The ADOPT Study: Symptoms and Health Status in a Recently-Diagnosed Type 2 Diabetic Population

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ADOPT is a global, randomized, controlled, clinical trial designed to compare the efficacy and safety of initial monotherapies in patients with type 2 diabetes (T2D). This analysis evaluated baseline symptoms and health status of 4,381 subjects. All had been diagnosed within 3 years and had fasting plasma glucose (FPG) levels of 126–179 mg/dl. Symptoms were assessed using the Diabetes Symptom Checklist (DSC) and health status with the SF-36. Results were analyzed by tertiles of body mass index (BMI), $HbA_{1c}$, FPG, systolic blood pressure and total cholesterol:high density lipoprotein ratio. Mean age of patients was 57 years (range: 26–78) and 58% were male. The largest differences in symptoms and health status were seen by tertile of BMI and $HbA_{1c}$.

| | | Tertile 1 | Tertile 2 | Tertile 3 | *P* value |
|---|---|---|---|---|---|
| **BMI** | Range (kg/m$^2$) | 20.1–28.79 | 28.8–33.59 | 33.6–50.0 | |
| | DSC (sd)† | 0.62 (0.59) | 0.72 (0.69) | 0.92 (0.74) | <0.0001 |
| | SF-36 physical (sd)‡ | 49.48 (8.08) | 48.43 (8.77) | 45.34 (9.52) | <0.0001 |
| | SF-36 mental (sd)‡ | 52.39 (8.88) | 52.65 (9.03) | 51.53 (9.80) | 0.0287 |
| **$HbA_{1c}$** | Range (%) | 3.5–6.89 | 6.9–7.59 | 7.6–12.8 | |
| | DSC (sd)† | 0.69 (0.66) | 0.76 (0.68) | 0.81 (0.72) | <0.0001 |
| | SF-36 physical (sd)‡ | 47.83 (8.86) | 47.6 (9.16) | 47.53 (9.13) | 0.9141 |
| | SF-36 mental (sd)‡ | 52.26 (9.52) | 52.36 (8.92) | 51.9 (9.38) | 0.6222 |

† Higher DSC denotes worse symptoms, ‡higher SF-36 denotes better health-status.

In this relatively homogenous population with recent onset T2D and few diabetic complications, symptoms were few. Symptoms were related both to increasing BMI and to hyperglycemia. However, worsening health status, specifically the physical SF-36 component, was related to increasing BMI but not to $HbA_{1c}$. This suggests that obesity and possibly correlates such as the metabolic syndrome, and not hyperglycemia are related to health status in early T2D. In assessing the impact of initial pharmacological therapies on health status, it will be important to assess the independent contributions of both changes in body weight and glycemic control.