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# Clinical and Psychological Predictors of Incidence of Self-Reported Erectile Dysfunction in Patients With Type 2 Diabetes

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**Purpose:** We evaluated the predictors of the incidence of erectile dysfunction in patients with type 2 diabetes mellitus and identified subgroups of patients in whom the interaction between clinical and psychological characteristics determined an increase in the risk of erectile dysfunction.

**Materials and Methods:** The study was based on 670 individuals. The presence of erectile dysfunction and the severity of depressive symptoms were investigated with a questionnaire filled in every 6 months for 3 years. Poisson regression was used to calculate incidence rates. To evaluate interactions among the different variables and identify distinct and homogeneous subgroups in terms of incidence of erectile dysfunction, RECURSIVE Partitioning and AMalgamation method was used.

**Results:** Overall erectile dysfunction developed in 192 men with type 2 diabetes, with an incidence rate of 166.3 per 1,000 person-years. Age, insulin treatment, hemoglobin A1c greater than 8.0%, total cholesterol greater than 3.88 mmol/l and severity of depressive symptoms represented independent predictors of erectile dysfunction. RECURSIVE Partitioning and AMalgamation analysis identified 5 classes with a marked variation in the risk of erectile dysfunction. Patients with low levels of depressive symptoms and hemoglobin A1c 8.0% or less showed the lowest risk of erectile dysfunction. Compared with this subgroup patients with higher levels of depressive symptoms and treated with insulin had a 3-fold risk of erectile dysfunction. Age, smoking, high cholesterol levels and neuropathy were globally predictive variables associated with an increased risk of erectile dysfunction.

**Conclusions:** The incidence of erectile dysfunction is predicted by modifiable risk factors. Even in diabetes, psychological problems can contribute to the pathogenesis of erectile dysfunction, in addition to organic causes.

*Key Words:* diabetes mellitus, type 2; impotence; incidence; depression; questionnaires

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It is estimated that in 2025 there will be more than 300 million men worldwide who will experience ED<sup>1</sup> along with the psychological and clinical sequelae. Therefore, preventive strategies to avoid the development of this disorder become of particular importance. To be effective, preventive strategies should be addressed to those individuals in whom ED is more likely to develop. This approach is particularly relevant in patients with T2DM, who have an associated prevalence of erectile problems 3-fold that of the general population.<sup>2</sup>

The longitudinal results from the MMAS offered the first population based estimate of the incidence of ED, and showed that in men with diabetes the incidence rate was almost 2-fold that of the general population.<sup>3</sup> These findings were confirmed in a large diabetic population.<sup>4</sup> Predictors of ED in individuals with diabetes have been seldom investigated.<sup>4,5</sup> In particular, with the assumption that in diabetes

ED is mainly related to organic factors, only clinical and lifestyle aspects have been explored. Thus, the role of physical and psychological factors in predicting the development of erectile problems in individuals with diabetes has never been investigated.

In the context of the QuED project we have previously documented the high prevalence of erectile dysfunction in patients with T2DM<sup>6</sup> and its profound impact on quality of life.<sup>7,8</sup> In this study we estimated the incidence of self-reported ED and its predictors during 3 years of followup. We also identified subgroups of patients in whom the interaction between clinical and psychological characteristics determined a substantial increase in the risk of developing ED.

## MATERIALS AND METHODS

The study design has been previously described in detail.<sup>7</sup> Physicians were identified in all Italian regions and selected

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Nothing to disclose.

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**Editor's Note:** This article is the fourth of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 410 and 411.

according to willingness to participate in the project. Overall 114 diabetes outpatient clinics and 112 general practitioners participated in the study.

All patients with T2DM were considered eligible for this project regardless of age, duration of diabetes and treatment. In diabetes outpatient clinics patients were sampled by using random lists, stratified by age (younger than 65 or older than 65 years). Each center was asked to recruit at least 30 patients, whereas general practitioners enrolled only those patients for whom they were primarily responsible for diabetes care. Clinical information was abstracted from clinical records by the participating physicians and reported in ad hoc forms. Data were collected at baseline and 6-month intervals for 3 years. Baseline clinical variables referred to the last value in the previous 12 months. Because normal ranges for HbA1c varied among the centers, the percentage change with respect to the upper normal value (actual value/upper normal limit) was estimated and multiplied by 6.0. CVD included myocardial infarction, angina, coronary revascularization procedures, stroke, and lower limb complications (claudication, ulcer, gangrene, amputation and aortic-femoral revascularization procedure).

All patients were asked to complete a questionnaire upon study entry and at 6-month intervals during 3 years. The questionnaire was self-administered and then sent anonymously to the coordinating center in prepaid envelopes. The matching between clinical data and questionnaire was made possible through a code put by the physician on both sources of information. No other details of patient identity were contained in the questionnaire or in clinical data.

The presence of ED was investigated by asking the patient how often he had experienced problems in achieving and maintaining an erection during the last 6 months, with responses calibrated on a 5-level scale (from never to more than once per week). The study protocol did not include any clinical or instrumental diagnostic procedures. Incident cases of ED were considered those without ED at baseline who reported frequent erectile problems (almost every week or more than once a week) during followup.

Physical and psychological well-being were assessed using 2 summary measures of the SF-36 Health Survey,<sup>9,10</sup> the PCS and MCS. Scores are transformed linearly to a possible range of 0 to 100, with higher scores indicating more favorable physical functioning/psychological well-being.

Depressive symptoms were investigated using the CES-D scale, a self-reported measure of depression composed of 20 items addressing symptoms of depression during the previous 4 weeks. Values of the CES-D scale range from 0 to 60 with higher values indicating more severe depressive symptoms.<sup>11</sup>

In terms of statistical analysis baseline patient characteristics were compared with the chi-square test and Mann-Whitney U test for categorical and continuous variables, respectively. IRs were calculated as the number of new cases of ED divided by the number of person-years of followup and expressed as number of cases per 1,000 men per year.

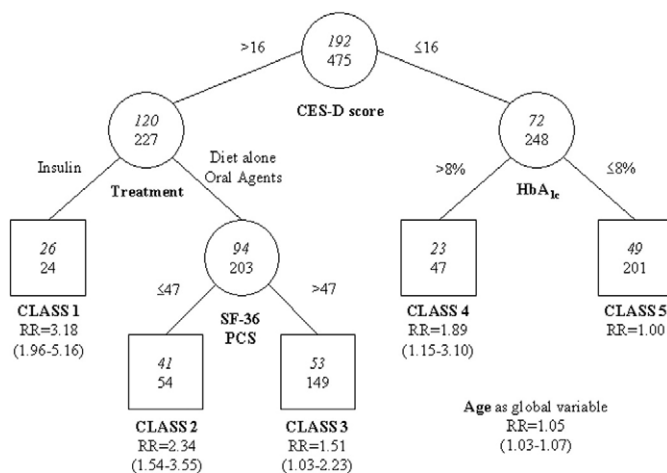
Poisson regression was used to calculate IRs and relative risks (incidence rate ratios) with their 95% confidence intervals. RRs were first adjusted for age only, and then for all the other covariates within multivariate models. The latter included the covariates age, smoking, diabetes duration, HbA1c, diabetes therapy, cholesterol levels, previous history of CVD, retinopathy, neuropathy, micro/macroalbuminuria,

use of diuretics,  $\beta$ -blockers, lipid lowering drugs, cardiac drugs (digoxin, verapamil, clonidine and methyldopa) and antidepressants, CES-D score, and PCS and MCS scores. Attributable risks for modifiable risk factors were estimated from age adjusted RRs.<sup>12</sup>

To evaluate interactions among covariates, and identify distinct and homogeneous subgroups of patients in terms of incidence of erectile dysfunction, the RECPAM method was used.<sup>6,13</sup> This tree based method integrates the advantages of main effects standard regression and tree growing techniques. At each partitioning step the method chooses the covariate and its best binary split to maximize the difference in the outcome of interest. The algorithm stops when user defined conditions (stopping rules) are met.<sup>13</sup> We tested in the RECPAM Poisson model the same set of variables used in the multivariate analysis, without categorizing continuous variables, to allow the algorithm to choose the natural cutoff points. Patient age served as the global predictor, ie its effect has been considered to be equally important in all subgroups identified by the algorithm. The figure and legend report major details that can be helpful for interpreting the analysis. Finally, to assess the importance of additional variables as global correlates, we ran a final multivariate Poisson regression analysis with the RECPAM classes forced in the model, testing all other characteristics not entering the tree. All analyses were performed using SAS® release 9.1. For the RECPAM analysis we used an SAS macro routine written by F. Pellegrini.

**RESULTS**

The study involved 1,456 patients, of whom 500 reported ED at baseline. Among the 956 patients without ED at baseline, information on ED status during followup was available for 670 patients (70%). Individuals who did not report ED sta-



Identification of subgroups at different risks for erectile dysfunction: results of RECPAM analysis. RECPAM analysis identified patient subgroups at different risks for ED. Tree growing algorithm modeled relative risks for ED as outcome after Poisson regression with age as global variable. Splitting variables (bold) are shown between branches, while condition sending patients to left or right sibling is on relative branch. Class 5 with lowest incidence of erectile dysfunction was reference category (RR=1). Circles indicate subgroups of patients. Squares indicate patient subgroup RECPAM class. Numbers inside circles and squares represent patients with (italics) and without erectile dysfunction, respectively. There were 3 observations excluded from analysis due to lack of information relative to age.

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