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Good Outcome of Anti-Diabetic Therapy: A Proposal for Evidence-Based Process Indicators

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ABSTRACT

Background: The need to search for reliable process indicators for the effectiveness of anti-diabetic therapy has been expressed in the literature. Process indicators have been described as essential processes that contribute to achieving outcomes.

Objective: This study seeks to identify and propose evidence-based process indicators for a good outcome (effectiveness) of anti-diabetic therapy in a Nigerian University Teaching Hospital.

Methods: A crossectional study was conducted using a questionnaire about the degree of subjects' knowledge/practice of lifestyle/dietary modification based on set criteria. Glycemic control based on the latest monitoring tests and physician's remarks were extracted from the case notes of each selected subject: sample Size, n=1200. Subjects were selected by systematic random sampling (Sampling Interval=1).

Results: Three Hundred and Thirteen (77.7%) out of 403 subjects with reasonable glycemic control were effects by exercise. Those were with excellent knowledge about signs and symptoms of hyperglycemia, the beneficial effects of exercise, treatment, and excellent practice of self-monitoring. About 311 (77.2%) out of 403 subjects who had reasonable glycemic control were those who had excellent knowledge about dietary modification. Almost 308 (76.4%) out of 403 subjects who had reasonable glycemic control were those who had excellent knowledge about lifestyle modification. Three Hundred and Six (75.9%) out of 403 subjects who had reasonable glycemic control were those who had excellent knowledge about complications of diabetes mellitus. Many subjects with excellent lifestyle/dietary modification practices had reasonable glycemic control.

Conclusion: Evidence-based process indicators for a good outcome (effectiveness) of anti-diabetic therapy have been identified/proposed as the degree of knowledge about signs and symptoms of hyperglycemia, complications of diabetes mellitus, beneficial effects of exercise, treatments, dietary modification, and lifestyle modification. Other process indicators identified/proposed are the degree of self-monitoring practice, lifestyle, and dietary modification.

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Introduction

Diabetes Mellitus is a chronic, incurable condition that affects 3% of the Nigerian population1, 2. There is evidence that the prevalence of non-communicable diseases is increasing, including diabetes mellitus, which, if not adequately managed, can result in a wide range of complications with clinical, social, and economic implications, primarily due to decreasing age onset3, 4. Pharmaco-Economic tools, using the economic, clinical, and humanistic outcome (ECHO) model, help achieve the effectiveness of therapy. Cost-Effective therapy of diabetes mellitus will not only ensure rational drug use but also reduce patients dropping out of treatment because of cost, thereby reducing the incidence of therapeutic failure by enhancing the economic, clinical, and humanistic outcome of therapy. Complications due to this disease would be reduced, and improved patients' quality of life would be achieved3, 4, 5.

There was reported impaired glucose tolerance (IGT) of 7.7% rate among Hausa-Fulani in North-Eastern Nigeria who have no history of diabetes mellitus6. It was opined that this would increase the incidence of diabetes mellitus, as one in three individuals with IGT will develop Type II diabetes mellitus6. Although WHO (2007) accorded priority status to diabetes mellitus, many public health planners remain unaware of its magnitude and complications1.

Diabetes Mellitus is one of the most common non-communicable diseases, and its epidemic proportion has placed it at the forefront of public health challenges currently facing the world. The estimated global burden of diabetes mellitus was 135 million cases in 1995, 171 million in 2000 (2.8% prevalence rate) in a worldwide adult population of under 4 billion, and it has projected that there will be 299 million cases by the year 2025 and 366 million (4.4% prevalence rate) in 20302. A quarter of these populations are over 65 yrs old, while 25% of adults affected are less than 44 yrs of age2. An increase in the number of people with diabetes is attributable to population growth, an increase in the aging population, urbanization, increase in the prevalence of obesity7, 8.

Dietary and lifestyle modifications are the mainstay of managing Type II diabetes mellitus. The majority of people with Type II DM are overweight and usually have other metabolic disorders of the insulin resistance syndrome, so the significant aims of dietary and lifestyle changes are to reduce weight, improve glycemic control and reduce the risk of coronary heart disease (CHD), which account for 70-80% of death among those with diabetes9.

Collaborating with doctors and other healthcare professionals, pharmacists can improve diabetic patient's quality of life through pharmaceutical care10. Implementing identified relevant pharmaceutical care standards in the practice setting11 can achieve this. Pharmaceutical care has been defined as a practice in which the practitioner takes responsibility for a patient's drug-related needs and holds him or herself accountable for meeting those needs. It is a responsible provision of drug therapy to achieve definite outcomes 12, 13, 14.

The need to search for reliable process indicators for the effectiveness of diabetes care has been expressed in the literature15. Process indicators have been described as essential processes that contribute to achieving outcomes15. The diabetes care program should be deliberately designed like a step-care approach to diabetes management15. These indicators need to be stated in the literature.

This study aimed to identify/propose evidence-based process indicators for anti-diabetic therapy's good outcome (effectiveness) in a University Teaching Hospital in North-Eastern Nigeria.

Method

The study was conducted at the University of Maiduguri Teaching Hospital (UMTH), Maiduguri, Borno State, Nigeria. The Hospital was chosen because it was the only University Teaching Hospital in North-Eastern Nigeria, serving the six catchment states of North-Eastern Nigeria at the time of this study.

Diabetes Mellitus cases were usually referred to UMTH from these catchment states at the time of conducting this study.

Ethical approval was obtained from the research and ethics committee of UMTH. The selected diabetic patients were told that they would be interviewed and that their prescriptions and case notes would be examined and used for research purposes. Their consent was sought and obtained at the pharmacy exit point before the interview and data collection.

Type II diabetes mellitus patients registered with and attended the diabetes clinic of UMTH were the subjects of the study. Their population was 2,528, obtained from Medical Records Department, and is assumed /used to estimate the population size of serviced Type II diabetes mellitus patients. Fischer's Formula was applied to determine the sample size from this estimate. The required sample size was 351. However,

1200 of the estimated population were studied due to the availability of resources and to reduce error.

A crossectional study whereby each selected subject was seen and interviewed once in the study at the point of exit from the out-patient pharmacy was adopted for a collection of information about the degree of subjects' knowledge/practice of lifestyle/dietary modification based on set criteria for assessment17, 18, 19, 20.

A pre-tested, standardized interviewer's administered questionnaire with sections on socio-demographic data, degree of subjects' knowledge/practice of lifestyle/dietary modification, and glycemic control based on the latest monitoring tests and physician's remark from case-note of each subject was designed and used for this study. The instrument was used to obtain information on socio-demographic data, degree of subjects' knowledge/practice of lifestyle/dietary modification from the subjects at the point of exit from the out-patient pharmacy on consecutive diabetes clinic days (Tuesdays) in a systematic random sampling (using a sampling interval of 1) of subjects that fall within the inclusion criteria until a total of 1,200 subjects were interviewed.

Criteria for assessing the degree of subjects' knowledge about lifestyle and dietary modification were obtained from the literature and used in rating the degree of knowledge/ practice of specific lifestyle/dietary modification into excellent, good, fair, or poor. The glycemic Control category based on the latest monitoring tests and physician's remarks was extracted from traced case-note of each subject into their respective questionnaires, coded by the hospital number of individual subjects.

The collected data were analyzed using EPI-INFO software version 3.5.3 2011. Data were presented as frequency distribution tables and charts. Chi-Square Analysis was used to compare proportions and test the hypothesis. P-Values < 0.05 were considered significant.

Results

Three Hundred and Thirteen (77.7%) out of 403 subjects who had reasonable glycemic control were those who had excellent knowledge about the signs and symptoms of hyperglycemia. About 275 (100%) out of 275 and 436 (83.5%) out of 522 subjects with adequate and poor glycemic control were those with fair and poor knowledge about signs and symptoms of hyperglycemia, respectively. There was an association between the degree of subjects' knowledge about signs and symptoms of hyperglycemia and glycemic control*. (Figure 1).

Three Hundred (74.4%) out of 403 subjects with reasonable glycemic control were those with excellent knowledge about hypoglycemia's signs and symptoms. Two hundred and Seventy-two (98.9%) out of 275 and 436 (83.5%) out of 522 subjects with adequate and poor glycemic control were those with fair and poor knowledge about signs and symptoms of hypoglycemia, respectively. There was an association between the degree of subjects' knowledge about signs and symptoms of hypoglycemia and glycemic control (c2 =1890.78; df = 6; p = 0.000)

Three Hundred and Thirteen (77.7%) out of 403, 233 (84.7%) out of 275, and 436 (83.5%) out of 522 subjects who had good, fair, and poor glycemic control were those who had excellent, fair, and poor knowledge about the beneficial effect of exercise respectively. There was an association between the degree of subjects' knowledge about the beneficial effect of exercise and glycemic control (c2 = 1701.33; df = 6; p = 0.000)

About 311 (77.2%) out of 403, 271 (98.5%) out of 275, and 278 (53.3%) out of 522 subjects who had good, fair, and poor glycemic control were those who had excellent, fair, and proper knowledge about dietary modification respectively. There was an association between the degree of subjects' knowledge about dietary modification and glycemic control (c2 = 1423.52; df = 6; p = 0.000)

Almost 308 (76.4%) out of 403, 275 (100%) out of 275, and 431 (82.6%) out of 522 subjects who had good, fair, and poor glycemic control were those who had excellent, fair, and poor knowledge about lifestyle modification respectively. There was an association between the degree of subjects' knowledge about lifestyle modification and glycemic control (c2 = 1941.54; df = 6; p = 0.000)

Three Hundred and Six (75.9%) out of 403, 275 (100%) out of 275, and 424 (81.2%) out of 522 subjects who had good, fair, and poor glycemic control were those who had excellent, fair, and poor knowledge about complications of diabetes mellitus respectively. There was an association between the degree of subjects' knowledge about complications of diabetes mellitus and glycemic control (c2 = 1860.69; df = 6; p = 0.000). About 313 (77.7%) out of 403, 275 (100%) out of 275, and 421 (80.7%) out of 522

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subjects who had good, fair, and poor glycemic control were those who had excellent, fair, and poor knowledge about their treatment respectively. There was an association between the degree of subjects' knowledge about their treatment and glycemic control (c2=1892.58; df = 6; p = 0.000)

Three Hundred and Thirteen (77.7%) out of 403, 275 (100%) out of 275, and 436 (83.5%) out of 522 subjects who had good, fair, and poor glycemic control were those who had excellent, fair, and poor practice of self-monitoring respectively. There was an association between the degree of subjects' practice of self-monitoring and glycemic control*. (Figure 2).

Almost 187 (65.2%) out of 287, 359 (60.4%) out of 594, 202 (99.5%) out of 203, and 116 (100%) out of 116 subjects who never smoked, smoked occasionally, smoked frequently, and smoked very frequently were those who had excellent, fair, poor and poor knowledge about lifestyle modification respectively. There was an association between the degree of subjects' knowledge about lifestyle modification and the practice of cigarette smoking (c2 =1423.9; df=9; p =0.00)

About 154 (58.3%) out of 264, 359 (58.1%) out of 618, 202 (100%) out of 202, and 116 (100%) out of 116 subjects who never took alcohol, took alcohol occasionally, frequently, and very frequently were those who had excellent, fair, poor and poor knowledge about Lifestyle modification respectively. There was an association between the degree of subjects' knowledge about lifestyle modification and the practice of alcohol intake (c2 =1307.1; df= 9; p =0.00)

About 427 (73.2%) out of 431, 210 (73.7%) out of 364, and 239 (72.0%) out of 310 subjects who never exercised, exercised occasionally and daily, respectively, were those who had poor, fair, and excellent knowledge about Lifestyle modification respectively. There was an association between knowledge about lifestyle modification and the practice of exercise (c2 =1363.1; df=6;

p =0.00)

Overall, there was an association between knowledge about lifestyle modification and practice of lifestyle modification among subjects.

Almost 313 (43.3%) out of 723 and 355 (74.4%) out of 477 subjects who reduced carbohydrate intake and those who did not change their carbohydrate intake after diagnosis of their diabetes mellitus were those who had excellent and fair knowledge about dietary modification respectively. There was an association between the degree of subjects' knowledge about dietary modification and modification of carbohydrate intake (c2 = 414.4; df = 3; p =0.00)

One Hundred and Four (57.5%) out of 181, 313 (76.2%) out of 411 and 466 (76.6%) out of 603 subjects who reduced protein intake, increased and did not change their protein intake after diagnosis of their diabetes mellitus were those who had fair, excellent and fair knowledge about dietary modification respectively. There was an association between knowledge about dietary modification and modification of protein intake (c2 =1264.9; df=6;

p =0.000)

Three Hundred and Thirteen (55.9%) out of 560 and 394 (74.4%) out of 640 subjects who reduced their fat intake and those who did not change their fat intake after diagnosis of their diabetes mellitus were those who had excellent and fair knowledge about

dietary modification respectively. There was an association between knowledge about dietary modification and modification of fat intake (c2 =733.4; df=3; p =0.00).

Overall, there was an association between knowledge about dietary modification and practice of dietary modification among subjects.

Two Hundred and Eighty-Two (70.0%) out of 403 and 275 (100.0%) out of 275 subjects with excellent and fair glycemic control were those who never smoked and those who occasionally smoked, respectively. There was an association between the degree of cigarette smoking and glycemic control*. (Figure 3).

Two Hundred and Forty Four (60.5%) out of 403 and 275 (100.0%) out of 275 subjects with good and fair glycemic control were those who never took alcohol and those who occasionally took alcohol, respectively. There was an association between the degree of alcohol intake and glycemic control (c2 =1135.0; df=6; p = 0.000)

Three Hundred and Twenty-Eight (81.4%) out of 403 and 436 (83.5%) out of 522 subjects with good and poor glycemic control were those who exercised daily and those who never exercised, respectively. There was an association between the degree of exercise and glycemic control*. (Figure 4). Overall, there was an association between lifestyle modification and glycemic control (outcome of anti-diabetic therapy).

Four Hundred and Three (100.0%) out of 403 and 275 (100.0%) out of 275 subjects with reasonable and fair glycemic control were those who reduced and did not change their

carbohydrate intake, respectively. There was an association between carbohydrate intake modification and glycemic control*. (Figure 5).

Four Hundred and Three (100%) out of 403 and 275 (100%) out of 275 subjects who had reasonable and fair glycemic control were those who increased and those who did not change their

Protein intake after diagnosis of their diabetes mellitus, respectively. There was an association between protein intake modification and glycemic control*. (Figure 6).

Four Hundred and Three (100.0%) out of 403 and 365 (69.9%) out of 522 subjects with good and poor glycemic control were those who reduced and those who did not change their fat intake after diagnosis of their diabetes mellitus, respectively. There was an association between fat intake modification and glycemic control*. (Figure 7)

Overall, there was an association between dietary modification and glycemic control.

Discussion

The observed association between the degree of subjects' knowledge about dietary modification and glycemic control and the association between the degree of subjects' knowledge about lifestyle modification and glycemic control are significant because they imply that when diabetes patients acquire knowledge about the benefits and practice of lifestyle/dietary modification through a comprehensive educational program, they would most likely adopt positive behavioral changes that would show clinically significant improvement in glycemic control, coronary heart diseases risk factors and quality of life measures19. It was opined that behavioral change, although difficult to obtain, is possible with regular support19. A smoking cessation rate of 36% in diabetes patients undergoing lifestyle modification educational programs compared with only 8% in the usual care group was reported19. The present study had an association between the degree of cigarette smoking and glycemic control. Cigarette Smoking markedly increases the risk of coronary heart disease (CHD) in diabetes, while its cessation is effective in CHD risk reduction in diabetic patients20. In one study, compared to those who never smoked, the relative risk (RR) for CHD across smoking categories was 1.21 for past smokers, 1.66 for current smokers of 1-14 cigarettes/day, and 1.66 for current smokers with more than 15 cigarettes/day21. Smokers with diabetes have an increased risk of death, nerve damage, kidney diseases, and foot infection. As such, smoking should be avoided by people with diabetes 21.

In the same trend, there was an association between the practice of alcohol intake and glycemic control (outcome of anti-diabetic therapy). In people with diabetes, alcohol consumption should be avoided in those suffering from hypertriglyceridemia, those who are overweight, and those with hypertension22, 23. In general, alcohol use is discouraged in diabetes patients. However, an individual diabetic should be assessed to determine if the advantages of alcohol consumption (e.g., reducing emotional tension, anxiety, etc.) outweigh the potential effects on blood glucose control18.

One of the significant risks of alcohol consumption among individuals with diabetes is the potential danger of hypoglycemia, especially among those who use sulphonyl ureas20.

An association between the practice of exercise and glycemic control was observed in this study. Improved insulin sensitivity and insulin-induced glucose metabolism (glycolysis, glycogenesis, and conversion of glucose to fats) with exercise have been previously observed 24. Exercise improves circulatory function, an essential factor in diabetes management. It helps maintain average body weight and aids in breathing, digestion, and metabolism18. Exercise contributes positively to well-being physically and mentally. It also increases glucose utilization. People with diabetes should participate in regular exercise as it will enhance stable blood glucose. Overall, this study revealed an association between lifestyle modification and glycemic control (outcome of anti-diabetic therapy). A comprehensive lifestyle program improves glycemic control, lowers the risk of cardiovascular diseases and potential complications of Type II diabetes mellitus, and improves the quality of life outcomes19. Research showed that intensive lifestyle changes might prevent and even reverse CHD25, which occurs 2.5 times more in people with diabetes than non-diabetics26.

Furthermore, there is evidence of the effectiveness of lifestyle and behavioral changes, including diabetes self-management training, in Type II diabetes mellitus patients27.

Lifestyle changes that focus on healthy eating, physical activity, weight control, and diabetes

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care can prevent or delay the complications associated with Type II diabetes mellitus. People with Type II diabetes mellitus who improve their metabolic control through an intensive self-care regimen have been confirmed to decrease the onset and progression of micro-vascular complications28 significantly. There was an association between carbohydrate intake modification and glycemic control (outcome of anti-diabetic therapy). Carbohydrate consumption is acceptable, provided that it is rich in soluble fiber and is of low glycemic index20. Sixty to seventy percent of caloric intake in the form of carbohydrate have been recommended29. Dietary carbohydrates from cereal, bread, other grain products, and sugars should provide 50-60% of the individual energy requirement30. Current guideline on carbohydrate consumption still emphasizes the importance of total carbohydrate intake, but it focuses on selecting carbohydrate with a low glycemic index31.

Similarly, there was an association between protein intake modification and glycemic control. Current evidence indicates that people with diabetes have similar protein requirements to the general population, about 0.8g/kg/day30. An association between saturated fat intake modification and glycemic control was also found in this study. Fat is the most energy-rich of all nutrients, and reducing fat intake helps reduce total energy intake, which is vital for many people with Type II diabetes mellitus.

Seventy-five percent (75%) occurrence of reasonable glycemic control with

25% and 0% occurrence of moderately and poorly controlled glycemia based on monitoring tests in 24 subjects on a diet only, respectively. In the present study is evidence that dietary modification enhanced glycemic control. Overall, this study showed an association between dietary modification and glycemic control. Also, it agrees that adherence to dietary modification caused a 25% reduction in overall mortality due to poor glycemic control and a 33% reduction in death from cardiovascular diseases32. This study's results support the use of dietary modification (low fat, low carbohydrate, moderately high protein) and lifestyle modification (exercise and maintenance of ideal body weight) as the mainstay of managing Type II diabetes mellitus29. The use of hypoglycemic agents in Type II diabetes mellitus is not to replace dietary and lifestyle modification but to complement it33.

The present study revealed that the following indicators could rationalize the effectiveness of anti-diabetic therapy to ensure optimum economic, clinical, and humanistic outcomes (ECHO): Patient counseling and patient education (to impact knowledge) about signs and symptoms of hyperglycemia/hypoglycemia, the beneficial effect of exercise, complications associated with diabetes mellitus, treatment, and self-monitoring.

Others are the degree of exercise, knowledge/practice of dietary/lifestyle modification, evidence from medication records/case notes of physician's remark on glycemic control to rationalize treatment compliance monitoring by the pharmacist, physician, patient relations, and self-monitoring.

The findings from this study have addressed the concern to consider individual and societal costs of diabetes and search for reliable process indicators for the effectiveness of care for the disease15. The identified process indicators from the current study, when designed into a guiding/standardized checklist for diabetes management program, would measure the program's activities/output and indicate whether the diabetes management program is being implemented as planned, identify and fill the gap where necessary with the resultant effect of contributing to the achievement of definite diabetes management outcomes. It also would improve the credibility of our healthcare settings by ensuring the effectiveness of drug therapy and the efficiency of health services.

Conclusion

Subjects significantly differ in degree of knowledge about signs and symptoms of hyperglycemia/hypoglycemia, the beneficial effect of exercise, dietary modification, lifestyle modification, complications associated with diabetes mellitus, treatment, and practice of self-monitoring, with the majority having poor knowledge in all cases and poor practice of self-monitoring.

There was an association between the degree of subjects' knowledge about signs and symptoms of hyperglycemia/hypoglycemia, beneficial effects of exercise, dietary modification, lifestyle modification, complications of diabetes mellitus, treatment, the practice of self-monitoring, respectively, and glycemic control. There was an association between the degree of subjects' knowledge about lifestyle modification and the practice of lifestyle modification. There was also an association between the degree of knowledge about dietary modification and the practice of dietary modifications. There was an association between the practice of lifestyle modification and glycemic control. There was

also an association between dietary modification and glycemic control.

This study has identified/proposed evidence-based process indicators for effectiveness (Good Outcome) of anti-diabetic therapy as the degree of knowledge about signs and symptoms of hyperglycemia, complications of diabetes mellitus, beneficial effects of exercise, treatments, dietary modification, and lifestyle modification. Other process indicators identified/proposed are the degree of self-monitoring practice, lifestyle, and dietary modification. The process indicators identified/proposed in this study could be adopted, developed into the appropriate checklist, and enforced in anti-diabetic therapy to ensure the effectiveness and efficiency of health services.

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Ethical Considerations

Compliance with ethical guidelines

This study was approved by the ethical committee of the Tehran University of Medical Sciences (TUMS). All the participants accepted enrollment in the study orally and all of the data that were gathered was considered confidential.

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Conflict of interest

All authors declare no potential conflicts of interest in conducting the study and publishing the article.

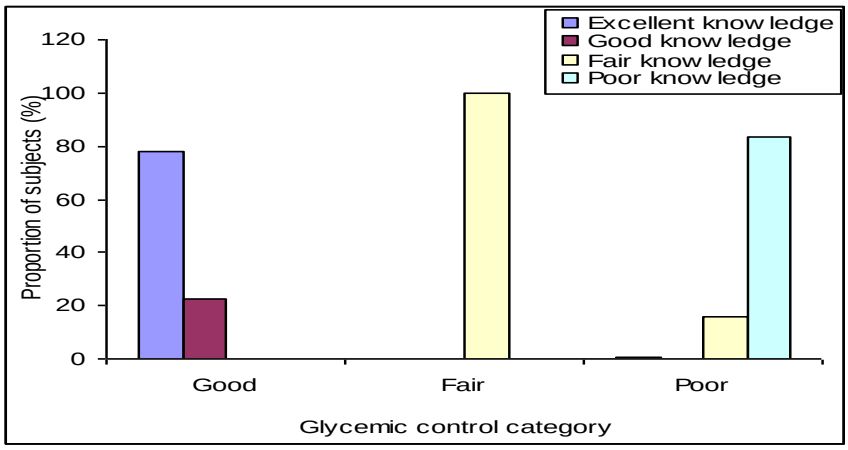

Figure 1: Relationship between the Degree of Subjects' Knowledge about Signs and Symptoms of Hyperglycemia and Glycemic Control (Outcome of Anti-Diabetic Therapy)
*(χ^2=1960.8; df=6; p=0.000).

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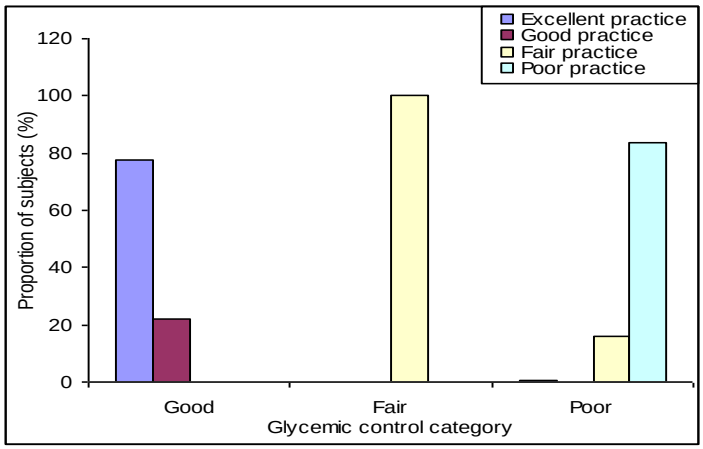


Figure 2: Relationship between Degree of Practice of Self Monitoring and Glycemic Control (Outcome of Anti-Diabetic Therapy)

*(χ^2 = 1960.81; df = 6; p = 0.000)

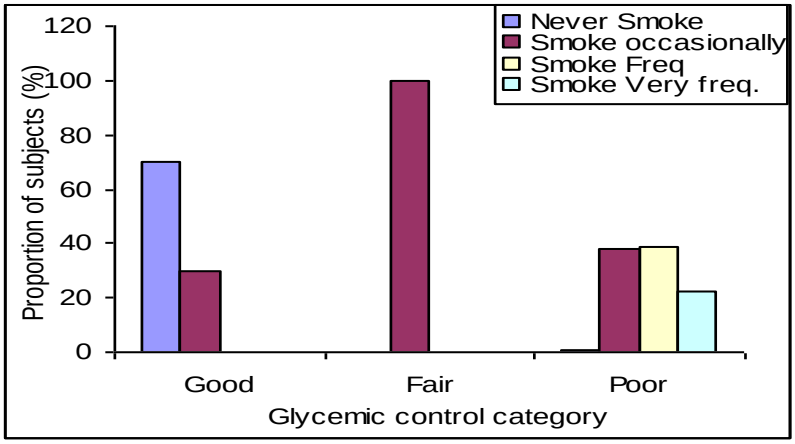
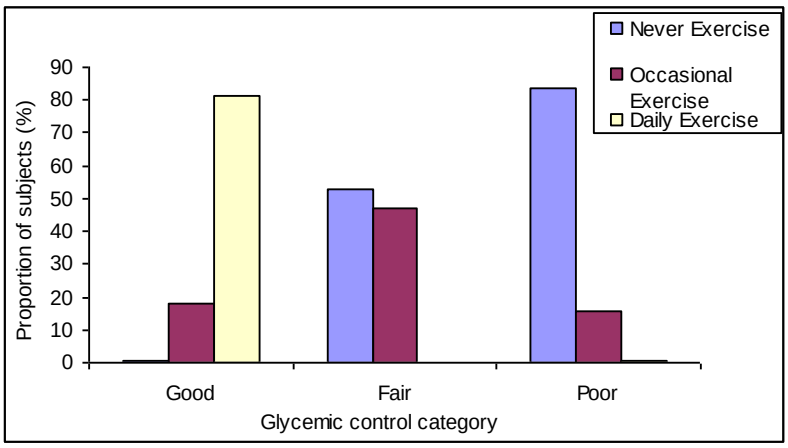


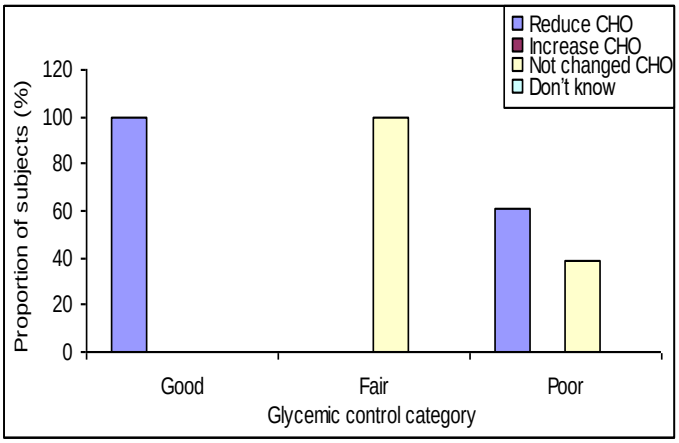
Figure 3: Relationship between the Degree of Subjects' Cigarette Smoking and Glycemic Control (Outcome of Anti-Diabetic Therapy)

*(χ^2 =987.8; df=6; p = 0.00)



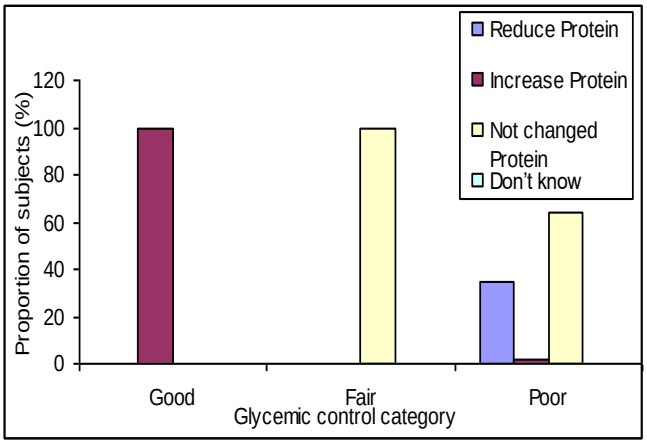
*(χ^2 =1040.7; df=4; p = 0.00)

Figure 4: Relationship between Degree of Subjects' Exercise and Glycemic Control (Outcome of Anti-Diabetic Therapy)



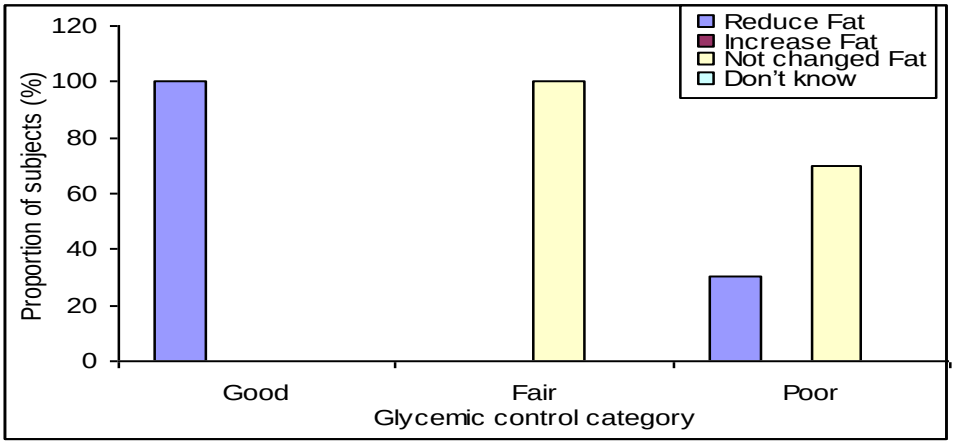
*(χ^2=682.9; df=2; p = 0.00)

Figure 5: Relationship between Carbohydrate Intake Modification and Glycemic Control (Outcome of Anti-Diabetic Therapy)



*(χ^2 =1355.1; df=4; p = 0.00).

Figure 6: Relationship between Modification of Protein Intake and Glycemic Control (Outcome of Anti-Diabetic Therapy)



*(χ^2 =758.9; df=2; p=0.00)

Figure 7: Relationship between Modification of Fat Intake and Glycemic Control (Outcome of Anti-Diabetic Therapy)

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