A CROS-SOVER RANDOMISED CONTROLLED TRIAL TO COMPARE PSYCHOLOGICAL BARRIERS TO INSULIN SELF-INJECTION WITH THE INNOLET AND VIAL/SYRINGE

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OBJECTIVES: The timely initiation of insulin therapy in patients with type-2 diabetes who fail to achieve good control on oral antidiabetic therapy is pivotal to successful health outcomes in diabetes. Yet, significant barriers exist to patient acceptance of insulin therapy and to adequate self-management of insulin regimens once initiated. The disposable insulin device, InnoLet, is designed to meet the needs of elderly patients. This study set out to evaluate the differences in psychological fear of self-injecting insulin and perception of barriers to compliance with the insulin regimen in patients using the InnoLet pre-filled device and the vial and syringe. METHODS: Eighty diabetes patients >60 years of age and having visual and or motor disabilities were enrolled in this two-period crossover study, which had as primary aim to evaluate resource utilisation and patient preference. Subjects had difficulty or required caregiver assistance for their previous regimen of injections by vial/syringe. Subjects were randomised to use of either vial and syringe or InnoLet for 6 weeks, and then assigned the opposite treatment for six weeks. At baseline and at the end of each period, subjects completed the Diabetes Fear of Self-injection Questionnaire (D-FISQ) and questions about barriers to insulin self-care, treatment satisfaction and preference. RESULTS: The D-FISQ showed good internal consistency. Compared to baseline values, InnoLet treatment resulted in an improvement of 39% and 67% respectively in each of the 2 groups in fear of self-injection, whereas vial-syringe treatment resulted in small improvements of 4.7% and 17% respectively from baseline. Detailed statistical analyses of the relationships between injection fear, treatment barriers and health care utilisation further demonstrate the clinical importance of injection fear. CONCLUSION: The prefilled InnoLet device offers important psychological benefits to elderly insulin-dependent diabetes patients with visual and or motor disabilities. The clinical significance of these findings is substantial, given the significant health gains that can be obtained with effective insulin therapy.

TYPE 1 DIABETES, LONG-TERM COMPLICATIONS AND QUALITY OF LIFE MEASURED WITH RAND-36 HEALTH PROFILE MEASURE

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OBJECTIVES: Profile measures of health-related quality of life (HRQoL) are not adequate for all purposes in health economics, but when the effects of a disease or medical treatment to some specific domain of health are considered, profile measures can provide results that are illustrative and easy to interpret. In this study we examine how the effects of type 1 diabetes (TID) and the symptoms of its chronic long-term complications affect the hypothesized physical and mental domains of HRQoL. METHODS: A representative sample of patients with TID was selected randomly from the Finnish drug reimbursement registry. Patients then reported symptoms, diagnoses, and treatments indicating time of appearance and presence of long-term complications, and filled RAND-36 questionnaire. An exploratory factor analysis was performed to test the hypothesis of 2-factor model of health. The results were validated with split-sample analysis. Regression analyses were used in estimating the effects of age, gender and symptoms of long-term complications to the factor component T-scores. RESULTS: Of the 752 (70.8%) patients who responded, 592 were with TID and 96.2% completed the RAND-36 questionnaire. Factor analysis of our data supports the theory of the 2-factor model of health; physical and mental health components were reflected unambiguously by different RAND-36 dimensions. The regression results show that the symptoms of long-term complications influence much stronger on physical than mental domain of the HRQoL. The number of significant symptoms was higher in physical component model (5/8 vs. 3/8) and the coefficient values of those were higher (3.1–4.4 vs. 2.3–3.7). CONCLUSIONS: TID and especially the symptoms of its long-term complications affect mainly the physical domain of health, although the mental domain is also affected. The prevalence of long-term complications of TID in different age groups is sufficiently high to substantially influence on the quality of life of the patients.

SELF-ASSESSMENT OF DIABETES CONTROL: ACCURACY OF PATIENTS’ PERCEPTIONS

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OBJECTIVE: To determine the accuracy of self-reported glucose levels among people with diabetes. METHODS: In August 1999, 903 people with diabetes were sent an at-home HbA1c test kit and a brief questionnaire about blood glucose monitoring and diabetes management. The sample was obtained through an on-going, longitudinal diabetes study. A total of 430 respondents provided a self-reported range of blood glucose levels and completed the home test kit. The midpoint and highest glucose level were compared to laboratory HbA1c values using a regression equation calculated from a previously published formula. The percentage of respondents misestimating their diabetes control was determined. RESULTS:
When evaluating the midpoint of self-reported glucose, there is a positive correlation between respondents’ perceptions and the objective measures of their diabetes control ($r = 0.434, p < 0.001$). However, based on their midpoint values, most of the patients (92%) overestimated their level of control. Self-reported values for about two-thirds of respondents (62%) differed from laboratory results by a clinically relevant amount of more than 25%. When evaluating respondents’ highest reported blood glucose values rather than the midpoint of their range, there was a slightly higher correlation, ($r = 0.467, p < 0.001$). More importantly, based on this comparison, fewer respondents (69%) overestimated their level of control. Only about one-third of respondents (36%) misreported their glucose by more than 25%.

**CONCLUSION:** Objective measures of diabetes control correlate best with highest self-reported glucose. These findings underscore the importance of obtaining frequent objective measures of average glucose control, and the need to monitor glucose values at times of day when they might be highest, rather than lowest. When it is necessary to utilize self-reported data, researchers should realize that the maximum of a self-reported range may most accurately reflect true blood glucose levels.

**DIABETES—Healthcare Policy**

**PDB13**

**REAL WORLD ADHERENCE BENEFITS FROM COMBINATION PRODUCTS UTILIZED IN DIABETICS: SULFONYLUREAS & METFORMIN**

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**OBJECTIVES:** To determine if medication adherence differs when a combination sulfonylurea/metformin is utilized versus each component separately. **METHODS:** Diabetes mellitus (DM) is a chronic and progressive disorder that leads to significant morbidity and mortality and imposes a large economic burden on the health care expenditures in the United States. Although there have been major improvements and modifications in the diagnosis and treatment strategies of diabetes, it estimated that one-third of patients suffering from diabetes are undiagnosed, and hence untreated. The prevalence of diabetes has risen along with disease-related complications nationwide. Therefore, we decided to evaluate patient care by analyzing Health Partners’ pharmacy and medical claims databases for a period of 12 months to determine our own standard of care by evaluating in-house data on HbA1c and lipid profiles and compare it with the standards set forth by the NCQA required HEDIS measures. A computer database search of pharmacy claims identified diabetic patients taking oral diabetic agents, insulin or a combination therapy from January 2001–December 2001 according to the Universal System Classification (USC) codes indicative of diabetic agents. Patients were eligible for inclusion if in a 12-month period, they received mono-therapy on Glucovance, or combination therapy of sulfonylureas and metformin for at least three months during the year. Adherence was defined as having received medication for a minimum of 80% of the therapy’s duration. Lab claims for HbA1C values on these members were collected as well. Results indicated that members on Glucovance ($n = 562$) were more adherent to therapy (55% vs 52%) than those on combination therapy ($n = 932$). In terms of HbA1C control, 18.9% of members adherent to Glucovance therapy had a HbA1C value of $<6.5$ mg/dl versus 16.6% of those adherent with combination therapy. We hope to further explore these initial findings.

**PDB14**

**MEDICAID MANAGED CARE QUALITY AMONG BLACK AND WHITE ADULTS WITH DIABETES MELLITUS**

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**OBJECTIVE:** This study used Georgia Medicaid claims data to evaluate the quality of care among African American (Black) and Caucasian American (White) adults with diabetes mellitus who are enrolled in the mandatory Georgia Better Health Care (GBHC) primary care management program, a managed care delivery model. **METHODS:** This cohort study evaluated the quality of care in relationship to the risk (i.e. rate) of diabetes-related complications and hospitalization using Georgia Medicaid eligibility and provider claim data for the period 1996–1998 (by Chi square and multivariate logistic regression statistics). Black and White Medicaid beneficiaries with newly diagnosed diabetes in 1996 and 1997 were followed for a 12-month period since diabetes diagnosis through year 1997 and year 1998, respectively, according to claim histories. Diabetes diagnoses are based on physician-reported news claims of type 2 diabetes (ICD-9-CM codes 250.0–250.9). Quality of care was based on adherence to American Diabetes Association (ADA) recommendations. **RESULTS:** The results of this investigation indicated poor adherence to ADA recommendations. Among the 3514 Medicaid beneficiaries with diabetes who were enrolled for the entire 12-month period after the initial diagnosis, only 22%, 11%, 15%, and 2% received the ADA annually recommended HbA1c test, eye exam, lipid profile, or any nephropathy tests, respectively. Although similarly likely to receive HbA1c and nephropathy tests, Blacks were less likely to receive eye exams ($p = 0.0347$) and lipid profiles ($p < 0.0001$), independent of such variables as age, gender, insulin status, number of clinic visits, and health plan option. The results also indicated that the 12-month hospitalization rate among Black beneficiaries was 1.6 times higher than the rate among White beneficiaries. **CONCLUSIONS:** GBHC, currently the only health plan option for Medicaid beneficiaries, has not achieved quality standards or an equitable system of care for Georgia Medicaid beneficiaries with diabetes.