Clinical inertia in general practice: widespread and related to the outcome of diabetes care

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Background and aims. Clinical inertia is considered a major barrier to better care. We assessed its prevalence, predictors and associations with the intermediate outcomes of diabetes care.

Materials and methods. Baseline and follow-up data of a Dutch randomized controlled trial on the implementation of a locally adapted guideline were used. The study involved 30 general practices and 1283 patients. Treatment targets differed between study groups [HbA1c < 8.0% and blood pressure (BP) < 140/85% versus HbA1c ≤ 8.5% and BP < 150/85]. Clinical inertia was defined as the failure to intensify therapy when indicated. A complete medication profile of all participating patients was obtained.

Results. In the intervention and control group, the percentages of patients with poor diabetes or lipid control who did not receive treatment intensification were 45% and 90%, approximately. More control group patients with BP levels above target were confronted with inertia (72.7% versus 63.3%, \( P < 0.05 \)). In poorly controlled hypertensive patients, inertia was associated with the height of systolic BP at baseline [adjusted odds ratio (OR) 0.98, 95% confidence interval (CI) 0.98–0.99] and the frequency of BP control (adjusted OR 0.89, 95% CI 0.81–0.99). If a practice nurse managed these patients, clinical inertia was less common (adjusted OR 0.12, 95% CI 0.02–0.91). In both study groups, cholesterol decreased significantly more in patients who received proper treatment intensification.

Conclusion. GPs were more inclined to control blood glucose levels than BP or cholesterol levels. Inertia in response to poorly controlled high BP was less common if nurses assisted GPs.

Keywords. Diabetes.

Introduction

In the last decades, clinical trials provided evidence that tight control of glycated haemoglobin, blood pressure (BP) and dyslipidemia decreases the risk of developing diabetes-related macrovascular and microvascular complications and cardiovascular death.\(^1\)\(^6\) In line with these findings, diabetes guidelines have set ambitious treatment goals for HbA1c, BP and cholesterol levels.\(^7\)\(^8\) Their introduction is expected to improve the quality of diabetes care and ensure the translation of evidence into daily practice.\(^9\) A treatment gap, however, still exists when best practice is compared with usual care.\(^10\)\(^13\) In part, this discordance may be a consequence of physicians’ inability to adjust their medical regimen in time.\(^11\)\(^14\) This failure to initiate or intensify therapy when indicated has been called clinical inertia.\(^15\) It has been attributed to overestimation of care provided, use of ‘soft’ reasons to avoid intensification of therapy and lack of education, training and practice organization.\(^15\) Although some progress has been made, our understanding of clinical inertia is still far from complete. Therefore, more attention should be devoted to understanding and ameliorating factors that contribute to clinical inertia.\(^16\)

We performed a randomized controlled trial aimed at the implementation of a local guideline on the shared care for patients with type 2 diabetes. After 1
year, there was proof of intensified diabetes care, but we were unable to show significant differences in body mass index, HbA1c or BP levels between the intervention and control group. Neither could we demonstrate a difference in the percentage of patients who had been treated to target. We hypothesized that these results were at least partially a consequence of clinical inertia. To test this hypothesis, we investigated the occurrence of clinical inertia in the intervention and control group and the relationship between inertia and the outcome of diabetes care. Furthermore, we studied possible predictors of clinical inertia.

Research design and methods

A cluster-randomized trial was carried out near Apeldoorn, a city with 150 000 inhabitants in The Netherlands. Participating practices were randomized to treat their patients either in accordance with local guidelines or in line with the 1999 guidelines for the treatment of type 2 diabetes of the Dutch College of General Practitioners. In the local guidelines, stricter targets were agreed on for satisfactory glycaemic control (HbA1c ≤8% versus ≤8.5%) and adequate BP control (BP <140/85 mmHg versus <150/85 mmHg). In both study groups, patients' total cholesterol levels should be ≤5.0 mmol/l (non-smokers without vascular complications ≤6 mmol/l).

Study participants
All general practices (n = 70) in the greater Apeldoorn region were asked to participate in the trial. All patients with type 2 diabetes on the lists of the participating practices were considered eligible. Exclusion criteria were the inability to complete a questionnaire, severe mental illness, unwillingness to attend the practice regularly and a limited life expectancy. Patients taking insulin at baseline were excluded for the present study because we were unable to monitor changes in their insulin regimen. As it was our aim to investigate clinical inertia in general practice, patients being treated in the secondary care setting were excluded also. All 18 pharmacists in the Apeldoorn region took part in the study.

Randomization
Participating general practices were randomized into an intervention and control group. Prior to randomization, practices were divided into groups according to the following criteria: practice type (single-handed, duo or group practice) and presence of a specialized nurse. An independent researcher then carried out a restricted randomization procedure using a random number table to ensure equal number of practices in each group.

Multifaceted interventions
Details on the intervention have been reported elsewhere. Briefly, in the intervention group practices, two nurse specialists interviewed practice staff, analysed barriers to change, discussed means to overcome these barriers and trained GPs, practice assistants and nurses in the use of the guidelines. Furthermore, they encouraged the introduction of structured diabetes care, emphasized the need for three-monthly control and gave assistance in managing people with type 2 diabetes. Practices in the control group were asked to continue the care for their patients with diabetes as usually.

Measurements
At baseline and ~1 year after the start of the trial, GPs and practice nurses examined all participating patients and recorded their demographics, duration of diabetes, smoking habits, co-morbidity, level of formal education and presence of macrovascular or microvascular complications. Fasting blood samples and urine samples were obtained and analysed at the local laboratory. HbA1c was determined by the Variant II Turbo Hemoglobin Testing System (Bio-Rad). Plasma glucose, total cholesterol, high-density lipoprotein cholesterol, triglycerides, albumin/creatinine ratio and microalbumin were determined with the Architect ci8200SR (Abbott).

The electronic records of all 18 pharmacists and those of three GPs having their own pharmacy were used to obtain accurate medication histories of all patients using blood glucose-lowering medications (ATC code A10) or being diagnosed by their GP with diabetes. Subsequently, these histories were matched with our research data. Prior to the start of the study, GPs completed a questionnaire about different aspects of their practice, including number of enlisted patients, percentage of patients diagnosed with type 2 diabetes, location of the practice, practice type (solo, duo or group practice), presence of a practice nurse, role of the practice assistant (participating versus non-participating in diabetes care), involvement of the GP in diabetes care, gender and age of the GP and length of his/her professional career.

Clinical inertia and intensification of therapy
In line with current views, clinical inertia was defined as the failure to intensify therapy when indicated. In the intervention group, adjustment of drug therapy was required in patients with HbA1c levels >8.0%, BP ≥140/85 mmHg or total cholesterol ≥5 mmol/l (>6 mmol/l for non-smoking patients without microvascular or macrovascular complications). In the control group, intensification of therapy was indicated in patients with HbA1c levels >8.5%, BP ≥150/85 mmHg or total cholesterol ≥5 mmol/l (>6 mmol/l for non-smoking patients without microvascular or macrovascular complications).
It should be kept in mind that both, the shared care guidelines and the guidelines of the Dutch College state that HbA1c should be <7.0%, whereas HbA1c between 7.0% and 8.0% (8.5%) is acceptable. Glucose-lowering drugs were categorized into three categories (metformin, sulfonylurea and thiazolidinediones), anti-hypertensive drugs into six (diuretics, beta blockers, calcium channel blockers, angiotensin-converting enzyme inhibitors, AT2 antagonists and central working agents) and lipid-lowering drugs into one (statins). At baseline and after 6 months, defined daily dosages were determined for all drugs that belonged to one of the categories mentioned above. By comparing the defined daily dosages used at the start of the study with those prescribed 6 months later, we established whether pharmacotherapy had been intensified. This 6 months period was decided upon as in our opinion it would have been inappropriate to allow for a longer period of, for example, 12 months. After all, it is hardly defensible to start treatment intensification >6 months after exceeding treatment targets. Intensification of therapy was defined as an increase in the number of drug classes, increased dosage of at least one medication or a switch to another medication in a different drug class. A switch to medication in the same therapeutic class was only regarded as intensification of therapy, if the defined daily dose of the new drug represented a higher bioequivalent dose compared with the previous agent. Patients receiving three maximally dosed medications for hypertension or two maximally dosed blood glucose-lowering drugs and those receiving the maximal dose of a statin were classified as receiving maximal therapy.

Statistical analysis

Patients’ level of formal education was split into two categories. Patients who visited primary school only or both primary school and secondary school at a non-advanced level were considered to have a low level of formal education. All others were regarded to be highly educated. For comparison of continuous and categorical variables, Student’s t-test and chi-square test were used when appropriate. In an univariate analysis, we explored possible predictors of clinical inertia, including gender, age, duration of diabetes, education, microvascular and macrovascular complications, HbA1c% at baseline, systolic and diastolic BP levels at baseline, total cholesterol level at baseline, the percentage of patients with HbA1c% above target, the percentage of patients with poorly controlled hypertension and the percentage of patients with poor lipid control. Significantly associated variables were entered into multivariable logistic regression models to determine adjusted odds ratios (ORs) for predictors of clinical inertia. We constructed separate models for the failure to intensify blood glucose-lowering, anti-hypertensive and cholesterol-lowering treatment in the intervention as well as the control group and in the group consisting of all poorly controlled patients from both study groups. As it was our desire to investigate the relationship between clinical inertia and practice-related factors also, we performed a separate analysis with the practices as the unit of study. After gradually increasing the cut-off level, it became apparent that best separation into two groups appeared at a level of 60%. Therefore, if in a practice >60% of the participating patients did not receive intensification of treatment, this practice was considered clinically inert. Again, separate models were constructed for the failure to intensify blood glucose-lowering, anti-hypertensive and cholesterol-lowering treatment. Generalized Estimating Equations (GEEs) were used to construct multivariable regression models to control for the clustered design of the study. Except for the GEEs, all analyses were carried out using the statistical package SPSS version 12.0 for Windows. We used SAS software version 8 (SAS Institute, Cary, NC) for the GEEs model.

The number of missing values per variable varied between 0% and 25.2%; mean 17.6%. Ignoring cases with a missing value may lead to biased results and loss of power. Therefore, we imputed missing values using the regression method available in SPSS. The imputation was based on the correlation between each variable with missing values and all other variables as estimated from the complete subjects.

Results

Participants

In total 11 single-handed, 16 duo and 3 group practices agreed to participate. Reasons for non-participation were lack of time, dislike of research projects, a lack of confidence in the outcome of the study and the conviction that the practice performed well and did not need enhancement of diabetes care. Overall, 2286 patients were eligible for the trial and 1569 patients gave informed consent. Of these, 1283 were included in the present study (Fig. 1).

Baseline characteristics

In the intervention group, more patients had a low level of formal education and fewer patients were suffering from macrovascular complications. Almost 17% of the intervention group patients and 8.6% of the controls met criteria for poor diabetes control. Poor BP control and total cholesterol levels above target were highly prevalent in both study groups. Only 9.1% of the intervention group patients and 18.3% of those in the control group were at target for all three parameters (Table 1).
GPs managing intervention group practices were younger and had more patients on their lists. In control group practices, more practice assistants were involved in the care for patients with type 2 diabetes (Table 2).

**Clinical inertia**
The percentage of patients with poorly controlled diabetes who did not receive appropriate treatment intensification did not differ significantly between the intervention and the control group (42.9% versus 46.4%, $P = 0.7$). The same applied to the percentage of patients with cholesterol levels above target (89.8% versus 92.8%, $P = 0.2$). There was a significant difference in the percentage of patients with a poorly controlled high BP who did not receive treatment intensification between the intervention and the control group (63.3% versus 72.7%, $P < 0.01$).

Using a 60% cut-off point, 35.3% of the participating intervention group practices were clinically inert regarding blood glucose-lowering treatment. The same applied to 64.7% and 94.1% of the practices with regard to BP- and cholesterol-lowering treatments. In the control group, these percentages were 30.0%, 85.0% and 100%, respectively. All differences between study groups were not significant.

**Factors associated with clinical inertia in response to poor diabetes control**
In the intervention group, patients with poorly controlled diabetes and a high level of formal education were less likely to receive intensification of treatment than those with a low level [adjusted OR 2.17, 95% confidence interval (CI) 1.03–5.04]. In the control group, the failure to intensify treatment with blood glucose-lowering drugs was associated with HbA1c% at baseline (adjusted OR 0.44, 95% CI 0.25–0.75). In the group consisting of all poorly controlled patients from both study groups, there were no significant associations between clinical inertia and any of the tested factors.
Factors associated with clinical inertia in response to poor BP control

In the intervention group, there was a positive association between physicians’ failure to intensify antihypertensive treatment and the height of systolic BP at baseline (adjusted OR 0.99, 95% CI 0.98–0.99). In the control group, inertia was related to the frequency of BP control visits (adjusted OR 0.83, 95% CI 0.74–0.93). In the group consisting of all poorly controlled patients, clinical inertia was associated with the frequency of BP control visits (adjusted OR 0.89, 95% CI 0.81–0.99) and the height of systolic (adjusted OR 0.98, 95% CI 0.98–0.99) and diastolic BP at baseline (adjusted OR 0.98, 95% CI 0.96–0.99).

Factors associated with clinical inertia in response to poor cholesterol control

No significant relationships between clinical inertia in response to poorly controlled hypercholesterolaemia and any of the tested factors were found.

Practice-related factors associated with clinical inertia

In practices that intensified anti-hypertensive treatment in >60% of their poorly controlled patients, nurses were more often involved in diabetes care, than in practices that did not make these changes adequately (77.8% versus 67.9%, \(P = 0.016\)). All other differences between inert and non-inert practices were not significant. In the group consisting of all participating practices, clinical inertia in response to poor BP control was less common if a practice nurse was actively involved in diabetes care (adjusted OR 0.12, 95% CI 0.02–0.91). We were unable to demonstrate this finding in the intervention or control group separately. In all these groups, there were no significant associations between any of the investigated practice-related factors and the failure to intensify treatment with blood glucose-lowering drugs or lipid-lowering drugs.

Clinical inertia and the outcomes of diabetes care

We were unable to demonstrate significant differences in mean HbA1c% and BP levels between poorly controlled patients who received proper treatment intensification and those who did not. However, total cholesterol decreased significantly more in patients who received intensification of treatment when indicated (Tables 3 and 4).

Discussion

This study confirmed the widespread of clinical inertia as the majority of the participating patients with BP or cholesterol levels above target and ~45% of those with poor glycaemic control did not receive proper treatment intensification. During the first 6 months of the intervention, clinical inertia in response to BP levels above target was significantly more prevalent in the control group than in the intervention group.
However, as we are not informed about the prevalence of clinical inertia prior to the start of the study, this result may not be attributed unambiguously to the successful implementation of locally adapted guidelines in the intervention group. Among diabetes patients with poor BP control, those with more severe systolic or diastolic hypertension and those with more frequent BP control visits were less likely to be insufficiently treated. This finding suggests a tendency in general practice to treat at least those patients with the highest BP levels. Of all investigated practice-related factors, only the presence of a practice nurse was associated with more appropriate intensification of anti-hypertensive therapy. This finding is striking because at present there is only little evidence that task delegation to nurses improves BP control. In this respect, it should be kept in mind that nurses are not allowed to prescribe oral blood glucose-lowering, anti-hypertensive or cholesterol-lowering drugs in the Netherlands. Therefore, nurses can only advise on treatment intensification, but they are unable to perpetrate such intensification independently. We were unable to demonstrate differences in HbA1c and BP levels between patients who received proper treatment intensification and those who did not. These results may seem surprisingly, but are in line with previous studies. Possibly, some stronger but unmeasured factors are operating to prevent an association between inertia, achieved HbA1c% and BP levels. However, in patients with cholesterol levels above target, the failure to intensify treatment was associated with a significantly smaller decrease of total cholesterol levels.

Some of the limitations of this study need to be discussed. Firstly, as practices participated voluntarily, GPs may have been selected with a particular interest in diabetes. Therefore, we may have underestimated the prevalence of clinical inertia. Secondly, as we were unable to monitor changes in daily insulin dose, we could not verify whether patients already on insulin were treated adequately. Therefore, the results of this study are not applicable to these patients. Thirdly, we may have overestimated clinical inertia because our data did not permit to take into account some forms of treatment intensification, like increasing the dose of a medication the patient has already a supply of. However, as in the Netherlands by law, only a 3-month supply of medications can be dispensed and our follow-up was 6 months; it is unlikely that many new, higher dosed prescriptions were not accounted for. One could argue that 6 months may have been a short time for change to take place. Considering the fact that this period allowed for three planned visits, there may have been insufficient time to appreciate a change in multiple parameters. However, as guidelines recommend not only planned visits but also frequent follow-up intervals (2–4 weeks) in poorly controlled patients, we feel there must have been ample opportunity to change management and achieve treatment goals. One of the strengths of our study is ascertainment of drug coverage: we had complete knowledge on the prescribed medications, as all pharmacies in the greater Apeldoorn region participated. Furthermore, our study was conducted among insured patients who had no financial barriers to care. This design helps to isolate the relationship between clinical inertia and all predictors investigated but may limit generalizability to other populations.

The frequency of clinical inertia in our study was comparable with that found in previous studies. It should be kept in mind that most studies on clinical inertia were performed in the USA. Inertia occurred in 68% of the visits made by Veteran Administration patients with an HbA1c >8% over 16 months. In an academic medical centre, the failure to initiate or intensify pharmaceutical therapy among diabetes patients with poor glycaemic, BP or cholesterol control was equally high. A recent study from Kaiser Permanente showed more optimistic results. A total of 66% of 48 568 patients with poor control of HbA1c experienced intensification of therapy within 6 months of observation. The same applied to 64% of patients with a poorly controlled systolic BP and to 56% of those with low-density lipoprotein cholesterol above target.

Clinical inertia has been attributed to many different factors, including overestimation of care provided, use of soft reasons and lack of training and practice organization focused on therapeutic goals. In our study, clinical inertia in response to poor diabetes control was associated with patients’ level of education and HbA1c% at baseline. These findings are in line with the results of other studies. In contrast with the results of the Kaiser Permanente study, we were unable to demonstrate an association between the presence of a poorly controlled hypertension or hypercholesterolaemia and the failure to intensify blood glucose-lowering drugs. A recent qualitative study recognized both patient- and physician-associated factors that could explain why GPs failed to prescribe lipid-lowering medications to patients with diabetes. According to the GPs, prescribing could be influenced by patients’ reluctance to start or continue pharmacotherapy. From a shared decision making point of view, physicians have to accept such refusals as a legitimate reason for not prescribing lipid-lowering drugs. After all, not adhering to a guideline after thorough discussion with a patient may well be an example of high-quality care. GPs also had difficulties in prescribing medications to patients with a short life expectancy, limited adherence or near goal lipid levels. Furthermore, they postponed the start of treatment due to competing demands, medication-related factors, including contraindications, side effects and interactions, lack of knowledge (confusing guidelines), practice organization and problems at the secondary–primary care.
interface (reluctance to interfere with treatment when a patient is seeing a specialist). From a recent study on reasons for not intensifying anti-hypertensive treatment in patients with diabetes and elevated BP levels, it became also apparent that when no action was taken the reasons for inaction were likely to be competing demands, new or transient increase, unfamiliarity with patient or BP near goal.27 When action was undertaken, pharmacological interventions became more likely at higher BP levels. This finding is in accordance with the results of our study in which physicians were more inclined to treat those patients with the highest BP levels.

A recent study on the relationship between inertia and the outcome of diabetes care made clear that on average a 15% higher frequency of treatment intensification was associated with a 0.15% lower level of HbA1c.28 We were unable to confirm this result. In our study, BP and HbA1c were not related with the failure to intensify therapy. We did find, however, that physicians’ failure to intensify cholesterol-lowering therapy was associated with less decrease of mean total cholesterol levels. Generally, the use of statins is a powerful determinant of change in cholesterol level, whereas a complex web of patient factors modifies the impact of pharmacotherapy on BP and HbA1c.16 Therefore, the impact of inertia on BP levels and HbA1c% is probably less predictable.

Unsatisfactory outcomes of diabetes care may be a consequence of poor patients’ adherence. The World Health Organization, for example, stated that only 50% of the patients diagnosed with diabetes are fully compliant with their treatment regimens.29 Adherence to prescribed medications is crucial to reach metabolic control, as non-adherence with blood glucose-lowering or lipid-lowering drugs has been associated with higher HbA1c and cholesterol levels.30–33 Recently, we performed a study on polypharmacy and patients’ adherence.34 For this study, the same baseline and follow-up data were used that had been at the base of this paper on clinical inertia. It became apparent that ~80% of the participating patients adhered to their blood glucose-, BP- and cholesterol-lowering medications. These results are at the upper limit of those reported previously.35 As it has been demonstrated

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### Table 3 Intervention group

<table>
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<tr>
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<th>No intensification of treatment during study</th>
<th>Intensification of treatment during study</th>
<th>Decrease between baseline and end of study</th>
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<tbody>
<tr>
<td></td>
<td>Baseline (SD)</td>
<td>End of study (SD)</td>
<td>Baseline (SD)</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>8.9 (1.3)</td>
<td>7.6 (1.2)</td>
<td>8.8 (0.8)</td>
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<td>Systolic BP (mmHg)</td>
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<td>150 (17)</td>
<td>158 (15)</td>
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<tr>
<td>Diastolic BP (mmHg)</td>
<td>90 (6)</td>
<td>85 (9)</td>
<td>91 (5)</td>
</tr>
<tr>
<td>Cholesterol (mmol/l)</td>
<td>5.9 (0.7)</td>
<td>5.6 (0.9)</td>
<td>5.8 (0.6)</td>
</tr>
</tbody>
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Decrease in HbA1c%, BP and total cholesterol in poorly controlled patients. *Adjusted for baseline value and clustering at practice level.

### Table 4 Control group

<table>
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<th>Intensification of treatment during study</th>
<th>Decrease between baseline and end of study</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (SD)</td>
<td>End of study (SD)</td>
<td>Baseline (SD)</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>9.3 (0.7)</td>
<td>8.1 (1.2)</td>
<td>10.0 (1.4)</td>
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<td>Systolic BP (mmHg)</td>
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<td>155 (19)</td>
<td>170 (14)</td>
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<tr>
<td>Diastolic BP (mmHg)</td>
<td>90 (5)</td>
<td>86 (9)</td>
<td>93 (7)</td>
</tr>
<tr>
<td>Cholesterol (mmol/l)</td>
<td>5.9 (0.7)</td>
<td>5.7 (1.0)</td>
<td>5.9 (0.7)</td>
</tr>
</tbody>
</table>

Decrease in HbA1c%, BP and total cholesterol in poorly controlled patients. *Adjusted for baseline value and clustering at practice level.
that limited access to pharmaceutical care contributes to poor patients’ adherence,\textsuperscript{36} the high percentage of adherent patients found in our study may have been a consequence of the Dutch health care system in which basic health care insurance is mandatory for all persons and all diabetes-related costs are reimbursed. Given the high percentage of adherent patients, it is unlikely that patients’ non-adherence largely explains the existing gap between best practice and usual care in The Netherlands.

In conclusion, we demonstrated that inertia in response to poor glycaemic control was less common than inertia in response to a poorly controlled hypertension or hypercholesterolaemia. Furthermore, poor BP control and high lipid levels were far more common than high HbA1c%. Finally, inertia in response to a poorly controlled high BP was less common if nurses assisted GPs. These findings may indicate a glucose-centric view of GPs. In this respect, it should be kept in mind that control of BP and lipid levels is at least as important as glycaemic control to prevent cardiovascular complications and an increase in the associated communal costs.

Declaration

Funding: AGIS Insurance Company.

Ethical approval: The medical ethics committee of the University Medical Centre Utrecht approved the protocol of the study and all participants gave informed consent.

Conflicts of interest: none.

References


\textsuperscript{31} Parris ES, Lawrence DB, Mohn LA, Long LB. Adherence to statin therapy and LDL cholesterol goal attainment by patients


