

Abstract:

Although hypoglycemia has been studied intensively in type 1 diabetes, less attention has been given to type 2 patients even though they comprise 90% of all persons with the disease. Recent surveys of the U.S. population have shown that a substantial proportion of patients with type 2 diabetes do not have adequate glycemic control. Intensifying treatment can reduce the risk of microvascular complications but is accompanied by a higher rate of hypoglycemia. Hypoglycemia can cause unpleasant neuroglycopenic and autonomic symptoms, disrupt routines, increase the risk of accidents or injuries, create fear and anxiety, cause the patient or provider to abandon treatment plans, and lead to permanent neurologic injury or death. As a result, it is the most formidable impediment to intensifying treatment and can prevent many patients from achieving the benefits so convincingly demonstrated by randomized clinical trials.

This randomized clinical trial is designed to evaluate an individualized education program for preventing hypoglycemia in elderly insulin-treated veterans with type 2 diabetes mellitus. The education program will increase factual knowledge of hypoglycemia, train patients to become aware of their episodes, encourage them to monitor during high-risk time periods and behaviors, and improve their self-management of hypoglycemic events. The ultimate objectives are to improve the safety of insulin therapy and minimize the most important barrier to treatment intensification. These objectives will help inform practice guidelines for self-monitoring of blood glucose (SMBG) and serve as a model for educational programs at other facilities.

One hundred and forty patients, 55 years or older, will be enrolled into this study, with 70 patients in the intervention (education program) and control group, and are followed for 1 year. This trial has 80% power to detect a decrease of 2.5 symptomatic hypoglycemic episodes per year at an alpha of 0.05.

We must find a way to decrease hypoglycemic episodes so that providers can feel comfortable keeping tight control of a patient's blood glucose. Additionally, hypoglycemic episodes can be harmful and the safety of the patient is very important, and decreasing the rate of hypoglycemic events would promote patient safety. This would be an innovative role for a pharmacist in reducing hypoglycemic events and promoting patient safety.

2. Specific aims and objectives:

This randomized clinical trial is designed to evaluate an individualized education program for preventing hypoglycemia in elderly insulin-treated patients with type 2 diabetes mellitus. The education program will increase factual knowledge of hypoglycemia, train patients to become aware of their episodes, encourage them to monitor during high-risk time periods and behaviors, and improve their self-management of hypoglycemic events. The ultimate objectives are to improve the safety of insulin therapy and minimize the most important barrier to treatment intensification. If successful, our study will validate a new and important role for clinical pharmacists, can be used as the basis for practice guidelines for self-monitoring of blood glucose (SMBG), and serve as a model for educational programs at other facilities.

The primary objective is the reduction of the rate of hypoglycemia events attributable to high-risk patient behaviors. This goal would require patients to recognize and avoid behaviors that are associated with an increased risk of hypoglycemia.

The secondary objectives are to:

- a) determine the rate and identify the causes of hypoglycemia in elderly insulin-treated patients;
- b) obtain information on the monitoring habits of the target population; and
- c) increase the detection of asymptomatic hypoglycemic episodes. This change would imply that patients have improved their screening of high risk time periods through self-monitoring of blood glucose (SMBG).

The study will test the following hypotheses: Compared to controls, subjects receiving the educational intervention will have significantly fewer symptomatic hypoglycemic episodes attributed to high-risk behaviors.

This study will be performed at the New Mexico VA Health Care System, last 2 years, and involve 140 subjects, each of whom would be followed for 52 weeks.

3. Rationale:

Although hypoglycemia has been studied intensively in type 1 diabetes, less attention has been given to type 2 patients even though they comprise 90% of all persons with the disease (1). Recent surveys of the U.S. population have shown that a substantial proportion of patients with type 2 diabetes do not have adequate glycemic control.