

Retrospective Study Protocol Sample

Onset of Diabetic Retinopathy in Men versus Women

Introduction

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. There are two major classes of diabetes, designated types 1 and 2. In type 1 diabetes, insulin is deficient due to failure of pancreatic beta cells. Type 2 diabetes, in contrast, is a condition characterized by hyperinsulinemia and relative insensitivity or resistance to its glucose-metabolizing effects (1). If the metabolic abnormality is mild, patients may be asymptomatic, while in the presence of overt hyperglycemia, characteristic symptoms such as polyuria, polydipsia, and polyphagia often occur (2). Diabetes is becoming more common in the United States and type 2 diabetes accounts for 90-95% of all diabetes mellitus, exhibiting a worldwide prevalence of 150 million that is predicted to increase to 225 million by 2010 and to 300 million by 2025 (3). From 1980 to 2002 the number of Americans with diabetes more than doubled, from 5.8 million to 13.3 million (4).

Fifty percent of patients with diabetes mellitus in the US (5) are undiagnosed and not receiving the aggressive metabolic control that has been shown to be beneficial in clinical trials (6). It has been suggested that diabetes may be present 4-7 years before diagnosis (7). Undiagnosed diabetes is not a benign condition since many of the complications appear to be present at the time of the diagnosis (5). Diabetes and its costs are a problem of enormous importance in the United States today. Costs of caring for the complications of diabetes account for 90% of the direct and indirect costs of diabetic care (8). Complications of diabetes, including diabetic eye disease, nephropathy, neuropathy, and peripheral vascular disease, are common in patients with type 2 diabetes. Moreover, type 2 diabetes is a major risk factor for cardiovascular disease. The linkage between hyperglycemia and the complications of diabetes has been firmly established (9). With long duration of hyperglycemia, diabetes-specific complications constitute the major causes of morbidity and mortality in diabetic patients (2).

The obese Zucker fa/fa rat has been used as a model of type 2 diabetes for almost 40 years. These rats spontaneously develop a type of diabetes with a sequence of events that parallel those hypothesized to result in type 2 diabetes in humans (10). Several experimental animal models of diabetes exhibit sexual dimorphism, with the male rats having a more severe presentation (11). Zucker diabetic rats exhibit a more severe endotheliopathy and prothrombotic status in comparison with their female diabetic littermates (12). In the Zucker fa/fa rat, a male preponderance is seen in the incidence of hyperglycemia (13). The male fa/fa rat exhibits hyperinsulinemia and hyperlipidemia as early as four to six weeks of age (14,15) while the female fa/fa rats exhibit hyperglycemia at 13-14 weeks (14,16). Therefore there may be a difference in the progression of

diabetes in men compared to women. These gender differences may shed light on factors that contribute to the pathophysiology as well as factors that may influence therapy, including therapy for the prevention of diabetic complications. It is now clear that aggressive control of hyperglycemia in patients with type 2 diabetes can attenuate the development of chronic complications (3). The hypothesis states that men have accelerated retinopathy complications due to Type II diabetes. The specific objective is to determine whether diabetic retinopathy presents earlier in men than women.

Methodology

This protocol describes a retrospective study based on 500 medical records at South Pointe Hospital. Records will be sourced by ICD-9 codes for Diabetes with ophthalmic manifestations. Only de-identified or non-identifiable data will be used in this study. All resulting data will be stored in electronic format; files will be stored on a password-protected computer, stored in a limited-access, locked facility. Inclusion criteria for this study are limited to the following: participants over age 18 without any major medical diagnoses such as cancer or AIDS. Participants will not be excluded based on socioeconomic, racial or religious identity. There is little-to-no risk associated with this retrospective study. The data collection and storage processes will protect both confidentiality and privacy; HIPAA guidelines will be followed. The recruitment process will be limited to ICD-9 search; no individual consent will be necessary. No form of deception will be used in this study. No costs will be incurred; no compensation will be provided to participants. The working hypothesis of this study follows: Males have accelerated retinopathy complications due to type II diabetes. Both descriptive and inferential statistics will be produced. An independent t-test will be used to test for statistically significant differences between males and females. An index for homogeneity of variance will be produced. An index for relative effect will also be produced. While there will be no direct benefits to the participants, there will be contribution to the medical/scientific community. If there is a difference in the onset of diabetic retinopathy in men versus women, the treatment modalities may be different according to gender especially therapy for the prevention of diabetic retinopathy complication.

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