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Effectiveness of a Multidisciplinary Patient Assistance Program in Diabetes Care

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Describing patient health outcomes at the Diabetes Resource Center at St. Joseph Health Services of Rhode Island

Background

Presently, there are over 23.6 million Americans with diabetes mellitus.[7] Approximately 65% of people with diabetes mellitus die of cardiovascular disease,[4] which is largely preventable by simultaneous control of multiple cardiovascular risk factors.[5] It is estimated that nearly 21 million patients with diabetes are uninsured or underinsured.[7] Patient assistance programs have been proposed to be an effective model to improved diabetes related outcomes through efficient use of resources, improvement of access to care, intensive medication up-titration and promotion of behavioral change through group support.[9] However, little is known about the effectiveness of these types of programs in diabetes care.

Abstract

Objectives: The primary outcome for diabetes analysis is the change in hemoglobin A1C (HbA1c). This value describes the average glucose level in a patient's blood stream over the preceding three months. Secondary outcomes will be changes in blood pressure, serum lipids, and patient body mass index.

Study Design: This retrospective chart review is to evaluate the changes in personal health markers that serve as prognostic indicators in the progression of type 2 diabetes mellitus.

Methods: Assessing electronic medical records of selected patients in the DRC database from baseline to a twelve-month follow-up period can show how effective the Patient Assistance Liaison (PAL) program is. A statistical analysis of the data will be performed between the data sets of PAL Program patients and insured (non-PAL) patients to show significance. It is hoped that the data will serve as pilot data to determine if a prospective, randomized-controlled study should be performed to evaluate the efficacy of patient assistance program strategies in reducing the overall cardiovascular risk of patients with

type 2 diabetes. Subjects in the PAL Program at the Diabetes Resource Center (DRC) of the St. Joseph Health Services of Rhode Island Hospital for Specialty Care have no health insurance to pay for needed services and medications. It is desirable to know if the care they are receiving is equivalent to patients at the DRC that have prescription drug insurance from a third party provider.

Results: From baseline to follow-up, the PAL program patients experienced improvements in health that were equivalent to that of the non-PAL patient group. In the outcomes of total cholesterol and low-density lipoprotein cholesterol (LDL-C), the PAL group had statistically significant improvements that were not seen in the non-PAL group.

Conclusion: If properly managed and funded, a patient assistance program can be an effective outlet for patients with little or no resources.

Introduction

The patients seen at the Diabetes Resource Center (DRC) of the St. Joseph Health Services of Rhode Island are served to prevent cardiovascular disease and microvascular complications associated with uncontrolled diabetes and disease progression. It is beneficial to observe whether having health insurance can cause disparities in health care delivery at the DRC and influence overall outcomes in long-term disease management. The DRC Patient Assistance Liaison (PAL) Program enrolls patients without health insurance referred to the program from the Adult Primary Care clinic in the St. Joseph Health Services Hospital. The PAL program was initiated in July 2006 and has continued to grow. To gauge the efforts of the program, an audit was conducted to assess the health status of the PAL patients.

Research Design and Methods

Study Design:

This was a retrospective chart review of the electronic medical records of patients diagnosed with type 2 diabetes enrolled at the St. Joseph Health Services DRC from July 1, 2006 to March 31, 2007. There were assessments for medical history, systolic blood pressure (SBP), diastolic blood pressure (DBP), hemoglobin A1c (HbA1c), lipid profile, body mass index (BMI) and enrollment in the PAL program. This study resembled a cohort design.

The University of Rhode Island's Institutional Review Board in conjunction with the St. Joseph Health Services of Rhode Island approved this study.

A total of 199 patients were assessed to see if clinical significance exists in the care provided to the patients served at the DRC. This care must meet national standards. The American Diabetes Association, American Heart Association, and the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure have set the guidelines employed.

Inclusion Criteria:
All patients eligible for inclusion had to be at least 18 years of age with a chart documentation of type 2 diabetes mellitus in the St. Joseph Health Services DRC. Patients must be enrolled between July 1, 2006 and March 31, 2007, and have documented follow-up visits twelve months after the original enrollment date. Subjects must have complete lipid profiles, blood pressures, HbA1c values, and body mass index measurements upon entry into the program and then 12 months after. Subjects must see a primary care provider at the St. Joseph Health Services of Rhode Island's Adult Primary Care clinic and have a record in the electronic medical system of the DRC database.

Exclusion criteria:
Any patient who does not have baseline values for serum lipids, blood pressure, HbA1c or body mass index, as well as the corresponding values 12 months later.

Diabetes Resource Center (DRC) Patients:
Patients are referred to the DRC by primary care physicians in the Adult Primary Care clinic of the St. Joseph Health Services Hospital for Specialty Care, by outside primary care physicians or social service agencies, or are self-referred for case and diabetes management. The DRC provides access to diabetes education, individualized primary care visits for diabetes and referral for specialty care services within the DRC. Specialty care services consist of consultation with Certified Diabetes Outpatient Educator (CDOE) nurses, pharmacists, nutritionists or visits with treatment specialists such as ophthalmologists and podiatrists, as well as enrollment into the PAL program to obtain free medication for their diabetes and related conditions.

Patient education consists of six, one hour class sessions consistent with American Diabetes Association standards for self-management eduction.[6] Visits with a primary care physician are held approximately every 3-4 months and last approximately 20 minutes. Specialty visits

can last up to one hour in length with the DRC CDOE nurses, pharmacists, nutritionists, ophthalmologists and podiatrists.

PAL Program:

Patients eligible for the PAL program were uninsured and were unable to pay for their medications for the treatment of diabetes or diabetes-related conditions. Under the supervision of a physician, the CDOE nurses were the primary providers in the DRC. At the initial visit, nurses assessed medication adherence and laboratory parameters, and developed a treatment plan to control blood pressure, lipids and diabetes. Options for smoking cessation were discussed when applicable. Individualized diet and exercise programs were also created, and referral to a nutritionist and physical therapist were made on an as-needed basis. The Pharm.D. intern assisted with medication reconciliation and pharmacotherapeutic recommendations for the treatment of hypertension, hyperlipidemia, diabetes and tobacco cessation and made recommendations for therapeutic interchange based on the current availability of free medications in the clinic supply.

Outcomes:

The primary outcome is the change in HbA1c values, serum lipids and blood pressures in patients with diabetes enrolled in the PAL Program at the St. Joseph Health Services of Rhode Island Hospital for Specialty Care DRC after twelve months of enrollment.

Secondary outcomes include the difference in national guideline adherence rates for serum lipids[1], glycemic control[2] and blood pressure[3] between patients who are enrolled and those who are not enrolled in the PAL program at the St. Joseph Health Services DRC after twelve months of the patient baseline date. Guideline adherence at twelve months will be defined as an HbA1c < 7%, SBP < 130mmHg, DBP <80mmHg, total cholesterol <200mg/dL, LDL-C <100mg/dL, HDL-C > 40mg/dL, and triglycerides < 150mg/dL. Recommendations for weight loss were given to all patients in the DRC when applicable. A successful outcome for BMI would therefore be classified as < $30kg/m^2$.

Statistical Analysis:

Continuous variables will be expressed as mean ± SD, and categorical variables as percentages. We will use statistical software (SPSS 9.0 for

Windows; SPSS, Inc., Chicago, Illinois) for data analysis. MANOVA with repeated measures will be used to compare the serum lipids, glycemic measures, blood pressure and BMI values at baseline and twelve months after enrollment in the St. Joseph Health Services DRC in both those enrolled in the PAL program and those not enrolled. Discriminant function analysis (DFA) can be used to determine the relationship between the demographic variables and change in dependent variables during treatment. Chi-square testing will be used to compare the frequency of patients that achieved American College of Cardiology / American Heart Association[3] and American Diabetic Association[7] guideline recommended goals for the major cardiovascular risk factors at baseline and twelve months after. In order to detect the apparent effect of the PAL program vs. those not enrolled in PAL, we will repeat the above analyses by excluding those patients who were at target goals for individual risk factors at baseline. In addition, the change in weight will be reanalyzed in those patients with a baseline BMI > 30kg/m^2. Stepwise logistic regression modeling will be used to determine the predictors of improvement as defined as guideline adherence when patients met the therapeutic goal of SBP < 130 mm Hg, A1C < 7%, total cholesterol < 200 mg/dl and LDL Cholesterol < 100 mg/dL. All tests will be considered significant when 2-sided P is less than 0.05.

Sample size calculations and power analysis:

Based on preliminary data, a sample size of 170 would provide >90% power to detect a 10% difference between baseline values and 12 months of follow-up in the DRC for each of the individual outcome measures: serum lipids, glycemic measures, and BMI values with a type I (alpha) error of <5%. The sample size was increased by 15% to account for potential missing data given that this was a retrospective analysis.

Results

Population:

Patient demographics between July 1, 2006 and March 31, 2007

Table 1. Baseline Characteristics (n=199)

Characteristic	PAL Group n=93	Non-PAL Group n=106	P-value
Age (Years)	54.1±10.3	57.9±10.9	0.01
Male	41.8	41.0	1.0
Ethnicity			
White	15.2	5.7	0.03
Hispanic	64.1	77.1	0.06
Black	15.2	11.4	0.06
Asian	5.4	5.7	0.93
Body Mass Index (kg/m^2)	33.0±7.1	33.3±6.8	0.81
Hypertension	61.3	67.9	0.37
Hyperlipidemia	63.4	47.2	0.02
Microvascular Complications			
Neuropathy	12.0	21.9	0.09
Nephropathy	4.4	11.4	0.11
Retinopathy	5.4	3.0	0.48
Smoking Cessation	2.2	3.8	0.69
Medication Utilization			
Sulfonylurea	10.9	15.2	0.41
Metformin	10.9	10.5	1.0
Thiazolidinedione	7.6	17.3	0.05
Insulin	4.4	5.7	0.75
Aspirin	5.4	13.6	0.002
ACE-Inhibitor	6.5	16.2	0.04
Lipid Agent	4.4	11.4	0.11

Patients were similar at baseline from what the data indicate. Significance only existed for age, the white ethnicity, hyperlipidemia, aspirin and ACE-Inhibitor use. It is possible that more people were taking aspirin than as indicated here since it is easily available over-the-counter.

Twelve-month follow up in HbA1c were similar for the PAL and non-PAL groups (8.1±1.9% v 8.1±2.0%, p=0.98), respectively. Total cholesterol values were statistically significant at baseline for the PAL-group and the non-PAL group (184.2±37.5 v 167.2±39.9, p=0.0022), respectively, but were not statistically significant at the twelve-month follow-up period (169.3±36.7 v 169.9±44.6, p=0.9179). LDL-C values

were significantly different at baseline for the PAL group and the non-PAL group (110.1±34.1 v 97.4±33.5, p=0.0089), respectively. There was however, no difference at the twelve-month follow-up period (97.3±31.6 v 102.3±38.3, p=0.3227). BMI values were not different at baseline or follow-up for the PAL group and the non-PAL group (32.8±7.0 v 33.3±6.8, p=0.6697) and (34.0±7.1 v 33.3±6.2, p=0.6126), respectively (Table 2).

Both PAL and non-PAL patients had similar adherence to guideline standards in the HbA1c values. At enrollment, 34.41% of PAL patients were at goal compared to 33.02% of non-PAL patients. At follow-up twelve months later, 35.48% of PAL patients were at goal, compared to 30.19% of non-PAL patients. There exists no statistical significance between these two groups in HbA1c values at follow-up (P=0.88). Significance did exist in the LDL-C values at baseline as 36.56% of PAL patients were at goal, compared to 52.83% of non-PAL patients (P=0.02). No statistical significance existed between the two groups at the follow-up period. There were 63.04% of PAL patients at goal, compared with 52.83% of non-PAL patients (P=0.15) (Figure 2).

Discussion

These data demonstrate that patients enrolled into a patient assistance program are able to achieve a similar level of HbA1c, blood pressure, lipids and BMI as insured patients. In the PAL Program, all patients were receiving the same standards of care, were given the same weight loss, blood pressure and lipid goals, reduction strategies, and received similar care for diabetes. Despite the similarities at baseline, and the equality of care provided to all patients, it appears that the PAL program patients experienced some significant reductions in cardiovascular risk that were not witnessed to the same extent for the patients not in the PAL group.

The effectiveness of the multidisciplinary patient assistance model as assessed by changes in guideline adherences at the 12-month follow-up show that significant progress can be made in individual patient health. Patients in the PAL program often started out below standard guidelines and experienced improvements in health that met national guidelines and were comparable to the non-PAL group. This is attributed to increased access to care and free medications provided by grants and samples from pharmaceutical corporations. This is encouraging as patient assistance programs are often difficult to enroll

in, and can still end up draining a patient's financial resources. From the guideline adherence rates and actual patient values, having health insurance did not cause disparities in patient health.
This is important because many patient assistance programs exist but there is little data substantiating their effectiveness.

Intriguing are the trends of the HbA1c values over the 12-month duration for the separate categories. While the non-PAL patient values went up, the average values for the PAL program patients decreased from baseline. As diabetes care is a primary concern for the DRC, and diabetes itself is an independent cardiovascular risk factor, guidelines recommend tight blood glucose control to maintain overall health. Other important improvements occurred in HbA1c values. Although some patients, particularly in the PAL program, did not achieve a value under 7%, there were still significant reductions. Many patients had poor disease control before entrance into the program. Some patients started at HbA1c values over 12%, and achieved a value under 10%. This would still qualify as a positive difference, and this is important for a patient to know. For this analysis, we employed national guidelines, and further information about all patients that had HbA1c values decline is not provided in this discussion.

Most notable are the results from the LDL-C, triglyceride and total cholesterol analyses. Patients in the PAL program achieved a statistically significant reduction while the majority of insured patients stayed the same or worsened. The lipid values are broken up into total and LDL cholesterol values, which are the two main independent risk factors for atherosclerotic vascular events in diabetic patients. In the LDL-C category, the PAL group had a statistically significant reduction, which is demonstrated by the guideline adherence rate and the comparative analysis with the non-PAL group. Triglycerides are important to assess as well since they serve as an objective measure of circulating fatty acids. While the non-PAL patients had slightly better outcomes in triglycerides, the differences are not statistically significant.

Study limitations include a single site program. Nonetheless the results demonstrate the effectiveness of a PAL program to manage a population with multiple comorbidities that traditionally is considered difficult to treat. A second limitation is that there is only a twelve-month follow-up period, and it is difficult to know if effectiveness can be maintained over longer periods of time. Third, given the training and experience of the PAL providers, it is uncertain whether the success of this model can be easily reproduced through another PAL

team with different training and experience. Further, randomized-controlled trials with a different team of providers of different experiences and in other institutions would be necessary to assess the generalizability of the PAL model. Finally, there is no cost-assessment of the PAL Program, as costs were not formally tracked. However, a simple cost estimation associated with the program can be attempted by including personnel salaries, facility costs, medication supplies, and laboratory costs per participant. The cost for the personnel in this program was calculated using the hourly rate for time required by each provider for preparation, intervention and documentation. The hourly rate was calculated using the annual salaries of providers from the official job site for the United States Federal Government (www.usajobs.gov) by July, 2008. Facility costs were estimated by including the cost for support staff, space, electricity, mail, fax and telephones. Laboratory costs included the cost for a chem-7, lipid panel and HbA1c tests ordered at baseline and 12-month follow-up. These added for a total of $49.23 per patient per hour. It is reasonable to assume that the control of cardiovascular risk factors may reduce long-term costs via reduction of acute care visits, hospitalization and diabetes related complications.

Conclusion:

This study suggests that a PAL program model is feasible and effective for improving multiple cardiac risk factors in patients with type 2 diabetes.

Appendix:

Figure 1. Patient Selection

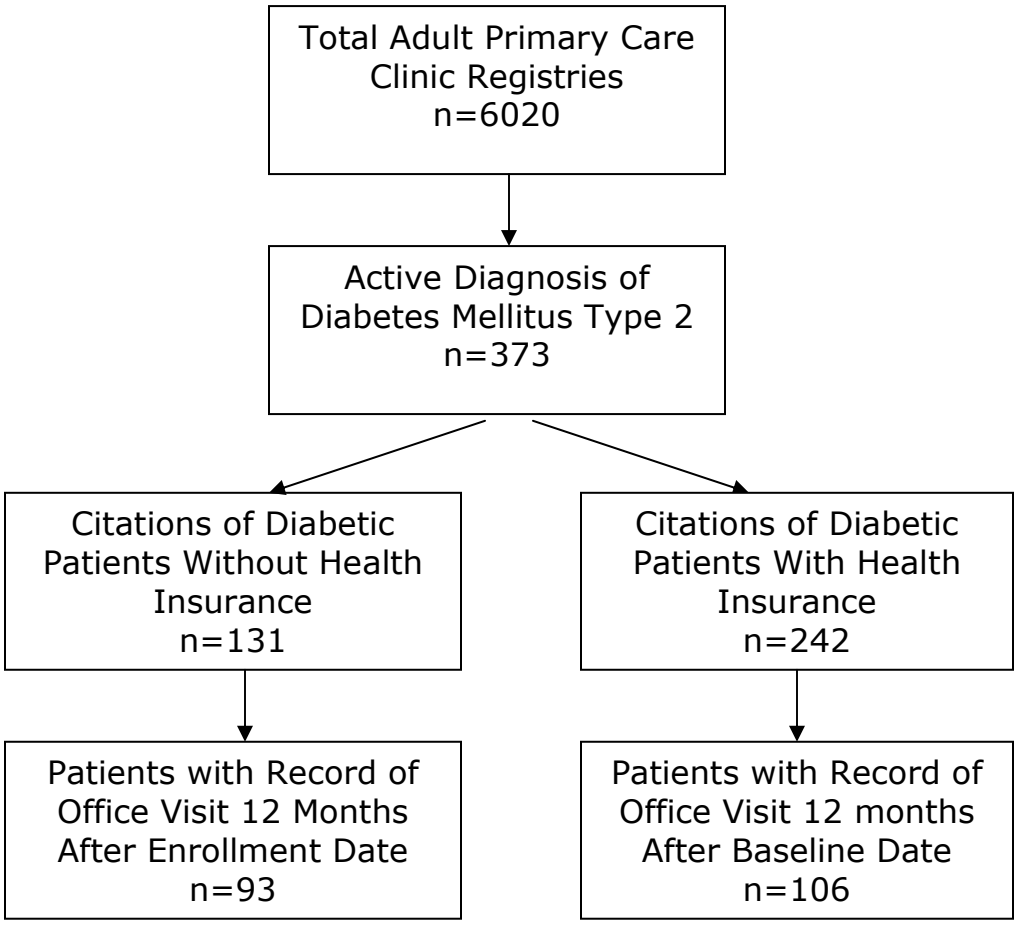
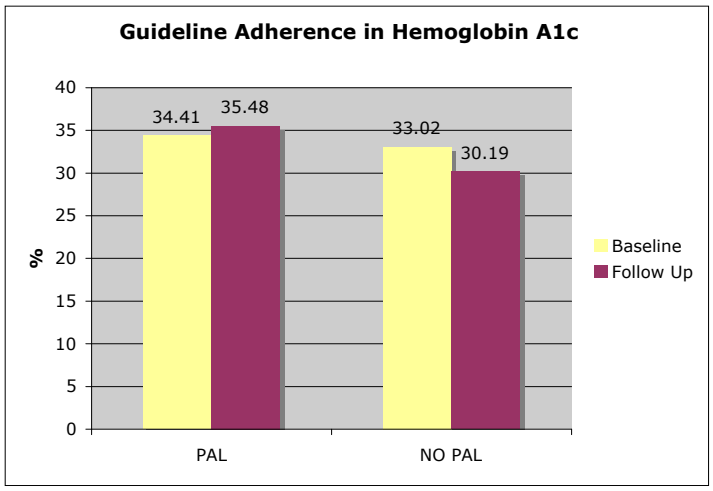
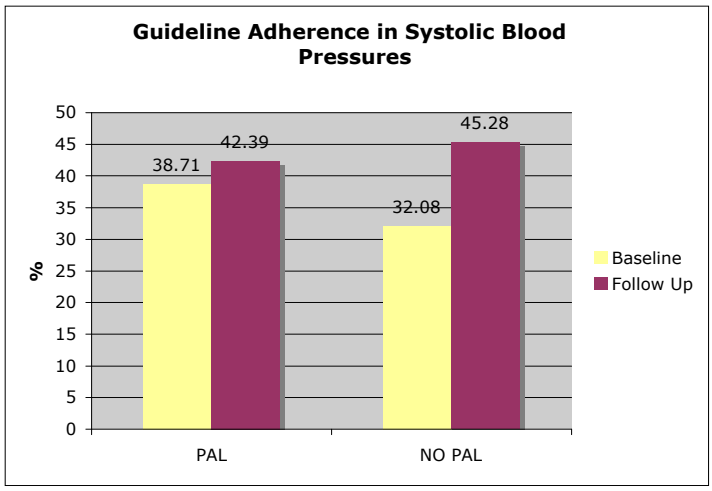


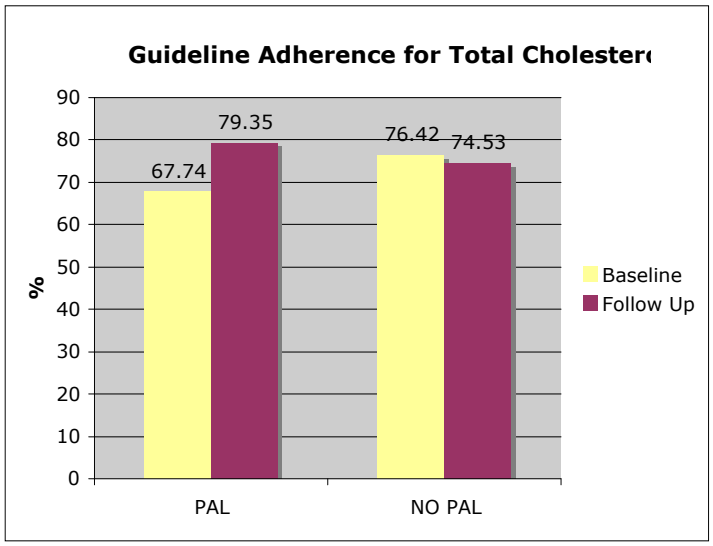
Table 2. Baseline to Follow-Up Value and Average Change
P-value for Total Cholesterol Parameter=0.0023
P-value for LDL-C Parameter=0.0015

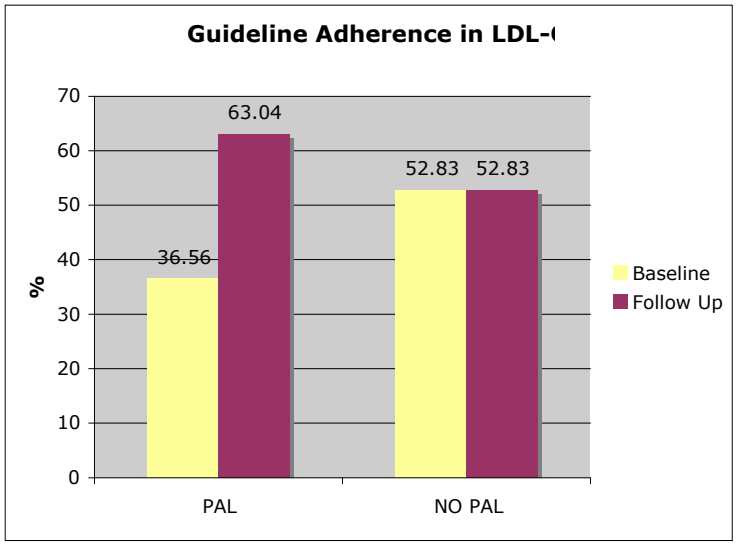
	PAL Group			Non-PAL Group		
	N=93			N=106		
Parameters	Baseline	12 Months	Average Change	Baseline	12 Months	Average Change
HbA1c (%± SD)	8.3 ± 2.2	8.1 ± 1.9	-0.2 ± 1.7	8.2 ± 2.0	8.1 ±2.0	-0.1 ± 1.4
SBP (mmHg ± SD)	136.7 ± 21.1	133.6 ± 17.1	-3.3 ± 20.7	139.1 ± 20.1	134.3 ± 20.7	-4.8 ± 22.2
DBP (mmHg ± SD)	81.3 ± 10.9	78.7 ± 9.2	-2.5 ± 11.1	79.4 ± 11.0	77.1 ± 10.4	-2.3 ± 12.7
Total Cholesterol (mg/dL± SD)	184.2 ± 37.5	169.3 ± 36.7	-15.7 ± 45.3*	167.2 ± 39.9	169.9 ± 44.6	2.7 ± 37.7
LDL-C (mg/dL± SD)	110.1 ± 34.1	97.3 ± 31.6	-13.4 ± 41.9*	97.4 ± 33.5	102.3 ± 38.3	4.9 ± 37.2
HDL-C (mg/dL ± SD)	45.6 ± 12.4	44.8 ± 12.1	-0.7 ± 12.2	45.0 ± 13.9	42.0 ± 12.0	-3.0 ± 12.5
Triglycerides (mg/dL ± SD)	145.9 ± 104.8	128.9 ± 74.9	-18.2 ± 109.4	122.2 ± 72.8	128.7 ± 73.1	6.5 ± 68.0
BMI (kg/m^2 ± SD)	32.8 ± 7.0	34.0 ± 7.1	1.1 ± 4.3	33.3 ± 6.8	33.3 ± 6.2	0.2 ± 2.7

Figure 2. Guideline Adherence of Baseline and Follow-Up Analysis









REFERENCES

1. Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). NHLBI. 2004. (Accessed July 6, 2005, at http://hin.nhlbi.nih.gov/cvd_frameset.htm.)
2. American Diabetes Association. Standards of Medical Care in Diabetes-2006. Diabetes Care 2006;29(suppl_1):S4-42.
3. The sixth report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. Arch Intern Med 1997;157(21):2413-46.
4. Centers for Disease Control. The Burden of Chronic Diseases and Their Risk Factors: National and State Perspectives 2004. National Center for Chronic Disease Prevention and Health Promotion, 2004. (Accessed at
5. Gaede P, Vedel P, Larsen N, Jensen GVH, Parving H-H, Pedersen O. Multifactorial Intervention and Cardiovascular Disease in Patients with Type 2 Diabetes. In; 2003:383-93.
6. Mensing C, Boucher J, Cypress M, et al. National Standards for Diabetes Self-Management Education. In; 2002:140S-7.
7. American Diabetes Association. Health Insurance Information for People with Diabetes. (Accessed March 1, 2009, at http://www.diabetes.org/advocacy-and-legalresources/ healthcare/ insurance.jsp.)
8. American Diabetes Association. All About Diabetes. (Accessed March 1, 2009, at http://www.diabetes.org/about-diabetes.jsp.)
9. Rhode Island Department of Health. Diabetes Prevention and Control Program. Comprehensive
Healthcare Improvement Project. (Accessed March 1, 2009, at http://www.health.ri.gov/disease/diabetes/ whatisdcp.php)