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Therapeutic inertia amongst general practitioners with interest in diabetes.

Introduction/Background

As the armamentarium of therapeutic options in management of type 2 diabetes increases, there is an increasingly complex range of options which can create confusion among health care professionals leading to the phenomenon of therapeutic inertia. Therapeutic inertia is defined as the failure of healthcare professionals to initiate or intensify or de-intensify therapy when indicated[1,2]. Early in the disease, there are clear guidelines about diet and lifestyle modifications and the use of oral hyperglycaemic agents (OHAs)[3]. As the disease progresses and there are increasing comorbidities such as renal and cardiovascular disease, a more individualised approach to treatment is required. For example, in older patients[4], quality of life becomes a more important factor. Therapeutic inertia could be due to a lack of training or knowledge, difficulty accessing specialist care advice in a timely manner or deviation from clinical guidelines[5]. There are also wider system level factors in therapeutic inertia such as the high cost of newer agents[6].

Therapeutic inertia is present at all levels of treatment, although, it manifests at a higher level when injectable therapies are indicated. Studies in the UK have shown there was a delay in intensification for patients on one OHA with an HbA1c >7% (>53 mmol/mol) of 1.6 years, compared with >6.9 years for those taking two OHAs[7]. The median time to intensification with insulin was >7.1, >6.1, or 6.0 years for those taking one, two, or three OADs[7].

The delay in intensification leaves a hyperglycaemic legacy which acounts for the complications later in the disease[8]. Therapeutic inertia has been shown to lead to an increase risk of myocardial infarction by 67% (CI 39–101%), stroke by 51% (CI 25–83%), heart failure by 64% (CI 40–91%) and with a composite cardiovascular events by 62% (CI 46–80%) in people with type 2 diabetes with a HbA1c of >7% and not receiving treatment intensification within 1 year were[8].

Since therapeutic inertia has been blamed on the lack of training or knowledge and the difficulty in accessing specialist care advice in a timely manner, it is worth up skilling the primary care base to prevent the phenomenon. This will bring not only clinical benefits to the patients, but also financial benefits to the health system and the providers. To our

knowledge, therapeutic inertia has never been reported in any studies focusing solely on primary care physicians with an interest in diabetes, however, this group is increasingly becoming the focus of managing complex diabetes care in the community, albeit with the support from specialists[9-13].

Therefore, in this study, we sought to assess the prevalence of the phenomenon of therapeutic inertia amongst primary care physicians with interest in diabetes in the UK. We also assessed the predictive abilities of various patient level characteristics on therapeutic inertia amongst this group of clinicians. When there has not been intensification of treatment, we assessed if this was due to the knowledge of the clinical context of the patient by the clinician.

In this study, we defined intensification or de-intensification as the change of a therapeutic dose of existing glucose lowering drug or addition or withdrawal of another glucose lowering drug. This may not always occur, but that is not always therapeutic inertia, as there may be other clinical reasons such as the patient being stated to be within an individualised acceptable target of glycaemic control. Therapeutic inertia is failure to intensify or de-intensify treatment when there is a clinical justification for this to occur. Broadly, "Intensification" refers to situations when the patient is less than 65 years and HbA1c has remain more than 53mmol/mol (7%) for more than twelve months when there is no risk of hypoglycaemia - *this represents those who are younger, and may require tightening of treatment to achieve recommended HbA1c control. "*De-intensification" refers to those over 65 years and have risk of hypoglycaemia but have HbA1c less than 53 mmol/mol (7%) yet no treatment change occurred in past 12 months – *this group represents those who clinically may need a higher HbA1c targets and may be candidates for treatment relaxation.*

Methods

Primary care physicians with interest in diabetes across the UK were invited for this quality assurance programme. These clinicians were identified through the Primary Care Academy of Diabetes Specialists (PCADS). At the time of the study, the group consisted of 27 general practitioners with interests in diabetes in the UK who liaise with others to foster

understanding on the key elements essential for delivering a diabetes service and the potential challenges involved. Between January and March 2016, each participating clinician retrospectively audited the last twenty consecutive patients with type 2 diabetes seen in their clinic. From this audit, they assessed if therapeutic inertia had occurred or not, based broadly on the aforementioned definitions, and their holistic knowledge of the patients. Anonymised demographic, biochemical and pharmacological data were extracted by the individual clinicians and assembled for analysis. The variables extracted included age, sex, duration of diabetes (date of diagnosis), stated glycated haemoglobin (HbA1c) target, Last recorded Hba1c, number of oral hypoglycaemic agents, glucagon-like peptide 1 (GLP-1) receptor agonists and insulin.

Statistical analysis.

Data were analysed using SPSS for Windows (version 22, SPSS Inc., Chicago, IL, USA). The categorical variables were reported as numbers (percentages) and the continuous variables as means (standard deviations). For the continuous demographic variables, independent sample t-tests we performed between the groups of patients in whom therapeutic inertia occurred and those it did not. For the categorical variables, we used the chi-squared test to compare the various demographic and pharmacological variables between those in whom therapeutic inertia was present and those in whom it was not. Logistic regression was used to assess whether the eight variables together as a model or individually could distinguish between situations in which therapeutic inertia occurred and when it did not occur, after ensuring there was no significant interactions between the independent variables.

Results

In total, there were twelve respondents from England, Wales and Northern Ireland, each supplying data for twenty patients with type 2 diabetes. Four of the respondents were female and eight were male. Four worked in rural practices and the other eight worked in urban inner-city practices. All the respondents worked in the National Health Service (NHS). Out of the 240 patients reported on, therapeutic inertia was judged to have occurred in 53 (22.1%) of patient. Table 1 illustrates the detail characteristics used in the analysis. The mean age of

the patients was 62.2 years (standard deviation (SD) of 12.10). The group had a mean duration of diabetes of 9.9 years. The mean of their most recent HbA1c was 70.8 mmol/mol, (SD=16.5). On the average, their target HbA1c set in partnership with their clinicians was 56.2 mmol/mol. Except for the duration of diabetes, there were no differences in these demographic characteristics between the patients in whom therapeutic inertia occurred and those in whom it did not occur.

In the patients in whom therapeutic inertia was occurred, there was an increased male preponderance (58.5%). Also, 15 (28.3%) of them were on triple oral therapies, 19 (35.8 %) on dual therapies and 14 (26.4%) on mono therapy. Only 4 (7.5%) of them were on GLP1 agonist and 12 (22.6%) were on insulin.

We assessed whether there was an association between therapy intensification or de-intensification and therapeutic inertia. There was a significant association between therapeutic inertia and whether therapy was intensified or not, p=0.000. Only in 37.6% of the population of patients in whom therapy was not intensified did the clinicians demonstrate therapeutic inertia, implying that in almost two-thirds of people in whom therapy was not intensified, there was a clinical justification for that decision.

As shown in table 2, the full model containing all the 8 variables was not statistically significant, p=0.59. So, the model was not able to distinguish between situations in which therapeutic inertia occurred and when it did not occur in the general practitioners with interest in diabetes. None of the patient level characteristics on its own was predictive of therapeutic inertia. No significant association between therapeutic inertia and the number of oral hypoglycaemic agents, p=0.062.

Discussion

Among general practitioners with interest in diabetes care, the problem of therapeutic inertia occurred only in a little over a fifth of the patients. This is contrasted with findings in purely generalist practitioners[14].

Not many studies have attempted to quantify the prevalence of inertia in any setting. However, in a multispecialty group practice in Michigan between 2000 and 2005, 27% of patients had periods of sustained hyperglycaemia, defined as two A1C values of >8% with no intervening medication intensification[15]**.** In another previous study in the US, a comparison was done on the management of a people with diabetes from a deprived population in a primary care site supervised by general internal medicine faculty, and the Diabetes Clinic, a specialty site supervised by endocrinologists. Use of pharmacotherapy including less use of insulin, was less intensive in the primary care site[14]. Even when patients had raised glucose levels in clinic, therapy was less than half as likely to be escalated in the primary care centre compared to the Diabetes Clinic ($P < .0001$), regardless of the type of therapy considered. The HbA1c averaged 8.6% in the primary care centre versus 7.7% in the Diabetes Clinic ($p < .0001$). Thus, the more specialised the clinical team, the less likely the issue of therapeutic inertia[14]. In our evaluation, in the situations when the therapeutic inertia has occurred, it is difficult to identify a single most important contributing factor. However, it appears that, often, when therapy intensification does not occur, they may be a clinical justification for this.

The relatively less frequent occurrence of therapeutic inertia amongst primary care clinicians with an interest in diabetes in this study could be attributed to many factors not accounted for in this evaluation. First, unlike the generalist physician in primary care that may be running a generalist clinic and seeing patients with multiple medical problems, the generalist with interest in diabetes may selectively have a separate diabetes clinic. In these clinics, they would focus on diabetes in a lot of detail, albeit with consideration for other competing multi-morbid conditions, and thus more likely to suggest medication intensification or de-intensification in patients with inadequate glycaemic targets. In a study on 211 consultations in people with type 2 diabetes in primary care, it was noted that for people with HbA1c levels above 7%, each additional patient concern was associated with a 49% less likelihood of changes in medications independently of the level of Hba1c or length of consultation[16],

Second, the relationship between the unit costs of drugs for diabetes and therapeutic clinical inertia remains largely unknown. In most areas, choice of regimen is influenced by prescribing budgets. In England, most areas will have some newer antidiabetic agents reserved for prescribing by only specialists either in secondary care centres on primary care centres. Ideally, patients should receive an antidiabetic drug regimen that is consistent with safe and

timely correction of blood glucose, regardless of cost. This ideal however is seldom exercised by the generalist physician. It is very possible that with the increasing long-term effects of suboptimal glycaemic control, the rising medico-legal costs of therapeutic inertia may encourage greater prioritisation of therapeutic inertia during patient-physician contacts, irrespective of whether they are specialist of not[17]. In the UK, claims against healthcare professionals involving diabetes increased by 28%, from 162 during 2003-2007 to 207 in 2008-2012[18].

Third, psychological or physical stresses in patients have been cited as one of the reasons for therapeutic inertia[19]. When the clinician has a holistic knowledge of the patient's biopsychosocial state, they can judge a level of control as adequate for that patient even if there is poor control, especially in the geriatric population. It is possible that social undesirability may have led to not intensifying treatment, leaving only more socially acceptable reasons.

Finally, if health care organisation that promote the use of primary care physicians with specific interest in diabetes, can demonstrate less therapeutic inertia, it is hoped that this will translate in better outcomes for the patients at a lesser cost for the society. In Australia, researchers recently demonstrated that an innovative integrated primary–secondary model of care for people with complex type 2 diabetes could lead to fewer admissions for a diabetes-related complication and the care provided at a cheaper cost than those receiving usual care[10,20,21]. Similarly, after a similar evaluation, researchers in England also suggested that the use of well-trained, well-organised primary care teams, offering enhanced diabetes care, has the potential to lead to longer lasting benefits[22].

Strengths and limitations

To our knowledge, this is the first study to look at the phenomenon of therapeutic inertia amongst primary care physicians with interest in diabetes. In an era where diabetes management is increasingly being conducted in primary care settings by enhanced primary care teams[22], the findings in this evaluation supports diabetes care models that are led by generalists with specialist interest in diabetes. Another strength of this evaluation is that the

respondents were clinicians practicing in England, Northern Ireland and Wales, thus making the findings grossly generalizable to these home countries in the UK.

The main limitation of our study is the small number of participating clinicians who also merely did a self-reporting of whether therapeutic inertia occurred or not. To make the results more generalizable, it would have been better to have a larger sample of generalists with specialist interest in diabetes responding the audit request. Additionally, there is no generally accepted definition for a generalist with specialist interest in diabetes. The respondents all have varying levels of expertise in clinical diabetes, either through working alongside specialist colleagues or through further academic training in diabetes. As there is no standard accreditation for this role, it is difficult to attribute the results of this evaluation wholly to generalists with special interest in diabetes.

Conclusion

Therapeutic inertia is present only in about a fifth of patient patients with diabetes being managed by primary care physicians with interest in diabetes. Often times, when there has been lack of intensification of therapy, there was a clinical justification for that decision. Patient level characteristics studied here have not predicted the inertia.

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