Opportunities in pharmaceutical care in Hungary, in the case of type 2 diabetic patients

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Summary

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Diabetes mellitus, especially type 2 diabetes which occurs usually over 35 years means greater and greater public health problem.
In my surveys, I dealt with already diagnosed type 2 diabetic patients. They represent the target population of the third, most complex step of the pharmaceutical care programme. Within the framework of my Ph.D. thesis, I was the first who measured the therapy, the interest, the compliance and the quality of life of type 2 diabetic patients in Hungary. I also studied the opportunities of improving quality of therapy and care with the role of pharmacists.
The Hungarian therapeutic practice develops in accordance with international and national guidelines. The use of antidiabetics is dynamically growing which is incidental to the change of the emphasis of therapeutic groups. However, some out-of-date drugs are still in use. I measured the ratio of types of treatment. Thus, I recognized more data about the use of unreasonable combinations and about the use of insufficient and out-of-date cardiovascular drugs.
Type 2 diabetic patients have great interest in pharmaceutical diabetes care programme. I discovered that the interests of patients with different general and health parameter are different.
Compliance of diabetic patients in relationship with life style and medication is very low in each field. 50-60% of the reasons of drug purchasing and drug taking non-compliance could be prevented with modifying the therapy and with giving advices. According to my study, EQ-5D quality of life questionnaire can be well used to forecast non-compliance.
My own studies also confirmed the results of foreign surveys that type 2 diabetes lower the patients’ quality of life.
In the care of type 2 diabetic patients it is necessary to reach more development. In Hungary, it can be reasonable to involve pharmacists in definite areas. The results of this Ph.D. thesis could be the basis of the Hungarian protocol.
INTRODUCTION, OBJECTIVES

Diabetes mellitus, especially type 2 diabetes which occurs usually over 35 years means greater and greater public health problem.

There are 194 million diabetic patients in the world. Among them 185 million are type 2 diabetic. According to forecasts, until 2030 the number of diabetic patients can exceed 366 million. The prevalence of the disease in the developed countries, (North-America, Europe) will doubled, can reach 10%.

The amount of money spent on diabetic patients and on their micro- and macrovascular complications (myocardial infarction, stroke, nephropathy, neuropathy, retinopathy) mean considerable part of health expenses. About 5-10% of the total health budget is spent on diabetes and its complications. The largest part of the expenses is spent on the treatment of long term complications.

Diabetes is a major risk factor in several diseases. It is the leading cause in case of blindness occurring in adults and non traumatic leg amputations. This patient group is 2-4 times more likely to develop cardiovascular diseases and twice more likely to develop stroke than people without diabetes. People with type 2 diabetes have the same risk of heart attack as people without diabetes who have already had heart attack. Therefore diabetes is the 4th main cause of death in the most developed countries.

Therefore, patients' high quality treatment is necessary in this chronic, progressive, quality of life decreasing disease. In 1989 WHO initiated the St. Vincent declaration with the following goals: the prevention and early detection of diabetes, to achieve high quality care of diabetes and its complications, to improve length and quality of life. According to the declaration, the cooperation of health care professionals (family doctor, pharmacist, dietitian, nurse) is necessary to
achieve the goals. In the protocol the role of pharmacists is to promote the adaptation of healthy lifestyles, to choose the adequate therapy, to increase patient compliance to treatment, to monitor therapeutic outcome. For the above reasons, EuroPharmForum in collaboration with WHO has established the Pharmadiaß diabetes care protocol. The protocol contains the precondition and the concrete guidelines (promotion of healthy lifestyles, promotion of early identification of patients with diabetes, consultation, education and communication with diabetic patients and monitoring them) of each level of diabetes care program.

Each country has to adopt the expectations and the requirements to the local circumstances to optimize the effectiveness of pharmaceutical care.

The aims of pharmaceutical care are to promote effective, safe and cost-effective drug therapy in collaboration with doctors, to promote the adaptation of healthy lifestyle, to guide the drug therapy of patients, increase patients’ compliance, to increase quality of life in quality controlled circumstances.

In my Ph.D thesis, I examined the conditions of the implementation of pharmaceutical diabetes care and the opportunities of needed interventions. I focused on already diagnosed type 2 diabetic patients who represent the target population of the third, most complex step of the pharmaceutical care programme. Moreover, my objective was to measure the Hungarian therapeutic practice.

In further studies I used close-ended questionnaire to measure type 2 diabetic patients’ expectations for pharmaceutical services, lifestyle, compliance and general quality of life.
METHODS

The analysis of the consumption of antidiabetic agents

The nationwide drug consumption data were from 1998 to 2003, and the regional drug utilization data were from 2000 to 2003. The analysis included the drugs of A10 (antidiabetic therapy) ATC class. The used data were from the National Health Insurance (OEP), from MIS Consulting and from IMS (International Medical Statistics) Health database. Drug utilization methods were used in the analysis. The consumption data were given in DDD/1000 inhabitants/day.

In the next utilization study I examined the consumption of antidiabetic agents of type 2 diabetic patients in another point of view. The used data were from OEP database of 2003. By their Health Insurance Identification Number (TAJ) those patients were chosen who were treated in out-patient clinics and in the 26th point of the ambulance data file contained (E1100-E1190) National Classification of Diseases (BNO) codes which determine type two diabetes. In 2003 258,322 patients were found in the database of OEP with the mentioned BNO code. Then 1002 patients were chosen randomly. By the patients’ TAJ number the following data were asked: sex, date of birth, the date of purchasing antidiabetic and cardiovascular agents, the purchased quantity, producer price, subsidizing of social insurance. The compliance was stated from DDD values of active substances of purchasing drugs (compliance of taking the given active substance) and from DDD values connected with patients (compliance of taking the drug).

The expectations of type 2 diabetic patients for pharmaceutical care

I carried out a close ended questionnaire survey from April until August 2003. 10 community pharmacies (4 capital, 3 town and 3 village pharmacies) were
participating in the survey. The pharmacists handed out the questionnaire during dispensing to those patients who brought prescription of oral antidiabetic drug, or oral antidiabetic drug and insulin or only insulin. Besides these, selection criteria was that the patient’s onset of diabetes had to be over 35 years. In the first part of the questionnaire general and some health related questions were asked. In the second part of the questionnaire the expectations of type 2 diabetic patients for pharmaceutical care were examined on the basis of the EuroPharmForum protocol. In the research I handed out 200 and evaluated 121 (60.5%) questionnaires. In the study besides the descriptive statistical methods, in some cases I used two sample t test. Moreover, I applied one factor variant analysis (ANOVA) to identify the differences between groups. When it was necessary I used Holm method, out of the post hoc methods. I applied Microsoft® Excell and Statistica 6.0 to calculate the results. I worked with the usual 5% significance level in the used statistical methods.

The compliance of type 2 diabetic patients
I made a close ended questionnaire survey from March 2004 until May 2004 to measure the compliance of type 2 diabetic patients. 14 community pharmacies (7 capital, 4 town and 3 village pharmacies) were participating in the survey. The selection of patients was as described in the former study. The self confession method was used out of the other methods which measure compliance. In the first part of the questionnaire general and some health related questions were asked. In the second part of the questionnaire I measured the lifestyle and the therapeutic compliance of patients. In the study I handed out 220 and evaluated 142 (64.5%) questionnaires. Descriptive statistical methods were used to characterize the examined sample. Moreover when examining the factors that influence
compliance $\chi^2$ test was used to compare the distribution of groups of different characteristics of compliance and non-compliance. In those cases when the condition of the test was incomplete yates correction was used. I applied Microsoft® Excell and Statistica 6.0 to calculate the results. I worked with 5% significance level.

*The quality of life of type 2 diabetic patients*

I used the Hungarian adapted and validated form of EQ-5D (EuroQol Group, 1993) general quality of life measuring questionnaire to measure the quality of life of type 2 diabetic patients. This questionnaire survey was together with the compliance study. 125 (56.8%) questionnaires were evaluated. The index of quality of life was calculated. In the evaluation I used two sample t test and Kruskall-Wallis test. I applied Microsoft® Excell and Statistica 6.0 to calculate the results. I worked with the usual 5% significance level.

**NEW SCIENTIFIC RESULTS**

Within the framework of my Ph.D. thesis, I was the first who measured the therapy, the interest, the compliance and the quality of life of type 2 diabetic patients in Hungary. Thus, I studied the opportunities of improving quality of therapy and care with the role of pharmacists marking out the points of intervention.

*The analysis of the consumption of antidiabetic agents*

The Hungarian therapeutic practice develops guidelines accordingly of the results of multicentered studies. The consumption of antidiabetics has been dynamically increasing and in 2003 it reached 53.8 DDD/1000inhabitants/day. This means the
change in the emphasis of therapeutic groups in the practice. The number of insulin treated patients increases and among oral antidiabetics more patients get insulin resistance decreasing agents. In therapeutic practice out-of-date products are still used (non micronisated glibenclamide in 2003: 47018 therapeutic dose/day, buformin in 2003: 16890 therapeutic dose/day). This was corroborated by my study with smaller patient population.

I revealed the proportion of diet (23%), OAD (52%), OAD and insulin (17%) treatment of type 2 diabetic patients with my utilization study. I stated the followings: the used combinations, each part of the therapy depends on the age, and in spite of therapeutic recommendations the higher ratio of Sulphanylureas monotherapy in the treatment of diabetic patients. In the case of examined population, incorrect combinations were used in 5% (non-micronisated glibenclamide-buformin, duplication in the same group of antidiabetics). I found out that less patients get thrombocyte-aggregation blockers (19,4%) and lipid level decreasing (34,4%) treatment than expected.

I showed differences in the consumption of antidiabetic agents of each Hungarian region as it was compared with therapeutic guidelines. This showed connection with the economic and the general health status of the region.

**Expectations of type 2 diabetic patients for pharmaceutical care**

Type 2 diabetic patients have high expectations for pharmaceutical care program which takes place in community pharmacies. The most popular consultation areas and pharmacy service: the advices about OTC products, late complications, healthy nutrition and blood glucose, blood-pressure and blood cholesterol level measuring pharmacy services. Advices about drug therapy, self-monitoring and physical activity do not get enough emphasis. The study also proved that groups of
patients of different general and health parameters have different interests and expectations. Patients who take exclusively oral antidiabetic drug (p=0.002), or/and have diabetes recently diagnosed (p=0.025) are significantly more interested and therefore easier to win them to the care program. Moreover, the expectations were higher in village pharmacies where the consultations are more personal and informal (p=0.002).

*The compliance of type 2 diabetic patients*

The compliance of patients connection with lifestyle and medication low in all areas (compliance of diet: 23.2%, physical activity: 66.5%, compliance of drug purchasing: 79.2%, compliance of drug taking: 55.2%). These statements are supported by several similar foreign studies.

Besides the questionnaire survey, the insufficiency of secondary non-compliance was also verified by drug taking compliance which was originated from drug purchasing. 50-60% of the reasons (taking the drug several times a day, side-effects, many drugs in medication etc.) of drug purchasing and drug taking non-compliance could be prevented with modifying the therapy and with giving advices. According to my study, besides the above mentioned, many patients take the antidiabetic agents connected with meals in incorrect time. Besides data of literature, health and demographic parameter EQ-5D quality of life questionnaire can be well used to predict non-compliance.

Problems in different dimensions of quality of life significantly influence compliance negative tendency.
Influencing factors | Diet | Physical activity | Drug purchasing | Drug taking
--- | --- | --- | --- | ---
Ability of movement | - | + (p=0.007) | + (p=0.016) | + (p=0.023)
Self- sufficiency | - | - | + (p=0.004) | + (p=0.008)
Daily activity | - | + (p=0.048) | + (p=0.003) | + (p=0.01)
Pain | - | - | - | -
Anxiety | - | + (p=0.024) | + (p=0.042) | -

Table 1: The influence of the different dimensions of quality of life to compliance

+ significantly negative influence of compliance
- there is not significant influence of compliance

Type 2 diabetic patients average monthly (32.89 day) go to pharmacies to purchase their medicines. Thus the follow up of these patients can be solved.

Quality of life of type 2 diabetic patients

Foreign studies, Hungarian surveys and my research also prove that type 2 diabetes decrease quality of life of patients (EQ-5D\textsubscript{ind}=0.75±0.25). The occurring of problems in case of three dimensions (pain, ability of movement, anxiety) is about 50% which need more attention from health care professionals, present and potential care providers. Similarly other surveys, my study showed that with age quality of life index is lower, the present complications and the increasing number of complications decrease quality of life. I found significant connection between non-compliance of drug therapy and quality of life index.
THE USE OF THE RESULTS

Development in the care of type 2 diabetic patients is necessary to reach more development. In Hungary, it can be reasonable to involve pharmacists in definite areas. In the pharmaceutical care program the different expectations of predictable patient groups has to be considered. Less interested patient groups and consultation areas need more attention. Pharmacists’ main task can be the improvement of compliance. Diet and physical activity, the two areas of lifestyle advices need big emphasis. Drug therapeutic plans should be made for the problems of drug taking problems which could be the basis of pharmaceutical care. The unsatisfactory secondary drug taking compliance rise from the problems of medication. In these cases the causes of non-compliance should be examined and by developing the adequate drug therapeutic plan could solve most of the causes. Drug therapeutic plan provide additional help to rationalize and modernize therapy and to find unreasonable combinations.

Pharmaceutical care needs appropriate conditions, quality assured circumstances, and strict protocols. The results of this Ph.D. thesis could be the basis of the Hungarian protocol.
PUBLICATIONS AND LECTURES

ARTICLES IN CONNECTION WITH THEME OF DISSERTATION


OTHER ARTICLES


POSTERS


LECTURES

2. Balázs. Hankó The realization of diabetes care as patients expect and the professional opportunities allow. XXXVIII. Mátyás Rozsnyay memory competition, Budapest, 2003. (third place)


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