one-third of patients who were treated with TAK-875 had a decrease in HbA1C of 1.5% or more at Week 12, a rate that was comparable with that for the glimepiride group and significantly better than that for the placebo group ($p<0.05$).

TAK-875 rapidly reduced the FPG, with a substantial difference by Week 1. The mean reduction in the 2-hour glucose level during OGTT was significantly greater with doses of TAK-875 ≥25 mg compared with placebo ($p<0.05$). β-cell function also appeared to improve, with significantly higher HOMA-β scores for TAK-875 at doses ≥50 mg compared with placebo ($p<0.05$).

All doses were well tolerated over the course of the study. The incidence of hypoglycemia in all of the TAK-875 groups was similar to that in the placebo group (2.0% vs 3.3%) and was significantly lower than that in the glimepiride group (16.1%; $p<0.05$).

The rates of treatment-emergent adverse events in the TAK-875 groups ranged from 1.0% (hyperglycemia) to 5.3% (urinary tract infection). The rate of any adverse event was lower for TAK-875 compared with glimepiride (48.7% vs 61.3%).

TAK-875 is the first agent in its class to reach clinical development for the treatment of type 2 diabetes. The drug is being developed as an adjunct therapy to diet and exercise for improving glycemic control in patients with type 2 diabetes.

Intensive Lifestyle Intervention and Metformin Are Cost-Effective for Diabetes Prevention

Written by Rita Buckley

The Diabetes Prevention Program (DPP) was a multicenter trial that examined the impact of an intensive lifestyle intervention or metformin to prevent or delay the development of diabetes in a high-risk population with impaired glucose tolerance (IGT). The DPP ended early, demonstrating that lifestyle modification reduced diabetes onset by 58% versus 31% by metformin [Diabetes Prevention Program Research Group. *N Engl J Med* 2002].

The Diabetes Prevention Program Outcomes Study (DPPOS; NCT00038727) followed participants for another 7 years. The main objective was to assess the longer-term outcomes, including cost-effectiveness of the lifestyle and metformin interventions, with an intent-to-treat analysis that spanned the combined 10 years of DPP/DPPOS. William H. Herman, MD, MPH, University of Michigan, Ann Arbor, Michigan, USA, presented findings from the study.

Data on resource utilization, cost, and quality of life (QoL) were collected prospectively during DPP and DPPOS. Economic analyses were performed from a health system perspective that considered direct medical costs. Sensitivity analyses were performed from a societal perspective that considered both direct medical costs and direct nonmedical costs (diet- and activity-related costs, participant time, and transportation).

The DPP randomized overweight adults with IGT and an elevated fasting glucose level to intensive lifestyle (ILS), metformin (MET), or placebo (PBO) for an average of 3 years. During the DPPOS, ILS and MET participants were encouraged to continue those interventions, and all were offered a modified lifestyle intervention.

An analysis demonstrated that the beneficial effects of ILS and MET on the incidence of type 2 diabetes persisted 10 years after randomization [DPP Research Group. *Lancet* 2009].

During DPP, the costs of ILS were greater than the cost of MET, which were greater than the cost of PBO. During DPPOS, the costs of ILS and MET were substantially lower than during DPP, and the costs of PBO were higher than during DPP.

Over 10 years, the cumulative, undiscounted, per capita direct medical costs of the interventions were greater for ILS and MET than for PBO ($4601 ILS vs $2300 MET vs $769 PBO). The direct medical costs of care outside the DPP/DPPOS increased over time for all groups but were highest for PBO. The cumulative undiscounted, per capita, direct medical costs of nonintervention-related medical care were greater for PBO ($27,468) than MET ($25,616) or ILS ($24,563).

The undiscounted, per capita, total direct medical costs over 10 years were $29,164 for ILS, $25,616 for MET, and $28,236 for PBO. Quality of life was better for ILS compared with MET or PBO, and the undiscounted quality-adjusted life-years (QALYs) that accrued over 10 years were greater for ILS (6.81) than MET (6.69) or PBO (6.67). From a payer perspective, MET was less expensive and more effective than PBO, and ILS cost only about $1000 per QALY.

From a payer perspective, the MET intervention was cost-saving, and the lifestyle intervention was cost-effective compared with PBO. The increased cost of the ILS, relative to PBO, was largely offset by lower nonintervention-related medical care costs. Health policy should support the funding of intensive lifestyle and metformin for diabetes prevention in high-risk adults.