AMERICAN UNIVERSITY OF ARMENIA

COLLEGE OF HEALTH SCIENCE

MASTER OF PUBLIC HEALTH PROGRAM

PATIENT- DEPENDENT CHARACTERISTICS RELATED TO

POOR GLYCEMIC CONTROL IN TYPE 2 DIABETES IN

YEREVAN:

A CASE- CONTROL STUDY.

A THESIS PROJECT

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Abstract

Introduction: Although it is well recognized now that level of glycemic control in patients with diabetes depends on many factors related to patient himself/ herself, health care providers, and care environment, a controversy exists in literature in terms of main characteristics associated to poor glycemic control in patients with the disease.

There is no study done in Armenia to identify major factors related to non-satisfactory glucose control in type 2 diabetes patients, and there is a high need of such type of information.

Objectives: This study was aimed to assess several patient and the disease- related variables for their effect on glycemic control in people with type 2 diabetes living in Yerevan, as well as to reveal current situation with type 2 diabetes in the Republic to help policy- makers to design appropriate strategies to overcome existing problems related to disease management.

Design and methods: The study was an expansion of the cross- sectional epidemiologic study "Survey of type 2 diabetes mellitus patients in Yerevan" done in September 1998, i.e. a case- control secondary analysis of the data collected (1) during household interviews from 72 patients randomly selected from all the patients registered at the Yerevan's polyclinic as having type 2 diabetes, as well as (2)from medical records of those patients. Descriptive analysis was used to determine characteristics of cases and controls. Independent variables [such as age; gender; body mass index (BMI), socio- economic, smoking, self- rated health status, knowledge about diabetes, as well as duration of the disease and type of prescribed treatment] were studied for their association with poor glycemic control.

Results: Statistically significant association was found between poor glucose control and (1)being older than 60 years (odds ratio (OR)= 3.3); (2) having BMI higher than 28 (OR = 2.8); (3) positive past smoking status (OR = 3.18); and (4) being treated by hypoglycemic pills vs. treatment by insulin (OR = 0.142). In addition several problems related to current diabetes management in Yerevan (quality of medical records, patient awareness about their rights) were revealed.

Recommendations: Polyclinic-based endocrinologists should closely monitor patients at increased risk of poor glycemic control (age over 60, BMI over 28) and improve the quality of record keeping. Officials responsible for diabetes care in Yerevan (1) implementing diabetes related programs should take into account the most vulnerable groups in terms of poor glycemic control, (2) use more efficient ways of informing patients about their rights and services under the BBP, (3) to improve situation with diabetes education introduce new category of specialists, namely nurse- educator at the polyclinic level, (4) develop and inculcate unified medical record form to be used by polyclinic -based endocrinologists.

Introduction.

I. Diabetes Mellitus.

One of the major global public health problems as well as one of the most common pathologies in worldwide medical practice today is diabetes mellitus. The incidence and prevalence of diabetes is escalating around the world: the estimated number of 80 million sufferers in 1990 is expected to double by the year 2000, becoming a global epidemic; the major part of the increase will occur in developing and newly industrialized countries.[1]

According to contemporary notions, diabetes mellitus is a group of metabolic diseases characterized by elevated blood glucose level (hyperglycemia)[*] and by microvascular[**] and macrovascular[***] complications that substantially increase the morbidity and mortality associated with the disease and reduce the quality of life.[2, 3]

The most prevalent form of the disease is Type 2 diabetes, previously called Non- Insulin-Dependent- Diabetes- Mellitus (NIDDM). It constitutes about 85-90% of all diagnosed cases of the disease in developed countries[2]. In developing countries, nearly all cases fall into this category.[1] According to the American Medical Association Science News press: Science News Update for the week of November 1, 1995: "Type 2 diabetes is an increasingly common, serious condition that affects about 15 million Americans and represents the fourth-leading cause of death by disease in the United States. It affects more than 3% of all adults and more than 10% of those older than 65 years."[4]

As Armenian Information Agency "Noyan Tapan" recently reported, diabetes is the third most widespread disease in Armenia after cardiovascular and oncologic diseases. Reliable prevalence and incidence rates of the disease in the Republic are difficult to estimate due to low utilization of health care services and the lack of accurate population figures.[5] According to local official data, provided by the main endocrinologist of the Ministry of Health [personal communication, May 1999], totally 34,643 patients with diabetes were registered in the Republic by the end of 1997; about 78 % of them (26,971) as having type 2 diabetes.

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[*] fasting plasma glucose higher than 7.0 mmol/l, or two hour post 75g oral glucose load plasma glucose higher than 11.1 mmol/l, on two or more occasions)

[**] retinopathy (diabetic eye disease with potential loss of vision), nephropathy (diabetic kidney disease leading to renal failure), peripheral neuropathy (diabetic damage of nerves of extremities increasing risk of foot ulcers, amputation, and Charcot joints), autonomic neuropathy (diabetic damage of nerves of internal organs leading to cardiac, gastrointestinal, sexual, and bladder dysfunction)

[***] (atheroma affecting large vessels and leading to myocardial infarction, stroke or peripheral vascular disease)

Absolute number of new cases registered during 1997 was 1702. More recent information (from 1998) shows that approximately 15, 000 patients with type 2 diabetes were registered in all polyclinics of Yerevan.

The impact of diabetes on any society is enormous. Aging of the population and technological advances have increased the costs of diabetic care.[6] Diabetes cost to the US health care system has been estimated at more than $100 billion per year.[7] Analogous figures are not available in Armenia, but, definitely, care of patients with the disease requires a large part of health care resources available to most countries.

Most of the diabetes-related health care expenses are in-hospital costs for management of the long-term microvascular and macrovascular complications of the disease[7], leading to early disability and death. Each year in the US about 35,000 people with diabetes become blind; nearly 13,000 develop kidney failure and around 55,000 have a foot or other body part amputated.[4] Although statistics concerning diabetes in Armenia are limited and often approximated, there is no doubt that one of the major problems related to diabetes in Armenia is the high rate of chronic complications.[5]

II. Chronic hyperglycemia

Already in the early part of this century an association between chronic complications of diabetes and persistent hyperglycemia was postulated. In the last three decades a substantial body of animal experimental as well as human observational studies and clinical trials have accumulated sufficient evidence that diabetes- specific complications are directly linked to long- term hyperglycemia [8-32]: *a strong independent association was identified by different research groups between hyperglycemia and the rate of microvascular complications* when factors such as blood pressure, body weight, insulin levels, and duration of diabetes were controlled for.[3, 33] A new term "glucosotoxicity"[*] was introduced in endocrinology to emphasize the role of hyperglycemia as a primary causative factor in the development of chronic diabetic complications.

In terms of type 2 diabetes, it is also clearly recognized now "that hyperglycemia is the principal cause of retinopathy, nephropathy, and neuropathy and that improved glycemic control is likely to prevent or delay the onset and progression of those microvascular and neuropathic complications in patients with the disease. Theoretical considerations seem to

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[*] It is scientifically proven now that for optimal functioning of β- cell, producing insulin, which is necessary for normal glucose metabolism, glycemia should be within the narrow range - from 4 to 7 mmol/l. **If glucose level is higher than 8- 10 mmol/l, secretion of insulin is affected**.[34]

favor a beneficial effect, and observational studies have shown a strong consistent association between close to normal glycemia and a decreased risk of CHD; but limited clinical studies have had conflicting result"[33].

In light of the above- mentioned studies showing that tight glycemic control is associated with improved clinical outcomes, one of the main principles of proper diabetes care is postulated as: "Blood glucose level should be kept as near to normal level as it safely possible."[35] Dieting, exercising, pharmacological treatment with oral antidiabetic agents and/ or insulin, as well as education, counseling, monitoring, self management are recognized as the essential components of appropriate treatment [35, 36] The goals of therapy include the maintenance of normal health and the prevention of the progression of the metabolic abnormalities and complications of diabetes[37] by "optimum blood glucose control as well as detection and correction of other risk factors for diabetic complications."[38]

Thus, it is correct to say "that we are dealing with a disease about which we can do a great deal in terms of prevention."[7] At the same time, the reality shows that despite major technologic al breakthroughs in the care of diabetes[39] there has been little improvement in glycemic control of patients with diabetes even in the United States[40]. The fact is that in the United States less than half of patients with diabetes have good glycemic control[41]: "…yet community-based studies of diabetic patients show that their mean fasting plasma glucose concentration is generally > 180 mg/dl compared with 100 mg/dl for nondiabetic individuals."[42]

[Unfortunately in Armenia, due to several reasons: (1) lack of respect paid to education of patient, dieting and exercising; (2) reduction of treatment of diabetes mainly to hypoglycemic medications prescription (which are not always affordable); etc., it is possible to expect even worse situation related to glycemic control.]

Being a cornerstone risk factor for diabetes complications, hyperglycemia is not the only factor that should be controlled: in the last 10 years, numerous studies have identified that in people with diabetes elevated blood pressure, total cholesterol and triglycerides; and obesity are the other risk factors for diabetes complications. It has been also documented that besides control of glycemia, some clinical interventions, particularly control of hyperlipidemia and early intervention in diabetic nephropathy and retinopathy, are effective.[6]

III. Diabetes complications.

Although many principal risk factors of diabetes complications are already identified, and there are known ways of controlling them in practice, the reality is that even in such high developed country as the US "approximately 25,000 people lose their vision each year, or 70 people each day, because of diabetes, even though if early changes of diabetes in the eye are detected and

get laser treatment, 90 percent of blindness can be prevented. Simple inspection of the feet could prevent about half of the 54,000 amputations that come as a result of diabetes each year, but we're talking about almost 150 amputations every day." [43]; "tens of thousands of individuals with diabetes unnecessarily develop severe complications from the disease each year including blindness, heart disease, kidney disease, amputations and nerve damage. The situation does not have to exist now that research and new drugs are providing the foundation for delaying and treating the disease."[7]

Thus, one of the major problems in contemporary diabetes care is the *poor translation of knowledge derived from clinical research into routine clinical practice*.[44] The need for improved primary care of patients with diabetes mellitus has been widely recognized.[41] That is why it is not by chance that auditing of diabetes care *to identify the characteristics related to poor glycemic control* and to the high rate of chronic complications, so as to reveal the potential that care has for improving the outcomes observed today, and the barriers existing to translate that potential to reality, is becoming common worldwide.[45] It is well understood now that "every center/ geographic area needs to perform quality assessment based on patient-oriented outcomes."[46]

IV. Situation in Armenia.

Few published data are available on diabetic care in Armenia (no article was found through a Medline and main Russian and Armenian diabetes- related journals search concerning auditing the quality of care provided to patients with diabetes in our Republic). One of the recent epidemiologic studies related to the situation with type 2 diabetes in Armenia is the "Survey of type 2 diabetes mellitus patients in Yerevan"[5]. In September 1998 by using multi- stage cluster and then systematic random sampling techniques, 148 persons were chosen as a sample for that study from 15, 000 type 2 diabetes patients registered in 28 polyclinics of Yerevan. During the survey 80 personal household interviews were performed by using questionnaire designed at the Center for Health Services Research of the Public Health Department of the American University of Armenia. (The questionnaire was developed on the basis of one currently used in the Health Services Center of the University of Colorado and, after translation into Armenian and pretest, used for the survey.) Respondents were asked questions related to their demographic characteristics; general health status; diabetes- related complications; knowledge, beliefs, practices related to the disease; utilization of care provided to them at the local polyclinics.

In general, on the basis of gathered data, several major problems affecting patients with type in Yerevan were recognized. Among them were (1) high rate of chronic complications;

(2)poor individual diabetes management: patients were confused about dietary issues; they were not engaged in regular physical activity; blood sugar monitoring was not done on regular basis; (3) low access to medical care.[4]

V. Factors influencing glycemic control.

Being a chronic illness, diabetes mellitus usually accompanies the affected person all his/ her life. It requires lifelong self-management with regular health professional support and supervision.[47] The level of glycemic control in patients with diabetes has been shown to *depend on many factors,* involving *the patient* and *the general practitioner (GP)* [*] as well as *the care environment.[48]*

A controversy exists in literature in terms of *major factors influencing achievement of appropriate glucose control in patients with diabetes.* Results/ conclusions are heterogeneous between the trials done in different countries.

In the evidence table (see Appendix A) a selection of some related studies is presented. [In majority of cases only the abstracts but not the full texts of the articles were available, hindering analysis of the studies.]

Considering the findings presented in the evidence table, summarizing results of the studies, aimed at investigating principal characteristics related to poor glycemic control in patients with diabetes, the followings should be recognized as possible main risk factors for chronic hyperglycemia:

1. Factors related to patient   Age, gender, socio- economic group, lifestyle - smoking, alcohol consumption, attitudes to diabetes, knowledge about diabetes, level of education, level of physical activity/ exercising, self-rated health status, self- care ability, perceiving that benefits of self-care were, outweighed by the disadvantages, obesity, adherence to the treatment/ level of compliance

2. Factors related to disease process*:   Diabetes duration, age at the time of diagnosis, treatment type (hypoglycemic pills vs. insulin), number of diabetes related clinical events/ complications

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[*] Unlike many Western countries where a team of specialists (including at least a GP, dietitian, nurse-educator) provides care to patients with diabetes, in Armenia as well as in the majority of former Soviet Republics, endocrinologists at the local polyclinics are the only care providers as well as the conveyors of information regarding diabetes to those patients. Nurses mainly perform registrations.

3. Factors related to physician: Age, gender, attitudes to diabetes, knowledge of diabetes, consultation style, personality

4. Factors related to practice of care Equipment, staff, facilities; practice protocol for diabetics

5.Factors related to process of care Shared care status, number of consultations, health workers seen

In terms of *patient-dependent factors* influencing glycemic control following findings were observed.

Gender.

Pringle M and others studying 318 randomly selected patients from 12 different clinics in the UK have revealed that "females had significantly worse glycemic control than males"[50]. At the same time some researchers did not observe that glycemic control was influenced by sex[49, 51].

Age.

A few identified related studies [49, 50] testing for possible association between age of the patient with type 2 diabetes and level of glycemic control did not observe significant relationship between those two factors.

Obesity.

In "Barriers to care in non- insulin- dependent diabetes mellitus: the Michigan experience"Hiss RG have mentioned that " diabetes advisory council determined that one of the main barriers to optimal care of community- based patients with NIDDM is that the genetic basis for and refractory nature of obesity are not generally appreciated."[59] Some other authors [49, 51] on the basis of their findings did not consider obesity as a risk factor for poor glycemic control.

Duration of diabetes.

Blaum CS, Velez L, Hiss RG, Halter JB reporting the findings of the cross- sectional secondary analysis of data from 393 patients with type 2 diabetes mentioned that "longer time since diagnosis was independently associated with poor glycemic control"[49]. Pringle M and others have reached same conclusion: "glycemic control was significantly related to the disease process as measured by years since diagnosis"[50]. The findings of those authors are consistent with the hypothesis that NIDDM is a disorder of progressive failure of pancreatic

β- cell function. However Erasmus RT, Sinha AK assessing long- term glycemic control using glycosylated haemoglobin in 83 diabetic patients, of mean age 47 years, of mean known duration 4.5 years did not observe that glycemic control was influenced by duration of diabetes.[51]

Type of treatment.

Pringle and coworkers [50] have observed that type of treatment was the factor independently influencing random hemoglobin A_1 value, i.e. level of glycemic control. They have found out that in case of "oral hypoglycemic medications vs. insulin" regression coefficient was 0.29, standard error- 0.37, p value- 0.04; in case of "diet alone vs. insulin" corresponding values were -0.37; 0.46; and 0.04. At the same time Erasmus and Sinha reached the conclusion that "glycemic control in patients under their study was not influenced by treatment."[51] The same conclusion that " pharmacological treatment were not significantly related to poor glycemic control" was made by Blaum CS and coworkers.[49]

Knowledge about diabetes management.

Hawthorne K, Tomlinson S studying 201 Pakistani moslems with type 2 diabetes observed that "women had poorer glycemic control that men", and "the women were less likely than men to understand why glucose level should be monitored".[53] Disagreement exists in terms also of this factor: Pringle M and others did not reveal any association between patient knowledge and glycemic control.[50]

Socio- economic status.

Personal communications with the endocrinologists working at Yerevan's polyclinics revealed existence of a strong opinion (based on their experience) that socio- economic status of patient influences level of glycemic control- patients with low income often had poor glycemic control. In terms of findings of relevant articles devoted to this question it should be mentioned that the study[50] done by Pringle M with others have revealed that "social class had no association with glycemic control".

Taking into account above presented information, it is possible to conclude that to achieve appropriate glycemic control in patients with the disease different patient- related characteristics should be controlled in different countries.

Since there is no study done in Armenia to identify the main barriers to proper glucose control in type 2 diabetes patients, and there is a high need of such type of information for planning appropriate reform strategies to improve outcomes, quality of diabetologic care, optimum health care delivery infrastructure, etc., it was decided to conduct a case- control study of type 2 diabetes patients in Yerevan. (This type of the study was chosen taking into consideration its

advantages. It is relatively (1) short in length; (2) inexpensive; (3) relatively small sample size needed for it; (4) can study associations of a disease/ condition with several exposures.)

Description of the study.

I. Objectives/ Main research questions/ Hypotheses

The study was aimed:

- to assess patient- related variables for their effect on glycemic control in type 2 diabetes patients living in Yerevan in order to (1) determine main factors leading to chronic hyperglycemia in those patients, and (2) identify the most vulnerable groups among those patients;

- as well as to reveal current situation with type 2 diabetes in Yerevan in order to help policy- makers to design appropriate management strategies to improve glycemic control in type 2 diabetes patients in Yerevan and overcome existing problems related to the disease management.

The *main research questions* of the present study were:

(1) what is the current situation with glycemic control in type 2 diabetes in Yerevan;

(2) what are the main patient- related characteristics associated with poor glycemic control in patients with type 2 diabetes in Yerevan.

Taking into account findings of related studies following *hypotheses* were planned to be tested in this study:

1. There is an association between the *age* of the patient with type 2 diabetes in Yerevan and his/ her glycemic control level.

2. There is an association between *gender* of the patient with type 2 diabetes in Yerevan and his/ her glycemic control level.

3. There is an association between *body mass index* of the patient with type 2 diabetes in Yerevan and his/ her glycemic control level.

4. There is an association between *socio- economic status* of the patient with type 2 diabetes in Yerevan and his/ her glycemic control level.

5. There is an association between *smoking status* of the patient with type 2 diabetes in Yerevan and his/ her glycemic control level.

6. There is an association between *self- rated health status* of the patient with type 2 diabetes in Yerevan and his/ her glycemic control level.

7. There is an association between *duration of diabetes* and glycemic control level in patients with type 2 diabetes in Yerevan.

8. There is an association between *knowledge about diabetes* of the patient with type 2

diabetes in Yerevan and his/ her glyc emic control level.

9. There is an association between *patient practice/ behavior in terms of diabetes management* and his/ her glycemic control level.

Thus, it was hypothesized that poor glycemic control in type 2 diabetes patients would be related to variety of patient characteristics including age, gender, body mass index, socio-economic, smoking, self- rated health status, knowledge about diabetes management, as well as duration of the disease.

II. <u>Study design</u>.

This study was planned as expansion of the cross- sectional epidemiologic study "Survey of type 2 diabetes mellitus patients in Yerevan" done in September 1998, described above. This time it was decided to go back to the same sample and do a case- control secondary analysis of the data aiming to identify major barriers to proper glucose control in type 2 diabetes patients. [The sample was representative- consisted of 80 patients randomly chosen from the 15, 000 people registered in Yerevan's polyclinics as having type 2 diabetes. This representative sample was chosen in order to have possibility to generalize the findings].

For this study *eligibility criteria* were formulated as:

1- being involved in the "Survey of type 2 diabetes mellitus patients in Yerevan" (i.e. being registered at September 1998 at one of Yerevan's polyclinic as having type 2 diabetes),

2- absence of such complication as end stage of diabetic kidney disease. (Patients with end stage of diabetic kidney disease usually have low glycemia due to that complication.)

3- having medical record available for auditing (Period from 01.0198 to 12.3198 was chosen as auditing period),

4- having at least one blood glucose check done during 1998 (from 01.01.98 to 12.31.98)

72 of 80 patients involved in the "Survey of type 2 diabetes mellitus patients in Yerevan" were recognized as eligible for the present study. 8 patients were not eligible for the study since they never checked blood glucose level during 1998.

A main criterion used today in developed countries to assess long-term glycemic control is glycosylated hemoglobin [*]. Since in 1998, as well as today, this test in Armenia is not widely available and affordable (it is available only in one outpatient clinic in Yerevan and costs about 4000 drams being not affordable for the majority of patients with type 2 diabetes who are

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[*] Glycosylated hemoglobin (also called hemoglobin A1c) is a test that indicates the average blood glucose over the previous 8-12 weeks.

pensioners or jobless people), fasting plasma glucose test is in use for assessing glycemic control. This test is available in all polyclinics of Yerevan. Moreover, according to the resolution (N 174) of the Government of the Republic adopted on 03.13.98, for patients with diabetes since March 1998, this test is performed free of charge 8 times a year.

In accordance with "criteria of compensation for type 2 diabetes" offered by European NIDDM Policy Group in 1993, on the basis of fasting blood glucose level diabetes can be considered as "compensated" (properly controlled) if fasting plasma glucose is 4.4- 6.1 mmol/l, "subcompensated" if it is not more than 7.8 mmol/l, and "decompensated" (uncontrolled) if it is higher than 7.8 mmol/l. In real practice our endocrinologists usually assess fasting blood glucose level lower than 10 mmol/l as "compensated- subcompansated" and higher than 10 mmol/l as "severely decompensated".

Considering above mentioned information and the idea of "glucosotoxicity"(see footnote on page 3) the following definitions for "case" and "control" were used for the study:

"controls" (compensated and subcompensated patients)- patients who in majority of blood glucose tests done during 1998 had fasting blood glucose le ss than 10 mmol/l

"cases" (severely decompensated patients)- patients who in majority of blood glucose tests done during 1998 had fasting plasma glucose level higher than 10 mmol/l

In case of equal number of the tests where fasting blood glucose was less than 10 mmol/l and tests where fasting plasma glucose level was higher than 10 mmol/l the patient was considered a "case" (worse scenario was chosen).

III. Sample size:

In order to calculate sample size needed for the study the formula from the textbook of Sempos and Kahan was used. [61] According to that formula *for following settings:*

Prevalence in controls   0.4

delta (increase in prevalence)   0.2

Alpha level (type I error)   0.05

Beta level (type II error)   0.2

Controls per case   1

	one tail	two-tail
sample size needed (cases):	113	160
sample size needed (controls):	113	160

does not include allowance for losses/ non-respondents

In fact we have had 72 eligible patients under the study. Dividing them into groups, by applying foregoing definitions of "case" and "control", we have got respectfully 36 cases and 36 controls. The data collected from them and from their medical records were used in the study.

IV. Data collection.

In addition to the questionnaires filled at September 1998 (see appendix B) also information obtained from the medical records of the patients was used for the study. The patients were called and asked to name the polyclinics where they had accepted diabetologic care in 1998. Ten polyclinics, being used in 1998 as clusters, were recognized. Corresponding endocrinologists supervising those 80 patients were identified and asked to provide medical records of those patients for auditing. (The endocrinologists were informed through a letter from the Public Health department of the AUA about the study; asked to collaborate by answering some questions related to the patients, and told that any information they provide would be anonymous and not cause harm to them and their patients.) All of them gave a verbal agreement for record auditing and answering the questions.

The record auditing was done on the basis of Record Auditing Form (see appendix C) including (1) extraction of information about the type of the treatment prescribed to the patient, and (2) identification of all the results of fasting blood glucose tests done for that patient during 1998.

While gathering the data for the study a problem related to availability of medical records was faced. Medical records of many patients with diabetes were not at the polyclinics as it was in Soviet period. Since the years when there was an energy crisis in Armenia, and polyclinics were not provided by electricity, registration department did not work, routine lab tests were not always available, etc. and medical records were given to the patients. They brought records when they came for blood glucose check, etc. During the last several years, when the situation improved some of those patients brought back their records to the local polyclinic, but many of them did not. In cases when the medical record of a patient involved in the study was not kept at the polyclinic (about 80% of the patients), s/he was called and asked to bring it to the local polyclinic. Some patients, who did not bring their records to the polyclinic for auditing during following 7- 10 days (about 30% of those 80%) were asked to read by phone the datas and the results of all the blood glucose tests done for them during 1998. Since not all of the glucose tests' results were extracted during record auditing- some of them were read by patients, the possibility of mistakes were taken into consideration as limitation of the study. To reduce possible mistakes which could lead to misclassification it was decided to have additional source of the same information- all endocrinologists were asked to classify each patient according to our criteria of "cases" and "controls". Correlation between the

information about the glucose tests results extracted from the records/ read by patients and the assessment of patient' glucose level done by their endocrinologists was 87 percent.

V. <u>Study variables.</u>

Level of glycemic control was chosen as the *dependent variable for the study* (as nominal/ binary variable: 0 "controls" and 1 "cases")

Taking into account the findings of the related studies and also the opinion of local endocrinologists, the following factors related to the patient and the disease process were chosen *as independent variables of the study:*

1. Age

2. Gender

2. Smoking status

3. Socio- economic status (patient's family income)

4. Type of treatment (being treated by hypoglycemic pills vs. by insulin)

5. Body mass index

6. Self-rated health status

7. Diabetes duration

8. Knowledge of diabetes management

9. Patient practice in terms of diabetes management

Information about *data of birth, gender, socio- economic, smoking, self - rated health status, knowledge of diabetes, treatment group, duration of diabetes* was obtained from the questionnaires. Information about *age and treatment group* was also extracted from the available medical records. There were no differences revealed during comparison.

Since in many medical records there was no data about the time when the disease was diagnosed, *duration of the disease* was assessed only based on the information given by patients (extracted from questionnaires.)

Body mass index (BMI) was calculated as weight (in kilograms) divided by height (in meters) squared. According to the recent WHO Expert Committee report (TRS No 854), it is recommended to distinguish three degrees of overweight, defined by the critical levels of BMI:

Normal range   BMI 18.5- 24.9

Grade 1 overweight   BMI 25.0- 29.9

Grade 2 overweight   BMI 30.0- 39.9

Grade 3 overweight   BMI   40- or greater.

Since in many medical records height and weight of the patients were not mentioned, this information was obtained from the questionnaires, and used for BMI calculations.

Patient knowledge about diabetes was assessed on the basis of answers to questions related

to diabetes management in general and also about diet, exercising, regular blood glucose checks, etc.

Socio - economic status of each patient was determined taking into account the amount of money patient mentioned during interview as the sum his/ her family spend on average per month. (It was taken into consideration that such type of private information often is very approximated.)

Since in many records full diagnosis of patient, including confirmed diabetes complications, their stage, comorbidities was not mentioned, self - rated health status was used as proxy of it.

VI. Data analysis

At the beginning database was created in Microsoft Excel 97 program, then after cleaning and transforming into the text format, it was imported to the Stata program where analysis was conducted.

Descriptive analysis was used to determine characteristics of cases and controls. Independent variables [such as age; gender; type of treatment; body mass index; duration of diabetes; smoking status; socio - economic status of patient family; level of knowledge about diabetes management, including knowledge about importance of medications, dieting, exercising; self-assessment of health in general; patient behavior related to management of the disease; hypoglycemic medication usage practice.] were studied for their association with poor glycemic control by using chi2 and Fisher's exact tests. Statistical analysis was done by using Intercooled Stata 6.
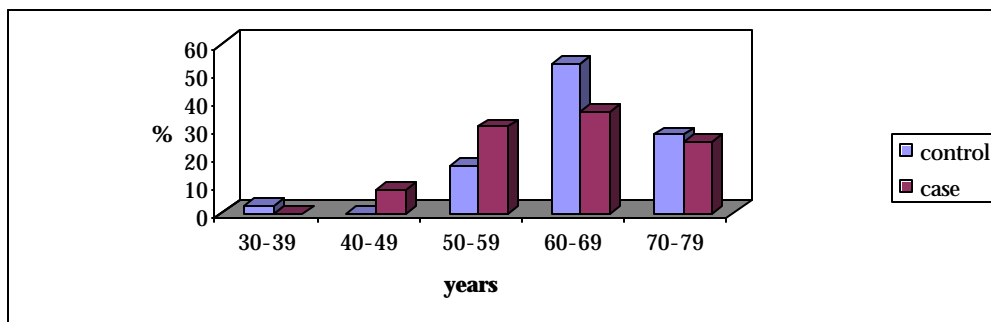
Results.

I. Descriptive results.

#1. Age

The mean age for controls was 60.3 years, for cases 57.8 years. According to t test results, (P-value=0.2363), we failed to reject the Ho: mean (x) - mean (y) = diff = 0, and should conclude that there is no evidence that true difference exists between mean ages of cases and controls. There was no association revealed between the age and poor blood glucose control.

An analysis of **age distribution** of cases and controls reveals that about half of controls (52.78%) were 60- 69 years old; while about one third of the cases (36%) have fallen in "60-69 years old" subgroup and other third in "50-59" subgroup.

There was no true difference between cases and controls in terms of age distribution. (Fisher's exact test for trend revealed P= 0.141)

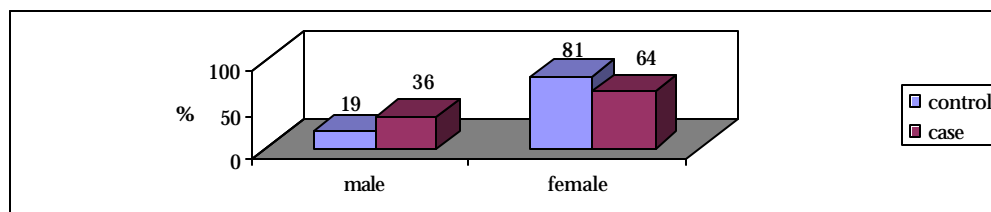Fig1. Distribution on age among cases and controls.

#2. Gender

The study sample predominantly consisted of females (72%).

For cases: 64% were females and 36% males. For controls: 81% were females and 19 % males.

Fig2. Distribution on gender among controls and cases.

According to the result of performed chi2 test for trend (Pr = 0.114> 0.05) the groups were not different in terms of gender distribution.

#3. **Smoking status ("ever smoke till start of the study")**

Table. The distribution on smoking status among controls and cases.

| Smoking status	Controls	**Cases**	Total
Never smoke (negative smoking status)	30	22	52
	83. 33%	61. 11%	72. 22%
Positive smoking status	6	14	20
	16. 67%	**38. 89%**	27. 78%
Total	36	36	72
	100. 00%	100. 00%	100. 00%

As we can see from the above presented table, about one third of all cases have had positive smoking status (38.89%), while only about 17% of all controls have fallen into this category.

Pearson chi2 test for trend revealed Pr = 0.035< 0.05, and it was concluded that there is a statistically significant difference between cases and controls in terms of their smoking status.

#4. Type of treatment

Treatment with medications used to manage patients with type 2 diabetes can be divided into two main categories: (1) those who are treated by hypoglycemic pills (without insulin), (2) with insulin. The majority of all patients under the study (90%) were treated by pills. Almost all controls were treated by pills (97%), while among cases- 83% were treated by them. As the performed test for trend has shown the two groups under the study were not equal in terms of type of treatment (Pr>chi2= 0.0467 <0.05)
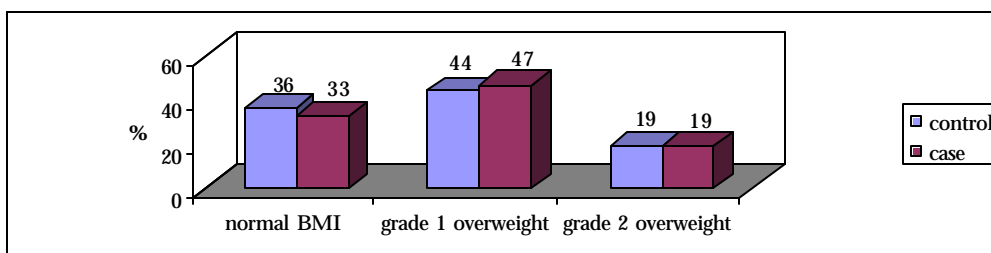
Fig3. Distribution on type of treatment among controls and cases.
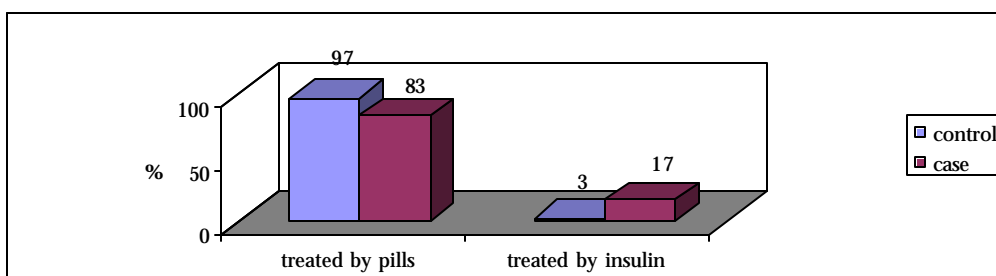
#5. Body mass index (BMI)

About half of cases and controls (47% and 44% correspondingly) were slightly overweight- have fallen into subgroup "grade 1 overweight".

Fig.4. Distribution on BMI among controls and cases.

As chi2 test for trend have shown cases and controls were equal in terms of body mass index (P-value=0.965 > 0.05). So, there was no association revealed between BMI in general and poor glucose control.

When "grade 1 overweight group" was divided into two subgroups:

"1a"- with BMI higher than 25 but less than28, and

"1b"- with BMI 28 and higher but less than 30, and

the patients who had normal weight or was slightly overweight, i.e. "grade 1a overweight" was recognized as one group-"having BMI lower than 28" and others- "1b and 2 grade overweight" organized as another group- "having BMI higher than 28" we had the distribution on BMI among controls and cases, which is presented in the table below.

Table **.** The distribution on BMI among cases and controls.

BMI	Controls	Cases	Total
lower than 28	16 44.44%	8 22.22%	24 33.33%
28 and higher	20 **55.56%**	28 **77.78%**	48 **66.67%**
Total	36 100.00%	36 100.00%	72 100.00%

Performed chi 2 test for trend revealed statistically significant difference among cases and controls in terms of being slightly/ significantly overweight.

#6. Self- assessment of health in general

75% of all patients under the study have rated their health as poor; more cases described their health as "poor" than controls (80.6% and 69.44% correspondingly).

Table. The distribution on " self- assessment of health in general" among cases and controls.

General health assessment	Controls	Cases	Total
good	1 2.78%	1 2.78%	2 2.78%
satisf.	10 27.78%	6 16.67%	16 22.22%
poor	25 **69.44%**	29 **80.56%**	54 **75.00%**
Total	36 100.00%	36 100.00%	72 100.00%

There was no statistically significant difference found between cases and controls in terms of self- assessment of health in general. (Fisher's exact reveled P- value = 0.693)

#7. Presence of hypertension

In general, 72% from all diabetics under the study have mentioned that they were told by their physicians about being hypertensive. More cases than controls have mentioned presence of hypertension (81% and 63.9%), although the difference between the groups in terms of having hypertension was not statistically significant (P-value = 0.114 > 0.05).

#8. Duration of diabetes

One- third of controls had diabetes diagnosed 6-10 years ago, while one - third of cases had "older" diabetes- recognized 16 –20 years ago.

Fig.5. Distribution on duration of diabetes among controls and cases.
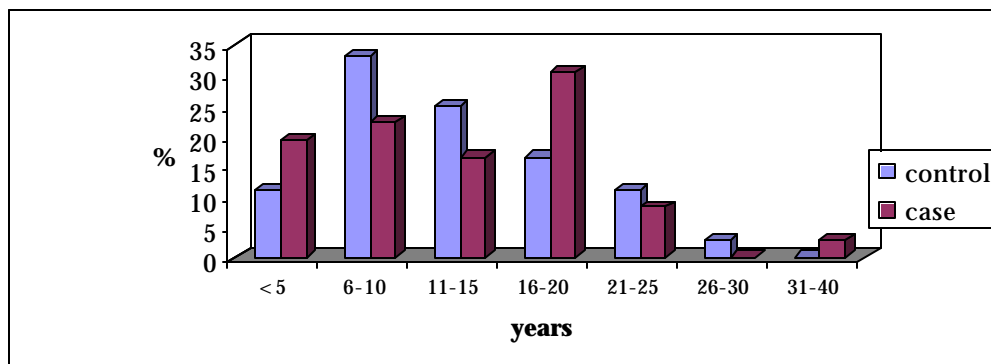
 But taking into account the results of Fisher's exact test (P=0.443), it should be stated that cases and controls were not different in terms of diabetes duration distribution.

#9. Knowledge about diabetes

To assess knowledge of patients about diabetes management they were asked to enumerate the ways to be used to control the disease.

a. Knowledge about importance of hypoglycemic medications for diabetes management

Only 39% of all patients involved in the study have mentioned usage of hypoglycemic medications as one of the tools to be used to control diabetes. Among cases only 44% mentioned the importance of the medications for disease management, among controls- only 33%, i.e. 67% of controls and 55.6% of cases did not tell about usefulness of medications for controlling hyperglycemia There was no statistically significant difference found between the group of cases and the group of controls in terms of knowledge about importance of hypoglycemic medications for diabetes management.

 b. Knowledge about diet

More cases (75%) mentioned importance of diet than controls (70%) but there was no statistically significant difference found between these two groups in terms of knowledge about importance of diet in diabetes management.

c. Knowledge about importance of regular blood sugar tests (BST)

Only about 3 % of controls and 14 % of cases have mentioned about importance of regular BST.

Results of assessment revealed that there was no statistically significant difference found between the two groups in terms of knowledge about importance of BST in diabetes management (Fisher's exact = 0.199)

d. Knowledge about importance of exercising

The situation with that question as well as with the previous one was highly unsatisfactory since 93% of all patients involved in the study did not mention exercising as a way of dealing with diabetes. But the groups were not statistically different in terms of knowledge about importance of exercising (Fisher's exact = 1.000)

e. General knowledge about diabetes management:

By defining as "absence of knowledge and superficial knowledge" the situations when patients have not mentioned any way of diabetes management or have mentioned only 1- 2 ways of it, and as "profound knowledge" when 3 - 6 ways of it was mentioned, we have found out that 97 % of controls and 81 % of cases had no more than superficial knowledge about diabetes management. There were marginally significant difference found between two groups in terms of general knowledge about diabetes. (Fisher's exact = 0.055)

#10. Assessment of patient practice (behavior) in terms of diabetes management:

a. patient practice in terms of hypoglycemic medications usage

83 % of controls as well as 81% of cases have mentioned that they use hypoglycemic medications. No statistically significant difference between cases and controls was found in terms of usage of hypoglycemic medications (P value = 0.637).

b. patient practice in terms of diet

About 47% of controls and 53% of cases have mentioned that they keep diet. Performed test for trend did not reveal statistically significant difference between cases and controls in terms of dieting (P value = 0.637)

c. patient practice in terms of blood glucose control (BGC)

Cases and controls were not different in terms of BGC - only about 53 % of controls and 56 % of cases mentioned that they controlled their blood glucose to manage diabetes.

When studying **how many times during last two months patient did blood glucose check**, the followings were found out:

# of blood glucose checks done during 2 months (July- August 1998)	Controls	Cases	Total
0	12 **33.33%**	13 **36.11%**	25 **34.72%**
1	10 27.78%	10 27.78%	20 27.78%
2 (once per month)	6 16.67%	6 16.67%	12 16.67%

3	1 2.78%	1 2.78%	2 2.78%
4 (twice per month)	4 11.11%	2 5.56%	6 8.33%
5	1 2.78%	1 2.78%	2 2.78%
8 (four times per month)	2 5.56%	1 2.78%	3 4.17%
60 (once a day)	0 0.00%	1 2.78%	1 1.39%
120 (twice a day)	0 0.00%	1 2.78%	1 1.39%
Total	36 100.00% 100.00%	36	72 100.00%

As we can see from the above-presented table 33% of cases and 36% of controls never check blood glucose level during the 2 months. According to the result of test for trends, cases and controls were no different in terms of number of times they did blood glucose check during those 2 months (Fisher's exact = 0.982).

All the patients under the study were asked about the problems related to blood glucose tests they had faced. 58 patients of 72 have mentioned different problems. 74% of those 58 mentioned that tests are not affordable (16 controls and 27 cases). [It should be mentioned here that according to existing rule at least 8 times per year any patient with diabetes in Armenia could have blood glucose test free of charge.]

d. patient practice in terms of exercising

Only about 22% of controls and 31% of cases have mentioned that they do exercises to control diabetes. There was no statistically significant difference found between the two groups in terms of exercising (Pr = 0.422)

#11. In terms of **health care services utilization** also the followings were studied:

(1) **number of visits to local endocrinologist** done by patient during last three- month period (June- August 1998). As it was recognized about 42% of controls and 47% of cases did not visit their endocrinologist during those three months.

(2) in terms of data of **last visit to the endocrinologist** at local polyclinic it was revealed that

about 75 % of controls and 63% of cases visited their doctor more than 6 months ago. No statistically significant difference between cases and controls was found out in terms of last visit to local endocrinologist (P-value = 0.319).

II. Hypotheses testing.

The study main findings can be presented as following table:

	Risk factor	Odds ratio	P- value
1	**Body mass index (BMI) higher than 28**	**2.8**	**0.0455**
2	**Being older than 60 years**	**3.3**	**0.0229**
3	**Positive past smoking status**	**3.18**	**0.0353**
4	**Treatment by hypoglycemic pills**	**0.142**	**0.048**
5	Gender	0.1144	0.0427
6	Patient perception of his/ her general health	0.2763	1.823
7a	Duration of diabetes longer than 5 years	0.3766	0.1728
7b	Duration of diabetes longer than 10 years	0.3766	0.8119
7c	Duration of diabetes longer than 15 years	1.6238	0.3264
7d	Duration of diabetes longer than 20 years *Knowledge of patient about diabetes*	0.775	0.7216
8a	Improper knowledge of patient about importance of hypoglycemic medications	0.625	0.3336
8b	Improper knowledge of patient about importance of diet	0.7576	0.6
	Risk factor	OR	P-value
8c	Improper knowledge of patient about importance of regular blood sugar checks	0.1771	0.088
8d	Improper knowledge of patient about importance of exercising	0.6471	0.64
8e	Improper general knowledge about diabetes management	1.2069	0.76
	Assessment of patient practice (behavior) in terms of diabetes management		
9a	non regular usage of hypoglycemic medications	1.2068	0.76
9b	non dieting	1.2491	0.6374
9c	non regular blood glucose checking	0.89	0.81
9d	non regular exercising	0.649	0.42
	Amount of money patient family spent per month (as proxy of socio- economic status)		
10a	spending per month not more than 50$	0.64	0.3458
10b	spending per month not more than 100$	0.564	0.358

According to the data presented in the table statistically significant association was observed between poor glycemic control and such factors as (1) being older than 60; (2) BMI higher than28; (3) positive past smoking status; and (4) treatment by pills.

#1. Age

Dividing age into categories, an association between "age greate r than 60" and poor glycemic control was observed (OR = 3.31, p< 0.03). Subsequent stratification by potential confounder such as duration of the disease indicated that observed association was not due to confounding. Since the association was not equally strong in strata formed on the basis of third variable- duration of the disease, presence of interaction was recognized. (The association was stronger in patients with longer duration of diabetes (OR = 5) than in patients with shorter duration of the disease (OR = 2.75).

#2. Body mass index (BMI)

No association between BMI and poor glycemic control was observed when as an exposure "second grade overweight" was used. (See the classification of obesity on page 13.)

While dividing obesity into subcategories, a significant difference was observed for BMI higher than 28 (being Ib and II grade overweight) between cases and controls (Pr >chi2 = 0.0455<0.05, OR= 2.8. Testing for possible confounder such as gender presence of interaction, not confounding was identified since for male patients OR was 4.125; for group of female diabetics OR = 2.302.

#3. Past smoking behavior

There was an association found out between smoking in the past (positive past smoking history) and poor glycemic control: Odds ratio = 3.18; Pr>chi2 = 0.035< 0.05

Testing for possible confounder (level of education) revealed that it was not due to confounding: for the patients with low level of education (only high school education) OR = 8.636, p = 0.0357; for the patients with higher education (having more than high school education) OR = 1.8, p- value = 0.4. Thus, presence of interaction was recognized.

#4. Type of treatment

An association between being treated by hypoglycemic pills and having poor glycemic control was found out: (Pr>chi2 = 0.0467 < 0.05, OR = .1428571 < than 1). [Score test for trend of odds: chi 2 (1)= 3.90, Pr>chi2 = 0.0483] Since, as practice shows, patients with longer duration of diabetes often have more complications, and they are the main users of insulin among type 2 diabetes patients, subsequent stratification by potential confounding such as duration of diabetes was performed. The results indicated that observed association was not

due to confounding. Presence of interaction was recognized since the association was of different strengths in different strata formed on the basis of duration of diabetes: for patients with duration of diabetes less that 14 years OR was 0.4333, p- value = 0.5; for patients with duration of diabetes more that 14 years OR was 0.25, p- value= 0.2175.

Discussion

This study is the first *case- control study* of type 2 diabetes patients in Yerevan. It was aimed to assess some patient and disease related variables for their effect on glycemic control in people with type 2 diabetes living in Yerevan in order to (1) determine main factors leading to chronic hyperglycemia in those patients, and (2) identify the most vulnerable groups among those patients; as well as to reveal current situation with type 2 diabetes in the Republic to help policy- makers to design appropriate management strategies to overcome existing problems related to the disease management.

Since the study population was randomly selected from all patients registered at the Yerevan's polyclinics as having type 2 diabetes, it is possible to generalize study findings.

The study have revealed that type 2 diabetes in Yerevan is mainly observed among women; people older than 50 (94% of all patients involved in the study were older than 50 years). About 50% of the patients under the study had graduated from the universities; majority were non- smokers; about half of all patients were slightly overweight; 72% had recognized hypertension; 75% have assessed their general health as "poor".

In terms of diabetes related knowledge about 70 % of all patients (67% of controls and 56% of cases) did not mention (and it is possible to assume that they did not know) about importance of hypoglycemic medications for the disease management. A high proportion of the diabetics did not know / mention positive role of dieting for diabetes management, and the necessity of testing regularly blood glucose. Almost all the study sample (93%) did not know about positive role of exercising in disease management.

In terms of patient behavior/ practices it should be mentioned that about 80 % of cases and controls said that they use hypoglycemic pills to control the disease; about 67% of all patients who did not use their medications mentioned that it was due to financial reasons. Only about 50 % of the study sample (52.8% of cases and 47% of controls) mentioned that they are keeping a diet. (As a result of additional analysis it was recognized that they often had improper understanding about what food products are wholesome and what products should be used in limited amount.) 73% of all the patients (78% of cases and 69% controls) did not do any type of physical exercising, including regular walking.

Low level of utilization of services related to diabetes management was revealed by the study: about one- third of cases and one- third of controls not once have their blood glucose level checked over the last 2 months. 42% of controls and 47% of cases never met their endocrinologist over the last 3 months. 74% of all controls and 63% of all cases met their physician last time more than 6 months ago. 48% of controls as well as 45 % of cases had eye check done more than one year ago.

On the basis of survey data the influence of life conditions on diabetes management / patient practice was determined (such as non-affordability of hypoglycemic medications, although no statistically significant association was found between this factor and poor glucose control). Low level of patient awareness about their rights related to diabetes management was recognized: many patients enumerating reasons of not regular blood glucose testing have mentioned non affordability of them, while during more than one year this test for diabetics is offered free of charge (under the BBP).

As a result of this study *statistically significant association was found* between poor glucose control and the following factors: (1) being older than 60; (2) having body mass index higher than 28, i.e. being Ib and II grade overweight; (3) having positive past smoking status; (4) being treated by hypoglycemic pills.

As it was mentioned by Pickup J. in the article "The pursuit of perfect control in diabetes" published in British Medical Journal in 1988: "It is impossible to achieve uniform and ideal control in every patient with diabetes."[62] "Some patients inevitably have better control than others, and some explanations for this are not amenable to change."[50] Our study revealed that being older than 60 increased the odds of having poorly controlled diabetes. Duration of diabetes has been tested as possible confounder, but results of statistical analysis did not confirm that assumption. Even if some other factors such as presence of comorbidities or decreased self- care ability were the real reasons why people older than 60 more often than younger diabetics had poor glycemic control, recognized factor "being older than 60" should be taken into consideration since (even without being cause for poor glycemic control) it would help to identify persons at high risk for inappropriate glycemic control. While searching for related studies only two researches[49,50] aimed to reveal possible association between age of the patient and level of glycemic control were identified. Their authors did not observe significant relationship between those factors. It should be mentioned that our cases and controls also were not significantly different in terms of mean age, nevertheless "being older than 60" was associated with poor glycemic control.

It is well known that most patients with type 2 diabetes are obese. According to Horton E S, Jeanrenaud B in some groups approximately 80% patients with the disease are obese."[63] The

findings of our study have shown that considerable obesity (BMI higher than 28) also associated with poor glycemic control, and that is why serious attention should be paid to early detection and treatment of that condition. This finding is inconsistent with what was observed by some authors [49, 51]. Since there is no information available about did the authors test as possible risk factors different BMI subcategories as we did in our study, or run analysis only using main categories of obesity, it is difficult to make comparisons between the findings. (While comparing our cases and controls in terms of BMI distribution in general we also did not observe statistically significant difference, the difference was observed when as an exposure "being Ib or II grade overweight" i.e. BMI higher than 28 was tested.)

Although the majority of the patients under our study were non- smokers but as statistical analysis has shown more cases than controls had "positive smoking history", i.e. ever smoke before. Since in Armenia (as simple observation shows) smoking more common among males than females, gender was tested as possible confounder. No data were obtained confirming that the association was due to that confounder. Although it is possible that some eating habits associated with smoking but not the factor "positive smoking history" itself is a real reason of poor glycemic control in those who have smoked in the past, nevertheless this finding of the study should be used to encourage people with diabetes in Yerevan to quit smoking. Comparing the finding of our study with the results of relevant studies it should be mentioned that only one study [50] where lifestyle factors (smoking, alcohol consumption) were tested for possible association with poor glycemic contol was identified. It did not reveal a significant association between smoking and poor glycemic control. (We have no information how exposure was defined in that study to make comparisons.)

In terms of type of treatment it should be mentioned that although it is well known that usually the shift from treatment by hypoglycemic pills to treatment by insulin is due to development of secondary inefficiency of used pills or development of some severe complications requiring insulin in order to be controlled (more complicated cases of type 2 diabetes usually require insulin treatment). At the same time when using insulin it is easier to achieve better control of glycemia than by hypoglycemic pills. Our study has revealed that treatment by pills decreased the odds of having poor glycemic control. This might be due to above discussed fact that usually less severe cases of type 2 diabetes need insulin, or as a result of incorrect treatment by insulin (due to inappropriate amount or type of insulin). Our finding that there is an association betwen type of treatment and glycemic control is consistent with findings of the study done by Pringle and others[50], but inconsistent with findings observed by Erasmus and Shina.[51]

There was *no statistically significant association found* between poor blood glucose control and the following factors: gender; duration of diabetes; patient self- assessment of his/ her health in general; knowledge about importance of hypoglycemic medications, role of dieting, exercising in diabetes management; patient practice related to diabetes management in general as well as to hypoglycemic medications usage, dieting, exercising; socio- economic status of patient's family.

Limitations of the study

Several limitations of the study should be considered when interpreting the results:

(1) The main limitation of the study is its *small sample size.*

(2) All the patients involved in the study were divided into cases and controls based on the level of blood glucose they had during 1998, but since we have no information about quality of performed analysis (accuracy of the tests might be different in different polyclinics), and because some patients had only one- two blood glucose checks done during the year, some *misclassifications of the cases and controls* are possible. For the studies related to glucose level control in patients with diabetes, to avoid possible mistakes in assessment of glycemia, it is much more preferable to use not the fasting blood glucose test but glycosylated hemoglobin test (see discussion in the background part). Since the latter was not affordable and widely available in Armenia, it was not used.

(3) Selection bias due to usage of prevalent cases ("longer survivors") is possible.

(4) Our study is limited by the fact that it is a case- control study: it is possible to have misclassifications of exposure due to problems related to the sources of information- limitations of recall, recall bias, unsatisfactory quality of medical records.

In terms of recall bias it has to be mentioned that the patient might remember and mention information which on his/ her opinion is somehow connected with the disease.

In terms of quality of medical records it should be mentioned that since some medical records did not include such important information as full diagnosis, confirmed stage of the disease, enumeration of diabetes related complications, their stages, comorbidities, height, weight of the patient some mistakes related to values of the variables based on this information (for example, body mass index) are possible.

 (5) Some biases related to misunderstanding of questions included in questionnaires also possible.

(6) Revealed associations can be due to confounding, although for each one an appropriate cofounder was tested and rejected. Further analysis can be done in the future to test for some other possible confounders and also to characterize revealed interactions (synergy or antagonism; large or small).

Recommendations.

Based on the study findings, the following recommendations could be made:

I. to the endocrinologists working at the Yerevan's polyclinics:

(1) much more attention should be paid to questions related to patients education (how they should manage the disease, especially about the role of regular hypoglycemic medications usage, content of diet they need to use, high importance of regular physical exercises, negative role of smoking in development of complications and high necessity to quit smoking, etc.) While educating patients special attention should be devoted to those who are at higher risk in terms of poor glycemic control: people older than 60; with body mass index higher than 28, etc.;

(2) appropriate follow-up system should be established at the polyclinics; patients with diabetes should be regularly informed about services available for them free of charge and be stimulated to use those services;

(3) necessary attention should be paid to quality of medical records: way of their organization and content.

II. to officials responsible for diabetes care in Yerevan:

(1) implementing diabetes related programs take into account the most vulnerable groups in terms of poor glycemic control,

(2) use more efficient ways of informing patients about their rights and services under the BBP,

(3) to improve situation with diabetes education introduce new category of specialists, namely nurse-educator at the polyclinic level,

(4) develop and inculcate unified medical record form to be used by polyclinic-based endocrinologists,

(5) create supportive environment for researches devoted to diabetes care in Armenia

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[*] The Diabetes Control and Complications Trail (DCCT) is a prospective randomized clinical trail done in the US conclusively demonstrated that in patients with type 1 diabetes the risk of development or progression of retinopaty, nephropathy, and neuropathy is reduced 50- 75% by intensive treatment regimens, keeping blood glucose close to normal range, when comparing with conventional treatment regimens.

[**]The United Kingdom Prospective Diabetes Study (UKPDS) is a multicenter, randomized, controlled clinical trial, the largest and longest study on type 2 diabetic patients, recruited 5,102 patients with newly diagnosed type 2 diabetes in 23 centers within the UK between 1977 and 1991 on the basis of average 10- year follow- up conclusively demonstrated that improved blood glucose control in this patients reduced the risk of developing retinopathy and nephroathy and possibly reduces neuropathy. The overallmicrovascular complications rate was decreased by 25% in patients receiving intensive therapy versus conventional therapy.

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Evidence table.   **Appendix A**

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
1.	**Characteristics related to poor glycemic control in NIDDM patients in community practice**[49] Blaum CS, Velez L, Hiss RG, Halter JB USA	To identify **clinical characteristics** related to poor glycemic control in patients with NIDDM cared for by Michigan primary care physicians.	This study was **a cross-sectional secondary analysis of data** from 393 NIDDM patients (mean age, 63 +/- 11 years; 54% female; 92% white) in the 1990-1991 Michigan Diabetes in Communities II Study. The authors evaluated patient demographic, clinical, and physiological characteristics, attitudes toward diabetes, and self-care ability. Logistic regression was used for multivariate evaluation of the characteristics of those patients whose glycosylated hemoglobin (normal GHb 4-8%) was in the upper 25% of the study sample (GHb > 11.6%).	A high meal-stimulated plasma C-peptide was associated with a lower likelihood of poor control (odds ratio [OR] for highest quartile vs. all others = 0.37; 95% CI 0.23-0.58**). Longer time since diagnosis** (OR for each 5 years duration = 1.28; 95% CI 1.07-1.53), **poor self-care ability** (OR = 1.85; 95% CI 1.27-2.71), and **perceived absence of dietary recommendations** (OR = 2.37; 95% CI 1.11-5.08) were also independently associated with presence in the highest GHb quartile. Characteristics that **were not significantly related to poor glycemic control included sex, age, obesity, educational level, exercise, self-rated**

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
				health status, and pharmacological treatment.
2	**Influences on control in diabetes mellitus: patient, doctor, practice, or delivery of care?**[50] Pringle M, Stewart-Evans C, Coupland C, Williams I, Allison S, Sterland J United Kingdom	**To assess patient, doctor, practice, and process of care variables for their effect on glycaemic control** in diabetes mellitus, and to quantify their relative effects.	Search of general practice **medical records**, patient **questionnaires** and examination, doctor **questionnaire, videotaping and analysis of consultations**, and practice **questionnaire**. SETTING--12 practices with 32 participating general practitioners in Nottinghamshire. SUBJECTS--**318 patients randomly selected** from those with diabetes in each practice, 10 for each participating doctor. MAIN OUTCOME MEASURE--Glycaemic control as measured by random glycated haemoglobin A1c estimation (random haemoglobin A1 measurement).	Glycaemic control was significantly related **to the disease process as measured by years since diagnosis, treatment group, and number of diabetes related clinical events. Females had significantly worse control than males**. Other patient factors, such as **age, social class, lifestyle, attitudes, satisfaction, and knowledge, had no association with glycaemic control.** Of all the doctor factors examined, only doctors who professed a special interest in diabetes achieved significantly better glycaemic control. **Bigger and better equipped practices and those with a diabetic miniclinic had patients with significantly better glycaemic control, as did those with**

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
				access to dietetic advice. Patients attending hospital clinics had worse glycaemic control, but this seemed to be attributable to the case mix and practice characteristics. Shared care did not contribute to the multiple linear regression model.
3	**Assessment of long-term glycaemic control in diabetic patients attending Port Moresby General Hospital.**[51] Erasmus RT, Sinha AK Papua New Guinea,	To assess long-term glycaemic control in diabetic patients.	The authors assessed long-term glycaemic control using glycosylated haemoglobins in 83 diabetic patients, of mean age 47 years and of mean known duration 4.5 years, attending Port Moresby General Hospital over a one-year period. We assessed long-term glycaemic control using glycosylated haemoglobins in 83 diabetic patients,	Significant improvement in glycaemic control was observed in only 11 (13%) of the patients. Glycaemic control worsened in 13 (16%) and no change was observed in the remainder (71%). Mean glycosylated haemoglobin and fasting plasma glucose levels were similar at the beginning and end of the study period. Over a one-year period 53 patients (64%) exhibited poor control with mean glycosylated haemoglobin levels exceeding 10%. Among the 19 newly diagnosed

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
	Port Moresby.			diabetic patients (23% of the total) glycaemic control improved in only 2 (11%). **Glycaemic control was not influenced by sex, treatment, obesity or duration of diabetes.**
4	**Glycaemic control of insulin-dependent diabetes mellitus in Sudan: influence of insulin shortage.**[52] Elbagir MN, Eltom MA, Rosling H, Berne C Sweden.	Insulin availability and routine diabetes care were studed	Insulin availability and routine diabetes care were **cross-sectionally** investigated in 122 (M/F; 59/63) insulin-dependent diabetic patients aged 6-60 years with > or = 1 year duration using **a structured questionnaire interview followed by a free conversation**. Haemoglobin A1c, blood glucose, and serum lipids were measured in the fasting state to assess the metabolic control	Only 12% of the patients had acceptable glycaemic control (HbA1c < 7.5%). **Increased age, shorter diabetes duration, and higher body mass index were associated with better metabolic control**. Omission or reduction of the insulin dose was experienced by 51% of the patients due to insulin shortage. **The interview data consistently indicated that insulin non-availability had induced poor compliance to therapy regimens and lack of motivation for optimum glycaemic control.**

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
				Due to limited resources, most of the patients received insufficient diabetes care and education, leading to lower rates of clinic attendance (55%), and dietary non-compliance (78.5%). Elevated haemoglobin A1c was associated with higher fasting blood glucose levels (P < 0.001), serum triglycerides (P < 0.05), and urinary glucose (P < 0.001). **Measurable fasting C-peptide was observed in 52.5% of the patients and was related to the age at diagnosis, and body mass index (P < 0.001 for both).**
5	**Lost to follow-up: the problem of defaulters from diabetes clinics.** [47]	To estimate prevalence of failed appointments at diabetes clinics and identify characteristics and problems of	No information about the study design and used methods was available in the abstract.	**The patients who do not attend have significantly more risk factors and complications than those who keep their appointments. In addition, failed appointments reduce clinic efficiency. To**

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
	Griffin SJ UK	defaulters from diabetes clinics.		date, research on non-attendance for health care has largely focused on the characteristics of defaulters and evaluation of simple interventions aimed at directly altering their appointment-keeping behaviour, such as mailed reminders. However, like the broader issue of adherence, **there are many factors that predispose to non-attendance ranging from patient health beliefs and attitudes of health professionals, the organization of the clinic and the financial costs of attendance, to the degree of patient participation within consultations**.
6	**Pakistani moslems with Type 2 diabetes mellitus: effect of sex, literacy skills, known diabetic complications**	To study factors such as **sex, educational status and place of care, which might influence knowledge**	**Two hundred and one patients with Type 2 diabetes entered the study. They took part in a one-to-one semi-structured interview and gave blood for haemoglobin A1c levels.**	Knowledge about diabetic diets was good (average scores 72%), and patients claimed to perform regular glucose measurements (66%), but they

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
	and place of care on diabetic knowledge, reported self-monitoring management and glycaemic control.[53] Hawthorne K, Tomlinson S UK	**and self-management of diabetes, and glycaemic control in a Pakistani moslem diabetic** population attending primary care general practices (GP) and secondary care clinics at the Manchester Diabetes Centre (MDC).		were not good at applying their knowledge to problems in daily life. Only 24% knew how to manage persistent hyperglycaemia. **Women were worse than men at this** (19 vs. 31% (chi2 = 3.8, P = 0.05)), were less likely to understand why glucose levels should be monitored, and **had poorer glycaemic control overall** (HbA1c 8.8 vs. 8.1%, P = 0.04). Fifty-four patients were completely illiterate. They had similar knowledge scores to readers but were less able to handle problem scenarios. Forty-five of these patients were women, and **multiple regression analysis showed** they were more likely to have

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
				the poorest glycaemic control. **No major differences were found between general practitioner and hospital attenders, or between patients with and without known complications, except that hospital attenders were more likely to have complications and poorer control.**
7	**Care process and patient outcome in diabetes mellitus.** [54] Romm FJ, Hulka BS	The relationship between the process of medical care and patient outcome was examined .	244 patients with adult-onset diabetes mellitus, who were under the care of private internists and family physicians were studed. Process measures included physician awareness of patients' concerns, communication of information from physician to patient, medication-taking behavior, physician adherence to minimum care criteria, and extent of patient utilization of services.	**There was a small statistically significant correlation between physician awareness and control status, but the association was not maintained when controlling for other variables.** Communication of information from physician to patient was significantly (p less than .005) associated with satisfaction in the multiple regression analysis but explained only 4 per cent of the variance in patient satisfaction. **Thus, in patients under**

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
			Outcomes measured during and after a 6-month follow-up period, included diabetic control status and patient satisfaction with medical care. Potentially confounding variables included practice and physician characteristics, patient demographic characteristics, and measures of disease severity.	**treatment for diabetes, there was little association between certain measures of care process and patient outcome.**
8	**Factors associated with implementation of preventive care measures in patients with diabetes mellitus.** [7] Streja DA, Rabkin SW	To identify physician characteristics associated with implementation of measures for preventive care in patients with diabetes mellitus and the distribution of implementation of	**A retrospective chart audit of 519 patients eligible for health maintenance organization insurance on** December 31, 1994, representing patients with diabetes receiving care from 22 primary care physician-providers of a managed care medical group in suburban North Los Angeles, Calif, and seen by physicians between January 1993 and December	Over a period of 2 years 78% of the patients had a high-density lipoprotein cholesterol determination, 80% had a test for proteinuria, and 62% were referred to an ophthalmologist. After adjustment for patient pool differences, physicians who were perceived by the administration of the medical group as "fast," based on a blinded evaluation of

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
		these measures among them.	1994. **A short retroactive questionnaire for participating physicians was also used.** The outcome measures were (1) measurement of serum high-density lipoprotein cholesterol; (2) urinalysis for the detection of proteinuria; and (3) ophthalmology referral for dilated fundus examination.	their number of patient encounters per unit time, had an odds ratio of 0.60 (95% confidence interval [CI], 0.37-0.95; P=.03) to obtain a high-density lipoprotein cholesterol determination in their patients and an odds ratio of 0.53 (95% CI, 0.32-0.87; P=.01) to test their patients for proteinuria. In patients requiring insulin, of fast physicians, the odds ratio for a referral for ophthalmology screening was 0.25 (95% CI, 0.07-0.85; P= .03). **Duration of time in practice of over 15 years and disagreement with practice guidelines were associated with better outcomes. There was no association**

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
				between **physician sex, internal medicine training, or number of patients with diabetes in the practice and the implementation of outcomes. There was a highly significant association between the implementation of an outcome and the implementation of the other 2, resulting in a nonhomogeneous distribution of health care delivery**. Physicians' estimate of their rate of implementation of outcomes, as assessed by the questionnaires, overestimated their actual performance while being in proportion with the documented rates. Most physicians took responsibility for the nonimplementation, accepting that it was an oversight on their part as opposed to an encounter with patient resistance.
9	**Comparison of**	The study was aimed	**A cross-sectional study was conducted.**	**Results showed no significant differences**

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
	metabolic control among diabetic subjects at two clinics.[57] O'Connor PJ, Fragneto R, Coulehan J, Crabtree BF	to investigate whether glucose control in 20 non-insulin-dependent diabetic subjects seen at a remote rural clinic was comparable to control achieved in 66 diabetic subjects seen at the regional hospital clinic	Sampling was done to assure that study subjects were representative of all care-seeking, diagnosed diabetics in a well-defined Navajo community. The two groups of patients were comparable in terms of age, sex, and duration of diabetes from time of diagnosis. Compliance with care, hospitalization rates, and complication rates were similar in each group.	**in glycemic control between the rural clinic (mean fasting plasma glucose = 177, mean random plasma glucose = 227) and the regional hospital clinic (mean fasting plasma glucose = 187, mean random plasma glucose = 249).** The percentages of diabetics under "acceptable" control by American Diabetes Association guidelines was 40 percent at the rural clinic and 29 percent at the hospital clinic (P greater than .05).
10	**Community diabetes care in the 1980s.**[58] Anderson RM, Hess GE, Davis WK, Hiss	This is a study of diabetes care and care outcomes for patients under the active care of private physicians.	**Randomly selected communities, physicians, and patients** in Michigan were the subjects of this study. Data on the care practices of physicians and patients and care outcomes were	We found that the use of multiple injections of insulin and self-monitoring of blood glucose increased significantly, whereas hospitalizations for diabetes control decreased. The mean glycosylated

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
	RG USA		collected from 1980 to 1981 and again in 1985 from eight communities, 61 physicians, and 261 patients.	hemoglobin values for this cohort of patients remained unchanged. The study results suggest that, for patients under the active care of community physicians, modern methods of diabetes care are being implemented, but **the results of improved care do not show an impact on blood glucose control as measured by glycosylated hemoglobin values.** The study was not designed to establish causation for the decrease in hospitalizations for these patients, but the data suggest that decreases may be more a function of changes in health-care policies rather than changes in patient health.
11	**Barriers to care in**	To determine the	Comprehensive evaluation of the	The diabetes advisory councils

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
	non-insulin-dependent diabetes Mellitus: the Michigan experience.[59] Hiss RG USA	barriers to optimal care at the community level for patients with non-insulin-dependent diabetes mellitus (NIDDM).	clinical, psychosocial, and educational status of community- based patients with NIDDM, with subsequent review by local diabetes advisory councils of this status and the care those patients received The frequency with which patients visited their physician for diabetes management, received patient education, received deit counselling, and were examined by an opthalmologist-- four services universally recognized to be components of optimal diabetes care-- was determined for all the patients. Setting: Eight Michigan communities, four large and four small. Patients: From 1988 to 1994, 1,056 patients with NIDDM (defined by stimulated C- peptide criteria) were studied.	determined that **the main barriers to optimal care of community-based patients with NIDDM are that 1) NIDDM is not considered or managed as a serious problem by most physicians and their patients; 2) the genetic basis for and refractory nature of obesity are not generally appreciated; and 3) as a complex, multisystemic chronic illness, diabetes fits poorly in a health care delivery system designed to deal with acute and episodic illnesses**.

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
12	**Personal barriers to diabetes care: lessons from a multi-ethnic community in New Zealand.[60]** Simmons D, Weblemoe T, Voyle J, Prichard A, Leakehe L, Gatland B New Zealand.	The aim of this study was to identify and quantify barriers to diabetes care perceived by diabetic subjects from a multiethnic, urban community (mainly New Zealand Europeans, Maori, and Pacific Islanders)	**A qualitative survey including 57 diabetic subjects and health care providers from a diverse range of backgrounds was followed by a cross-sectional household survey.** Barriers to care were quantified among 1862 (2.1%) diabetic residents of a total surveyed population of 90477.	**Thirty barriers to care categories were generated incorporating patient beliefs, internal and external physical barriers, educational, psycho-social and psychological barriers**. In spite of major difference in culture, acculturation, and socio-economic status, the top 10 barriers were similar between the ethnic groups. **The most important barriers were perceiving that the benefits of self-care were outweighed by the disadvantages (20% Europeans, 20% Maori, 29% Pacific Islanders, 16% others, p<0.001), lack of community-based services (13% Europeans, 27% Maori, 25% Pacific Islanders, 11% others, p<0.001) and the limited range of services available (15% Europeans, 22% Maori, 20% Pacific Islanders, 14%**

N	TITLE/ AUTHORS/ COUNTRY	OBJECTIVES/ AIMS	RESEARCH DESIGN AND METHODS	RESULTS
				others, p<0.05).

Record Auditing Form   **Appendix C**

Name of the patient_____

Name of his/ her care provider

(endocrinologist)_____

Number of the polyclinic_____

1. Type of treatment prescribed to the patient: (should be circled)

a. no hypoglycemic medications (diet only)

b. hypoglycemic pills

c. hypoglycemic pills and insulin

d. insulin

2. Blood glucose tests done during 1998

N	Data	Result
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		

Appendix D

List of appropriate journals where this study might be published:

1. " Diabetographia" (Russia)
2. "Problems of endocrinology" (Russia)
3. Practical Diabetes International (UK)
4. "Diabetes Care" (USA)