Reasons given by general practitioners for non-treatment decisions in younger and older patients with newly diagnosed type 2 diabetes mellitus in the United Kingdom: a survey study

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Abstract

Background: Older patients with newly diagnosed type 2 diabetes mellitus are less likely to receive antihyperglycaemic therapy compared to their younger counterparts. The purpose of this study was to assess the reasons of general practitioners (GPs) for not treating younger and older patients with newly diagnosed type 2 diabetes mellitus with antihyperglycaemic agents.

Methods: In a survey conducted between November 2009 and January 2010, 358 GPs from the United Kingdom selected reasons for not initiating antihyperglycaemic therapy in younger (< 65 years) and older (≥ 65 years) patients with newly diagnosed type 2 diabetes mellitus and untreated with any antihyperglycaemic agent for at least six months following diagnosis. Thirty-six potential reasons were classified into four major categories: Mild hyperglycaemia, Factors related to antihyperglycaemic agents, Comorbidities and polypharmacy, and Patient-related reasons. Reasons for non-treatment were compared between younger (n = 1,023) and older (n = 1,005) patients.

Results: Non-treatment reasons related to Mild hyperglycaemia were selected more often by GPs for both younger (88%) and older (86%) patients than those in other categories. For older patients, Factors related to antihyperglycaemic agents (46% vs. 38%) and Comorbidities and polypharmacy (33% vs. 19%), both including safety-related issues, were selected significantly (p < 0.001) more often by GPs. No between-group difference was observed for the Patient-related reasons category. The GP-reported HbA1c threshold for initiating antihyperglycaemic therapy was significantly (p < 0.001) lower for younger patients (mean ± standard deviation: 7.3% ± 0.7) compared to older patients (7.5% ± 0.9).

Conclusions: GPs selected reasons related to Mild hyperglycaemia for non-treatment of their untreated patients with newly diagnosed type 2 diabetes mellitus, despite nearly one-third of these patients having their most recent HbA1c value ≥7%. The findings further suggest that safety-related issues may influence the non-treatment of older patients with type 2 diabetes mellitus.

Background

In 2009, the prevalence of diabetes was 4% in the United Kingdom (UK), with the number of people diagnosed with diabetes increasing from 1.4 million in 1996 to 2.6 million [1]. This estimate is projected to reach 4 million by 2025. Most of these patients will be diagnosed with type 2 diabetes mellitus due to the increasing population of older adults and prevalence of obesity. At the time of diagnosis of type 2 diabetes mellitus, initiating treatment with metformin along with lifestyle changes is recommended for most adults without special considerations for older people [2]. NICE (National Institute of Health and Clinical Excellence) recommends initiating metformin therapy in UK patients with type 2 diabetes mellitus after a period of lifestyle modification [3].
Approximately 40% of patients with diagnosed type 2 diabetes mellitus remain untreated with antihyperglycaemic agents despite having inadequate glycaemic control [4-7]. Some studies have shown that older patients with newly diagnosed type 2 diabetes mellitus are less likely to receive antihyperglycaemic therapy [8,9]. Furthermore, although older patients appear to have improved therapeutic outcomes if antihyperglycaemic therapy is intensified compared to younger patients, younger patients are more likely to receive therapy intensification [10]. Others have reported that age does not influence the initiation or intensification of antihyperglycaemic therapy [4,11]. Nonetheless, delayed treatment initiation or intensification may have significant negative outcomes for older patients who typically present with greater medical comorbidity and vulnerability to untreated hyperglycaemia. Therefore, it was important to understand the reasons of general practitioners (GPs) for not treating younger (< 65 years) and older (≥65 years) patients with newly diagnosed type 2 diabetes mellitus with antihyperglycaemic agents.

Methods

Physician and Patient Selection and Data Collection

A survey was conducted in a sample of GPs from the UK between November 2009 and January 2010. GPs treating patients with type 2 diabetes mellitus in usual care settings across the UK were the primary target group. The GPs originated from the Kantar Health Physician Panel containing over 6,000 GPs from which a random sample was invited to take part in the survey. All participating physicians had to fulfill the following screening criteria in order to be eligible to take the survey: specialty being general practice, at least two years in practice, at least 50% of professional time spent on direct patient care, be primarily responsible for the diabetes management of at least ten patients per month, and had no participation in a physician’s panel activity in the last two months.

Additionally, the GPs must have available patient records of at least one patient from each age category (< 65 or ≥65 years at the time of type 2 diabetes mellitus diagnosis). Each eligible and participating GP provided data from chart review for individual patients who met the following inclusion criteria: at least 18 years of age at time of type 2 diabetes mellitus diagnosis, received no treatment with antihyperglycaemic agents for at least six months following diagnosis and potential reasons for non-treatment with antihyperglycaemic agents. After the survey was drafted according to the experts’ opinions, it was presented back to the experts for review and approval. A comprehensive list of 36 possible reasons for non-treatment with antihyperglycaemic agents was compiled. The 36 reasons were grouped into four high-level categories: Mild hyperglycaemia (three items), Factors related to antihyperglycaemic agents (eighteen items), Comorbidities and polypharmacy (five items), and Patient-related reasons (ten items). The list was provided to GPs using an electronic data capture form. GPs selected all applicable reasons why their patients had not been treated with antihyperglycaemic agents after diagnosis, and

provide results for more than one pair of younger and older patients. The following data were extracted from the patient’s charts: demographics, comorbidities, medication use, laboratory measurements, and vital signs. HbA1c and fasting blood glucose data were collected at the time closest to diagnosis and time closest to the survey date (i.e., most recent laboratory measurements). Remaining data were collected only at the time closest to the survey date (lipid levels, serum creatinine, estimated glomerular filtration rate, height, weight, and blood pressure). Body mass index was calculated as weight in kilograms divided by squared height in meters. GPs provided relevant patient data via the internet using an electronic data capture form. The target patient sample size was 2,000 patients, with 1,000 each for younger and older patients. Approximately 4,000 GPs were invited to participate. Of the 669 respondents who passed the initial screening questions, 571 GPs were considered eligible to participate. Of the eligible GPs, 358 participated and completed the survey and provided select patient results before the planned sample size was achieved.

According to the guidelines developed by the National Research Ethics Service (NRES: http://www.nres.npsa.nhs.uk/applications/guidance/research-guidance/?entryid62=66984), the present study did not require Research Ethics Committee review for the following reasons: it was a non-randomized physician survey including a brief retrospective chart review conducted by the participating physicians and did not involve any contact with patients or interventions. Furthermore, patients and participating physicians were both completely de-identified in data collection and analysis.

General Practitioners’ Reasons for Non-treatment

The survey was developed based on extensive interviews with an expert panel of practicing physicians and academic researchers. Interviews included discussions on treating older versus younger patients and scenarios where patients are not treated with antihyperglycaemic agents for at least six months after initial diabetes diagnosis and potential reasons relevant to non-treatment with antihyperglycaemic agents. After the survey was drafted according to the experts’ opinions, it was presented back to the experts for review and approval. A comprehensive list of 36 possible reasons for non-treatment with antihyperglycaemic agents was compiled. The 36 reasons were grouped into four high-level categories: Mild hyperglycaemia (three items), Factors related to antihyperglycaemic agents (eighteen items), Comorbidities and polypharmacy (five items), and Patient-related reasons (ten items). The list was provided to GPs using an electronic data capture form. GPs selected all applicable reasons why their patients had not been treated with antihyperglycaemic agents after diagnosis, and
then ranked the reasons in order of importance. In addition, the GPs were asked to provide an HbA1c threshold value for initiating antihyperglycaemic therapy for each patient.

Statistical analyses
Descriptive statistics were used to summarise patient demographics, disease characteristics, and reasons for non-treatment with antihyperglycaemic agents. Reasons for non-treatment were evaluated based on all reported reasons (all-reasons analyses) and the first-ranked reason (first-ranked reasons analyses). The between-age group comparisons were analyzed with t-tests or nonparametric tests for continuous data and χ² test for categorical data.

Results
Patient Characteristics
GPs provided data for 2,028 patients who were newly diagnosed with type 2 diabetes mellitus and also untreated with antihyperglycaemic therapy for at least six months following diagnosis: 1,023 younger patients (< 65 yrs; mean age at diagnosis = 48.2 years) and 1,005 older patients (≥65 years; mean age at diagnosis = 70.1 years) (Table 1). Compared with younger patients, older patients had a longer duration of type 2 diabetes mellitus (i.e., time from first diagnosis of type 2 diabetes mellitus to the survey date), a lower body mass index, and higher prevalence of cardiovascular conditions and microvascular complications (especially renal disease) and were taking a greater number of medications (all p < 0.001; Table 1). A higher proportion of younger patients was male and lived independently (Table 1). Measurements related to glycaemic control did not differ between age groups (Table 1). Although HbA1c tended to decline from baseline (i.e., difference between measurement closest to diagnosis and most recent measurement) in both groups, the proportion of patients with their most recent HbA1c ≥7% was approximately 31% and not different between younger and older patients (Table 1).

Survey Results
Collectively, reasons within the Mild hyperglycaemia category were chosen more frequently relative to those in the other categories by GPs as reasons for non-treatment in both age groups, with no significant differences between age groups in the all-reasons analysis (Table 2). Factors related to antihyperglycaemic agents were selected more often (p < 0.001) for older patients compared with younger patients. Within this category, numerous individual reasons accounted for the between-group difference including some related to side effects (e.g., hypoglycaemia, fluid retention, and fracture) and others related to the cognitive or physical function of the patient (Table 2). Reasons related to Comorbidities and polypharmacy were also selected significantly more often (p < 0.001) for older patients. Within this category, disease or medication burdens and factors related to polypharmacy (side effects or drug-drug interactions) were selected as reasons with greater frequency in the older patients. No differences overall were observed in the Patient-related reasons category. However within this category, fear of weight gain was chosen by GPs more often for younger patients, whereas non-significant trends were observed for more GPs selecting fear of hypoglycaemia and physical difficulty in taking medications as reasons for non-treatment in older patients (Table 2).

In an analysis using only first-ranked reasons, no significant differences within the high-level reasons categories were observed between age groups. With age groups combined, the overall percentage of GPs selecting reasons within the Mild hyperglycaemia category as the first-ranked reason was 79% followed by Patient-related reasons (14%), Comorbidities and polypharmacy (4%) and Factors related to antihyperglycaemic agents (3%). The GPs’ first-ranked reasons for non-treatment were also evaluated by category and most recent HbA1c stratum. HbA1c level was associated with selecting reasons within Mild hyperglycaemia category (Figure 1). GPs selected reasons within Mild hyperglycaemia category for 29% of their patients who had an HbA1c ≥7%.

GP-reported HbA1c threshold for initiating an antihyperglycaemic agent
GP-reported HbA1c threshold for initiating antihyperglycaemic therapy was significantly (p < 0.001) lower for younger patients (mean ± standard deviation: 7.3% ± 0.7) compared to older patients (7.5% ± 0.9). The proportion of patients with their most recent HbA1c measurement above their GP-reported HbA1c threshold was significantly higher (p = 0.002) in the younger patients (14.3%) compared to the older patients (10.4%).

Discussion
This study assessed the reasons reported by a sample of UK GPs for not initiating antihyperglycaemic therapy in younger (< 65 years) and older (≥65 years) patients with newly diagnosed type 2 diabetes mellitus who remained untreated for at least six months following the initial diagnosis. In patients whose HbA1c was well controlled at the time of the survey, the GPs reason for not initiating treatment was often that the patients had only Mild hyperglycaemia, whereas for less well-controlled patients, other reasons were more prominent. Interestingly, 29% of patients had an HbA1c ≥7% despite their GP’s selection of the first-ranked reason being Mild hyperglycaemia. In a cross-sectional survey study of US-based practices, physicians provided reasons of “improving/doing well” for over 50% of the patients who had an HbA1c ≥7% and no
action taken on therapy (i.e., lifestyle and/or medication) after a recent office visit [12]. These findings represent an important gap between treatment guidelines and the current clinical practice.

GPs were also requested to provide an HbA1c threshold for initiating antihyperglycaemic therapy for individual patients included in this study. The mean for the GP-reported HbA1c threshold for initiating antihyperglycaemic therapy was lower for younger patients than for older patients (7.3% vs. 7.5%). This lower threshold for younger patients may explain why a higher proportion of younger patients (14%) had their most recent HbA1c value exceed their GP-defined individualized threshold for initiating treatment than that of the older patients (10%). Interestingly, the GP-reported thresholds on average were near the HbA1c value of 7.5%, which was recently associated with the lowest incidence of all-cause mortality and progression to macrovascular events [13]. NICE recommends treatment targets between 6.5% and 7.5% depending on the extent of pre-existing comorbid conditions and agreement with the patient [3]. However, GPs actually applied an HbA1c threshold ≥7.5% for initiating antihyperglycaemic therapy in about half of these older patients.

### Table 1 Characteristics of patients provided by the general practitioners

| Demographics | Patients | Patients | p-value |
|--------------|----------|----------|---------|
| Age at survey, years | 50.7 ± 9.2 | 74.1 ± 7.3 | < 0.001 |
| Male | 61 | 54 | 0.001 |
| Body mass index, kg/m² | 31.2 ± 6.4 | 28.9 ± 5.4 | < 0.001 |

| Diabetes-related characteristics | Patients | Patients | p-value |
|----------------------------------|----------|----------|---------|
| Age at diabetes diagnosis, years | 48.2 ± 9.2 | 70.1 ± 8.5 | – |
| Duration of diabetes*, months | 18 (9, 36) | 25 (11, 60) | < 0.001 |
| HbA1c closest to diabetes diagnosis, % | 7.4 ± 1.1 | 7.4 ± 1.2 | 0.389 |
| Most recent HbA1c, % | 6.8 ± 0.9 | 6.8 ± 0.7 | 0.101 |
| HbA1c change from diagnosis, % | -0.5 (-6.9, 7.5) | -0.4 (-8.5, 1.5) | 0.189 |
| Proportion with most recent HbA1c ≥7% | 31 | 32 | 0.600 |
| FBG closest to diagnosis, mmol/L | 9.1 ± 2.8 | 90 ± 2.6 | 0.505 |
| Most recent FBG, mmol/L | 7.1 ± 1.9 | 70 ± 2.0 | 0.824 |
| Proportion with most recent FBG ≥7 mmol/L | 21 | 20 | 0.380 |

| Other characteristics and comorbidities | Patients | Patients | p-value |
|----------------------------------------|----------|----------|---------|
| Serum creatinine, μmol/L | 85.7 ± 25.5 | 97.7 ± 31.7 | < 0.001 |
| LDL-cholesterol, mmol/L | 2.7 ± 2.3 | 2.5 ± 1.3 | 0.019 |
| HDL-cholesterol, mmol/L | 1.3 ± 0.5 | 1.4 ± 0.5 | 0.084 |
| Triglycerides, mmol/L | 2.1 ± 1.3 | 1.7 ± 0.8 | < 0.001 |
| Cardiovascular conditions | 5.2 | 18.3 | < 0.001 |
| Ischemic heart disease | 3.5 | 9.4 | < 0.001 |
| Myocardial infarction | 1.8 | 4.4 | < 0.001 |
| Peripheral vascular disease | 0.9 | 2.1 | 0.027 |
| Stroke | 0.6 | 3.9 | < 0.001 |
| Microvascular complications | 4.3 | 15.4 | < 0.001 |
| Neuropathy | 0.7 | 1.3 | 0.184 |
| Retinopathy | 1.1 | 2.0 | 0.105 |
| Renal disease | 2.8 | 13.2 | < 0.001 |
| Total number of medications | 2 (0, 3) | 3 (1, 6) | < 0.001 |
| Patient’s living situation | 98.8 | 89.1 | < 0.001 |

Data are expressed as mean ± standard deviation, frequency (%), or median (interquartile range).

FBG = fasting blood glucose

*Time from first diagnosis of type 2 diabetes mellitus to survey date
Reasons within the categories of Factors related to anti-hyperglycaemic agents and Comorbidities and polypharmacy were selected more frequently by GPs as reasons for non-treatment of older patients. The individual reasons with significant between-group differences appeared to be focused on issues related to safety (e.g., risk of side effects or drug-drug interactions), disease or medication burdens for patients and cognitive or physical function of the patient. Although not assessed for age-related differences, similar reasons have been provided by physicians for their patients not receiving action in diabetes treatment despite having elevated HbA1c [12]. Diabetes therapies that have demonstrated efficacy and safety in patients, especially older patients, may allay some of these concerns raised by GPs. Furthermore, GPs in the present study set a higher HbA1c threshold for initiating treatment in older patients. These results are consistent with previous studies that have shown that older patients with newly diagnosed type

| Reasons, n (%) | Patients < 65 years n = 1,023 | Patients ≥ 65 years n = 1,005 | p-value |
|---------------|-------------------------------|-------------------------------|---------|
| Mild Hyperglycaemia | 897 (87.7) | 866 (86.2) | 0.323 |
| • HbA1c value stable, drug therapy not necessary | 278 (27.2) | 264 (26.3) | 0.652 |
| • HbA1c value close to NICE recommended threshold | 316 (30.9) | 326 (32.4) | 0.474 |
| • Blood glucose values under control with diet and exercise | 301 (29.4) | 330 (32.8) | 0.103 |
| Factors Related to Antihyperglycaemic Agents | 386 (37.7) | 463 (46.1) | < 0.001 |
| • May cause hypoglycaemia | 176 (17.2) | 250 (24.9) | < 0.001 |
| • May cause fluid retention | 67 (6.6) | 98 (9.8) | 0.009 |
| • May cause weight gain | 173 (16.9) | 157 (15.6) | 0.435 |
| • May cause gastrointestinal side effects | 203 (19.8) | 200 (19.9) | 0.999 |
| • May increase risk of fracture | 45 (4.4) | 68 (6.8) | 0.026 |
| • May increase cardiovascular risk | 49 (4.8) | 68 (6.8) | 0.057 |
| • May increase risk of lactic acidosis | 78 (7.6) | 96 (9.6) | 0.132 |
| • Uncertainty how to dose certain drug | 26 (2.5) | 25 (2.5) | 0.999 |
| • Not clear if several agents are safe | 30 (2.9) | 34 (3.4) | 0.612 |
| • Efficacy of agents not clear | 30 (2.9) | 24 (2.4) | 0.492 |
| • Safety of agents not clear | 34 (3.3) | 30 (3.0) | 0.704 |
| • Primary Care Trust cost concerns | 24 (2.4) | 26 (2.6) | 0.776 |
| • Cognitive burden of therapy administration too high for patient | 66 (6.5) | 121 (12.0) | < 0.001 |
| • Cognitive burden of monitoring glucose too high for patient | 48 (4.7) | 87 (8.7) | < 0.001 |
| • Difficulties/ability to change patient’s lifestyle | 118 (11.5) | 119 (11.8) | 0.836 |
| • Risk of non-compliance (not related to side effects) | 115 (11.2) | 132 (13.1) | 0.198 |
| • Risk of non-compliance due to side effects | 80 (7.8) | 115 (11.4) | 0.007 |
| • Lack of monitoring due to physical limitations (e.g., dexterity) | 32 (3.1) | 82 (8.2) | < 0.001 |
| Comorbidities and Polypharmacy | 192 (18.8) | 333 (33.1) | < 0.001 |
| • Patient has other severe disease(s) | 69 (6.7) | 172 (17.1) | < 0.001 |
| • Medical diabetes treatment is contraindicated | 27 (2.6) | 38 (3.8) | 0.166 |
| • Patient is taking several other medications already | 108 (10.6) | 216 (21.5) | < 0.001 |
| • Risk of side effects (related to polypharmacy) | 124 (12.1) | 191 (19.0) | < 0.001 |
| • Risk of drug-drug interactions (related to polypharmacy) | 60 (5.9) | 100 (10.0) | < 0.001 |
| Patient-Related Reasons | 443 (43.2) | 416 (41.4) | 0.419 |
| • Patient denial/anger/depression related to diabetes diagnosis | 120 (11.7) | 108 (10.8) | 0.527 |
| • Patient’s follow-up visit is overdue | 92 (9.0) | 64 (6.4) | 0.030 |
| • Patient does not want to take (additional) medication | 325 (31.8) | 305 (30.4) | 0.502 |
| • Fear of hypoglycaemia | 71 (6.9) | 93 (9.3) | 0.061 |
| • Fear of weight gain | 112 (11.0) | 78 (7.8) | 0.015 |
| • Fear to change from diet/exercise to oral agents | 100 (9.8) | 88 (8.8) | 0.445 |
| • Fear to change from diet/exercise to insulin | 54 (5.3) | 53 (5.3) | 0.999 |
| • Patient has physical difficulty taking medication | 29 (2.8) | 44 (4.4) | 0.073 |
| • Drug therapy decreases quality of life | 61 (6.0) | 76 (7.6) | 0.158 |
2 diabetes mellitus were less likely to receive antihyperglycaemic therapy [8,9]. The reasons identified in the present study may help explain the clinical inertia or inequality of health care observed in previous studies. It is understandable to focus on issues related to safety and functional capacity when considering diabetes treatments and management in older patients, especially frail patients [14]. However, in the present study, a majority of older patients lived independently. Furthermore, given that older patients have higher prevalence of comorbidities, failure to treat or delays in diabetes treatment for this population may have greater health implications than for younger patients.

There are many factors that influence the treatment of patients with type 2 diabetes mellitus. In a focus group setting with family physicians, Brown et al. [15] identified patient-, physician- and systemic-related factors that were considered barriers and facilitators to the management of patients with type 2 diabetes mellitus. For patient factors, physicians felt that many patients with type 2 diabetes mellitus failed to recognise the seriousness of their disease due to its asymptomatic nature. Education was seen as both a barrier and facilitator to disease management. Physicians indicated that early education led to better outcomes for their patients. Conversely, physicians felt overwhelmed with all of the different treatment guidelines for their diabetic patients and associated comorbid conditions [15]. In another study, reasons of GPs for not prescribing lipid-lowering agents in patients with type 2 diabetes mellitus were divided into patient- and physician-related factors [16]. Patient-related factors included compliance or refusal to take prescribed medication due to expected or perceived side effects. Physician reasons were related to proximity to treatment targets, perceived lack of benefits in patients with short life expectancy and expected compliance problems with their patients [16]. In the present study, risk of non-compliance was selected by up to 13% of GPs as a reason for non-treatment. Overall, these and the present results demonstrate that diverse factors influence the GP’s decision to initiate treatment in patients with type 2 diabetes mellitus.

The following limitations should be considered when interpreting the results of this study. Observed trends pertain to GPs and might not be generalisable to endocrinologists, diabetes, or GPs who do not treat many patients with type 2 diabetes mellitus. A selection bias may have occurred as the GPs needed to meet specific criteria in order to be eligible to participate, which may have limited the participating GPs to those who had a greater focus on diabetes care. Other reasons not identified may influence GPs for not initiating therapy (e.g., life expectancy, overall quality of life, or recent clinical findings). All physician-reported laboratory measures closest to diagnosis were included in the analysis regardless of the timing of measurement. Although GPs provided the clinical data of patients who met specific criteria, the GPs self-selected the patients from their practices. GPs entered select patient data in the online form and completeness of the form was assessed. Validation of data
Conclusions

GPs selected reasons related mainly to Mild hyperglycaemia for non-treatment with antihyperglycaemic agents for their untreated patients with newly diagnosed type 2 diabetes mellitus, despite nearly one-third of these patients having their most recent HbA1C ≥7%. In addition, the survey findings suggest that issues related to safety of antihyperglycaemic agents, burden to the patients, and cognitive or physical function of the patient influence the non-treatment of older patients with type 2 diabetes mellitus.

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Authors’ contributions

QZ, EM, KJ, LR, SM, and AS were involved in the concept and design of the study. QZ, EM, KJ, and SM were involved in the data collection and/or analysis. All authors were involved in interpretation of the results. MJ and EM drafted the article and all authors were involved in the critical revision and approval of the article.

Competing interests

QZ, EM, KJ, MJD, and LR are employees of Merck Sharp & Dohme Corp. SM and AJS have no conflicts related to this analysis.

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