Antibodies to Infliximab in Remicade-Treated Rheumatic Patients Show Identical Reactivity Towards Biosimilar CT-P12

- Daniel Nagore, MD, Director of Research and Development, Progenika Biopharma, Derio, Spain

Results of a retrospective analysis of 250 patients and 77 controls with active rheumatoid arthritis and spondyloarthritis treated with the biologic Remicade (infliximab, Janssen Biotech) showed that when antibodies develop in response to infliximab, they also cross-react with CT-P12, a biosimilar of infliximab, potentially leading to loss of response.

Dr. Nagore, the study’s lead author, noted that while biologics, such as infliximab, have revolutionized treatment of many rheumatic diseases, immune responses to them are generated in some patients. “While most studies show there are no significant differences in clinical response between a biosimilar and the original product, some physicians and patient advocacy groups have questioned how interchangeable they really are, and whether it is safe to switch from the brand-name version to the biosimilar,” Dr. Nagore said. He also said that over the past decade, biosimilars have been introduced in the U.S. and Europe with the goal of reducing treatment costs and increasing accessibility to therapy for patients. In the U.S., Inflectra (infliximab-dyyb, Celltrion/Pfizer) is an approved infliximab biosimilar.

Patients in Dr. Nagore’s analysis had not been treated previously with the biosimilar. Assessing concentrations of anti-infliximab antibodies with his company’s assay (Promonitor anti-IFX), he found that 50.4% of patients treated with infliximab tested positive for anti-infliximab antibodies. All of those patients also tested positive for antibody reactivity against the biosimilar. Similar findings, he noted, have been reported in infliximab-treated patients with inflammatory bowel disease.

Dr. Nagore pointed out that the presence of anti-infliximab antibodies is likely to augment drug clearance, weaken responses, and increase side effect risk. “Therefore, in patients where biological infliximab is ineffective due to the presence of circulating antibodies, switching to its biosimilar will lead to the same problems,” Dr. Nagore concluded.

Certolizumab Pegol for the Treatment of Axial Spondyloarthritis: Four-Year Outcomes From the RAPID-axSpA Trial

- Désirée van der Heijde, MD, Professor of Rheumatology, Leiden University Medical Center, Leiden, The Netherlands

In the RAPID-axSpA trial, certolizumab pegol treatment efficacy was maintained over four years in patients with axial spondyloarthritis (axSpA), a chronic inflammatory disease primarily characterized by inflammation of the sacroiliac joints and spine, which causes chronic back pain, according to Dr. van der Heijde.

Patients with axSpA (also called radiographic-axSpA) and nonradiographic (nr)-axSpA were enrolled in the RAPID-axSpA trial, which is the first to include both of these populations, Dr. van der Heijde said in an interview. The inclusion of patients with (nr)-axSpA is noteworthy because some clinicians, especially in the U.S., have held the view that this population has self-limiting disease and that, for them, symptoms are likely to disappear without treatment.

Treatment with certolizumab pegol, a monoclonal antibody to tumor necrosis factor-alpha, in RAPID-axSpA was double-blind and placebo-controlled for 24 weeks, dose blind to week 48, and open label to week 24. All patients had active axSpA (Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] score of 4 or more and spinal pain score of 4 or more) with positive sacroiliac joint magnetic resonance imaging and/or inflammation marked by a C-reactive protein level greater than 7.9 mg/L. Patients were originally randomized to certolizumab pegol 200 mg every two weeks or 400 mg every four weeks and were continued on their assigned dose in the open-label period. The primary objective of a 20% improvement using Assessment of SpondyloArthritis International Society criteria (ASAS20) at week 12 was met and has been previously reported.

Among the patients completing 48 weeks of treatment (65%; n = 211), the completers proportions were similar in both the axSpA (67%) and (nr)-axSpA (63%) subpopulations, Dr. van der Heijde said.

Overall, ASAS20, ASAS40, and ASAS-PR (partial remission) were achieved in 54.1%, 44.0%, and 23.4% of patients, respectively, using nonresponder imputation (missing data
MEETING HIGHLIGHTS: European League Against Rheumatism

Certolizumab Pegol for the Treatment of Psoriatic Arthritis: Four-Year Outcomes From the RAPID-PsA Trial

- P. J. Mease, MD, Director of Rheumatology Research, Swedish Medical Center and University of Washington, Seattle, Washington

Maintained efficacy for certolizumab pegol 200 mg every two weeks and 400 mg every four weeks was achieved for 409 patients with psoriatic arthritis (PsA) in the RAPID-PsA trial after long-term, four-year follow-up. Continuing increases in high-threshold outcomes between week 24 and week 216 were demonstrated.

Dr. Mease noted that more than half of PsA patients have chronic, progressive, erosive disease with subsequent radiographic changes. Increases in some high-threshold measures were observed from week 24 to week 216, he said, demonstrating that patients not achieving high-threshold outcomes at early time points may achieve them with continued treatment.

Effect of Secukinumab, an Interleukin-17A Inhibitor, on Spinal Radiographic Changes Through Two Years In Patients With Active Ankylosing Spondylitis: Results of MEASURE 1

- Juergen Braun, MD, Ruhr Rheumatology Center of the University of Bochum, Herne, Germany

In a first report of interleukin-17A inhibition on structural changes in ankylosing spondylitis (AS), 80% of patients receiving secukinumab over 104 weeks had no radiographic progression. Inhibition of radiographic spinal changes, which are primarily osteoporotic in nature in active AS, is a primary therapy goal, according to Dr. Braun. The objective of the phase 3 MEASURE 1 study was to assess secukinumab effects up to 104 weeks on radiographic progression. Patients (N = 1,371) in the secukinumab arm received a 10-mg/kg intravenous (IV) loading dose at baseline and at...
MEETING HIGHLIGHTS: European League Against Rheumatism

American Diabetes Association (ADA)
The American Diabetes Association’s 76th Scientific Sessions drew more than 16,000 diabetes care professionals to New Orleans, Louisiana, June 10–14. The selections below focus on new biosimilars in type-1 and type-2 diabetes; insulin titration; and a diabetes care delivery program that improves outcomes while reducing costs.

Bimekizumab, a Monoclonal Antibody That Inhibits Both IL-17A and IL-17F, Produces a Profound Response in Both Skin and Joints: Results of an Early-Phase, Proof-of-Concept Study in Psoriatic Arthritis

- Sophie Glatt, MD, UCB Celltech, Slough, United Kingdom

Interleukin (IL)-17 and IL-17F are key proinflammatory cytokines that are overexpressed in the skin lesions of patients with psoriasis. An early-phase study of bimekizumab, a monoclonal antibody potently and selectively inhibiting both IL-17 and IL-17F, demonstrated safety and profound responses in both skin and joints in patients with psoriatic arthritis.

In Dr. Glatt’s study, 52 psoriatic arthritis patients (mean disease duration, 6.6 years) were randomized to either one of four doses of bimekizumab (n = 38) or placebo (n = 14). All received a single loading dose of 80–560 mg bimekizumab administered at week 0; further doses of 40–320 mg bimekizumab were administered at weeks 3 and 6. Efficacy endpoints were American College of Rheumatology 20% improvement (ACR20), ACR50, mean Disease Activity Score (using C-reactive protein [CRP]) for joints, and Psoriasis Area Severity Index (PASI) scores for skin (mean, 90).

At baseline, mean CRP was 12.5 mg/L. In patients with skin involvement of 3% or more, the mean PASI score was 15.9. Dr. Glatt observed that onset of response was rapid for both skin and joints. For the top three bimekizumab doses, the ACR20 response rate (RR) was 80% at week 8, compared with 17% in the placebo group (n = 12). Dr. Glatt noted that Bayesian analysis showed a high posterior probability (greater than 90%) that the observed bimekizumab ACR20 RR at week 8 is greater than that of placebo and of that reported for anti-TNF and anti-IL-17A agents.

Increased ACR70 RRs were observed within two weeks of the first bimekizumab infusion, and maximal ACR response was achieved at week 16 (ACR70, 37%). Clinically relevant responses in disease activity measures were maintained to week 20.

Mean PASI75 and PASI100 RRs were 0% for placebo (n = 5) and 100% and 87% for bimekizumab (n = 15) at week 8. The scores are considered “really high,” Dr. Glatt said in an interview.

The majority of treatment-emergent adverse events were mild or moderate, with no severe adverse events attributed to treatment. Two cases of fungal infection (opharyngitis and vulvovaginal candidiasis) were classified as mild.

“These proof-of-concept study findings are very good in terms of ACR, and for those patients with skin involvement, they are also very good,” she said. Maximal responses were seen as early as week 8. “Of course, we need to see similar results in the larger phase 2 and 3 studies.”

“Bayesian analysis indicated that the bimekizumab ACR20 RR is greater than that reported for current therapies including anti-IL-17A. Our results support that inhibition of both IL-17A and IL-17F could provide additional clinical benefit in IL-17-mediated diseases,” she concluded.

Efficacy and Safety of MK-1293 Insulin Glargine Compared With Originator Insulin Glargine (Lantus) in Type-1 Diabetes

- Philip Home, MD, PhD, Professor of Diabetes Medicine, Newcastle University, Newcastle upon Tyne, United Kingdom

A 24-week, phase 3, active-controlled, open-label comparison of biosimilar MK-1293 and the originator insulin glargine (Lantus, Sanofi-Aventis) in patients with type-1 diabetes found the overall therapeutic profile of MK-1293 to be similar to that of Lantus.
MK-1293 has the same amino acid sequence, the same production cell type (*Escherichia coli*), and the same pharmaceutical formulation as the originator, Dr. Home said.

The trial enrolled 506 patients, all of whom were taking once-daily basal and prandial insulin and had hemoglobin A1c (HbA1c) less than or equal to 11% (mean, 8%). Average type-1 diabetes disease duration was approximately 22 years. Mean age was 42 years, and approximately 57.5% of the patients were men.

The primary endpoint of the trial was noninferiority in change from baseline HbA1c (margin of less than 0.4%). The primary safety objective was anti-insulin antibody (AIA) development. The primary self-monitored fasting plasma glucose (SMFPG) target was 70–100 mg/dL.

Change from baseline HbA1c at 24 weeks was −0.65 (95% confidence interval [CI], −0.82 to −0.48) for MK-1293 and −0.68 (95% CI, −0.85 to −0.52) for insulin glargine, a difference of 0.03 (95% CI, −0.12 to 0.18). Twenty-four week analysis of HbA1c revealed a difference of 0.04% (95% CI, −0.11 to 0.19), with 37.0% of patients receiving MK-1293 and 37.7% of those receiving insulin glargine meeting the goal of HbA1c less than 7% (−0.8; 95% CI, −9.7 to 8.1). The HbA1c goal of less than 6.5% was met by 20.5% of patients receiving MK-1293 and by 21.6% of those in the insulin glargine group (−1.1; 95% CI, −8.6 to 6.5). Differences were not statistically significant.

A higher rate (events/person-years) of severe hypoglycemic events with MK-1293 (6.1 versus 3.2) was attributed to two patients at the same center who together accounted for 49% of severe episodes. Differences in other measures were not significant (fasting plasma glucose change, seven-point average self-monitored plasma glucose, hypoglycemic events).

No relationship could be discerned between antibody positivity, antibody titer, or neutralizing antibody positivity with HbA1c or insulin dose, either for the population or in any individual. “There were so few immune events that you could say that there are no signals for any immunological problem with MK-1293,” Dr. Home said in an interview.

Dr. Home criticized the demand by regulatory bodies for the self-monitored approach, but regulators won’t allow that.”

**Nocturnal Glycemic Control With Glargine Titration Based on Bedtime Plasma Glucose In Addition to Fasting Plasma Glucose In Type-1 Diabetes**

• Francesca Porcellati, MD, University of Perugia, Perugia, Italy

Taking into account the relationship of fasting plasma glucose (FPG) and bedtime plasma glucose to “titrate basal insulin in a more dynamic way” may lead to several advantages in glycemic control, according to Dr. Porcellati.

Current practice is to titrate basal insulin in type-1 diabetes based on FPG after assessing the mean or median value over three consecutive days. “However, the carry-over effect of postdinner hypoglycemia or hyperglycemia, both frequent events in type-1 diabetes, may easily impact FPG and mislead titration calculations,” she said. While several algorithms have been studied and proposed for titrating basal insulin in subjects with type-2 diabetes, use of such algorithms in type-1 diabetes is less frequent and less popular. No study so far, to her knowledge, has specifically compared basal insulin titration options in type-1 diabetes.

Dr. Porcellati proposed that, in type-1 diabetes, the relationship of bedtime plasma glucose to morning FPG should be considered in order to titrate basal insulin more adequately. Such an algorithm would use this relationship between bedtime plasma glucose and next-morning FPG on days on which postdinner, clinically relevant hyperglycemia or hypoglycemia has not occurred.

In her study, the efficacy and safety of the proposed algorithm were compared with one based on FPG only: Standard evening glargine titration based on FPG (mean, six consecutive days) (as a once-weekly titration) was algorithm #1. Algorithm #2 was based on increments/decrements of nocturnal plasma glucose (the difference between bedtime plasma glucose and next-morning FPG on days with postdinner, clinically relevant hyperglycemia or hypoglycemia at target, with optimized evening prandial insulin titrated every two weeks). Both algorithms aimed at a target FPG of 100–130 mg/dL.

The study included 74 patients, all entering a one-month run-in followed by three months of treatment with either algorithm #1 or #2 (37 in each group; mean age, approximately 43 years). Diabetes duration was 21.2 ± 12.3 years in the algorithm #1 group and 24.5 ± 10.7 years in the algorithm #2 group. Mean FPG was 159 mg/dL in the algorithm #1 group and 158 mg/dL in the algorithm #2 group.

At the study end, FPG was lower in both groups but significantly lower (< 0.001) in the algorithm #2 group. Results for hemoglobin A1c (HbA1c) followed the same pattern, with significant (P = 0.002) reductions from baseline in the algorithm #2 group and with significantly greater reductions in the algorithm #2 group than in the algorithm #1 group (P < 0.002). Dr. Porcellati reported an opposite pattern for insulin doses, which, at study end, had significantly smaller increases (P = 0.038) in the algorithm #2 group.

Importantly, nocturnal confirmed hypoglycemia was significantly lower in the algorithm #2 group with respect to total confirmed events (P < 0.001), percentage of subjects affected (P = 0.065), and events per patient in three months (P < 0.001).

Dr. Porcellati concluded that, compared to an algorithm based on FPG only, one considering the relationship of bedtime plasma glucose to morning FPG may result in lower HbA1c, lower FPG, reduced intra-subject FPG variability, and reduced risk of nocturnal hypoglycemia. “Indirectly, the study suggests that optimization of postdinner plasma glucose to avoid hypoglycemia and hyperglycemia is a prerequisite for interpreting FPG for basal insulin titration,” she said. She noted also that in regions where dinner is not eaten as close to bedtime as it is in Italy, a bedtime glucose check may be important.

Commenting on the findings, Philip Home, MD, PhD, noted that one of the important trends in the trial was the reduction in hypoglycemia. “That surely is what people with diabetes are requiring from us—glucose control with less hypoglycemia. So these are promising results,” he said.
MEETING HIGHLIGHTS: American Diabetes Association

SWITCH 1: Reduced Hypoglycemia With Insulin Degludec Versus Insulin Glargine, Both U100, in Patients with T1D at High Risk of Hypoglycemia: A Randomized, Double-Blind, Crossover Trial

- Wendy S. Lane, MD, Mountain Diabetes and Endocrine Center, Asheville, North Carolina

The long duration of action—more than 42 hours—of insulin degludec (IDeg), a new-generation basal insulin approved last year, offers the distinct advantage of reduced peak-to-trough variations in insulin concentration at steady state, with reduced risk of hypoglycemia, compared with the standard insulin glargine (IGlar).

In the phase 3a development program, IDeg demonstrated noninferiority to IGlar (100 units/mL [U-100]) with respect to hemoglobin A1c (HbA₁c), with lower rates of confirmed nocturnal hypoglycemia. The phase 3 data, however, had potential limitations based on the lack of study blinding, inclusion of nonsymptomatic hypoglycemia, exclusion of patients with at least one risk factor for hypoglycemia, and insufficient tracking of IGlar administration timing.

To overcome these shortcomings, SWITCH 1 was designed to show noninferiority for IDeg plus insulin aspart (IAsp) versus IGlar plus IAsp in the rates of severe or blood glucose (BG)-confirmed symptomatic hypoglycemia episodes during a maintenance period commencing after 16 weeks of treatment. Severe episodes were defined as those requiring external intervention, and a confirmed symptomatic episode was defined as one confirmed by finger-stick with BG more than 56 mg/dL with symptoms.

Patients with type-1 diabetes (n = 501; 53.7% male; mean age, 45.9 years) were randomized 1:1 to once-daily IDeg plus IAsp or once-daily IGlar U100 plus IAsp, titrated for 16 weeks, followed by a 16-week maintenance period. Subsequently, all patients were switched over to the other regimen (titration and maintenance) for another 32 weeks. IAsp was given two to four times per day as part of a full mealtime basal-bolus regimen.

SWITCH 1 included a group of patients typically excluded from clinical trials: mean duration of diabetes disease in the cohort was 23.4 years, and baseline mean fasting glucose was 169.8 mg/dL. All included patients had at least one hypoglycemia risk factor; they were treated to a strict target of 71–90 mg/dL (lowest of three consecutive measurements).

The primary endpoint of noninferiority and superiority in rates of severe or BG-confirmed symptomatic hypoglycemia with IDeg versus IGlar in the maintenance periods was achieved, with an 11% lower rate for IDeg (estimated rate ratio [ERR], 0.89; 95% CI, 0.85 to 0.94; (P < 0.0001). For the same measure for rates of nocturnal hypoglycemia, a secondary endpoint that Dr. Lane described as “the most dangerous and most worrisome,” the reduction was 36% (ERR, 0.65; 95% CI, 0.56 to 0.73; (P < 0.0001). Severe hypoglycemia was reduced by 26% in the maintenance period (0.74; 95% CI, 0.61 to 0.90; P < 0.05). Similarly significant rate reductions were reported for the full treatment period for IDeg versus IGlar across these same measures.

HbA₁c, noninferiority in both treatment periods was also met. At the end of treatment period 1 (before crossover), mean HbA₁c was 6.92% for IDeg versus 6.78% for IGlar; the mean HbA₁c rates at the end of treatment period 2 (postcrossover) were 6.95% for IDeg and 6.97% for IGlar. Baseline HbA₁c was 7.6% in both treatment arms.

Adverse events, serious adverse events, and weight changes were all comparable between groups.

“Patients have a flat, peakless basal insulin for the first time. … This is progress in basal insulin therapy that we can offer to our patients with type-1 diabetes,” Dr. Lane said.

In type-2 diabetes patients in the phase 3a development program for IDeg, rates of confirmed and nocturnal confirmed hypoglycemia also were significantly lower with IDeg versus standard IGlar. The five trials of that program also revealed IDeg’s noninferiority to IGlar U-100 with respect to HbA₁c, Dr. Wysham said. Because of the same potential limitations stated for SWITCH 1, SWITCH 2 was launched for further confirmation of benefits.

Investigators enrolled 720 type-2 diabetes patients (53.1% male; mean age, 61.4 years) with a mean diabetes disease duration of 14.1 years and mean HbA₁c of 7.6%, randomizing them 1:1 to U-100 of IDeg or IGlar once daily and 1:1 to basal insulin in the morning or evening. A 16-week titration-to-target period was followed by 16 weeks of maintenance, then followed by crossover to the other drug with a identical titration and maintenance period. All patients had previously received basal insulin with or without oral antidiabetic drugs, excluding sulfonylurea/meglitinides. All patients had at least one of the following hypoglycemia risk factors: one or more severe hypoglycemic episodes in the last year; moderate chronic renal failure; hypoglycemia unawareness; insulin exposure of at least five years; and/or an episode of hypoglycemia using the ADA definition of 70 mg/dL or less (3.9 mmol/L or less) within the last 12 weeks. Basal insulin was titrated weekly to a fasting target glucose of 71–90 mg/dL (3.9–5.0 mmol/L).

Confirmed symptomatic hypoglycemia was defined by a BG of less than 56 mg/dL (less than 3.1 mmol/L), and nocturnal hypoglycemia was predefined as any episode occurring between 12:01 a.m. and 5:59 a.m., both inclusive.

In both treatment periods, the prerequisite of achieving noninferiority for change of HbA₁c was met. Mean HbA₁c at the end of treatment period 1 was 7.06% for IDeg and 6.98% for IGlar. At the end of treatment period 2, mean HbA₁c was 7.08% for IDeg versus 7.11% for IGlar.

The primary endpoint of severe or BG-confirmed symptomatic hypoglycemia in the maintenance period was 30% lower with IDeg versus IGlar (0.70; 95% CI, 0.607 to 0.801; P < 0.0001). The number of severe or BG-confirmed symptomatic nocturnal hypoglycemic episodes, a secondary endpoint, was also achieved with a 42% reduction for IDeg versus IGlar (0.58; 95% CI, 0.455 to 0.744; P < 0.0001). In the full treatment
MEETING HIGHLIGHTS: American Diabetes Association

Period, the severe hypoglycemia rate was 51% lower with IDeg compared with IGlar (0.49; 95% CI, 0.257 to 0.935; \( P = 0.0306 \)).

Adverse event and serious adverse event rates were similar between IDeg and IGlar with 332.6 versus 360.1 adverse events per 100 patient-years for IDeg and IGlar, respectively, and 20.6 versus 25.0 serious adverse events per 100 patient years, respectively.

The number of severe hypoglycemic episodes in both the maintenance and full treatment periods, while lower in the IDeg group, was statistically similar between groups. The lack of statistical significance, Dr. Wysham said, was attributable to the low overall event rate.

Concluding that SWITCH 2 confirmed earlier findings, Dr. Wysham commented in an interview, “These results are important clinically because we know that hypoglycemia is the primary impediment to achieving good glycemic control in our patients with long-standing type-2 diabetes. If we can achieve a very good glycemic goal with less hypoglycemia, it’s going to give us the confidence to titrate our patients more aggressively to lower target fasting glucose levels. With that we can achieve better \( \text{HbA}_{1c} \) control and still help our patients stay safe.”

Discussing the two SWITCH trials in an interview, Vivian Fonseca, MD, Professor at Tulane University, said, “I think any reduction in hypoglycemia is clinically meaningful. The bottom line is there was less hypoglycemia during the periods when patients were on IDeg insulin as compared to glargine insulin. Therefore, for patients at high risk for hypoglycemia or who have had prior hypoglycemia, considering such a switch might be appropriate.”

**Rio Grande Valley ACO Quantitative Achievements With a Type-2 Diabetes Mellitus Program**

- Jose F. Peña, MD, Chief Executive Officer and Chief Medical Director, Rio Grande Valley Accountable Care Organization, Donna, Texas

The Rio Grande Valley (RGV) contains Hidalgo County, one of the poorest in the nation. The Medicare per capita cost in this county of $12,300 is significantly higher than the national average of $8,874. Medicare and Medicaid beneficiaries, who make up an estimated 45% of the population, contribute to this high cost, Dr. Peña said. Type-2 diabetes prevalence among Medicare beneficiaries is 45%, and, in Medicaid populations, it is higher.

“Among patients with hemoglobin A1c (HbA\(_{1c}\)) greater than 9 and blood pressure greater than 140 mm Hg/90 mm Hg, the cost from amputations, retinopathy, open-heart surgery, and dialysis are enormous,” he said in an interview. “We know the problems, and we know there are medications that can fix them, but we have been missing the link of how to deliver the care.”

Data from Dr. Peña’s RGV Accountable Care Organization (ACO) program show both reduced costs and improved outcomes. In 2014, as part of their Medicare Shared Savings Program (MSSP) requirements, the RGV ACO used 33 performance measures. Their program includes the use of care coordinators, care coaches, a nutritionist, monthly point-of-care \( \text{HbA}_{1c} \) measurements (identification of uncontrolled diabetes), face-to-face education, phone calls, frequent office appointments, 24/7 availability, home visits, and, when necessary, bariatric surgery. At the core of the problem, Dr. Peña said, is “care coaching and care coordination. That means practicing ‘outpatient intensive care’ for those patients who need it most.” Program elements increase patient engagement and provider incentive.

The program uses a diabetes composite score encompassing six quality measures: HbA\(_{1c}\) less than 8%, low-density lipoprotein-cholesterol less than 100 mg/dL; blood pressure less than 140 mm Hg/90 mm Hg; tobacco nonuse; aspirin use in the presence of ischemic vascular disease; and poor HbA\(_{1c}\) control (HbA\(_{1c}\) greater than 9%).

When the program began in 2012, the type-2 diabetes comprehensive control rate was 23%. Through the ACO program, that figure was raised to 49% by 2014. At the program outset in 2012, 17.81% of patients had HbA\(_{1c}\) greater than 9%. The rate in Medicaid patients was 45%. “This is totally unacceptable,” Dr. Peña said. “Now the projected rate for 2015 was 9.93%. Our goal is to wipe the occurrence of HbA\(_{1c}\) greater than 9% off the map.”

For the composite score of type-2 diabetes metrics, RGV ACO was in the top 1% of all ACOs in the United States in 2014, and, in the same year, reduced per capita costs for Medicare beneficiaries by 14%. Lower rates of hospital admission and readmission contributed to this reduction.

Dr. Peña concluded that the RGV ACO has achieved success in delivering better quality of life and reducing cost of care at the same time. A further result has been “additional payments from Medicare to sustain reforms in care that are not normally reimbursed under fee-for-service.”

He commented on the importance of point-of-care testing. “Not only is there a benefit for the clinician to know the patient’s A1c in real time, but there’s one also to showing the result to the patient during the visit, rather than through a phone call a week later. You can say, ‘Your A1c is 8.5%. There is some work to do. We are going to increase this medication. You need to do more dieting,’ and so on. We can create a plan that makes sense right there. This increases compliance.”

A study presented at the ADA meeting evaluating the efficacy of the point-of-care fingerstick device used in Dr. Peña’s study (Evaluation of the Alere Afinion HbA\(_{1c}\) Dx test: Can Point of Care HbA\(_{1c}\) Testing Deliver the Performance Needed for Diagnostic Use? [Monica H. Swensen, Alere Technologies, Oslo, Norway]) found the device’s total error to range between 1.41% and 4.05% for HbA\(_{1c}\) readings between 5.0% and 12.0%. The Food and Drug Administration requires total error to be equal to or less than 6% for devices used as aids in diagnoses of diabetes. ■