Improving metabolic control in NIDDM patients referred for insulin therapy

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CHAPTER 1
INTRODUCTION

1 Scope of the thesis
2 Aims of the study
3 Methods
4 Outline of the thesis
1 SCOPE OF THE THESIS

It is estimated that in the Netherlands between 235,000 and 285,000 subjects are diagnosed with non-insulin-dependent diabetes mellitus (NIDDM), with possibly an equal number of patients not diagnosed yet.\textsuperscript{1-5} Increasing alertness of the medical profession will lead to earlier diagnosis. The absolute number of patients will definitely rise in the future, since life expectancy and the number of elderly people are increasing\textsuperscript{6}, thus the need for healthcare will increase.

The Diabetes Control and Complications Trial (DCCT) showed that in patients with insulin-dependent diabetes mellitus (IDDM) strict blood glucose control effectively delays the onset and retards the progression of diabetic microvascular complications such as retinopathy, nephropathy, and neuropathy.\textsuperscript{7} It is generally assumed that adequate glycemic control will delay or prevent the development of chronic complications in NIDDM as well, which is recently confirmed for microvascular complications in a randomized study in Japan.\textsuperscript{8} It is also expected that strict glycemic control in NIDDM has a beneficial impact on macrovascular complications. However, recently the feasibility trial of the Veterans Affairs Cooperative Study of Glycemic Control and Complications in Type II Diabetes (VACSDM) Group suggested that patients in the intensive treated arm are at a higher risk for cardiovascular events compared to patients in the standard treatment group.\textsuperscript{9} It is expected that the United Kingdom Prospective Diabetes Study (UKPDS), a randomized controlled trial which compares treatment modalities in more than 5000 newly diagnosed NIDDM patients, and longer follow-up of the Veterans Affairs Cooperative Study of Diabetes Mellitus will give more conclusive answers on the pros and cons of strict glycemic control in NIDDM patients.\textsuperscript{9-13}

In summary, the rise of the absolute number of NIDDM patients and the growing importance of strict glycemic control implies that in future more patients will be switched over to insulin therapy.
In the Netherlands, there is a great demand for evidence-based, practical treatment protocols, especially concerning insulin treatment. The national guidelines of the Dutch College of General Practitioners in 1989 for treatment of NIDDM patients ("NHG-standaard"), was released in 1989. However, the national guidelines do not give any indication how NIDDM patients should be treated when dietary measures and oral hypoglycemic agents (OHA) treatment are insufficient according to the general practitioner (GP), and insulin therapy should be considered.

Whether insulin-treated NIDDM patients should or can be treated in a primary care setting is also a point of discussion. In the Zwolle region we have argued since a decade, that as long as there is a good protocol and sufficient backup, insulin treatment in NIDDM can be taken care of in a primary care setting just as well as in a secondary health care facility. Switching over to insulin is done by a diabetes team in a secondary care facility, and patients are discharged to primary care as soon as stabilization in glucose reduction is reached.

The study described in this thesis examines the patient characteristics of NIDDM patients who were referred from a primary care setting to our outpatient department (OPD) of Hospital de Weezenlanden in Zwolle for consideration of insulin therapy, and it investigates the subsequent effects of improving glycemic control according to a standardized protocol on quality of life and cardiovascular risk factors. Additionally, it evaluates the use of the treatment protocol and GP as well as patient satisfaction with the diabetes treatment at the OPD.

2 AIMS OF THE STUDY

The purpose of this study was:

1 to study retrospectively the disease characteristics of NIDDM patients at our OPD between 1970 and 1992 in whom the use of insulin therapy was considered;

2 to study prospectively the diabetes and sociodemographic characteristics of a new cohort of NIDDM patients referred by general practitioners for consideration of insulin therapy and relate this to the chosen therapy to improve metabolic control;

3 to evaluate the reliability and validity of a new diabetes-specific quality of life questionnaire: the Diabetes Health Profile;

4 to study prospectively the impact of improvement of metabolic control on changes in quality of life in referred NIDDM patients during one year;

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5 to study prospectively the impact of improvement of metabolic control on
changes in cardiovascular risk factors in referred NIDDM patients during one year;
6 to study the maintenance of glycemic control in primary care after discharge from the OPD and to evaluate satisfaction of the GP and the patient concerning the treatment at the OPD.

3 METHODS

Study population

The Zwolle Study included 99 of 113 consecutive NIDDM patients which were referred to the Outpatient Department of Hospital the Weezenlanden during 18 months (1993 and 1994) by their general practitioners for consideration of insulin therapy. Refusal, incompetence for giving informed consent, and insufficient knowledge of the Dutch language were reasons for not participating in the study. Non-participants did not differ significantly in sex, age at referral, duration of diabetes or glycated hemoglobin (GHb). Informed consent was obtained from all the patients. The study was approved by the local ethics committee.

Treatment protocol

Our treatment protocol is based on national guidelines of the Dutch College of General Practitioners ("NHG-standaard") and a regional protocol ("Zwolse protocol"), without taking specific age groups into account. The first step in treatment consisted of visiting the dietician, the diabetes nurse and the physician who maximized oral therapy. The maximum dosage of diabetes medication was defined according to the national guidelines: in this protocol treatment is started with tolbutamide at 500 mg/day (max. 2 g/day). When the result is unsatisfactory, the medication is replaced by glibenclamide (max. 15 mg/day), gliclazide (max. 240 mg/day) or glipizide max. 20 mg/day. If this medication also fails, metformin is added (max. 1500 mg/day - officially 2550 mg/day but because of (gastro-intestinal) side-effects physicians generally did not prescribe more than 1500 mg/day). If maximum oral therapy was insufficient (poor control according to glucose day curve with glucose > 10 mmol/l), the patient was switched over to insulin therapy. When the glycemic situation was stabilized (glucose day curves stable and disappearance of hyperglycemic complaints), the patient (with or without insulin) was discharged to primary care.
4 OUTLINE OF THE THESIS

By way of introduction, the background of the research aims are described in Chapter 2. Chapter 3 contains retrospective data of 495 NIDDM patients at the OPD in whom the use of insulin therapy was considered. The longitudinal study described in Chapter 4 presents the characteristics of NIDDM patients referred for consideration of insulin therapy, evaluates the latest therapy before referral in respect to the national guidelines, and reports on the chosen therapy to improve metabolic control in relation with other diabetes characteristics. Chapter 5 investigates the validity and reliability of a new disease specific questionnaire, the Diabetes Health Profile, in referred NIDDM patients. Chapter 6 describes the longitudinal study on the association between improvement of glycemic control and quality of life in referred NIDDM patients. The relation between improvement of glycemic control and macrovascular risk factors is presented in Chapter 7. Chapter 8 describes GP and patient satisfaction concerning the treatment protocol (including switching over to insulin) and the effect on metabolic control when patients are discharged to their GP. The general discussion and conclusions as well as recommendations for the future will be discussed in Chapter 9.
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INTRODUCTION

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