Study Protocol and Statistical Analysis Plan

Evaluation of Medical Education With Telemedicine on Technical Knowledge and Quality of Care for Patients With Hyperglycemia and Diabetes in the Hospital Setting – A Multicenter Randomized Clinical Trial

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1. Introduction and Rationale

Diabetes mellitus is a major global health challenge with a growing burden in both outpatient and inpatient settings. In Brazil, recent data reveal a high prevalence of diabetes. A study conducted across six Brazilian capitals among public university employees aged 35 to 74 years found a prevalence of 20%, with approximately half of the cases previously undiagnosed.

It is estimated that 22% of all hospitalized patients have diabetes. In the United States, hospitalizations account for nearly half of the $174 billion in total annual medical expenditures related to diabetes. Each year, 1.6 million new cases are diagnosed in the U.S., with an overall prevalence of 23.6 million individuals—7.8% of the population—of whom approximately one-quarter remain undiagnosed.

Hospital admission rates for patients with diabetes range from 14% to 20%, particularly within the first 30 days following discharge. Major risk factors for readmission include lower socioeconomic status, race/ethnicity (e.g., Hispanic, African American, Native American, and Asian American), comorbid conditions, and recent hospitalizations.

Approximately 30% of patients with two or more hospitalizations account for more than 50% of all admissions and related costs. Although there is no universally accepted protocol to prevent readmissions, several effective strategies have been reported. These include targeted interventions for high-risk patients with poor glycemic control and the implementation of transitional care models.

Glycemic disturbances—such as hyperglycemia, hypoglycemia, and glucose variability—in hospitalized patients have been associated with adverse outcomes, including prolonged hospital stays, increased morbidity, and mortality. Evidence from clinical practice also highlights the relevance of physician knowledge and the role of specialized diabetes care teams as important predictors of improved glycemic control and reduced hospital length of stay.

Telemedicine has emerged as a valuable tool in diabetes management, especially through remote monitoring, communication platforms, and therapeutic adjustments. However, most studies involving telemedicine focus on outpatient or primary care contexts.

Given the severity of diabetes-related complications, the economic impact of hospitalizations, the persistently high readmission rates, and the need to strengthen medical knowledge for inpatient diabetes care, this study proposes a structured, telemedicine-based educational intervention. The objective is to evaluate its effectiveness in improving medical knowledge, insulin prescription quality, and the prevention and management of glycemic extremes during hospitalization.

2. Primary and Secondary Objectives

Primary objective:

To evaluate the impact of a structured educational intervention via telemedicine on internal medicine residents' knowledge regarding inpatient hyperglycemias.

Secondary objectives:

To assess the effect of the intervention on the quality of insulin prescriptions and capillary blood glucose monitoring.

To evaluate the effect on the occurrence of hypoglycemia and hyperglycemia during hospitalization.

To compare the length of hospital stay between the intervention and control groups.

3. Study Design

This was an open-label, multicenter, randomized clinical trial conducted at university hospitals located in southern Brazil. Internal medicine clinical teams were block-randomized using stratified allocation by center to ensure balance between groups.

The intervention group received a 30-minute online theoretical lecture on hospital hyperglycemia and participated in a 30-day telemedicine-based continuing education program delivered via a messaging platform. The control group continued standard clinical activities without any educational intervention.

Data collection occurred in two phases: a pre-post knowledge assessment using a validated questionnaire, and a retrospective chart review of hospitalized patients cared for by the participating teams.

4. Intervention

Residents in the intervention group received a 30-minute online theoretical lecture on inpatient hyperglycemia, followed by daily educational content for 30 days via a messaging application. Materials included short videos, texts, and clinical guidance on diabetes and hospital glycemic management.

The control group received no educational content and maintained routine clinical duties.

5. Inclusion and Exclusion Criteria

Inclusion criteria:

Internal medicine residents assigned to clinical teams at participating hospitals.

Exclusion criteria:

Residents on leave during the intervention period.

Teams supervised by endocrinologists.

Residents who declined participation.

6. Outcome Measures (Primary and Secondary)

Primary outcome:

Change in medical knowledge on inpatient hyperglycemia, assessed through a validated questionnaire before and after the intervention.

Secondary outcomes:

Quality of glucose monitoring and insulin prescribing.

Incidence of hyperglycemia (>180 mg/dL) and hypoglycemia (<70 mg/dL).

Length of hospital stay

7. Sample Size Calculation

Based on previous data showing 46.44% accuracy in key knowledge items, and assuming an increase to 80% after the intervention, with 80% power and a 5% significance level, a minimum of 62 completed questionnaires (including both pre- and post-intervention assessments) was required.

8. Statistical Analysis Plan

Categorical variables were described as frequencies and percentages. Continuous variables were expressed as means and standard deviations or medians and interquartile ranges, based on normality (Shapiro-Wilk test).

Between-group comparisons were made using Student's t-test or the Mann-Whitney U test for continuous variables, depending on distribution. Categorical variables were analyzed using Pearson's chi-square test or Fisher's exact test, as appropriate. Logistic regression analysis was performed to identify independent predictors, including variables with clinical relevance or $p < 0.20$ in the univariate analysis. Statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 29.0 (IBM Corp., Armonk, NY, USA). A two-sided p-value < 0.05 was considered statistically significant.

9. Ethical Considerations

All participating physicians provided informed consent. Data were collected with institutional authorization and approval by the local ethics committee. Confidentiality and privacy were strictly maintained for all participants and patient information.