# ACHIEVEMENT OF GOAL A1C (< 7%) BY US PATIENTS WITH T2DM ON BASAL INSULIN IN BOTH RANDOMIZED CONTROLLED TRIALS (RCTS) AND IN CLINICAL PRACTICE


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## ABSTRACT

Despite the efficacy of basal insulin therapy in individuals with T2DM, a significant number of patients may not achieve glycemic goals. Combined results from 11 RCTs of patients (aged ≥ 18 years) with T2DM on basal insulin (6 months' follow-up) and results from the GE Centricity electronic medical records (EMR) database (6 months' and 12 months' follow-up) were analyzed to identify those with an A1C ≥ 7%. Subjects were stratified based on plasma glucose (PG) levels (< 130 or ≥ 130 mg/dL). In the RCTs ~51% achieved A1C < 7% (recommended by the ADA for most diabetic patients). A1C < 7% was achieved by fewer patients (~27%) in the EMR database at both 6 and 12 months. Among those with A1C ≥ 7%, 55% of RCT and 27.8% and 27.7% of EMR patients at 6 and 12 months, respectively, had FPG < 130 mg/dL. Of RCT patients not achieving goal, about half had an FPG > 130 mg/dL, suggesting the need for further basal insulin titration, while those at goal likely required postprandial glucose control. In the EMR patients, > 70% likely needed additional basal insulin titration. Failure to adequately titrate basal insulin is an unmet need in many T2DM patients, even in RCTs. When basal insulin is adequately titrated and FPG is controlled, additional postprandial treatment may be needed. Understanding causes of failure to achieve control of FPG with basal insulin is another important unmet need.


## INTRODUCTION

- Type 2 diabetes mellitus (T2DM) is a progressive disease and, in most patients, intensification of treatment over time is necessary in order to maintain glycemic targets.[1]
- Hyperglycemia in T2DM is associated with macro- and microvascular complications.[2-4]
- The ADA recommends for most adults a goal glycated hemoglobin $A_1$ (A1C) of < 7.0%,[5] ideally with a fasting plasma glucose (FPG) level of < 130 mg/dL and peak postprandial glucose (PPG) level of < 180 mg/dL.[1]
- Initial treatment for T2DM tends to focus on FPG, which is a major influencing factor for A1C levels > 8.4%.[6]
- However, even with the use of basal insulin analogs, only 35-64% of patients achieve their goal A1C levels.[7]
- Thus, despite its efficacy in individuals with T2DM, there remains an unmet need for those patients who do not achieve glycemic goals with basal insulin therapy.
- Results from randomized clinical trials (RCTs) need to be translated to and bridged with clinical practice in order to help health care professionals improve real-world patient care.

## OBJECTIVES

- To assess achievement of goal A1C (< 7.0%) with basal insulin by US T2DM patients and to further characterize the population of these patients who do achieve a target FPG < 130 mg/dL.
- To compare the results from RCTs with real-world clinical practice data.

## METHODS

### Study Design and Patients

- This was a retrospective study of data from RCTs and an electronic medical records (EMR) database.
- The study analyzed prospective, randomized, controlled 24 week duration clinical studies conducted according to Good Clinical Practice standards, of patients using insulin therapy added to lifestyle modification alone, or stable oral antidiabetes drugs (OADs) therapy.
- The GE Centricity EMR database contains medical records for approximately 30 million patients in 49 US states as of 2007, with the number of physicians included in the database increasing by around 30% per year since then:
  - to include data from "real-world" clinical practice, data in the GE Centricity EMR database were included in the analysis from patients aged ≥ 18 years with a diagnosis of T2DM (ICD-9-CM diagnosis codes[8]: 250.x0 or 250.x2) who initiated basal insulin therapy between January 2005 and January 2012
  - patients had to have: EMR data available for ≥ 6 months before insulin initiation, with no previously prescribed insulin; received ≥ 1 OAD during the 6 months before insulin initiation; and ≥ 1 baseline and ≥ 1 follow-up (i.e. at 6 or 12 months post-insulin initiation) A1C measurement
- Data were included from patients in the RCTs with A1C and FPG values at 6 months and from the EMR database with A1C and FPG values at both 6 and 12 months after initiation of basal insulin

### Assessments

- The following outcomes were evaluated:
  - A1C level at 6 months (RCT and EMR data) and 12 months (EMR data only), categorized as < 7.0% or ≥ 7.0% for analysis
  - FPG level at 6 months (RCT and EMR data) and 12 months (EMR data only), categorized as < 130 mg/dL or ≥ 130 mg/dL for analysis
- Baseline demographics and clinical characteristics of those patients who achieved the A1C goal < 7.0% at follow-up were compared descriptively with those who did not achieve this glycemic target.
- Among those patients who did not achieve the goal A1C < 7.0%, the baseline demographics and clinical characteristics of those who did achieve FPG < 130 mg/dL at follow-up were compared descriptively with those who had FPG ≥ 130 mg/dL.

## RESULTS

### Patient Population

- Data from patients in 11 RCTs performed by Sanofi or predecessor companies were included (**Table 1**).[9-19]
- Patient enrollment occurred between 2000 and 2007 for the various RCTs.
- 2,975 RCT patients had A1C and FPG data available at 6 months.
- 12,562 and 14,038 EMR patients had both A1C and FPG data available at 6 months and 12 months, respectively.

**Table 1. RCTs Included in Analysis.**

| Study | Treatment/ Comparator | Treatment Duration | Patient Count | Insulin glargine, n (%) | Comparator, n (%) |
|---|---|---|---|---|---|
| Gerstein (2006)[9] | Lantus / OADs | 26 weeks | 390/405 | 197 (50.5%) | 193 (49.5%) |
| Riddle (2003)[10] | Lantus / NPH insulin | 28 weeks | 735/764 | 355 (48.30%) | 380 (51.7%) |
| Standl (2005)[11] | Lantus & Glimepiride, morning vs bedtime | 24 weeks | 624 | 624 | N/A |
| Rosenstock (2006)[12] | Lantus / rosiglitazone | 24 weeks | 216/219 | 104 (48.1%) | 112 (51.9%) |
| Meneghini (2010)[13] | Lantus / pioglitazone | 24/48 weeks | 336/353 | 159 (47.3%) | 177 (52.7%) |
| Data on file, HOE-901-4021[14] | Lantus / lispro 75/25 insulin | 24 weeks | 209/212 | 12 (53.6%) | 97 (46.4%) |
| Janka (2005)[15] | Lantus / NPH 30/70 insulin | 28 weeks | 354/371 | 174 (49.2%) | 180 (50.8%) |
| Bretzel (2008)[16] | Lantus / lispro insulin | 44 weeks | 402/415 | 198 (49.3%) | 204 (50.7%) |
| Yki-Järvinen (2007)[17] | Lantus | 24 weeks | 121 | 121 | N/A |
| Blickle (2009)[18] | Lantus / hygienic and dietary measures | 40 weeks | 183/215 | 100 (54.6%) | 83 (45.4%) |
| Yki-Järvinen (2006)[19] | Lantus/NPH | 36 weeks | 110 | 61 (55.5%) | 49 (44.5%) |

**Figure 1. Patients Achieving Goal A1C < 7.0% Target at Follow-Up.**

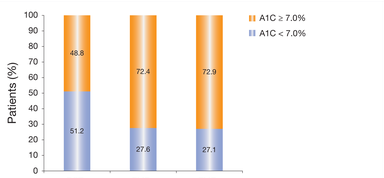



**Figure 2. Patients With A1C ≥ 7.0% Achieving Target FPG < 130 mg/dL at Follow-Up.**

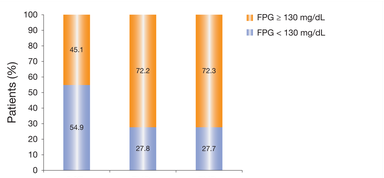
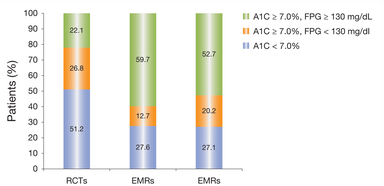



**Figure 3. Patients Stratified by A1C < 7.0% and FPG < 130 mg/dL Outcomes at Follow-Up.**




- Compared with the EMR patients, the RCT patients at baseline were younger, had lower body mass index (BMI), a longer duration of diabetes (RCTs), and a higher mean baseline A1C (**Table 2A** and **2B**).
  - as the date of first diabetes diagnosis cannot be confirmed in EMR reporting, duration of diabetes could not be assessed for the EMR data

### Glycemic Goal Outcomes

- In the pooled RCTs, 51.2% of patients achieved goal A1C < 7.0% at 6 months (**Figure 1**).
- Around 27% of patients in the EMR database achieved goal A1C < 7.0% at 6 and 12 months.
- Among those patients with A1C ≥ 7.0% at 6 months, 54.9% of those in the RCTs had FPG < 130 mg/dL at 6 months, as did 27.8% and 27.7% of patients in the EMR database at 6 months and 12 months, respectively (**Figure 2**).
- The overall breakdown of patients stratified by both A1C and FPG outcomes is shown in **Figure 3**.

**Table 2A. Baseline Characteristics of Patients by A1C Level at Follow-Up: RCTs.**

| RCT | 6-Month Follow-Up (N = 2,975) | |
|---|---|---|
| | A1C < 7.0% (n = 1,522) | A1C ≥ 7.0% (n = 1,453) |
| **Demographics** | | |
| Women, n (%) | 627 (41.2) | 688 (47.4) |
| Age in years, mean (SD) | 58.5 (9.6) | 58.1 (10.3) |
| White, n (%) | 1,331 (90.4) [n = 1,472] | 1,188 (85.7) [n = 1,387] |
| **Clinical characteristics** | | |
| BMI in kg/m$^2$, mean (SD) | 30.9 (5.0) | 30.8 (5.2) |
| Duration of diabetes in years, mean (SD) | 8.3 (5.7) | 9.5 (6. 4) |
| A1C, %, mean (SD) | 8.5 (0.9) | 9.1 (1.0) |
| A1C < 7.0%, n (%) | 30 (2.0) | 4 (0.3) |
| FPG in mg/dL, mean (SD) | 191.8 (49.4) | 204.5 (53.5) |
| FPG < 130 mg/dL, n (%) | 107 (7.1) [n = 1,497] | 75 (5.2) [n = 1,429] |
| **Treatment pattern, n (%)** | | |
| Insulin glargine use (n = 2,065) | 1,056 (51.1) | 1,009 (48.9) |
| NPH insulin use (n = 204) | 145 (71.1) | 59 (28.9) |
| Insulin lispro use (n = 429) | 215 (50.1) | 214 (49.9) |
| Premixed insulin use (n = 277) | 106 (38.3) | 171 (61.7) |

**Table 2B. Baseline Characteristics of Patients by A1C Level at Follow-Up: EMRs.**

| EMRs | 6-Month Follow-Up (N = 12,562) | | 12-Month Follow-Up (N = 14,038) | |
|---|---|---|---|---|
| | A1C < 7.0% (n = 3,464) | A1C ≥ 7.0% (n = 9,098) | A1C < 7.0% (n = 3,805) | A1C ≥ 7.0% (n = 10,233) |
| **Demographics** | | | | |
| Women, n (%) | 1,699 (49.0) | 4,644 (51.0) | 1,918 (50.4) | 5,171 (50.5) |
| Age in years, mean (SD) | 62.3 (12.4) | 60.2 (12.4) | 62.7 (12.2) | 59.8 (12.3) |
| **Payer type, n (%)** | | | | |
| Commercial | 740 (21.4) | 2,132 (23.4) | 832 (21.9) | 2,459 (24.0) |
| Medicaid | 72 (2.1) | 268 (3.0) | 83 (2.2) | 309 (3.0) |
| Medicare | 1,301 (37.6) | 2,935 (32.3) | 1,512 (39.7) | 3,256 (31.8) |
| Self-pay | 39 (1.1) | 226 (2.5) | 38 (1.0) | 235 (2.3) |
| Unknown | 1,312 (37.9) | 3,537 (38.9) | 1,340 (35.2) | 3,974 (38.8) |
| **Clinical characteristics** | | | | |
| BMI in kg/m$^2$, mean (SD) | 33.9 (8.32) [n = 3,254] | 34.4 (7.96) [n = 8,502] | 34.0 (8.20) [n = 3,535] | 34.3 (8.07) [n = 9,543] |
| CCI, mean (SD) | 1.28 (1.72) | 1.05 (1.56) | 1.27 (1.72) | 1.01 (1.51) |
| CCI score 0, n (%) | 1,636 (47.2) | 4,819 (53.0) | 1,799 (47.3) | 5,556 (54.3) |
| CCI score 1-2, n (%) | 1,137 (32.8) | 2,878 (31.6) | 1,279 (33.6) | 3,162 (30.9) |
| CCI score ≥ 3, n (%) | 691 (20.0) | 1,401 (15.4) | 727 (19.1) | 1,515 (14.8) |
| A1C, %, mean (SD) | 8.1 (2.01) [n = 3,161] | 9.0 (1.87) [n = 8,492] | 8.0 (1.97) [n = 3,444] | 9.0 (1.92) [n = 9,372] |
| A1C < 7.0%, n (%) | 1,019 (32.2) [n = 3,161] | 710 (8.4) [n = 8,492] | 1,149 (33.4) [n = 3,444] | 864 (9.2) [n = 9,372] |
| FPG in mg/dL, mean (SD) | 186.1 (90.3) [n = 2,963] | 207.4 (64.6) [n = 7,750] | 185.9 (90.5) [n = 3,252] | 209.5 (87.4) [n = 8,597] |
| FPG < 130 mg/dL, n (%) | 837 (28.2) [n = 2,963] | 1,276 (16.5) [n = 7,750] | 904 (27.8) [n = 3,252] | 1,426 (16.6) [n = 8,597] |

### Characteristics of Patients Not Achieving Goal A1C < 7.0%

- In general, compared with patients who achieved A1C < 7.0%, baseline differences suggest that those who did not achieve this glycemic goal tended to be younger, have a longer duration of diabetes, and have numerically higher mean A1C and FPG levels (**Table 2A** and **2B**).
- Patients who did not achieve A1C goal < 7.0% were less likely to have baseline FPG < 130 mg/dL.
- In the RCTs, a larger proportion of patients achieving glycemic control (A1C < 7.0%) received insulin glargine or NPH insulin at 6 months when compared with uncontrolled patients (A1C ≥ 7.0%):
  - a larger proportion of uncontrolled patients received premixed insulin when compared with patients achieving glycemic control

**Table 3A. Baseline Characteristics of Patients Not Achieving Goal A1C < 7.0% by FPG Level at Follow-Up: RCTs.**

| RCTs | 6-Month Follow-Up (N = 1,453) | |
|---|---|---|
| | FPG < 130 mg/dL (n = 797) | FPG ≥ 130 mg/dL (n = 656) |
| **Demographics** | | |
| Women, n (%) | 373 (46.8) | 315 (48.0) |
| Age in years, mean (SD) | 58.9 (10.0) | 57.2 (10.6) |
| White, n (%) | 634 (84.8) [n = 748] | 554 (86.7) [n = 639] |
| **Clinical characteristics** | | |
| BMI in kg/m$^2$, mean (SD) | 30.6 (5.3) | 31.1 (5.1) |
| Duration of diabetes in years, mean (SD) | 9.9 (6.6) | 9.1 (6.1) |
| A1C, %, mean (SD) | 9.1 (1.0) | 9.2 (1.0) |
| A1C < 7.0%, n (%) | 2 (0.3) | 2 (0.3) |
| FPG in mg/dL, mean (SD) | 197.3 (52.9) | 213.2 (53.0) |
| FPG < 130 mg/dL, n (%) | 53 (6.8) [n = 782] | 22 (3.4) [n = 647] |
| **Treatment pattern, n (%)** | | |
| Insulin glargine use (n = 1,009) | 582 (57.7) | 427 (42.3) |
| NPH insulin use (n = 214) | 127 (59.3) | 87 (40.7) |
| Insulin lispro use (n = 59) | 17 (28.8) | 42 (71.2) |
| Premixed insulin use (n = 171) | 71 (41.5) | 100 (58.5) |

**Table 3B. Baseline Characteristics of Patients Not Achieving Goal A1C < 7.0% by FPG Level at Follow-Up: EMRs.**

| EMRs | 6-Month Follow-Up (N = 6,969) | | 12-Month Follow-Up (N = 8,603) | |
|---|---|---|---|---|
| | FPG < 130 mg/dL (n = 1,938) | FPG ≥ 130 mg/dL (n = 5,031) | FPG < 130 mg/dL (n = 2,382) | FPG ≥ 130 mg/dL (n = 6,221) |
| **Demographics** | | | | |
| Women, n (%) | 990 (51.1) | 2,583 (51.3) | 1,177 (49.4) | 3,182 (51.1) |
| Age in years, mean (SD) | 62.3 (11.8) | 59.6 (12.6) | 62.4 (11.6) | 59.0 (12.4) |
| **Payer type, n (%)** | | | | |
| Commercial | 430 (22.2) | 1,154 (22.9) | 551 (23.1) | 1,463 (23.5) |
| Medicaid | 40 (2.1) | 166 (3.3) | 56 (2.4) | 214 (3.4) |
| Medicare | 657 (33.9) | 1,659 (33.0) | 850 (35.7) | 1,956 (31.4) |
| Self-pay | 34 (1.8) | 146 (2.9) | 34 (1.4) | 166 (2.7) |
| Unknown | 777 (40.1) | 1,906 (37.9) | 891 (37.4) | 2,422 (38.9) |
| **Clinical characteristics** | | | | |
| BMI in kg/m$^2$, mean (SD) | 33.1 (7.51) [n = 1,795] | 34.74 (8.05) [n = 4,706] | 33.3 (7.94) [n = 2,220] | 34.71 (8.16) [n = 5,809] |
| CCI, mean (SD) | 1.07 (1.59) | 1.05 (1.57) | 1.07 (1.54) | 0.99 (1.52) |
| CCI score 0, n (%) | 1,042 (53.8) | 2,651 (52.7) | 1,248 (52.4) | 3,419 (55.0) |
| CCI score 1-2, n (%) | 578 (29.8) | 1,624 (32.3) | 750 (31.5) | 1,915 (30.8) |
| CCI score ≥ 3, n (%) | 318 (16.4) | 756 (15.0) | 384 (16.1) | 887 (14.3) |
| A1C, %, mean (SD) | 8.77 (1.84) [n = 1,816] | 9.08 (1.87) [n = 4,668] | 8.66 (1.76) [n = 2,188] | 9.17 (1.98) [n = 5,698] |
| A1C < 7.0%, n (%) | 172 (9.5) [n = 1,816] | 377 (8.1) [n = 4,668] | 244 (11.2) [n = 2,188] | 490 (8.6) [n = 5,698] |
| FPG in mg/dL, mean (SD) | 185.5 (78.5) [n = 1,775] | 214.1 (84.4) [n = 4,572] | 183.9 (81.1) [n = 2,158] | 217.9 (86.9) [n = 5,571] |
| FPG < 130 mg/dL, n (%) | 431 (24.3) [n = 1,775] | 620 (13.6) [n = 4,572] | 551 (25.5) [n = 2,158] | 731 (13.1) [n = 5,571] |

### Characteristics of Patients Not Achieving Goal A1C < 7.0%, but Achieving FPG < 130 mg/dL

- In general, compared with patients who achieved neither glycemic target (i.e. those patients with A1C ≥ 7.0% and FPG ≥ 130 mg/dL at follow-up), baseline differences suggest that those who did not achieve goal A1C < 7.0% but did achieve FPG < 130 mg/dL tended to be older, have a longer duration of diabetes (RCTs), and have numerically lower mean A1C and FPG levels (**Table 3A** and **3B**).
- In the RCTs, a larger proportion of patients achieving FPG < 130 mg/dL received insulin glargine or NPH insulin at 6 months when compared with uncontrolled patients (FPG ≥ 130 mg/dL):
  - larger proportions of uncontrolled patients (FPG ≥ 130 mg/dL) received insulin lispro or premixed insulin when compared with controlled patients (FPG < 130 mg/dL)
- Data from the EMR analysis suggest that baseline OAD use, comorbidities (as measured by the Charlson Comorbidity Index [CCI]), or payer type did not influence glycemic outcomes in this patient group.

## LIMITATIONS

- The intensive monitoring of patients in RCTs as well as mandated management algorithms would probably lead to over reporting of laboratory parameters, which might not be frequently measured in real-world practice.
- With regard to the RCT data, these are limited to studies performed by Sanofi or predecessor companies and there may be differences compared to the general diabetic population.
- With regard to the EMR analysis, patients were identified based on primary care physician prescription order data, and we could not control for heterogeneity in the population receiving basal insulin.
- Differences in the patient demographics and outcome data collected for the RCTs, and the data available in the EMR databases, mean that comparisons between the two sets of data were not possible for all patient characteristics.

## CONCLUSIONS

- Large numbers of patients with T2DM, especially in real-world clinical practice but also in RCTs, do not reach glycemic goals, despite treatment with OADs and basal insulin.
- This highlights an unmet need in optimally titrating basal insulin to bring a patient's glycemia under control, even under the strict conditions of an RCT.
- Differences in baseline characteristics between the two populations of T2DM patients highlight the importance of bridging RCT and EMR data to fully understand unmet needs in real-world patient care.
- Appropriate therapeutic choices for patients not reaching A1C < 7.0% require assessment of FPG and PPG, in addition to A1C. Patients with A1C > 7.0% and FPG > 130 mg/dL would likely benefit from additional basal insulin titration and patients with A1C > 7.0% and FPG < 130 mg/dL would likely need PPG control to bring their A1C within recommended limits[20]
- Understanding the differences between patients who achieve A1C goal and/or FPG target, and those who do not, could assist in individualizing treatment regimens and optimizing patient outcomes.

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### DISCLOSURES

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Dalal: employee and stockholder of Sanofi US, Inc.

DiGenio: employee of Sanofi US, Inc. at the time of the study, currently employee of Isis Pharmaceuticals, Inc. Stockholder of Sanofi.

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