CO-OPERATION BETWEEN PRIMARY AND SECONDARY CARE: IMPROVING METABOLIC CONTROL IN NIDDM PATIENTS

Patricia Goddijn¹,²
Henk Bilo¹
Edith Feskens³
Evert van Ballegooie¹
Betty Meyboom-de Jong²

Department of Internal Medicine, de Weezenlanden Hospital, Zwolle¹, the Netherlands,
Department of General Practice, University of Groningen, Groningen², the Netherlands,
and Department of Chronic Diseases and Environmental Epidemiology, National Institute of Public Health and the Environment, Bilthoven, the Netherlands³
ABSTRACT

OBJECTIVE
To study maintenance of improved metabolic control and quality of life in primary care after OPD intervention aimed at strict glycemic control in NIDDM patients referred for insulin therapy.

RESEARCH DESIGN AND METHODS
Referred patients visited a diabetes-team (physician, diabetes specialist nurse, dietician, and ophthalmologist). After maximizing oral therapy according to the dosage-scheme of the national guidelines of the Dutch College of General Practitioners ('NHG-standaard'), patients were switched over to insulin therapy if glycemic regulation was poor. After improvement and stabilization of glucose values patients were discharged to their GP. The study evaluates whether the achieved metabolic control (with or without insulin therapy) at the OPD and improved quality of life outcome remains satisfactory after discharging patients to their general practitioner. In addition we studied whether GPs as well as patients were satisfied with the treatment protocol.

RESULTS
Forty-eight men and 51 women patients were included; mean age of 61.2 (10.9) yrs (31 - 84 yrs), duration of diabetes of 8.9 (8.3) yrs; oral hypoglycemic agents (OHA) use for 6.7 (5.4) yrs at baseline. During the intervention period, GHb was reduced by 2.7% to a mean level of 7.8% and lipid profile, serum creatinine and urinary albumin/creatinine ratio (ACR) showed beneficial changes. During the study, hyperglycemic complaints decreased from 45% to 13% and hypoglycemic complaints increased 6% to 13%.

Concerning quality of life, both the physical summary score and mental summary score were significantly better after intervention. All these changes remained stable after discharge to the GP, except for total cholesterol and ACR. Both increased, although total cholesterol did not return to baseline value whereas ACR did.

The majority of GPs (81%) and patients (97%) were satisfied concerning the treatment protocol and patients were positive of being switched over to insulin therapy, despite initial fears.

CONCLUSION
The treatment protocol shows to have beneficial effects on metabolic control as well as the patients' quality of life. These results can be maintained in primary health care by GPs. GPs and patients were satisfied concerning the treatment protocol. Switching over to insulin is not problematic to most patients.
INTRODUCTION

Non-insulin-dependent diabetes mellitus (NIDDM) or type 2 diabetes is a common chronic disease. The absolute number of patients with NIDDM rises, since the number of elderly people as well as the life expectancy of patients with diabetes are rising.1-3 Furthermore, growing alertness of the medical profession will lead to earlier diagnosis of the disease. According to Ruwaard, who validated and updated the forecasts of the number of diabetic patients in the Netherlands, there will be an increase in the number of known diabetic patients in the period 1990-2005 of 23% (static model) to 127% (dynamic model using data on trends in the incidence, prevalence, recovery, and life-expectancy). The real extent of increase will very much depend on the policy for detecting undiagnosed patients.4

NIDDM is associated with increased morbidity and premature mortality. Chronic complications are frequently observed and include cardiovascular problems, hypertension, renal failure, blindness and amputations.5 Therefore, NIDDM should be regarded as a disease with a potentially devastating effect on life expectancy and quality of life in the individual and a disease with a substantial impact on health care costs in general.6

A causal association between chronic diabetic complications and glycemic control has been suggested in animal and human studies, already several decades ago. This has been proved for microvascular complications (neuropathy, nephropathy and retinopathy) both in insulin dependent diabetes mellitus (IDDM) patients7,8 and in NIDDM patients.9 The same is assumed for cardiovascular (macrovascular) complications.

Available data suggest that in the United States patients with NIDDM, treated with oral agents, insulin therapy or both, usually have only fair to poor metabolic control.10 Presumably, physicians do not sufficiently optimize therapy in order to achieve normoglycemia. According to Colwell the rationale for such
an approach probably includes uncertainties regarding the proper approach towards insulin resistance in NIDDM (which usually demands large doses of insulin to produce near-normal glycemia); the paucity of information that can clearly identify chronic hyperglycemia as a major causative factor for macrovascular disease; and the fear of hypoglycemia or weight gain, or both, with intensive insulin therapy.\(^{10}\)

In the Netherlands, available data suggest the presence of insufficient glycemic control in a substantial part of NIDDM patients.\(^{11-13}\) Many general practitioners are hesitant to switch patients over to insulin therapy citing a variety of reasons.\(^{14}\) In the current national guidelines for treatment of NIDDM patients of the Dutch College of General Practitioners (‘NHG-standaard’, 1989) no attention is paid to treatment strategies for insulin therapy.\(^{15,16}\)

In the Netherlands, NIDDM patients are generally referred to a secondary health care facility for switching over to insulin therapy.\(^{17}\) Usually, the majority of patients thus switched over to insulin, remains treated in secondary health care. In the Zwolle region, most patients are discharged to the general practitioner after treatment changes have been effectuated and the metabolic situation is stable again.\(^{18}\) Still there is considerable doubt among diabetologists whether it is possible to maintain adequate metabolic control in insulin-using diabetic patients within a primary health care setting.\(^{19,20}\) Until now no data have been published concerning this issue.

We started a prospective study including NIDDM patients referred for insulin therapy to the outpatient department (OPD) of Hospital de Weezenlanden. We evaluated whether the achieved metabolic control at the OPD (with or without insulin therapy) remains satisfactory after discharging patients to their general practitioner. In addition, we studied whether GPs as well as patients were satisfied with the treatment protocol.

**RESEARCH DESIGN AND METHODS**

**Study population**

During 1.5 year, we included 99 consecutive NIDDM patients, referred by their general practitioners for consideration of insulin therapy to the outpatient department (OPD) of Hospital de Weezenlanden in Zwolle, following informed consent. The study was approved by the local scientific and ethical committee. Of the 99 included patients, data on 94 patients were available for follow-up. Five patients were lost for follow-up, two of them died of cancer during the study.
Study design and treatment protocol

The first visit (t = 0) consisted of taking a medical history, performing a physical examination, collecting blood and urine samples, and visiting the diabetes specialist nurse. The diabetes nurse provided information and education which included general knowledge of diabetes, drug management, and self care techniques (e.g. self-monitoring of blood glucose, general health habits, and foot care). Initially, twice a week a glucose day curve (before and after each meal and before going to sleep) was made. Patients were asked to take home a self-administered quality of life booklet, which had to be completed and returned within two weeks. Appointments were made for a visit to a dietician and an ophthalmologist (for the latter, when the last visit was more than half a year ago). Concerning the treatment, the initial goal was to optimize oral therapy according to the national guidelines of the Dutch College of General Practitioners.15,16 When maximal oral therapy proved to be insufficient (continuous poor control according to glucose day curves with blood glucose levels on average > 10 mmol/l, patients were switched over to insulin therapy. As soon as glycemic control was sufficiently improved and stable (no further reductions in mean glucose concentrations), they were returned (with or without insulin) to primary care (t = GP) with again a self-administered quality of life booklet. After one year (t = 1 year) patients were fully examined again, and blood and urine samples were collected. Patients were asked to fill in the quality of life questionnaire once more and an evaluation form to assess their opinion regarding the treatment at the OPD and the use of insulin therapy.

For assessment of quality of life the patients completed the RAND-36 which is a reliable and valid generic measure of health status21 also validated for the Dutch language.21,22 A more compact analysis of the RAND-36 was used assessing the Physical Component Summary (PCS) and the Mental Component Summary (MCS). The PCS is the total score of physical functioning, social functioning, functional role impairment, vitality, pain, and general health perception divided by six. The MCS consists of the sum of the score of social functioning, emotional role impairment, mental health, vitality, and general health perception divided by five.24

To evaluate the treatment protocol and the use of insulin therapy, a questionnaire with multiple choice questions as well as open questions were supplied to be filled in at home. Both GP and patient were asked whether they were satisfied with the diabetes treatment (yes/no) and the reason for their opinion (open question). All patients were initially asked whether they were
worried about the possibility that they had to self-inject insulin (provided with a 4-point Likert scale: very much, quite a bit, a little, not at all).

For evaluation of insulin therapy itself, all insulin-treated patients were asked the following questions:
- Did you find injecting insulin easier or more difficult than expected.
- How difficult or easy do you find it to inject insulin (provided with 4-point Likert scale: very easy, quite easy, not very easy, not at all easy).
- How are you feeling now that you are using insulin (provided with 5-point Likert scale: much better, a little better, about the same, a little worse, much worse).
- Would you like to stop using insulin (yes/no), and why (open question).

Medical examination
Patients were examined according to a standardized protocol by a trained physician. For medical history a standardized questionnaire was used containing questions about diabetes and its complications, diabetes treatment, smoking, alcohol consumption, and educational level.

GHB was measured by affinity chromatography (Pierce columns, upper limit of normal 6%). Hyperglycemic complaints were considered to be present when patients had at least two or more of the following complaints during the preceding month: fatigue, weight loss, itching, thirst, or increased fluid intake or increase urine production. Hypoglycemic symptoms were considered to be present when patients had at least two of the following complaints during the preceding month: excessive sweating, shaky sensations, attacks of dizziness, and sudden hunger, which disappeared when food was taken.

Routine clinical chemistry assays (total serum cholesterol, HDL-cholesterol and creatinine in serum) were performed on a Hitachi 717 chemistry analyzer based on commercially available techniques (Boehringer Mannheim). The upper limit of serum total cholesterol is defined as normal at 6.5 mmol/L and the lower limit of HDL-cholesterol as 0.9 and 1.2 mmol/L, for men and women respectively. Urinary albumin was determined by nephelometry on a Beckman Array analyzer. Urinary albumin excretion rate was assessed by measuring albumin/creatinine ratio (ACR, mg/mmol) in a morning urine. Blood pressure was measured twice, lying down after a minimum of 5 minutes in supine position. The measurement was performed with a calibrated automatic device (Philips, type HP 5330). The mean value of the two repeated measurements was used in the analysis. Body Mass Index (BMI) was calculated from weight and height (kg/m²). Height
was measured with a microtoise and rounded to the nearest 1 cm. Body weight was recorded to the nearest 0.5 kg on a calibrated scale.

Statistical analysis

Continuous variables were compared between categories using the paired Student t-test or Wilcoxon paired test if variables were skewed. For categorical variables the chi-square test was used. All p values were based on two-sided test of significance. P values < 0.05 were considered statistically significant. The SPSS programme (SPSS/PC+, version 4, Chicago, IL) was used for data analysis.

RESULTS

General characteristics

Forty-five men and 49 women were included, all but one of them living independently. All but two subjects were Caucasian (table 1). Initially, 89 patients (95%) used a sulphonylurea-derivate (SU). Forty-two patients a combination of SU and biguanide. Seventy-seven patients (82%) used the maximum dose of SU (with or without metformin). Fourteen patients (14%) had a maximum dose of SU and biguanide. Some differences were observed between men and women. Mean body mass index (BMI) was lower in men than women (25.8 (3.1) kg/m² vs. 29.3 (5.3) kg/m², p<0.0005); the prevalence of alcohol use was 73% for men and 22% for women, (p<0.001).

After one year significantly more patients were able to measure their own blood glucose by means of self-monitoring (17% vs. 97%, p<0.001).

The 94 patients were referred by 64 GPs: one GP referred four patients; three GPs referred three patients; 21 GPs referred two patients; 39 GPs referred one patient.

Of the GPs, 55 (61.8%) had a regular appointment with the patient, 19 GPs had special diabetes office hours, six GPs (6.7%) counted on initiative of the patient for making an appointment, nine GPs (10.1%) did not fill in this question and 5 GPs did not return the questionnaire.

During the study 28 men (62%) and 33 women (67%) were switched over to insulin therapy; the other 33 patients (35%) remained on OHA therapy.
TABLE 1

PATIENTS’ BASELINE CHARACTERISTICS (N = 94)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at referral DM (yrs)</td>
<td>61.4 (11.0)</td>
</tr>
<tr>
<td>Age at onset DM (yrs)</td>
<td>52.9 (10.6)</td>
</tr>
<tr>
<td>Known duration DM (yrs)</td>
<td>8.5 (7.5)</td>
</tr>
<tr>
<td>Duration OHA-use (yrs)</td>
<td>6.8 (5.4)</td>
</tr>
</tbody>
</table>

**Sociodemographic characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Count (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>45 (47.9%)</td>
</tr>
<tr>
<td>Caucasian</td>
<td>92 (97.9%)</td>
</tr>
<tr>
<td>Cohabitants(^a)</td>
<td>77 (81.9%)</td>
</tr>
<tr>
<td>Primary school(^*)</td>
<td>51 (54.3%)</td>
</tr>
<tr>
<td>Smoking</td>
<td>19 (20.2%)</td>
</tr>
<tr>
<td>Drinking alcohol(^**)</td>
<td>44 (46.8%)</td>
</tr>
</tbody>
</table>

Data are means (SD) or number of patients n (%);

\(^*\) P < 0.05, higher in men than in women;

\(^**\) P < 0.001, higher in men than in women;

\(^a\) Cohabiting with spouse or partner

Discharge to primary care within six months

Sixty-two patients (63%) were discharged to the primary care within six months. Compared to the group remaining in secondary care (non-discharged patients), the patients discharged to their GP did not differ in duration of DM and in any of the biochemical variables, prevalence of hypoglycemic and hyperglycemic complaints or BMI. The non-discharged patients were older (63.6 (10.4) yrs vs. 57.3 (11.1) years, p < 0.05) and consisted of more patients who were switched over to insulin therapy compared to the discharged group, (27 (84%) vs. 34 (55%), respectively). Seventy-three patients (78%) returned to their GP within one year.
TABLE 2
Patients discharged within 6 months to GP (n = 62)

<table>
<thead>
<tr>
<th></th>
<th>T = 0</th>
<th>T = GP</th>
<th>T = 1 YEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHb (%)</td>
<td>10.5 (3.1)</td>
<td>7.7 (1.6)**</td>
<td>7.8 (1.7)</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>6.32 (1.63)</td>
<td>5.89 (1.16)*</td>
<td>6.07 (1.19)a</td>
</tr>
<tr>
<td>HDL-cholesterol (mmol/l)</td>
<td>1.04 (0.28)</td>
<td>1.14 (0.32)**</td>
<td>1.15 (0.30)</td>
</tr>
<tr>
<td>Serum creatinine (mmol/l)</td>
<td>88.8 (19.0)</td>
<td>93.5 (20.0)**</td>
<td>90.9 (20.6)</td>
</tr>
<tr>
<td>ACR1 (mg/mmol)</td>
<td>11.7 (21.0)</td>
<td>10.2 (25.0)</td>
<td>12.5 (21.4)a</td>
</tr>
<tr>
<td>Blood pressure (mmHg)</td>
<td>-</td>
<td>157/88</td>
<td></td>
</tr>
<tr>
<td>Hyperglycemic complaints (%)</td>
<td>28 (45%)</td>
<td>-</td>
<td>8 (13%)</td>
</tr>
<tr>
<td>Hypoglycemic complaints (%)</td>
<td>4 (6%)</td>
<td>8 (13%)*</td>
<td>8 (13%)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>79.6 (14.6)</td>
<td>-</td>
<td>82.1 (14.0)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.8 (5.0)</td>
<td>-</td>
<td>28.7 (4.8)</td>
</tr>
<tr>
<td>Physical score QoL</td>
<td>68.7 (20.7)</td>
<td>75.6 (17.5)*</td>
<td>75.7 (18.0)</td>
</tr>
<tr>
<td>Mental score QoL</td>
<td>69.2 (21.1)</td>
<td>76.8 (16.4)*</td>
<td>77.6 (16.6)</td>
</tr>
</tbody>
</table>

Data are means (SD) or number of patients n (%);
1 ACR: urinary albumin/creatinine ratio
¶ t = GP: moment of discharge to GP
* P < 0.05: t = 0 vs. t = GP; ** P < 0.001: t = 0 vs. t = GP
a P < 0.05: t = GP vs. t = 1 year

Impact OPD on patients characteristics (t=0 compared with t=GP, n=62)

In the group of patients who were referred within 6 months to their GP, mean
GHb concentration decreased on average 2.8% from 10.5% to 7.7% (table 2).
Serum total cholesterol decreased whereas HDL-cholesterol increased, both
changes are highly significant (p<0.0005). Serum creatinine increased (p<0.001)
and urinary albumin loss as defined by albumin/creatinine ratio (ACR) decreased
(p<0.05). The frequency of hypoglycemic complaints increased from 6% to 13%
(p>0.05).
Quality of life scores improved, showing an increase in the physical score
(p<0.05) as well as in the mental score (p<0.05).
Impact discharge on patient characteristics (t=GP compared with t=1 year, n=62)

After discharge to their GP, all biochemical variables of the study population remained stable, except for the total serum cholesterol which increased from 5.89 mmol/L to 6.07 mmol/L (p < 0.05) as well as for ACR which increased from 10.2 mg/mmol to 12.5 mg/mmol (p < 0.05). The frequency of hypoglycemic complaints as well as quality of life scores remained stable.

Satisfaction general practitioners and patients

The majority of the GPs (81%) was satisfied with the treatment protocol used at the OPD. As shown in table 3, main reasons of being satisfied were the education of the patient, the fast discharge to the GP and the good communication between OPD and GP. Ten GPs were not satisfied and complained about the lack of feedback and indistinctness about who is controlling the patient.

Almost all patients (97%) were satisfied with their treatment at the OPD. Especially education and guidance as well as personal attention were appreciated by the patients.

**TABLE 3**

Cited reasons GP and patient satisfaction

<table>
<thead>
<tr>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General practitioner</td>
</tr>
<tr>
<td>Education of the patient</td>
</tr>
<tr>
<td>Fast discharge</td>
</tr>
<tr>
<td>Good communication OPD and GP</td>
</tr>
<tr>
<td>Better glycemic control</td>
</tr>
<tr>
<td>Learning self-control</td>
</tr>
<tr>
<td>Good treatment protocol</td>
</tr>
<tr>
<td>Patient is satisfied</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education and guidance</td>
</tr>
<tr>
<td>Personal attention</td>
</tr>
<tr>
<td>Good treatment</td>
</tr>
<tr>
<td>Good atmosphere OPD</td>
</tr>
</tbody>
</table>
Evaluation inducement of insulin therapy

Most patients were not looking forward to the possibility that they had to switch over to insulin therapy. Nineteen patients (20.2%) did not like the idea at all, 24 patients (25.5%) rather did not like it, 25 patients (26.6%) were a little bit worried and 26 (27.7%) did not mind at all to be switched over to insulin therapy.

In all insulin using patients (n = 61), starting and maintaining insulin therapy turned out to be less unpleasant than was expected. Sixty-seven percent found injecting insulin very easy and 33% found it rather easy. None of the respondents found it not easy or not at all easy. Comparing their health status before and after insulin use, 57% of the patients felt much better and 14% felt a bit better. Twenty-nine percent of the patients felt the same and none of the respondents felt worse.

The last question concerning insulin therapy was whether patients wanted to go back to tablets instead of injecting insulin. The majority of patients (84%) did not want to go back to OHA therapy, giving as main reasons: I feel better/less tired/more fit (19 patients); now glucose regulation is good (9 patients); I can not do without insulin (7 patients). Fourteen percent would like to stop with insulin. Their main reason was that tablet use was easier than injecting insulin.

DISCUSSION

This study was meant to evaluate the use of a treatment protocol for NIDDM, in which patients were referred to a secondary health care facility for switching over to insulin, to be discharged to their GP as soon as metabolic control was improved and stabilized. During the intervention period, GHb was reduced by 2.7% to a mean level of 7.8% and lipid profile, serum creatinine and urinary albumin/creatinine ratio (ACR) showed beneficial changes. During the study, hyperglycemic complaints decreased from 45% to 13% and hypoglycemic complaints increased from 6% to 13%.

Concerning quality of life, both the quality of life scores (physical summary score and mental summary score) were significantly better after intervention. All these changes remained stable after discharge to the GP, except for total cholesterol and ACR. Both increased, although total cholesterol did not return to baseline value whereas ACR did.

The majority of GPs and patients were satisfied with regards to the treatment protocol and patients were positive of being switched over to insulin therapy.

Although all patients were referred for insulin therapy, only 61 out of 94 subjects turned out to need insulin therapy after one year. As for the remaining
33, there was a variety of reasons to remain on OHA. Main reasons were adjustments of OHA therapy, spontaneous improvement during time, education and learning self-control and treatment of underlying disease. Sixty-two patients (63%) were discharged to their GP within six months, and 73 patients (78%) were discharged within one year. This can be seen as a reasonable result. Although the majority of GPs were satisfied, it is important to note that nine GPs complained of non or miscommunication and completely lost the patient 'out of sight'. In future, this could be prevented by precise checking of discharge letters.

Although patients were not looking forward to injecting insulin, they were satisfied with their treatment at the OPD and the majority of insulin using patients did not want to go back to OHA therapy. This is in contrast with results of a recent study by Miedema and co-workers. They found that in primary care switching over to insulin in poorly controlled patients with maximal oral treatment was obstructed by insufficient motivation and fear of the patient and by the GP who felt that acceptable glycemic control could be gained without insulin. The authors suggest that good education might possibly diminish these obstructions. Indeed, education seems to work out well concerning switching over to insulin therapy as our study shows when patients are guided by a diabetes team.

Serum cholesterol and ACR increased again after discharge to the GP. This could be an effect by change in diet. It is worthwhile to examine this effect when the information from the dietician is repeated from time to time. However, in general our study underlines that adequate metabolic control can be maintained also in primary health care by GPs. Whether this means that insulin therapy as such can be initiated by GPs, remains to be seen, however. The main advantage in secondary care is the presence of a diabetes team, with a diabetes specialist nurse, a dietician, a podotherapist, and easy access to a surgeon, a dermatologist and a rehabilitation department. Access by primary care to the members of such a team seems strongly advisable to allow a safe and effective transition to insulin treatment within a primary care setting.

Based on our results, we are very positive about the follow-up of NIDDM patients in primary health care. However, longer term studies are needed to allow more definite conclusions on all the aspects mentioned.
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