1c and checks per day. The summary was stratified by treatment group and age group (<12 years old, ???12 years old).  
Linear mixed effects models were used to test whether there was a significant difference in the trend of A1c from baseline to year 3 by treatment group, after adjusting for age category, diabetes duration, and technology type (CGM only, Pump only, neither, or both). Least squares were used to test for whether there was a significant difference in A1c between treatment groups at baseline, year 1, year 2, and year 3. As a sensitivity analysis, the model was also fit separately for each age group. The linear mixed effects models were repeated for the outcome of checks per day, to test if there was a difference between LP and control patients in terms of checks per day during each year of the program.

Descriptive statistics for pump usage and CGM use by time period, age category, and treatment group were obtained. If a participant ever used a pump during a time period, pump usage was considered to be ‘Yes.’ If a participant never used a pump during a visit for a time period, pump usage was considered to be ‘No.’ The same logic was used for CGM use. A frequency and percent of pump usage and CGM usage for participants during baseline, year1, year 2, and year 3 were obtained by age cohort. Using all patients that had both baseline and year 3 pump/CGM data, a paired t-test reported whether there was significant change in usage from baseline to year 3.

#Summary Statistics **Table Demographics**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All (n=90) | Control (n=16) | LP (n=74) | P Value |
| **Gender** |  |  |  | 0.4409 |
| F | 50 (56%) | 7 (44%) | 43 (58%) |  |
| M | 40 (44%) | 9 (56%) | 31 (42%) |  |
| **Age at baseline** | 11.61Â±3.59 | 11.81Â±4.2 | 11.57Â±3.48 | 0.8299 |
| **Age group at baseline** |  |  |  | 0.4834 |
| greater than or equal to 12 | 52 (58%) | 11 (69%) | 41 (55%) |  |
| Less than 12 | 38 (42%) | 5 (31%) | 33 (45%) |  |
| **Duration of Diagnosis at Baseline** | 6.79Â±3.59 | 10.31Â±3.81 | 6.03Â±3.08 | 4e-04 |
| **A1C at Baseline** | 9.57Â±2.25 | 9.15Â±1.63 | 9.66Â±2.36 | 0.3094 |
| **Checks per day at Baseline** | 3.9Â±1.81 | 3.88Â±1.68 | 3.91Â±1.85 | 0.9597 |

**Table 1a: . Descriptive statistics for Latino Program group by year (of last value per time period)**

|  |  |  |
| --- | --- | --- |
| variable | Control | Trt |
| Base1: A1C - Last Measure in Year |  |  |
| meanÂ±sd | 9.15Â±1.63 | 9.66Â±2.36 |
| n | 16 | 74 |
| Year1: A1C - Last Measure in Year |  |  |
| meanÂ±sd | 8.99Â±1.43 | 9.53Â±2.12 |
| n | 15 | 74 |
| Year2: A1C - Last Measure in Year |  |  |
| meanÂ±sd | 9.27Â±1.92 | 10.22Â±2.46 |
| n | 16 | 74 |
| Year3: A1C - Last Measure in Year |  |  |
| meanÂ±sd | 9.9Â±1.78 | 10.21Â±2.2 |
| n | 16 | 75 |
| Base1: Checks per Day - Last Measure in Year (CGM=No) |  |  |
| meanÂ±sd | 3.88Â±1.68 | 3.91Â±1.85 |
| n | 16 | 74 |
| Year1: Checks per Day - Last Measure in Year (CGM=No) |  |  |
| meanÂ±sd | 3.51Â±1.81 | 3.78Â±2.18 |
| n | 15 | 74 |
| Year2: Checks per Day - Last Measure in Year (CGM=No) |  |  |
| meanÂ±sd | 3.89Â±2.13 | 3.97Â±2.28 |
| n | 16 | 74 |
| Year3: Checks per Day - Last Measure in Year (CGM=No) |  |  |
| meanÂ±sd | 3.57Â±2.3 | 3.29Â±2.14 |
| n | 16 | 75 |

Table 1 presents descriptive statistics of A1c and Checks per Day by time period, regardless of age group category.

**Table 2. A1c and BMI Descriptive Statistics by year, age category and group**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| variable | ControlYoung | ControlOld | TrtYoung | TrtOld |
| Base1: A1C - Last Measure in Year |  |  |  |  |
| meanÂ±sd | 8.44Â±0.75 | 9.473Â±1.843 | 9.218Â±2.06 | 2 10.012Â±2.548 |
| n | 5 | 11 | 33 | 41 |
| Year1: A1C - Last Measure in Year |  |  |  |  |
| meanÂ±sd | 8.96Â±0.321 | 9Â±1.767 | 8.727Â±1.62 | 5 10.168Â±2.262 |
| n | 5 | 10 | 33 | 41 |
| Year2: A1C - Last Measure in Year |  |  |  |  |
| meanÂ±sd | 9.32Â±1.704 | 9.245Â±2.096 | 8.773Â±1.73 | 9 10.827Â±2.477 |
| n | 5 | 11 | 22 | 52 |
| Year3: A1C - Last Measure in Year |  |  |  |  |
| meanÂ±sd | 9.3Â±0.992 | 10.168Â±2.019 | 8.556Â±0.57 | 7 10.656Â±2.27 |
| n | 5 | 11 | 16 | 59 |
| Base1: Checks per Day - Last Measure in Year (CGM=No) |  |  |  |  |
| meanÂ±sd | 5.24Â±1.694 | 3.264Â±1.328 | 4.606Â±1.56 | 2 3.341Â±1.883 |
| n | 5 | 11 | 33 | 41 |
| Year1: Checks per Day - Last Measure in Year (CGM=No) |  |  |  |  |
| meanÂ±sd | 4.3Â±2.791 | 3.11Â±1.046 | 5.16Â±2.053 | 2.774Â±1.663 |
| n | 5 | 10 | 33 | 41 |
| Year2: Checks per Day - Last Measure in Year (CGM=No) |  |  |  |  |
| meanÂ±sd | 4.36Â±1.466 | 3.65Â±2.427 | 5.917Â±2.34 | 5 3.187Â±1.736 |
| n | 5 | 11 | 22 | 52 |
| Year3: Checks per Day - Last Measure in Year (CGM=No) |  |  |  |  |
| meanÂ±sd | 5.067Â±4.02 | 3.067Â±1.459 | 5.3Â±2.447 | 3.001Â±1.96 |
| n | 5 | 11 | 16 | 59 |

Table 2 presents descriptive statistics of A1c and Checks per Day by treatment group, time period and age category.

#A1C Results

**Table 3a. A1c Over Time: WHOLE COHORT**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Value | Std.Error | p-value |
| (Intercept) | 5.073 | 0.814 | 0.000 |
| baseline\_a1c | 0.517 | 0.057 | 0.000 |
| factor(yeargrouping)Base1 | -0.702 | 0.516 | 0.175 |
| factor(yeargrouping)Year1 | -0.742 | 0.525 | 0.159 |
| factor(yeargrouping)Year2 | -0.544 | 0.513 | 0.290 |
| groupLess than 12 | -0.663 | 0.271 | 0.015 |
| factor(trt\_grp)LP | 0.157 | 0.513 | 0.760 |
| duration\_of\_diagnosis | 0.030 | 0.040 | 0.455 |
| technology\_type\_inyearCGM and Pump | 0.167 | 0.389 | 0.668 |
| technology\_type\_inyearCGM Only | 0.591 | 0.412 | 0.152 |
| technology\_type\_inyearPump Only | -0.798 | 0.266 | 0.003 |
| factor(yeargrouping)Base1:factor(trt\_grp)LP | 0.356 | 0.566 | 0.530 |
| factor(yeargrouping)Year1:factor(trt\_grp)LP | 0.343 | 0.574 | 0.551 |
| factor(yeargrouping)Year2:factor(trt\_grp)LP | 0.733 | 0.564 | 0.195 |

**Table 3b: Difference between Latino Program and Control A1c at each timepoint: WHOLE COHORT**

|  |  |  |  |
| --- | --- | --- | --- |
| contrast | estimate | SE | p.value |
| c\_base1 | 0.513 | 0.504 | 0.311 |
| c\_year1 | 0.500 | 0.514 | 0.333 |
| c\_year2 | 0.890 | 0.513 | 0.086 |
| c\_year3 | 0.157 | 0.513 | 0.760 |

Table 3A-3B show results of mixed effects modeling looking at whether there was a significant difference in A1c in Treatment and Control groups at baseline, year 1 and year 2 (table 3A), as well as results of specific contrasts of interest. There is not a significant difference in trend of A1c over time between groups (table 3A, p=0.64). There was no significant difference in A1c between groups at baseline, year 1 or year 2 (table 3B, p=xxx, p=xxx, p=xxx).

**Table 3c: Difference between Latino Program and Control A1c: <12 YEARS**

|  |  |  |  |
| --- | --- | --- | --- |
| contrast | estimate | SE | p.value |
| c\_base1\_young | 0.582 | 0.668 | 0.390 |
| c\_year1\_young | -0.418 | 0.673 | 0.538 |
| c\_year2\_young | -0.634 | 0.712 | 0.380 |
| c\_year3\_young | -1.203 | 0.738 | 0.112 |

There is not a significant difference in trend of A1c over time between groups (table 3A, p=0.304).

**Table 3d: Difference between Latino Program and Control A1c: 12+ YEARS**

|  |  |  |  |
| --- | --- | --- | --- |
| contrast | estimate | SE | p.value |
| c\_base1\_old | 0.240 | 0.672 | 0.723 |
| c\_year1\_old | 0.784 | 0.688 | 0.258 |
| c\_year2\_old | 1.463 | 0.671 | 0.033 |
| c\_year3\_old | 0.418 | 0.662 | 0.530 |

There is not a significant difference in trend of A1c over time between groups (table 3A, p=0.301).

**Table 3e: Difference between Latino Program and Control A1c: PUMP**

|  |  |  |  |
| --- | --- | --- | --- |
| contrast | estimate | SE | p.value |
| c\_base1\_pump | 0.432 | 1.319 | 0.745 |
| c\_year1\_pump | 0.764 | 1.038 | 0.467 |
| c\_year2\_pump | -1.970 | 0.911 | 0.037 |
| c\_year3\_pump | -1.808 | 0.819 | 0.034 |

There is not a significant difference in trend of A1c over time between groups (table 3A, p=0.025).

**Table 3f: Difference between Latino Program and Control A1c: NO PUMP**

|  |  |  |  |
| --- | --- | --- | --- |
| contrast | estimate | SE | p.value |
| c\_base1\_nopump | 0.330 | 0.531 | 0.536 |
| c\_year1\_nopump | 0.410 | 0.559 | 0.466 |
| c\_year2\_nopump | 1.695 | 0.578 | 0.004 |
| c\_year3\_nopump | 1.132 | 0.645 | 0.083 |

There is not a significant difference in trend of A1c over time between groups (table 3A, p=0.118).

#Checks Per Day Results

**Table 4a. Checks Per Day Over Time: WHOLE COHORT**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Value | Std.Error | p-value |
| (Intercept) | 1.481 | 0.628 | 0.019 |
| baseline\_checks | 0.461 | 0.062 | 0.000 |
| factor(yeargrouping)Base1 | 0.398 | 0.552 | 0.472 |
| factor(yeargrouping)Year1 | -0.132 | 0.560 | 0.814 |
| factor(yeargrouping)Year2 | 0.268 | 0.558 | 0.632 |
| groupLess than 12 | 0.978 | 0.259 | 0.000 |
| factor(trt\_grp)LP | -0.290 | 0.519 | 0.578 |
| duration\_of\_diagnosis | -0.018 | 0.035 | 0.614 |
| technology\_type\_inyearPump Only | 1.416 | 0.241 | 0.000 |
| factor(yeargrouping)Base1:factor(trt\_grp)LP | -0.006 | 0.616 | 0.992 |
| factor(yeargrouping)Year1:factor(trt\_grp)LP | 0.287 | 0.624 | 0.646 |
| factor(yeargrouping)Year2:factor(trt\_grp)LP | 0.063 | 0.623 | 0.920 |

p=0.954

**Table 4b: Difference between Latino Program and Control Checks Per Day at each timepoint: WHOLE COHORT.**

|  |  |  |  |
| --- | --- | --- | --- |
| contrast | estimate | SE | p.value |
| c\_base1 | -0.296 | 0.444 | 0.506 |
| c\_year1 | -0.004 | 0.455 | 0.994 |
| c\_year2 | -0.228 | 0.468 | 0.628 |
| c\_year3 | -0.290 | 0.519 | 0.578 |

**Table 4c: Difference between Latino Program and Control Checks Per Day: <12 YEARS**

|  |  |  |  |
| --- | --- | --- | --- |
| contrast | estimate | SE | p.value |
| c\_base1\_young | -0.420 | 0.712 | 0.559 |
| c\_year1\_young | 0.703 | 0.721 | 0.336 |
| c\_year2\_young | 0.684 | 0.769 | 0.381 |
| c\_year3\_young | -0.398 | 1.034 | 0.703 |

p=0.507

**Table 4d: Difference between Latino Program and Control A1c: 12+ YEARS**

|  |  |  |  |
| --- | --- | --- | --- |
| contrast | estimate | SE | p.value |
| c\_base1\_old | 0.059 | 0.543 | 0.913 |
| c\_year1\_old | -0.310 | 0.558 | 0.581 |
| c\_year2\_old | -0.629 | 0.561 | 0.267 |
| c\_year3\_old | -0.108 | 0.588 | 0.855 |

p=0.772

**Table 4e: Difference between Latino Program and Control A1c: PUMP**

|  |  |  |  |
| --- | --- | --- | --- |
| contrast | estimate | SE | p.value |
| c\_base1\_pump | -0.661 | 1.769 | 0.711 |
| c\_year1\_pump | -2.316 | 1.413 | 0.112 |
| c\_year2\_pump | -3.392 | 1.350 | 0.018 |
| c\_year3\_pump | -1.995 | 1.378 | 0.159 |

p=0.477

**Table 4f: Difference between Latino Program and Control A1c: NO PUMP**

|  |  |  |  |
| --- | --- | --- | --- |
| contrast | estimate | SE | p.value |
| c\_base1\_nopump | -0.051 | 0.409 | 0.902 |
| c\_year1\_nopump | 0.210 | 0.434 | 0.629 |
| c\_year2\_nopump | 0.120 | 0.451 | 0.790 |
| c\_year3\_nopump | 0.584 | 0.510 | 0.256 |

p=0.751

#Pump Use Results **Table 5a: Frequency of pump usage in greater than or equal to 12 years cohort by time period in the Latino Program group**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | Base1 (n=41) | Year1 (n=41) | Year2 (n=52) | Year3 (n=59) |
| **Any Pump Use in Given Year**\*\* |  |  |  |  |
| Yes | 4 (10%) | 7 (17%) | 14 (27%) | 21 (36%) |
| No | 37 (90%) | 34 (83%) | 38 (73%) | 38 (64%) |

Year 1 versus Year 3 pump use: 0.013

**Table 5B. Frequency of pump usage in greater than or equal to 12 years cohort by time period in the Control group**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | Base1 (n=11) | Year1 (n=10) | Year2 (n=11) | Year3 (n=11) |
| **Any Pump Use in Given Year**\*\* |  |  |  |  |
| Yes | 0 (0%) | 1 (10%) | 2 (18%) | 2 (18%) |
| No | 11 (100%) | 9 (90%) | 9 (82%) | 9 (82%) |

Year 1 versus Year 3 pump use: 0.48

**Table 6A. Frequency of pump usage in the less than 12 years cohort by time period in the Latino Program group**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | Base1 (n=33) | Year1 (n=33) | Year2 (n=22) | Year3 (n=16) |
| **Any Pump Use in Given Year**\*\* |  |  |  |  |
| Yes | 6 (18%) | 14 (42%) | 13 (59%) | 12 (75%) |
| No | 27 (82%) | 19 (58%) | 9 (41%) | 4 (25%) |

Year 1 versus Year 3 pump use: 0.008

**Table 6B. Frequency of pump usage in the less than 12 years cohort by time period in the Control group**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | Base1 (n=5) | Year1 (n=5) | Year2 (n=5) | Year3 (n=5) |
| **Any Pump Use in Given Year**\*\* |  |  |  |  |
| Yes | 1 (20%) | 1 (20%) | 1 (20%) | 2 (40%) |
| No | 4 (80%) | 4 (80%) | 4 (80%) | 3 (60%) |

Year 1 versus Year 3 pump use: 1

**Table 7A. Frequency of CGM usage in greater than or equal to 12 years cohort by time period in the Latino Program group**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | Base1 (n=41) | Year1 (n=41) | Year2 (n=52) | Year3 (n=59) |
| **Any CGM Use in Given Year**\*\* |  |  |  |  |
| Yes | 0 (0%) | 0 (0%) | 7 (13%) | 17 (29%) |
| No | 41 (100%) | 41 (100%) | 45 (87%) | 42 (71%) |

Year 1 versus Year 3 pump use: 0.013

**Table 7B. Frequency of CGM usage in greater than or equal to 12 years cohort by time period in the Control group**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | Base1 (n=11) | Year1 (n=10) | Year2 (n=11) | Year3 (n=11) |
| **Any CGM Use in Given Year**\*\* |  |  |  |  |
| Yes | 0 (0%) | 0 (0%) | 1 (9%) | 2 (18%) |
| No | 11 (100%) | 10 (100%) | 10 (91%) | 9 (82%) |

Year 1 versus Year 3 pump use: 0.48

**Table 8A. Frequency of CGM usage in the less than 12 years cohort by time period in the Latino Program group**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | Base1 (n=33) | Year1 (n=33) | Year2 (n=22) | Year3 (n=16) |
| **Any CGM Use in Given Year**\*\* |  |  |  |  |
| Yes | 0 (0%) | 3 (9%) | 4 (18%) | 10 (62%) |
| No | 33 (100%) | 30 (91%) | 18 (82%) | 6 (38%) |

Year 1 versus Year 3 pump use: 0.004

**Table 8B. Frequency of CGM usage in the less than 12 years cohort by time period in the Control group**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | Base1 (n=5) | Year1 (n=5) | Year2 (n=5) | Year3 (n=5) |
| **Any CGM Use in Given Year**\*\* |  |  |  |  |
| Yes | 0 (0%) | 0 (0%) | 0 (0%) | 2 (40%) |
| No | 5 (100%) | 5 (100%) | 5 (100%) | 3 (60%) |

Year 1 versus Year 3 pump use: 0.48

**Table Sensitivity**

|  |  |  |
| --- | --- | --- |
| variable | Control | Trt |
| Base1: A1C - Last Measure in Year |  |  |
| meanÂ±sd | 8.6Â±0.76 | 10.01Â±2.47 |
| n | 4 | 11 |
| Year1: A1C - Last Measure in Year |  |  |
| meanÂ±sd | 9Â±0.36 | 8.56Â±0.82 |
| n | 4 | 11 |
| Year2: A1C - Last Measure in Year |  |  |
| meanÂ±sd | 9.72Â±1.67 | 8.42Â±1.46 |
| n | 4 | 11 |
| Year3: A1C - Last Measure in Year |  |  |
| meanÂ±sd | 9.53Â±0.99 | 8.45Â±0.5 |
| n | 4 | 11 |