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Original research

Results from the UK cohort of SOLVE: Providing insights into the timing of insulin initiation in people with poorly controlled type 2 diabetes in routine clinical practice

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ABSTRACT

Aims: SOLVE was a large observational study of more than 17,000 insulin-naïve patients with type 2 diabetes, investigating basal insulin analogue initiation in a primary care setting across a diverse geographical area. The current analysis aimed to compare and contrast the results of the UK cohort with the previously published global population results.

Methods: This analysis compares the UK cohort of SOLVE ($n = 761$) with the global population ($n = 17,374$). Patients eligible for the study were those for whom a clinical decision had been made to initiate treatment with a basal insulin analogue once daily as an add-on to existing OAD therapy.

Results: The UK cohort had a higher baseline HbA1c compared to the global population of SOLVE (9.8% vs. 8.9%, respectively) despite a shorter duration of disease, indicating that strict glycaemic targets set by international organisations are not being achieved in the UK. Following 24 weeks' treatment with insulin detemir, patients in the UK achieved a reduction in HbA1c of −1.3%, the same as the reduction achieved in the global population; however, a higher dose of insulin detemir was required in the UK than in the global population.

Conclusions: Findings from the UK cohort of SOLVE show that it is possible to improve glycaemic control and reduce HbA1c in patients previously uncontrolled with oral antidiabetic drug therapy, in a primary setting, despite clinical inertia.

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1. Introduction

1.1. Guidelines recommend strict glycaemic targets

The United Kingdom Prospective Diabetes Study (UKPDS) identified that a reduction in HbA1c correlated with a reduction and delay in the occurrence of microvascular and macrovascular complications of diabetes [1] and that these benefits were associated with intensive glucose control from the time of diagnosis [2]. In light of landmark findings from the UKPDS, ambitious glycaemic targets for the clinical management of type 2 diabetes have been set by advisory bodies worldwide. Guidelines from the International Diabetes Federation (IDF), the National Institute for Health and Clinical Excellence (NICE) and the American Diabetes Association (ADA) in conjunction with the European Association for the Study of Diabetes (EASD) recommend stringent HbA1c targets in the range of 6.5–7.5% [3–5].

Type 2 diabetes is a disease in a state of flux, characterised by a gradual decline in beta-cell function and insulin resistance. In order to achieve the primary goal of diabetes management—the attainment of near-normoglycaemia—a dynamic clinical approach with continual treatment assessment is required. Some patients are able to achieve and maintain glycaemic control through changes in lifestyle and the use of oral anti-diabetic drugs (OADs) but treatment intensification with insulin will eventually be required by many patients with type 2 diabetes [6].

Despite the clear benefits of intensive therapy, it is not a one-size-fits-all strategy. In 2008, the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study was stopped early as a result of increased mortality observed in a subset of intensively treated patients with type 2 diabetes and high cardiovascular risk [7]. Subsequently, studies of populations at high risk of cardiovascular complications, including the Action in Diabetes and Vascular Disease (ADVANCE) and Veteran Affairs Diabetes Trial (VADT), have contributed to the body of evidence by showing that intensive treatment in type 2 diabetes improves outcomes and should be balanced against the risk of adverse events, particularly hypoglycaemia [8,9]. The long-term (>10-year) patient follow-up provided by UKPDS similarly highlights the benefits of early glycaemic control. Despite an early loss of glycaemic difference during post-trial monitoring of patients previously treated with either conventional or intensive therapy, reduction in macrovascular risk and emergent risk for myocardial infarction persisted [2].

1.2. Clinical inertia

Clinical inertia is defined as the failure to initiate or intensify treatment when required, and it is recognised as a major obstruction to achieving good glycaemic control [10,11]. Other barriers include failure to use medications appropriately, fear of hypoglycaemia and lack of medical education [12]. Patient and physician barriers to effective glycaemic control can be broadly categorised as *rational* (e.g. fear of injection); *irrational* (fear of amputation); *unproven* (effect of health literacy); or *proven* (risk of hypoglycaemia and weight gain) [13–17].

Recent guidance from ADA/EASD and NICE recommends that an individualised approach be used to overcome patient/physician barriers to treatment progression, incorporating a structured education programme tailored to each patient at the time of diagnosis and revisiting it regularly. Physicians should encourage a considerable element of self-care, providing patients with the opportunity to make informed decisions about their treatment [4,5] and agreeing realistic, risk-averse glycaemic targets in partnership with them, ensuring that patients understand the reasons for their goals as well as how to achieve them. The benefits of structured group education programmes have also been demonstrated with respect to improved quality of life [18], improved metabolic control and lower rates of moderate and severe hypoglycaemia [19].

1.3. The need for timely insulin initiation

In the UK, insulin initiation has historically been managed by diabetes specialists; however, the growing prevalence of diabetes has resulted in a transition of treatment from specialist to primary care settings [20]. This shift has placed greater pressure on the resources of primary care practitioners and considerable demands on the resources of healthcare teams.

In response to this increased need, the UK has developed initiatives that augment community care, improve the overall quality of patient healthcare, and enhance the proficiency of diabetes treatment in the primary care setting. More specifically, these initiatives include diabetes “intermediate” care (designed to bridge the gap between primary and specialist care) [21,22] and pay-for-performance schemes such as the Quality and Outcomes Framework (QOF), which rewards practitioners who achieve predetermined treatment targets [23]. Collectively, these initiatives play a vital role in ensuring both timely insulin initiation and continuous treatment monitoring.

SOLVE was a large observational study of more than 17,000 insulin-naïve patients with type 2 diabetes, investigating the initiation of insulin detemir, a basal insulin analogue, in a primary care setting across a diverse geographical area. Here we report data from the UK cohort of SOLVE, comparing and contrasting the outcomes from this population with previously published findings from the SOLVE global study population [24].

2. Methods

2.1. Study design

SOLVE was a 24-week, multi-centre, open-label, non-randomised, observational study investigating the initiation of once-daily insulin detemir in people with type 2 diabetes. Globally, SOLVE was conducted in 10 countries (Canada, China, Germany, Israel, Italy, Poland, Portugal, Spain, Turkey and the UK), in accordance with the Declaration of Helsinki (2004) and Guidelines for Good Pharmacoepidemiology Practice (2007).

Patients recruited to the study were unable to achieve their glycaemic targets on pre-study therapy, which included diet, exercise and one or more OAD. All patients in the UK were