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Depressive symptoms prior to and following insulin initiation in patients with type 2 diabetes mellitus: Prevalence, risk factors and effect on physician resource utilisation

Grzegorz Dzida[a,*], *Eddy Karnieli*[b], *Anne Louise Svendsen*[c], *Kristine Steensen Sølje*[d], *Norbert Hermanns*[e], *on behalf of the SOLVE Study Group*

[a] *Department of Internal Diseases, Medical University of Lublin, Poland*
[b] *Endocrinology, Diabetes & Metabolism, Rambam Medical Center and Rappaport Faculty of Medicine, Technion, Haifa, Israel*
[c] *Department of Biostatistics & Epidemiology, Novo Nordisk A/S, Søborg, Denmark*
[d] *Global Medical Affairs, Novo Nordisk A/S, Søborg, Denmark*
[e] *Diabetes Zentrum Mergentheim, Forschungsinstitut Diabetes-Akademie Bad Mergentheim (FIDAM GmbH), Bad Mergentheim, Germany*

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ABSTRACT

Aims: To study the frequency and intensity of depressive symptoms and associations with physician resource utilisation following insulin initiation in patients with type 2 diabetes mellitus.
Methods: SOLVE was a 24-week observational study. In this sub-analysis of data from Poland, depressive symptoms were evaluated using the Patient Health Questionnaire (PHQ)-9.
Results: PHQ-9 was completed by 942 of 1169 patients (80.6%) at baseline, and 751 (64.2%) at both baseline and final (24-week) visit. PHQ-9 scores indicated depressive symptoms in 45.6% ($n = 430$) at baseline, and 27.2% ($n = 223$) at final visit. Mean PHQ-9 change was −2.38 [95% CI −2.73, −2.02], $p < 0.001$. Depressive symptoms at baseline (OR 6.32, $p < 0.001$), microvascular disease (OR 2.45, $p = 0.016$), number of physician contacts (OR 1.16, $p = 0.009$), and change in HbA_{1c} (OR 0.60, $p = 0.025$) were independently associated with moderate/severe depressive symptoms at final visit. Patients with more severe depressive symptoms spent more time training to self-inject ($p = 0.0016$), self-adjust ($p = 0.0023$) and manage other aspects of insulin delivery ($p < 0.0001$). Patients with persistent depressive symptoms had more telephone contacts and dose changes at final visit than those without (both $p < 0.05$).

Abbreviations: ACCORD, Action to Control Cardiovascular Risk in Diabetes; CI, confidence interval; FBG, fasting blood glucose; HbA_{1c}, glycosylated haemoglobin A_{1c}; HADS-D, Hospital Anxiety and Depression Scale; OR, odds ratio; OADs, oral antidiabetic drugs; PHQ-9, Patient Health Questionnaire 9; SOLVE, Study of Once Daily LeVEmir; T2DM, type 2 diabetes mellitus.

* *Corresponding author at*: Department of Internal Diseases, Medical University of Lublin, SPSK-1, ul. Staszica 16, Lublin 20-081, Poland. Tel.: +48 815327727; mobile: +48 5013791593.
E-mail address: grzegorz.dzida@wp.pl (G. Dzida).

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Conclusions: Depressive symptoms are common with type 2 diabetes and associated with increased healthcare utilisation, reinforcing the need for holistic interdisciplinary management approaches.

1. Introduction

Patient involvement in diabetes disease management is critical to reaching agreed treatment goals; however, comorbid psychological conditions, such as depressive symptoms and diabetes distress, are common [1,2]. Depressive symptoms and major depressive disorder are estimated to be twice as prevalent in patients with diabetes compared with patients without diabetes [3]. Left unrecognised and untreated, even low levels of depressive symptoms can negatively affect self-care behaviour, which may ultimately impact glycaemic control [4] and contribute to poor health related quality of life and well-being [5]. These associations may be particularly important in patients with complex or insulin-based treatment regimens [6]. The presence of depressive symptoms has also been reported as a barrier to insulin initiation [7].

Increased recognition and follow-up of comorbid depressive symptoms in patients with diabetes is important to mitigate negative health outcomes associated with poor self-care behaviour, such as missed medical appointments [4]. Patients with diabetes and comorbid depressive symptoms have more frequent physician office visits, hospital admissions, and prescriptions, all of which contribute to an increase in healthcare costs of up to 65% [8]. Depressed patients are also more likely to switch, augment, and/or discontinue oral antidiabetic drugs (OADs) than non-depressed patients [9]. Thus, treatment aimed at improving patient well-being and self-care may also improve healthcare utilisation.

The purpose of this sub-analysis of a large observational study of insulin initiation in a cohort of patients with type 2 diabetes mellitus (T2DM) was to report on the prevalence of depressive symptoms prior to and following insulin initiation. Furthermore, we identified demographic and clinical factors associated with the severity and persistence of depressive symptoms and investigated the effect of depressive symptoms on physician resource utilisation.

2. Methods

SOLVE (Study of Once Daily LeVEmir) is an observational study of basal insulin initiation in people with T2DM treated with one or more OADs. The study was conducted in 10 countries and patient selection and study methodology has been previously described in detail [10,11]. The study was pre-registered with clinicaltrials.gov (NCT00825643 and NCT00740519) and was approved by local ethics committees in each participating country. In Poland, participating patients were managed exclusively by specialists in accordance with national guidelines, which recommend specialist care for all T2DM patients receiving treatment with insulin.

Patients were eligible for inclusion if they had been diagnosed with T2DM, were receiving treatment with one or more OADs, and were being started on treatment with insulin detemir. Children aged <18 years, patients who were pregnant or breast-feeding or who intended to become pregnant and patients deviating in the number of daily injections of insulin detemir from once daily were excluded from the study. Patients were observed at three time points: pre-insulin (baseline), 12 weeks (interim visit), and 24 weeks (final visit). The study was non-interventional and there was no imposed follow-up schedule. Instead, data were collected at the visit closest to the protocol-defined follow-up interval. All treatment decisions including the decision to initiate insulin detemir were at the discretion of the investigator.

The primary endpoint of the study was the incidence of severe adverse drug reactions. Secondary endpoints included severe hypoglycaemia (requiring third party assistance), any minor hypoglycaemia (blood glucose <3.1 mmol/L), minor nocturnal hypoglycaemia, change in glycosylated haemoglobin A_{1c} (HbA_{1c}), fasting blood glucose (FBG), weight and body mass index. Physician resource utilisation was assessed by a questionnaire, and reports of office visits and telephone contacts at interim and final visits.

This sub-analysis in Poland included the use of Patient Health Questionnaire (PHQ)-9 at baseline and final visits (online Appendix). PHQ-9 is a nine-item depression scale, which assesses symptoms and functional impairment over the preceding 2 weeks. Each item scores 0–3 according to a Likert scale; these scores are then summed as follows: none (score <5), mild (score 5–9), moderate (score 10–14), moderately severe (score 15–19), and severe (score $\geq$20) depressive symptoms. As such, PHQ-9 indicates whether or not a patient is likely to have clinical depression and evaluates the impact of depressive symptoms on patients' social interactions at home and in the work place. PHQ-9 is a validated tool for identifying depressive symptoms and monitoring severity of depression over time [12]; the questionnaire has also been used as a screening tool in patients with chronic illnesses including T2DM [13], and high symptom scores are associated with adverse outcomes [14]. According to the protocol, any patient with suspected major clinical depression (i.e., PHQ-9 scores indicating moderately severe or severe depressive symptoms) at baseline was referred to a psychiatrist for follow-up.

Physician resource utilisation was assessed by recording the time taken to train patients upon insulin initiation and the number of telephone contacts, office visits and dose changes at interim and final visits. Physicians recorded the amount of time spent on training patients to self-inject and dose self-adjust. Any training not related to these aspects was recorded as other training time.

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