Clinical inertia in the management of type 2 diabetes mellitus: a focused literature review

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Abstract

Achieving tight glycaemic control early on in the disease trajectory has been shown to have beneficial effects on macrovascular and microvascular complications and mortality in people with type 2 diabetes. International guidelines recommend individualised targets for glycaemic control, but many people with type 2 diabetes are not adequately reaching these targets. One major reason for not achieving these targets is 'clinical inertia', defined as 'failure of healthcare providers to initiate or intensify therapy when indicated'. This article gives an overview of clinical inertia in the management of type 2 diabetes, relating to the initiation of oral antidiabetic and insulin therapies, reasons for clinical inertia and strategies for overcoming clinical inertia.

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Key words: Type 2 diabetes, clinical inertia, individualised targets, antidiabetic medication, guidelines

Abbreviations and acronyms

ADA	American Diabetes Association
EASD	European Association for the Study of Diabetes
HbA_{1c}	glycated haemoglobin
NICE	National Institute for Health and Care Excellence
OAD	oral antidiabetic agent
THIN	The Health Improvement Network (UK patient database)

Background

Diabetes afflicts 387 million people worldwide, of whom about nine in ten have type 2 diabetes.[1] This chronic and highly prevalent condition is reported to be the fourth main cause of death and disability in Europe, and has reached epidemic proportions. The approximate cost of treating diabetes and its related complications is £14 billion in the UK alone, with much of the cost associated with management of complications. Achieving tight glycaemic control early on in the disease trajectory has been shown to have beneficial effects on macrovascular and microvascular complications and on mortality.[2] Despite this evidence, globally, people with type 2 diabetes are not achieving these targets in adequate numbers. A recent study of eight European countries emphasised how there is still room for further improvement in meeting targets, with only 53.6% of people with type 2 diabetes achieving HbA_{1c} <7% (53 mmol/mol), and only 6.5% of the cohort meeting all three targets for HbA_{1c}, LDL-cholesterol, and blood pressure.[3]

The Position Statement proposed jointly by the ADA and EASD recommends individualised targets based on various factors, including patient preferences, needs and values, co-morbidities, duration of diabetes, risk of hypoglycaemia, costs and, overall, ensuring a patient-centred approach.[4] It also recommends stringent HbA_{1c} targets of 6–6.5% (42–47.5 mmol/mol) in newly-diagnosed patients.[4] In the UK, NICE recommends targets of <6.5% (<47.5 mmol/mol) in newly-diagnosed patients and <7.5% (<58.5 mmol/mol) in patients on two or more therapies.[5] Nevertheless, it may not be necessary to intensify treatment in every individual.[4] One major reason for not achieving these targets is 'clinical inertia', defined as 'failure of healthcare providers to initiate or intensify therapy when indicated'.[6] Clinical inertia has been shown to be a significant barrier in intensification with both OAD and insulin therapies. This article gives an overview of clinical inertia in the management of type 2 diabetes, including initiating OADs and insulin, and the reasons for – and strategies for overcoming – clinical inertia.

Methods

A literature search for studies on clinical inertia relating to diabetes was conducted using MEDLINE, Scopus, PubMed and Google Scholar. Search terms included type 2 diabetes mellitus, barriers to treatment, facilitators of OAD or insulin prescribing, OAD or insulin initiation, clinical inertia, therapeutic inertia, insulin avoidance, beliefs, attitudes, perceptions, transition to insulin and resistance to insulin therapy. Table 1 illustrates some of the key studies, listed in chronological order.[7-13]

Clinical inertia in initiating OAD therapy

One study in 12,566 people with type 2 diabetes with HbA_{1c} ≥7% (≥53 mmol/mol) while on metformin monotherapy found

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Table 1 Studies reporting clinical inertia for oral antidiabetic agents (OAD) and insulin therapy

Study (author, year, country/region)	Number of patients	Primary or secondary care	Key findings
Initiation of OAD			
Guisasola *et al*, 2008, Europe[7]	2,023	Primary & Specialist care	Average HbA_{1c} was 7.2% after a mean of 2.6 years of treatment with combination OADs. The authors concluded that a quarter of the patients had adequate glycaemic control after 2.6 years following initiation of this therapy. However, control of glycaemia deteriorated over time, even though the patients were being treated with insulin.
Fu *et al*, 2011, US[8]	12,566	Not stated	The median time to treatment intensification was 14 months overall, i.e.t the median time to receive additional antihyperglycaemic medication in US clinical practice is >1 year for patients with type 2 diabetes who were hyperglycaemic despite metformin monotherapy.
Khunti *et al*, 2013, UK[9]	81,573	Primary care	For those patients with HbA_{1c} of ≥7%, ≥7.5% or ≥8%, the median time to intensification with an additional OAD was 2.9, 1.9 or 1.6 years, respectively.
Insulin initiation			
Shah *et al*, 2005, Canada[10]	2,502	Primary and Specialist care	Of the 591 patients under specialist care, and the 1,911 patients under exclusively primary care, less than half with high HbA_{1c} levels had intensification of treatment, irrespective of their physician's specialty. Specialists seemed more likely than primary care physicians to initiate insulin.
Evans *et al*, 2010, UK[11]	128,568	Primary care	67.7% of patients had received at least one OAD, of whom 17.4% advanced to insulin therapy. At initiation of insulin, mean HbA_{1c} was 9.5% (one OAD), 9.6% (two), 9.7% (three) and 10.1% (four). The average increase in HbA_{1c} prior to insulin initiation was 0.7%. Insulin therapy gave the greatest improvement in HbA_{1c}.
Calvert *et al*, 2007, UK[12]	14,824	Primary care	5,064 patients had HbA_{1c} measured. Mean HbA_{1c} before therapy was 9.07%, compared with 8.16% after therapy. For those prescribed multiple OADs, the median time to initiation of insulin therapy was 7.7 years. 1,513 patients commenced insulin during the study and had HbA_{1c} assessments: mean HbA_{1c} was 9.85% prior to insulin and 8.51% following insulin.
Khunti *et al*, 2012, UK[13]	17,374	Primary care	Variable proportions of patients had HbA_{1c} ≥9% between countries, from 64% (UK) to 23% (Poland). The authors concluded that there was considerable clinical inertia with respect to insulin initiation, despite clear guidelines stating the benefits of timely glycaemic control.
Khunti *et al*, 2013, UK[9]	81,573	Primary care	Median time to intensification with insulin was >7.1, >6.1 or 6.0 years, for patients taking one, two or three OADs, respectively.

that the median time to treatment intensification was 14 months.[8] Another observational study of 2,023 people with type 2 diabetes in seven European countries showed that only a quarter of patients had adequate glycaemic control after 2.6 years of treatment with OAD combination therapy (metformin and either a sulphonylurea or thiazolidinedione).[7] The most recent UK-based study, involving 81,573 people with type 2 diabetes, highlighted the delay in intensification of therapy in patients despite suboptimal glycaemic control.[9] For those on one OAD, the time to intensification for patients with a HbA_{1c} >7% (>53 mmol/mol), was 1.6 years, compared with >6.9 years for those taking two OADs.

Clinical inertia in initiating insulin

Clinical inertia in initiating insulin is also a global problem in clinical practice. A 24-week observational study of 17,374 people with type 2 diabetes receiving one or more OADs in 10 countries showed that mean HbA_{1c} at insulin initiation was 8.9% (74 mmol/mol), with large variations between countries.[13] The proportion of patients at insulin initiation with HbA_{1c} ≥9% (≥74.9 mmol/mol) ranged from 23% (Poland) to 64% (UK).

A further retrospective cohort study in people with type 2 diabetes in the UK (1995–2005) showed that the median time to initiation of insulin therapy was 7.7 years.[12] Mean HbA_{1c} prior to insulin was 9.85% (84.2 mmol/mol) and 8.51% (69.5 mmol/mol) following initiation. A study undertaken between 1999 and 2000, which involved all non-insulin-treated people with diabetes in eastern Ontario, showed that specialists were more likely to intensify insulin than primary care physicians.[10] A recent study from the UK reported that mean HbA_{1c} on insulin initiation was 8.7% (71.6 mmol/mol) for subjects taking one OAD, 9.1% (76.0 mmol/mol) for those taking two OADs and 9.7% (82.5 mmol/mol) for those taking three OADs. The median time to intensification was >7.1 years, >6.1 years and

6.0 years, respectively.[9] An analysis of a large UK cohort from the THIN database provided further support for these findings.[11] Patients on 1–4 OADs continued on oral therapy despite mean HbA_{1c} increasing to 9.5–10.1% (80–87 mmol/mol) before initiation of insulin. Intensification of treatment often comprised addition of another OAD to the regimen of patients with hyperglycaemia of sufficient severity that there was little hope of achieving adequate blood glucose control by this means. Delaying insulin initiation resulted in needless exposure of these patients to chronic hyperglycaemia.

Reasons for clinical inertia

The reasons for clinical inertia are complex, and include provider-, patient-, and system-level barriers.[14] Provider-level barriers include inertia related to clinicians and specialists, and time constraints, lack of knowledge, potential risks of hypoglycaemia, and variations in guideline recommendations. Patient-level barriers include non-adherence and concerns about hypoglycaemia and weight gain.[15] System-level barriers include inertia due to issues in healthcare, including costs of newer medications.

In addition, Philips and colleagues observed that inertia could be considered in three main areas.[6] The first of these was overestimation of care provided: healthcare professionals are overestimating their adherence to guidelines and the care they provide. The second reason was healthcare professionals providing "soft" reasons, to avoid intensification of treatment, including a perception that overall care of their patients was improving, that there was non-adherence among patients and concerns about results from recent large cardiovascular studies.[6] Finally, lack of training was a further reason for inertia, and many physicians lack the education and training needed to attain therapeutic goals.[6]

A UK-based study of 299 general practices examined reasons for not initiating OAD therapy for 6 months or more after diagnosis.[16] The survey revealed that nearly one- third of the patients left untreated with OADs had an $HbA_{1c} \geq 7\%$ ($\geq$53.0 mmol/mol). Thirty-six potential reasons for not treating the patients with OAD therapy were identified and categorised into four major classes: mild hyperglycaemia, concerns related to OAD therapy, issues with comorbidities and/or polypharmacy, and patients' concerns. This may indicate that non-adherence can affect the judgment of the professional involved; it is difficult to initiate therapies if patients request more time to adjust lifestyle factors. A further study described physicians' attitudes to the initiation of insulin in patients with type 2 diabetes and demonstrated reluctance in initiating insulin relating to attitudes regarding risks and benefits of insulin, patients' fears about insulin initiation, and patients' experiences of taking insulin.[17] The authors concluded that physicians need to be educated continually, with programmes that focus on knowledge about the condition and about the progression of type 2 diabetes, along with information about the effects of insulin and how to successfully initiate insulin when required.

A recent qualitative study of UK general practitioners identified a number of reasons for clinical inertia for insulin initiation, including beliefs about risks to patients, worries about excess weight gain by patients, risks in patients with comorbidities, physicians' concerns over hypoglycaemia and impaired quality of life, resource issues, beliefs about patients' competence, racial and ethnic disparities, socioeconomic status, communication between patient and healthcare professional, variations in healthcare settings, and non-adherence to medications.[18]

Overcoming inertia

There is an urgent need to overcome clinical inertia, as there is good evidence that effective management of diabetes can reduce long term costs, can benefit society and the economy, and can improve patients' outcomes and quality of life. Good quality studies on overcoming inertia are lacking, particularly randomised, controlled trials; however, a recent review outlined the key methods to overcome therapeutic inertia.[14] The approaches vary and range from measuring clinical inertia and linking the phenomenon to outcomes in glycaemic control, to self-examination of performance by health care professionals. Additional methods include consistent follow-up procedures, effective use of clinical information systems, reminding patients about their appointments (including proactive reminders), education of healthcare professionals, and the use of guidelines in assisting practitioners.

Other recommendations for avoiding clinical inertia include medical education on guidelines, and the provision of educational programs on inertia at all levels, but in particular for undergraduate and graduate medical students.[6] One randomised controlled trial showed that regular feedback on performance given to medical primary care advisors led to improvements in provider behaviour, and lower HbA_{1c} levels.[19] Another randomised controlled trial in 30 Dutch primary care practices with 1,283 patients, showed that 45% of patients with poor diabetes or lipid control did not receive treatment intensification following an intervention of nurses assisting general practitioners, compared with 90% in a control group.[20] The authors also concluded that inertia was less common in response to poorly controlled blood pressure if nurses assisted general practitioners. Nurses are often able to spend more time reviewing, educating and monitoring patients, which may help to improve outcomes by facilitating intensification of therapies.

Finally, 345 residents received computerised reminders that provided patient-specific recommendations and performance feedback every 2 weeks, within a further 3-year randomised controlled trial.[21] Feedback on performance improved behaviour and lowered HbA_{1c} levels, therefore leading to improved diabetes outcomes.

Conclusions

These studies highlight the phenomenon of clinical inertia as a continuing and significant problem, despite the availability of clear guidelines proposing specific therapeutic targets. Implementing guideline recommendations would be valuable as an initial step, but the evidence shows that clinical inertia has not improved significantly over the years, despite good evidence of tight glycaemic control.

Key messages

- Clinical inertia (failure of healthcare providers to initiate or intensify therapy when indicated) is an important barrier to optimal patent outcomes in the management of type 2 diabetes
- Clinical inertia delays appropriate treatment intensification to both oral antidiabetic agents and insulin
- Issues relating to physicians and patients promote inertia
- Improved education and self-examination by healthcare professionals, support from nurses, additional resources and measures to improve patient adherence to a regimen can all reduce the risk of clinical inertia
- More studies to overcome clinical inertia are required

Type 2 diabetes is a chronic condition with an increasing prevalence and tight glycaemic control and medication optimisation should occur in a timely manner to reduce long-term complications.[22] The evidence summarised above demonstrates that clinical inertia is common both with OAD- and insulin-based therapies. A number of factors are associated with inertia including lack of knowledge, training, and education, along with inadequate resources. Patients' and clinicians' beliefs on the benefits and side-effects of certain medications, along with patient adherence, also correlate with inertia. Interventions are essential to reduce the incidence of the phenomenon. The ADA/EASD Position Statement highlights the need for individualised targets for patients to ensure appropriate management of patients.

A number of approaches can overcome clinical inertia, including consistent follow-up procedures, performance self-examination by professionals, education of healthcare professionals, and improved access to resources for practitioners to ensure appropriate follow-up of patients. In addition, nurse support and improved adherence by patients can help to optimise the impact of these interventions and thus maximise benefit. In addition, clinical decision support aids are showing some early promise but definitive trials are currently lacking.[23] Introducing a structured management programme for healthcare professionals backed by an evidence base relating to appropriate timelines for intensification as suggested by the ADA/EASD Position Statement[4] may be a step forward. The wealth of evidence showing the existence of clinical inertia in the management of type 2 diabetes is sufficient justification to explore methods to overcome this phenomenon.

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