ARCHIMEDES
Quantifying Healthcare

Case Study

Comparative Effectiveness Analysis

Objective

The objective of this project was to use the Archimedes Model to compare the effects of current care, metformin, and lifestyle modification on the long-term incidence of diabetes and costs in high-risk individuals.

Introduction

This analysis was commissioned by the American Diabetes Association (ADA) to better understand the cost-effectiveness of screening and management guidelines to prevent or delay the development of type 2 diabetes among high-risk individuals. Although a three-year clinical trial called the Diabetes Prevention Program (DPP) comparing current care, metformin, and lifestyle modification was just being completed, the ADA wanted to compare the expected effects of the different strategies on long-term health and economic outcomes, as well as answer several other questions beyond the scope of the DPP trial. The only feasible way to get the information was to use a mathematical model and conduct a simulated trial with a larger population and a longer duration. The ADA chose the Archimedes Model because of its ability to realistically simulate the population and interventions in the DPP trial, and because of its proven accuracy in estimating the results of other trials related to diabetes.

Methods

We used previously published descriptions of the DPP trial[1, 2] to create a simulated population whose subjects met the trial's inclusion and exclusion criteria and had the same baseline characteristics as the subjects of the real trial. Then, to validate how well the Archimedes Model would be able to reproduce the trial's population, interventions, and outcomes, we ran a prospective simulation of the same duration and the same interventions as the real DPP trial and calculated how many people developed diabetes in each group.[1] Furthermore, we subjected the simulated population to a 30-year trial to explore the long-term health and cost outcomes to be anticipated with each intervention.

Results

When the results of the actual trial were eventually published, the percentage of people who developed diabetes in the current-care, metformin, and lifestyle groups after three years were 28.9%, 21.7% and 14.4%.[3] The Model's prospectively calculated rates of diabetes in these groups were 27.4%, 21.9% and 13.2% (see Figure 1.), building further confidence in the Model's calculations.

The Model's long-term health outcomes analysis showed that the 30-year probability of a high-risk person developing diabetes is about 72%, and that the lifestyle modification program, if maintained over the entire period, would reduce the relative risk by 15%, to about 61%. It would also reduce a high-risk person's chance of a serious complication from about 37.4% to 29.9%, and the chance of dying of a complication of diabetes from about 13.4% to 11.1%.

Compared with not implementing any prevention program, the expected 30-year cost per quality-adjusted life-year (QALY) of the lifestyle intervention from a health plan's perspective was calculated to be around $143,000.[4]

"The proven accuracy of the Archimedes Model in simulating clinical trials makes it an exceptional tool for comparing the effectiveness of interventions."

Richard Kahn, Ph.D.
Former Chief Scientific and Medical Officer of the ADA

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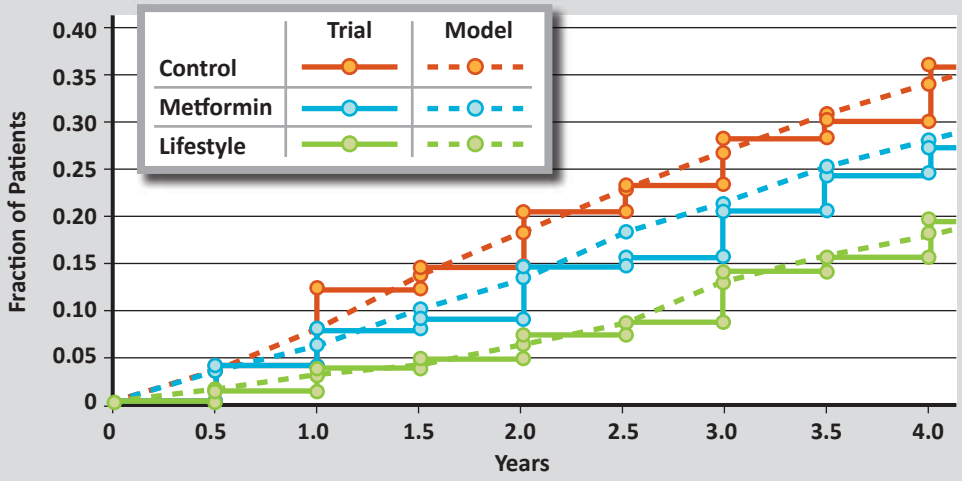
Numbers

- **High-risk individuals:**
  BMI: ≥ 24
  FPG: 95-125
  2hr-PG: 140-199 mg/dl
- **Actual trial size:**
  3,234 people
- **Simulated trial size:**
  10,000 people
- **Actual mean trial duration:**
  3.2 years
- **Simulated trial duration:**
  30 years
- **Actual trial cost:**
  > $300M
- **Simulated trial cost:**
  << $300M
- **Actual rates of diabetes:**
  28.9%, 21.7% and 14.4%
- **Simulated rates of diabetes:**
  27.4%, 21.9% and 13.2%

Figure 1 – Validity of the Archimedes Model



Comparison of percentages of people progressing to diabetes in the Control group (orange circles), Metformin group (blue circles) and Lifestyle group (green circles) observed in the real Diabetes Prevention Program (DPP) (solid lines) and in the simulation of the DPP by the Archimedes Model (dashed lines).

Business Application

The ADA policy statement required a comparison of the effects of three strategies for managing high-risk individuals – current care, metformin, and lifestyle modification. Furthermore, the policy statement had to be based on a quantitative understanding of the effects of the different strategies on long-term health outcomes and costs. Increasing the size of the trial, adding another treatment arm, and extending the trial's duration to 30 years was not feasible; the relatively small and short trial already cost more than $300 million. In such cases, mathematical modeling is the only solution that is cost- and time-effective. The Archimedes Model provided accurate, realistic outcomes and as a result of this work, the ADA has encouraged the development and implementation of interventions that are far less costly than the interventions used in the Diabetes Prevention Program.

References

[1] The Diabetes Prevention Program. Design and methods for a clinical trial in the prevention in type 2 diabetes. **Diabetes Care** 22:623-34, 1999

[2] The Diabetes Prevention Program Research Group: The Diabetes Prevention Program: Baseline characteristics of the randomized cohort. **Diabetes Care** 23:1619-29, 2000

[3] Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. **New England Journal of Medicine**. 2002;356:393-402

[4] Eddy DM, Schlessinger L, Kahn R. Clinical outcomes and cost-effectiveness of strategies for managing people at high risk for diabetes. **Annals of Internal Medicine**. 2005;143:251-264

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