ORIGINAL REPORT

Identifying targets to improve treatment in type 2 diabetes; the *Groningen Initiative to aNalyse Type 2 diabetes Treatment* (GIANTT) observational study

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SUMMARY

Purpose   Assessment of quality of cardiometabolic risk management in diabetes in primary care.
Methods   In a descriptive cohort study including 95 Dutch general practices, we assessed medication treatment in relation to the level of control for HbA1c, systolic blood pressure (SBP) and LDL-cholesterol (LDL-c) in 2007. We also applied a prospective measure of treatment quality by assessing treatment modifications in not well-controlled patients. In a subpopulation of 23 practices, we studied trends in these quality indicators from 2004 (2059 patients) to 2007 (2929 patients).
Results   In 2007, averages for HbA1c, SBP and LDL-c were 6.9%, 142 mmHg and 2.3 mmol/l, respectively. Of the patients with an HbA1c $> 8.5\%$, 16% were treated with one oral drug class and 50% used insulin. In 27% of these patients, therapy modification occurred subsequently. During the 4-year period, a slight decrease in average HbA1c was observed, but no changes in treatment level. In 2007, 56% of the patients had an SBP ≥ 140 mmHg, 19% of whom were not using antihypertensives. In the 13% with an SBP > 160 mmHg, 23% received a therapy modification. During the 4-year period, the average SBP decreased with 6 mmHg but the treatment level showed no substantial increase. In 2007, 39% had an LDL-c level ≥ 2.5 mmol/l, 49% of whom were not using statins. Of the patients with an LDL-c > 3.5 mmol/l, only 9% received a therapy modification.
Conclusions   The decreasing population averages of HbA1c, SBP and LDL-c values suggest improvement in quality of care. However, the relatively few therapy modifications observed in insufficiently controlled patients show room for improvement. Copyright © 2010 John Wiley & Sons, Ltd.

INTRODUCTION

Cardiovascular risk factor levels in primary care patients with type 2 diabetes appear to have decreased during the period 1999–2006 in The Netherlands.[1] It is not clear to what extent this reflects improved quality of care. Quality of care is not necessarily shown by measuring population averages of risk factor levels. In general, quality of care is usually assessed by a mixture of process and outcome indicators.[2–8] Process indicators focus on performed actions of health care providers, such as the measurement and registration of HbA1c or other recommended tests. Outcome indicators focus on clinical results, such as the percentage of patients who achieved a target HbA1c level. In quality assessments, there is remarkably little

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attention to how health care providers react to observed test results. This aspect of the medical process can be assessed using treatment indicators. The most commonly used treatment indicators measure whether patients are on recommended medication or not. This provides a limited view on the quality of care. Assessing the rate of starting or intensifying treatment in suboptimally controlled patients provides additional valuable information.[9–11]

To improve the quality of diabetes care, many (regional) projects have started in various countries which monitor the process and outcomes of care. These projects, such as the *Groningen Initiative to aNalyse Type 2 diabetes Treatment* (GIANTT),[12] enable the analysis of trends in quality of care and risk management in primary care. Our aim was to assess diabetes care quality for the risk factors HbA1c, systolic blood pressure (SBP) and LDL-cholesterol with special attention to quality of treatment for general practices participating in the GIANTT project in 2007. To provide more insight in actions taken in patients with suboptimal risk factor control, we assessed not only commonly used process and outcome measures but also new indicators that measure modifications of medical treatment in relation to the level of control. In a subpopulation of 23 practices participating since 2004, we studied how the results of these quality indicators evolved from 2004 to 2007.

METHODS

Study population and setting

For the first part of this observational study, we used data from the 95 general practices (124 general practitioners) that participated in the GIANTT project in 2007. GIANTT provides quality assessments for most general practitioners (GPs) in Groningen province, The Netherlands. The included practices cover a total population of over 304 000 people. The patient population for 2007 consisted of all patients with a GP-confirmed diagnosis of type 2 diabetes at the beginning of 2007, who were primarily managed by their GP ($n = 9646$). Excluded were only those patients who were managed by a specialist for their diabetes, as indicated by the GP ($n = 1615$). Secondly, the cohort of 23 general practices participating in GIANTT since 2004 was used for a 4-year quality assessment from 2004 onwards. For each year, all patients with type 2 diabetes managed primarily by their GP were included ($n = 2059$ in 2004 up to $n = 2929$ in 2007). In comparison to the other 72 practice, this first cohort of 23 practices had a slightly younger patient

population (average 7 months), with a shorter diabetes duration (average 4 months) in 2007 ($p < 0.05$). There were, however, no unequivocal differences in the averages of the risk factors HbA1c (-0.03%, $p > 0.1$), SBP (-1.5 mmHg, $p < 0.001$), LDL-cholesterol ($+0.05$ mmol/l, $p < 0.05$) or in treatment with glucose-regulating drugs (-1.8%, $p < 0.05$), antihypertensive drugs ($+0.4\%$, $p > 0.7$), and statins (-3.1%, $p < 0.01$).

Data collection

We collected all data on prescriptions and relevant measurements that were registered in structured as well as free text parts of the electronic medical records during the regular care process, using an automated and validated method.[13] The data were collected anonymously and concern patients that did not object to the collection.

Process indicators

We included commonly used process indicators focusing on the registration degree and the treatment level. Registration degree is defined as the percentage patients with at least one registered measurement of HbA1c, SBP or LDL-cholesterol. Treatment level is defined as the percentage patients treated with none, one or more glucose-, blood pressure and lipid-regulating drugs from different drug classes. This is in accordance with the stepped care treatment for these risk factors. A patient is considered treated if a drug is prescribed during the last 6 months of a calendar year. As new indicators, we used (A) treatment level in relation to level of risk factor control, and (B) percentage patients for whom medication therapy is started or intensified (increasing the daily dose or adding a drug from another drug class[14]) within 6 months after the observation of an inappropriately elevated risk factor level. Patients already on maximal treatment were excluded.[14] Switches from one drug to another within a drug class were not considered as treatment intensification for glucose-regulating or blood-pressure regulating drugs, since this is not part of stepped care treatment. For lipid-lowering drugs, however, we considered a switch from simvastatin, fluvastatin or pravastatin to atorvastatin or rosuvastatin as possible therapy intensification.

Outcome indicators

We included the average level of each risk factor, and the percentage of patients achieving specific target

levels as outcome indicators. Both are based on the last recorded measurement in a calendar year, which is in accordance with currently used quality indicators for diabetes care.[15,16] We distinguish the following cut-off points for respectively good, moderate and insufficient risk factor control: HbA1c <7%, 7–8.5%, >8.5%; SBP <140 mmHg, 140–160 mmHg, >160 mmHg; LDL-cholesterol <2.5 mmol/l, 2.5–3.5 mmol/l, >3.5 mmol/l. The target levels for good risk factor control are based on general practice treatment guidelines from 2006.[17] The subdivision into classes of moderate and insufficient control was made because it can be expected that prescribers will react differently to levels closer to target compared to more elevated levels.[18]

For the 4-year follow-up from 2004 onwards, we used total cholesterol instead of LDL-cholesterol as risk factor in accordance with the prevailing guidelines at that time. The used cut-off points were: <5 mmol/l, 5–7 mmol/l, >7 mmol/l. In this period, the registration degree of LDL-cholesterol was limited.

Analysis

We performed analyses on the whole population, and stratified for age (below 75 and ≥75 years) to enable detection of possible differences in risk management. Differences between means and percentages were tested using the Student's *t*-test and its z-approximation. For the 4-year follow-up percentages of treatment start and intensification were compared between consecutive years. Differences in class compositions were tested using the chi-square test. We present 95% confidence intervals.

For research using anonymous medical records no ethics committee approval is needed in The Netherlands.

RESULTS

In 2007, the patients were on average 67 years of age, and 52% were women (Table 1). The average time since diabetes diagnosis was almost 6 years. Mean body mass index was 30 kg/m^2, and 32% of the patients had albuminuria. The registration degree varied from 64% for LDL-cholesterol to 85% for blood pressure. Missing risk factor information was clustered: in 12% of the patients information on all three risk factor levels (HbA1c, LDL-cholesterol as well as blood pressure) was missing. These patients ($n = 1115$) with missing data were on average 2.2 years younger than the others ($p < 0.001$), less likely to be female (47 vs. 52%, $p < 0.01$) and their average diabetes duration was

11 months longer ($p < 0.001$). Patients with missing risk factor information were being prescribed less medication (Figure 1), except for lipid lowering drugs. In the period 2004–2007 the registration degree of the risk factors increased around 5% points after 2004 (Table 2).

Glycaemic control

The registration degree of HbA1c measurements was relatively high (84%) in 2007 (Table 1). The average HbA1c was 6.9%, with 61% of the patient population achieving good glycaemic control, and only 6% having insufficient control. There were no differences between

Table 1. Overview of the study population ($n = 9646$) in 2007

	Registration degree	Outcome	
	n (%)	%	Average (SD)
% Female	9646	52	
Age (years)	9646		66.6 (12.3)
DM duration (years)	9512 (98.6)		5.8 (5.7)
Patients per GP			78 (37)
HbA1c (%)	8114 (84.1)		6.9 (1.0)
<7 (good control)		61	
7–8.5 (moderate control)		33	
> 8.5 (insufficient control)		6	
Diastolic blood pressure (mmHg)	8255 (85.6)		78 (10)
Systolic blood pressure (mmHg)	8255 (85.6)		142 (20)
<140 (good control)		44	
140–160 (moderate control)		43	
> 160 (insufficient control)		13	
Total cholesterol (mmol/l)	6518 (67.6)		4.4 (1.1)
LDL cholesterol (mmol/l)	6139 (63.6)		2.3 (0.9)
<2.5 (good control)		61	
2.5–3.5 (moderate control)		29	
> 3.5 (insufficient control)		10	
Albuminuria*	4563 (47.3)		
		32	
BMI (kg/m^2)	5633 (58.4)		30.0 (5.5)
Glucose-regulating medication	8114		
None		17	
1 oral drug class		35	
>1 oral drug class		33	
Insulin		6	
Insulin + oral		9	
Blood pressure-regulating medication	8255		
None		24	
1 drug class		23	
2 drug classes		26	
3 drug classes		20	
>3 drug classes		7	
Lipid-regulating medication	6139		
None		28	
1 drug class		70	
>1 drug class		2	

*Concentration ≥20 mg/l, or albumine/creatinine ratio ≥2.5 (men)/3.5 (women) mg/mmol, or 24-hours albumine ≥30 mg/24 hour.
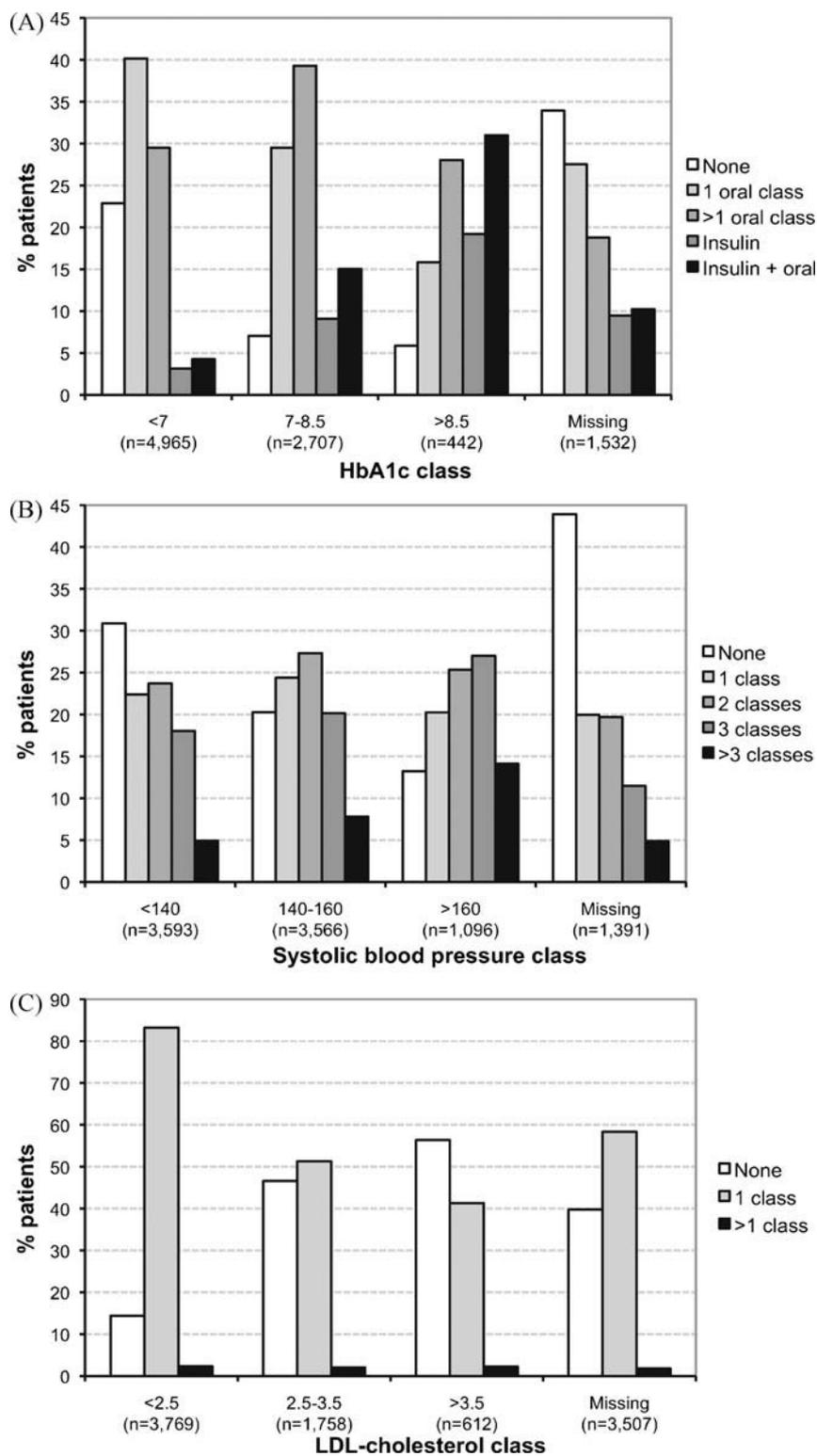
Figure 1.   Treatment level in relation to level of control for HbA1c (A), systolic blood pressure (B) and LDL-cholesterol (C) in 2007

Table 2. Overview of included populations from 23 general practices, 2004–2007

	2004	2005	2006	2007
Number of patients	2059	2266	2530	2929
% Female	54.8	52.9	51.8	51.5
Average age (SD)	66.2 (12.4)	65.7 (12.3)	65.7 (12.3)	66.1 (12.4)
Average DM duration (SD)	5.6 (5.8)	5.6 (5.8)	5.4 (5.6)	5.6 (5.7)
% with HbA1c data	80.6	85.9	86.3	86.6
% with SBP data	81.1	87.8	89.3	89.2
% with TC data	62.8	68.6	72.0	72.2

patients below and above 75 years of age ($p > 0.1$). Of the patients with an HbA1c above 7%, seven percent were not yet using glucose-regulating medication (Figure 1). Insufficiently controlled patients more frequently used oral multitherapy and/or insulin compared to those in moderate glycaemic control ($p < 0.001$). More than a third of the patients with moderate control and 22% of those insufficiently controlled were being prescribed none or just one oral drug class. The patients without HbA1c measurements in 2007 were treated less intensively compared to the others (Figure 1).

Therapy modifications. In fewer than 50% of patients with moderate or insufficient control, antihyperglycaemic therapy was started, and in less than a quarter therapy was intensified within 6 months (Figure 2).

There were no differences between patients below or above 75 years of age ($p > 0.1$, data not shown).

Four years follow-up. In the period 2004–2007, we observed no significant change in the population average of the HbA1c ($p > 0.2$) (Figure 3), although there was a reduction of the proportion of moderately controlled patients ($p = 0.01$). During this period, no significant increase in level of treatment was observed. Also no trends were observed in the level of starting or intensifying treatment in not well-controlled patients ($p > 0.05$, data not shown).

Blood-pressure regulation

The registration degree of blood pressure measurements was relatively high (85%) in 2007 (Table 1). The average systolic blood pressure was 142 mmHg, with 44% of the patients achieving good control. The portion moderately and insufficiently controlled patients differed between age categories: older (≥ 75 years) patients were more frequently insufficiently controlled (17 versus 12%, $p < 0.001$). Of the patients with an elevated blood pressure (SBP ≥ 140 mmHg), 19% were not yet on medication, and 23% used only one drug class (Figure 1). Of the moderately controlled patients, 28% used three or more drug classes, while this was the case in 41% of the insufficiently controlled patients. Patients without
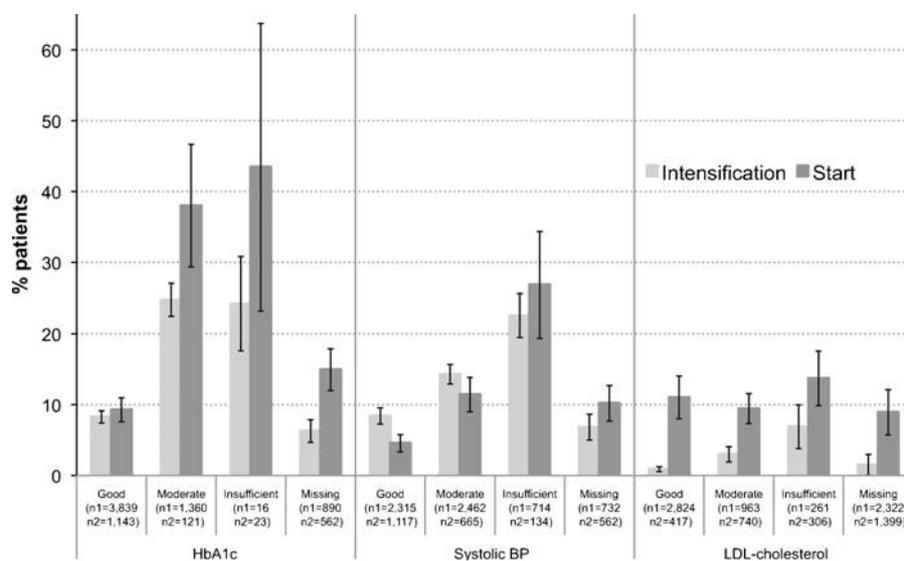

Figure 2. Medication modifications for three cardiovascular risk factors in relation to level of control in 2007. Percentages are calculated on the number of patients that either can intensify (n1) or start (n2).
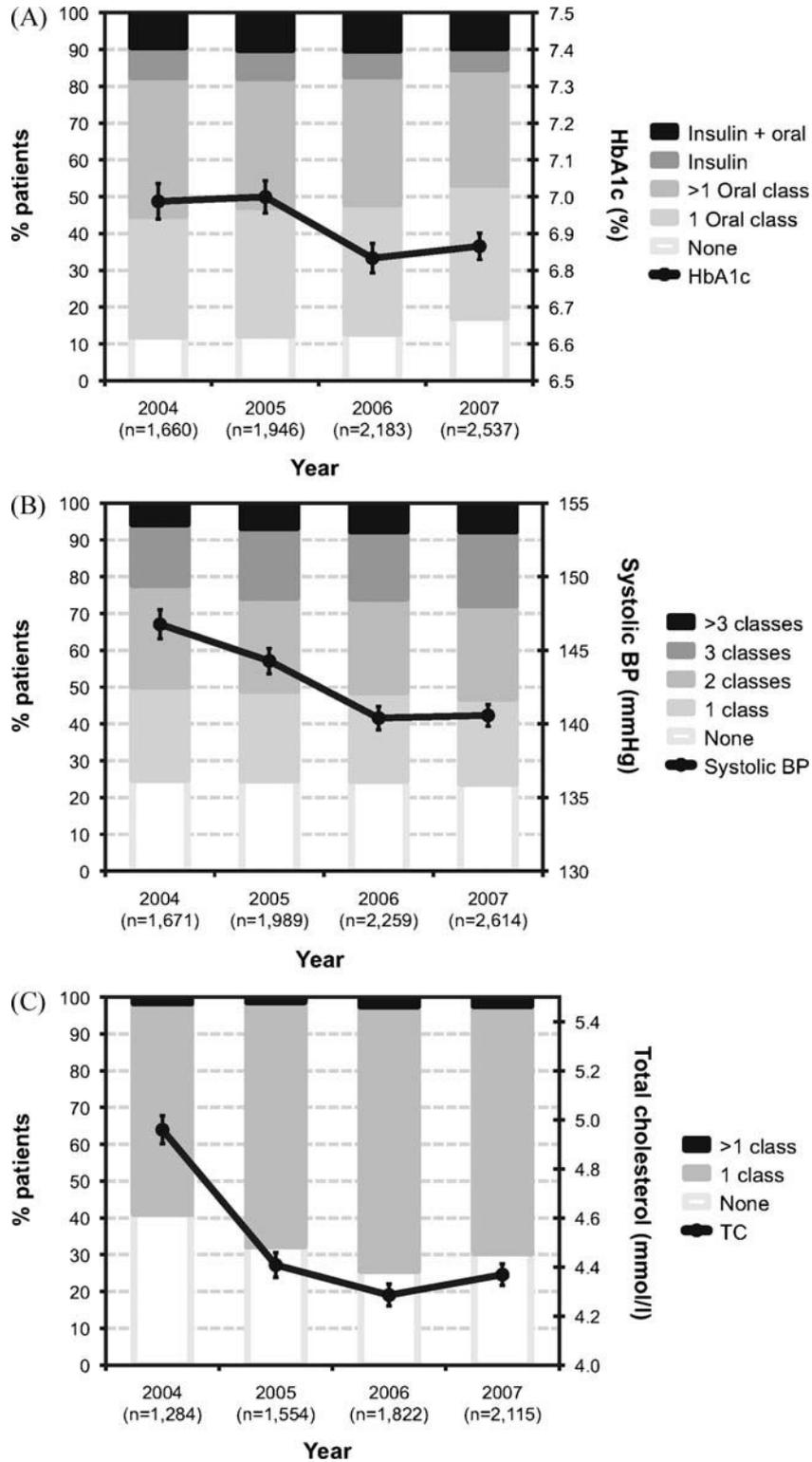
Figure 3. Treatment level and population averages for HbA1c (A), systolic blood pressure (B) and total cholesterol (C) in the period 2004–2007

available blood pressure measurements were treated less intensively compared to the others (Figure 1).

Therapy modifications. Only in a quarter of the patients with insufficiently controlled systolic blood pressure, medication treatment was either started or intensified (Figure 2). The level of starting and intensifying increased with increasing blood pressure levels ($p < 0.001$), with no differences between the age classes.

Four years follow-up. The average SBP fell with 6 mmHg in the period 2004–2007, and the portion insufficiently controlled patients decreased from 21 to 12% ($p < 0.001$). During this period, there was no significant change in treatment level (Figure 3). The level of starting and intensifying treatment also did not show significant trends (data not shown).

Lipid regulation

The registration degree of cholesterol measurements (64-68%) in 2007 is somewhat lower than that of HbA1c and SBP (Table 1). The average LDL-cholesterol was 2.3 mmol/l, with 62% of the patients achieving good control, and 10% being insufficiently controlled. There was no difference between the age categories ($p > 0.4$). Almost half of the insufficiently controlled patients were not using lipid-regulating drugs (Figure 1). This was higher in older (≥ 75 years of age) patients (65%), compared to younger patients (42%, $p < 0.001$). Patients without available LDL-cholesterol measurements were treated comparably to the others (Figure 1).

Therapy modifications. Although a considerable portion of the not well-controlled patients was not using lipid-regulating medication, we did not observe a significant higher level of starting or intensifying therapy in patients with higher risk factor levels (Figure 2). The treatment level of patients without LDL-cholesterol measurements was between that of the well and not well-controlled patients (Figure 1).

Four years follow-up. Between 2004 and 2005, the average total cholesterol fell with 0.6 mmol/l ($p < 0.001$, Figure 3). This decline was accompanied by a significant reduction of both moderately and insufficiently controlled patients (data not shown). The percentage of patients starting medication in 2004 was higher compared to the following years (29 versus 12%, $p < 0.001$).

DISCUSSION

In this study, we show that in 2007 the averages of HbA1c, systolic blood pressure and cholesterol in a large, average primary care population were either below or close to the recommended target levels. The percentages well-controlled patients, however, were 61% for HbA1c, 44% for systolic blood pressure and 61% for LDL-cholesterol. The treatment levels showed room for improvement. When looking at patients with different levels of risk factor control, it became evident that treatment of patients with elevated HbA1c levels is most stringent. In case of elevated blood pressure and cholesterol levels, no pharmacotherapeutic action is observed within the next 6 months in more than three quarter of the patients. We did not observe significant improvements regarding this treatment aspect in the period between 2004 and 2007.

There have been several developments that could have affected the treatment of patients with type 2 diabetes during the study period. In 2006, the recommended risk factor targets in the Dutch clinical guidelines have become more stringent.[15] Although one may expect that this would result in tighter control targets after 2006, trends towards this already started before 2006, and levelled off afterwards. The decrease in blood pressure in the beginning of the period is similar to those reported in other Dutch and European studies.[19–21] At the regional level, a project was started at the end of 2004 by the *Proeftuin Farmacie Groningen* to stimulate that all patients with type 2 diabetes were treated with a statin.[22] This can partly explain the high percentage of patients that started lipid-regulating drugs in 2004–2005, and the accompanied decrease in the average total cholesterol.

The percentage patients using antihypertensives of around 75% in 2004 is higher than reported in refs.[19,23] The low percentages of patients that either start medication or receive intensification of glucose-regulating and blood pressure-regulating drugs are similar to those reported in other studies.[19,24,25] Assessing how a prescriber reacts to an elevated risk factor is considered a good method to improve the action when needed.[9–11,26] In the whole population, 17% did not yet use glucose-regulating medication. In itself, this finding provides little insight into treatment quality.

When leaving the well-controlled patients aside, it becomes apparent that only few insufficiently controlled patients are untreated. On the other hand, the relatively low percentages of treatment start and intensification show room for improvement for the insufficiently controlled patients. Of the patients with

elevated blood pressure, 45% use at most one antihypertensive drug class, while the UKPDS has shown that often three or more drug classes are needed to achieve the target.[27] In the case of the 9% patients who, in spite of already using three or more drug classes, remain insufficiently controlled, the question is whether the existence of secondary hypertension has been sufficiently investigated.

For patients on insulin, the relative high portion insufficiently controlled patients is remarkable. Possibly, some of these patients are difficult to treat due to concomitant problems of long diabetes duration. The question remains whether enough has been invested in education or specialist referral in these patients.

A strong point of this study is that our data reflect an unselected group of general practitioners and patients who did not participate in a specific care organization or intervention program. The population covers all patients with type 2 diabetes who have the general practitioner as their main care provider. Since around 85% of all type 2 diabetes patients received care from their GP, our findings are relevant for a large part of the diabetes population. Previous research showed that patients treated by GPs were older, had a shorter duration of diabetes and fewer macrovascular and microvascular complications, whereas patients managed by specialists were more likely to be treated with insulin.[28] These population differences are the result of the Dutch healthcare system, in which GPs are gatekeepers and are advised to refer their patients with type 2 diabetes only in complex or advanced disease conditions. The data collection concerns full risk management data as is registered during the care process, enabling assessments of treatment start and intensification throughout a year. Presenting treatment indicators that represent an important link between measuring risk factors and their outcomes makes this study innovative.

As for all indicators, the indicators we present here should not be blindly used for external quality assessment.[11] A specific limitation of assessing medication modifications is that it ignores those patients already treated adequately. Besides this, these indicators only provide insights into medication treatment, and do not regard justifiable reasons not to intensify treatment. In a part of these cases, the care provider may try to improve outcomes by lifestyle or adherence advice. Tolerance issues or fear of insulin can further limit medication modification options.

A possible limitation of our study lies in its use of patient records. Although the registration degree of HbA1c and blood pressure is high (around 85%),

it is lower for LDL-cholesterol (64%). In 12% of the patients all relevant risk information is missing. This clustering makes the existence of a strong association between missing registration and risk factor level improbable. Patients with missing risk information, however, are being treated less intensely with glucose regulating and antihypertensive drugs which could indicate that these patients visit their GPs less frequently. We cannot assess whether they need less attention or might be care avoiders. In any case, these patients who are not regularly monitored in routine practice are a matter of concern, since they constitute a group whose treatment might be inadequate.

We acknowledged switches from low-potent statins to high potent counterparts as treatment intensification. However, this could have introduced some over-estimation, since part of these switches may not be intended as intensification.

CONCLUSION

We have shown that, despite decreasing trends in levels of cardiovascular risk factors, in over half of insufficiently controlled patients medication treatment is not promptly adjusted. We recommend applying this approach to quality assessment more often in addition to commonly used process and outcome indicators, since it provides a simple way for care providers to identify possible targets for improvement.

CONFLICT OF INTEREST

Authors declare no conflict of interest.

ACKNOWLEDGEMENTS

KEY POINTS

- Medication start or intensifications occur in less than half of the patients that are not well controlled for HbA1c, blood pressure or LDL-cholesterol.
- Treatment indicators measuring actions after observing an elevated risk factor, increase insight into where improvement is needed.
- Such treatment indicators are well assessable using routinely registered data in general practice.

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