Effects of Intensive Lifestyle Changes on Erectile Dysfunction in Men

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A B S T R A C T

Introduction. Limited data are available supporting the notion that treatment of lifestyle risk factors may improve erectile dysfunction (ED).
Aim. In the present study, we analyzed the effect of a program of changing in lifestyle designed to improve erectile function in subjects with ED or at increasing risk for ED.
Methods. Men were identified in our database of subjects participating in randomized controlled trials evaluating the effect of lifestyle changes. A total of 209 subjects were randomly assigned to one of the two treatment groups. The 104 men randomly assigned to the intervention program received detailed advice about how to reduce body weight, improve quality of diet, and increase physical activity. The 105 subjects in the control group were given general information about healthy food choices and general guidance on increasing their level of physical activity.
Main Outcome Measures. Changes in erectile function score (International Index of Erectile Function-5 [IIEF-5]; items 5, 15, 4, 2, and 7 from the full-scale IIEF-15) and dependence of the restoration of erectile function on the changes in lifestyle that were achieved.
Results. Erectile function score improved in the intervention group. At baseline, 35 subjects in the intervention group and 38 subjects in the control group had normal erectile function (34% and 36%, respectively). After 2 years, these figures were 58 subjects in the intervention group and 40 subjects in the control group, respectively (56% and 38%, $P = 0.015$). There was a strong correlation between the success score and restoration of erectile function.
Conclusions. It is possible to achieve an improvement of erectile function in men at risk by means of nonpharmacological intervention aiming at weight loss and increasing physical activity. **Esposito K, Ciotola M, Giugliano F, Maiorino MI, Autorino R, De Sio M, Giugliano G, Nicoletti G, D'Andrea F, and Giugliano D. Effects of intensive lifestyle changes on erectile dysfunction in men. J Sex Med 2009;6:243–250.**

Key Words. Erectile Dysfunction; Lifestyle Changes; Obesity; Metabolic Syndrome

Introduction

Erectile dysfunction (ED) is an important cause of decreased quality of life in men [1–3]. The prevalence of this condition increases with age. In a large cross-sectional, community-based study [4] among men between the ages of 40 and 49 years, the prevalence of complete or severe ED was 5%, and the prevalence of moderate ED was 17%; among men between the ages of 70 and 79 years, these rates were 15% and 34%, respectively.

It has been estimated that the worldwide prevalence of ED will be 322 million cases by the year 2025 [5,6]. However, ED cannot be defined as necessary consequence of aging: in the study of Nicolosi et al. [7], for example, 54% of the healthy and 41% of the diseased men in the oldest age group (65 to 70 years) did not complain of moderate or severe dysfunction.

There has been increasing recognition of the many physiological causes of the condition and of the potential for therapy to improve a patient's

quality of life, self-esteem, and ability to maintain intimate relationships [8]. In the Health Professionals' Follow-up Study [5], several modifiable lifestyle factors, including physical activity and leanness, were associated with maintenance of good erectile function. For instance, men with a body mass index (BMI; calculated as weight in kilograms divided by the square of height in meters) higher than 28.7 are likely to carry a 30% higher risk for ED than those with a normal BMI (25 or lower). Cross-sectional studies have similarly shown that higher levels of physical activity are associated with clinically significant lowering in the rate of ED [9]. Although epidemiological evidence seems to support a role for lifestyle factors, limited data are available suggesting that the treatment of underlying risk factors and coexisting illnesses—for example, with weight loss, exercise, stress reduction, and smoking cessation—may improve ED [10].

In the present study, we undertook further analysis in order to evaluate in more detail the effect of lifestyle changes on erectile function in subjects with ED or at increasing risk for ED. In particular, we used our database of subjects participating in randomized controlled trials evaluating the effect of lifestyle changes [11,12] to see whether improvement of erectile function was related to success in achieving lifestyle changes. This new analysis includes subjects already reported to have ED [11], as well as subjects in whom evaluation of ED is reported here for the first time [12].

Material and Methods

Participants

To be included in the present analysis, participants had to satisfy the following criteria: BMI > 25 kg/m^2 with or without the metabolic syndrome; evaluation of erectile function at baseline and follow-up; and complete follow-up in the study trial. Metabolic syndrome was diagnosed as recommended by the Adult Treatment Panel III [13] and patients had to have three or more of the following criteria to meet the diagnosis of the metabolic syndrome: (i) abdominal adiposity as defined by a waist circumference of >102 cm in men and >88 cm in women; (ii) low serum high-density lipoprotein (HDL) cholesterol (<40 mg/dL or <50 mg/dL in men and women, respectively); (iii) hypertriglyceridemia as defined by an elevated triglyceride of ≥150 mg/dL; (iv) elevated blood pressure as defined by a blood pressure of at least 130/85 mm Hg; and (v) abnormal glucose homeostasis

as defined by a fasting plasma glucose concentration of ≥110 mg/dL. Subjects were excluded if they had clinical or instrumental signs or symptoms of cardiovascular disease, psychiatric problems, a history of alcohol abuse (at least 500 g alcohol/week in the last year), and a history of diabetes mellitus (fasting plasma glucose ≥126 mg/dL). The present analysis was approved by the ethical committee of our institution.

Lifestyle Intervention

A total of 209 subjects were randomly assigned to one of the two treatment groups. The 104 men randomly assigned to the intervention program received detailed advice about how to reduce body weight, improve quality of diet, and increase physical activity. The goals of the intervention were: a reduction in weight of 5% or more; a reduction in intake of saturated fat to less than 10% of energy consumed; an increase in intake of monounsaturated fat to 10% or more of energy consumed; an increase in fiber intake to at least 15 g per 1,000 kcal; and moderate exercise for at least 30 minutes per day for at least 5 days in a week. Frequent ingestion of whole-grain products, vegetables, fruits, low-fat milk, meat products, and olive oil was recommended. The program involved education on reducing, if needed, dietary calories, personal goal-setting, and self-monitoring (food diaries) through a series of monthly small-group sessions. Behavioral and psychological counseling was also offered. The dietary advice was tailored to each subject on the basis of 3-day food records. Each subject in the intervention group had seven sessions with a nutritionist during the first year of the study and one session every 3 months thereafter. These subjects also received individual guidance on increasing their level of physical activity. Endurance exercise (such as walking, jogging, swimming, aerobic ball games, or skiing) was recommended. Supervised progressive, individually tailored, circuit-type resistance-training sessions were also offered; subjects were instructed to perform a moderate to a high number of repetitions, and to take a break of 15 to 60 seconds between the stations on the circuit. Compliance with the program was assessed by attendance at the meetings and completion of the diet diaries.

Subjects in the control group were given general oral and written information about healthy food choices and general guidance on increasing their level of physical activity at baseline and at subsequent visits, but no specific individualized program was offered to them.

Clinical Studies

At baseline and at each annual visit, all participants completed a medical-history questionnaire and underwent a physical examination that included anthropometric and blood pressure measurements, and the evaluation of erectile function. Height and weight were recorded with participants wearing lightweight clothing and no shoes using a Seca 200 scale with attached stadiometer (Seca, Hamburg, Germany). Twenty-four-hour nutrient intakes were calculated with food-composition tables and patients' weekly diet diaries. All subjects were asked to complete for 3 days a record a food intake, and to record occupational, household, and leisure time physical activity, to assess dietary adherence and exercise activity. Foods were measured using standard measuring cups and spoons and weight-approximation diagrams. Erectile function was assessed by completing the International Index of Erectile Function-5 (IIEF-5) that consists of Items 5, 15, 4, 2, and 7 from the full-scale IIEF-15 [14]. A score of 21 or less indicates the presence of ED. The abbreviated score was used for its simplicity and immediacy.

Laboratory Analysis

Assays for serum total and HDL cholesterol, triglyceride, and glucose and insulin levels were performed in the hospital's chemistry laboratory.

Statistical Analysis

Data are presented as mean ± standard deviation (SD) unless stated otherwise. Two-sided t-tests were used to analyze the differences between the groups at base line and during follow-up. The χ^2 test was used for comparing proportions of men in the two groups that obtained normal erectile function after treatment. To estimate the extent of the dependence of the restoration of erectile function (IIEF score ≥22) on the changes in lifestyle that were achieved, subjects were given a grade for each goal of the intervention at the 1-year visit (with 0 indicating that it was not achieved or 1 indicating that it was achieved), and a success score was computed as the sum of these grades. For each subgroup defined according to success score, the proportion of subjects in whom ED had resolved was calculated. To test for a statistical association between this proportion and the success score, logistic-regression analysis was performed with the use of the SAS GENMOD (SAS Institute, Cary, NC, USA) procedure. The expected proportion was modeled as a linear function of the success score. $P < 0.05$ was considered significant. All analyses were conducted using SPSS version 10.05 (SPSS Inc., Chicago, IL, USA).

Results

The clinical and metabolic characteristics of participants are shown in Table 1. Both groups were comparable, including the mean erectile function score, with values ranging from 7 to 21 in both groups. During the first year, the mean (±SD) body weight decreased by 9.2 ± 5.1 kg in the intervention group, and by 2.8 ± 3.7 kg in the control group ($P < 0.001$). Waist circumference, the fasting plasma glucose and triglyceride con-

Table 1 Characteristics of the study participants*

Characteristic	Intervention group (N = 104)	Control group (N = 105)	P value
Age, year	45.3 ± 6.9	45.7 ± 6.9	NS
Body mass index, kg/m²	31.9 ± 4.5	31.5 ± 4.8	NS
Waist circumference, cm	102 ± 9	103 ± 10	NS
Plasma glucose, mg/dL	110 ± 12	111 ± 11	NS
Serum insulin, μU/mL	17 ± 7	16 ± 7	NS
Serum lipids, mg/dL			
Total cholesterol	215 ± 36	210 ± 32	NS
HDL-cholesterol	41 ± 9	42 ± 9	NS
Triglycerides	158 ± 57	169 ± 64	NS
Blood pressure, mm Hg			
Systolic	136 ± 9	135 ± 8	NS
Diastolic	85 ± 5	86 ± 7	NS
IIEF score	17.6 ± 3.8	17.8 ± 3.7	NS
Smoker, %	10%	10%	NS
Hypertension, %	24%	26%	NS
Obesity, %	58%	60%	NS
Metabolic syndrome, %	69%	70%	NS

*Data are presented as mean ± standard deviation.
IIEF = International Index of Erectile Function; NS = not significant.

Table 2 Changes in assessed variables after 2 years

Variable	Intervention group (N = 104) Mean change	Control group (N = 105) Mean change	P Value
Weight, kg	−8.9 ± 4.8	−2.1 ± 2.8	<0.001
Body mass index, kg/m^2	−2.7 ± 1.8	−0.5 ± 0.5	<0.001
Waist circumference, cm	−4.9 ± 3.5	−0.9 ± 0.7	<0.001
Plasma glucose, mg/dL	−5 ± 5	−1 ± 2	<0.01
Serum insulin, μU/mL	−2 ± 7	−1 ± 5	<0.16
Serum lipids, mg/dL			
Total cholesterol	−5 ± 10	−3 ± 12	0.09
HDL cholesterol	3 ± 5	1 ± 3	<0.05
Triglycerides	−16 ± 23	−2 ± 10	<0.05
Blood pressure, mm Hg			
Systolic	−4 ± 8	0 ± 4	<0.05
Diastolic	−4 ± 4	−1 ± 3	<0.01

HDL = high-density lipoprotein.

centration, and systolic and diastolic blood pressure values decreased significantly more among subjects in the intervention group than among those in the control group (data not shown). At 2 years, the decrease in weight remained significantly greater in the intervention group (8.9 ± 4.8) than in the control group (2.1 ± 2.8 kg, $P < 0.001$; Table 2). At this time, men on the intervention diet had a significant decrease in glucose, insulin, low-density lipoprotein cholesterol, triglycerides, and blood pressure, and a significant increase of HDL cholesterol.

Erectile function score improved in the intervention group (Figure 1). At baseline, 35 subjects in the intervention group and 38 subjects in the control group had normal erectile function (34% and 36%, respectively). After 2 years, these figures were 58 subjects in the intervention group and 40 subjects in the control group, respectively (56% and 38%, $P = 0.015$).

The subjects in the intervention group were more likely to report changes in dietary and exercise habits. Success in achieving the goals of the intervention was estimated on the basis of the food records and exercise questionnaires collected at the 1-year examination (Table 3). The proportion of subjects in the intervention group who succeeded in achieving a particular goal varied from 29% (fiber intake) to 76% (exercise).

The study subjects were ranked according to their success in achieving the goals of the intervention (and given a success score between 0 and 5) at the 2-year examination, with higher scores indicating more goals met (Figure 2). There was a strong correlation between the success score and restoration of erectile function. Ten subjects in the intervention group and two subjects in the control group did achieve all the goals; restoration of erec-

tile function occurred in 60% and 50% of these subjects, respectively, during follow-up ($P = 0.58$). In participants who reached two goals or more (57 in the intervention group and 23 in the control group), the percentage of restoration was 36% and 21%, respectively ($P = 0.12$). According to a univariate analysis, the odds ratio for restoration of erectile function in participants in the intervention group who had lost more than 5% of their initial weight by the 2-year follow-up visit was 1.8 (95% confidence interval, 1.2 to 2.4) as compared with
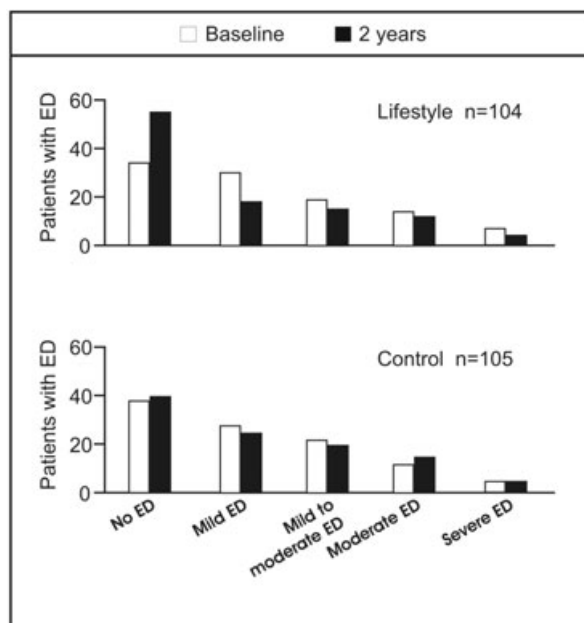

Figure 1 Changes in IIEF score in 209 men assigned to lifestyle changes or control. Level 1: no erectile dysfunction (ED), score 22–25; Level 2: mild erectile dysfunction, score 17–21; Level 3: mild to moderate erectile dysfunction, score 12–16; Level 4: moderate erectile dysfunction, score 8–11; Level 5, severe erectile dysfunction, score 5–7.

Table 3 Success in achieving the goals of the intervention by 2 years, according to treatment group

Goal	Intervention group	Control group	P value
	% of subjects		
Weight reduction >5%	50	15	0.001
Monounsaturated-fat intake ≥10% of energy intake	57	26	0.001
Saturated-fat intake <10% of energy intake	86	41	0.001
Fiber intake ≥15 g/1,000 kcal	29	12	0.001
Exercise >4 h/week	76	41	0.001

those in the intervention group who had lost less weight or none at all. Among the subjects in the intervention group who did not reach the goal of losing 5% of their initial weight, the odds ratio for restoration of erectile function in participants who had achieved the goal with respect to exercise (more than 4 hours per week) was 1.9 (95% confidence interval, 1.3 to 2.5) as compared with those in the intervention group who maintained a sedentary lifestyle. After adjustment for baseline BMI, the odds ratio for restoration of erectile function in participants in those in the intervention group who had achieved the exercise goal was still statistically significant (odds ratio, 1.8; 95% confidence interval, 1.3 to 2.4).

Discussion

This study provides evidence that improvement of erectile function can be obtained by changes in the lifestyles of men with or at risk for ED. In particu-

lar, restoration of ED occurred in 22 participants in the intervention group (32%) and only in five participants of the control group (7%). Our estimate of the effect of the intervention can be considered conservative: for ethical reasons, all subjects assigned to the control group also received general health advice at baseline and at annual follow-up visits and may have benefited from this advice. The effect of the intervention on the restoration of erectile function was most pronounced among subjects who made comprehensive changes in lifestyle.

Obesity and the metabolic syndrome are two risk factors for ED, and both are linked to unhealthy lifestyle [15]. In the Massachusetts Male Aging Study (MMAS) report [9], the prevalence of ED was directly affected by overweight and obesity: a baseline BMI ≥ 28 significantly predicted the development of ED in the longer term; moreover, those initially overweight subjects remained at high risk of ED, even in the event of
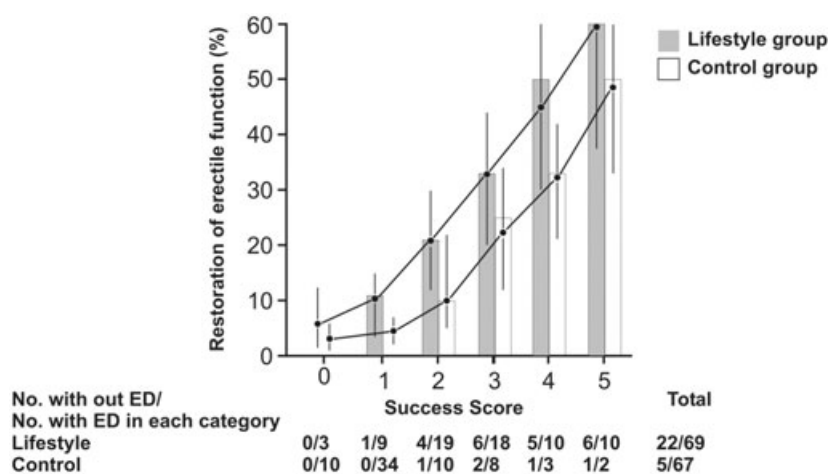

| | | No. with out ED/ |
| | | No. with ED in each category |

	0	1	2	3	4	5	Total
Lifestyle	0/3	1/9	4/19	6/18	5/10	6/10	22/69
Control	0/10	0/34	1/10	2/8	1/3	1/2	5/67

Figure 2 Restoration of erectile function during Follow-up, according to the success score. Each subject received a grade of 0 for each intervention goal that had not been achieved and a grade of 1 for each goal that had been achieved; the success score was computed as the sum of the grades. The association between the success score and the restoration of erectile function was estimated by means of logistic-regression analysis of the observed data; the curve whose data points align with the open bars represents the model-based incidence for the control group, and the curve whose data points align with the shaded bars represents the model-based incidence for the intervention group.

follow-up weight loss. A high percentage of overweight men (85%) has been observed in other ED populations [16]. In a large population study from Brazil, Nicolosi et al. [7] found that the prevalence of ED was inversely proportional to the level of physical activity.

Subjects in MMAS who had diets rich in cholesterol and unsaturated fats were more likely to develop ED in the follow-up period than those with more balanced diets. We have found that the intake of some foods was less represented in subjects with ED: in particular, the calculated intakes of vegetables, fruits and nuts, and the ratio of monounsaturated to saturated lipids were significantly lower in men with ED [17]. Interestingly enough, each of these nutrients has been associated with a decreased risk of coronary heart disease (CHD), through an effect of improving endothelial dysfunction and decreasing inflammation [18]. In general, the intake of foods that are more likely to be associated with increased CHD risk was higher in men with ED whereas the intake of foods that are associated with decreased cardiovascular disease risk was reduced.

Excess weight is usually accompanied by a sedentary lifestyle, which is a known cardiac risk factor [19]. Exercise has also been shown to affect ED prevalence and incidence. Derby et al. [9] collected data as part of the MMAS, including a random sample of 1,709 men aged 40 to 70 years at baseline, and 1,156 men at follow-up approximately 8.8 years later. The highest risk for ED was among men who were sedentary at both the baseline visit and at follow-up. Cross-sectional studies have similarly shown that higher levels of physical activity are associated with clinically significant lowering in the rate of ED. In the study of Bacon et al. [5], the highest category of physical activity was associated with lowest risk of ED compared with lower categories of physical activity. Conversely, higher levels of sedentary behavior were a positive predictor of ED. Nicolosi et al. [7] found a linear association between the level of physical activity and ED: 31.8% of men with a less-than-average level of physical activity demonstrated ED, compared with only 17.5% of men with an average level, and only 13.9% of men with a greater-than-average level of physical activity.

The epidemiological evidence linking unhealthy lifestyle with ED is intriguing, but may only generate working hypotheses that need to be tested in specific trials. In our randomized study comparing intensive lifestyle changes with an educational control in 110 obese men with moderate ED [11],

we found that approximately one of three patients in the intervention group recovered normal erectile function during the study compared with <1 in 10 in the control group. Rosen et al. [20] compared short- and long-term effects of a 12-week, combined nonpharmacologic intervention, with both placebo and β-blocker treatment in a sample of middle-aged men with hypertension. Patients who achieved the highest levels of fitness and blood pressure change also appeared more likely to show improvements in sexual function. Taken together, these studies show that significant improvements in sexual function can be expected in patients receiving intensive lifestyle changes (primarily weight loss and exercise), which are also likely to be accompanied by positive changes in weight, fitness levels, and other markers of cardiovascular health.

Men with ED show, as compared with age-matched men without ED, a difference in lifestyle attitudes that may play a role in the development and progression of ED. In particular, the prevalence of unhealthy dietary patterns and physical inactivity were significantly higher in men with ED [17]. A large proportion of deaths coming from chronic diseases in the United States are estimated to be caused by poor nutrition, sedentary living, and tobacco use, and are largely preventable [21]. The mechanisms by which lifestyle changes can help improve erectile function have already been proposed [11], and include amelioration of endothelial function, and reduction of insulin resistance and the low-grade inflammatory state associated with metabolic diseases, including obesity, metabolic syndrome, and type 2 diabetes [22], all risk factors for ED.

The present study has limitations. Psychological factors or relational situations may negatively influence erectile activity [23,24], and it remains possible that the general sense of well-being achieved in subjects of intervention groups may have contributed, at least in part, in the results obtained. Moreover, the overweight subjects we studied did not have known cardiovascular diseases, diabetes or hypertension, all commonly seen associated with ED in practice [25,26]. In theory, the presence of these comorbid conditions may lessen the effect of lifestyle changes on ED.

Conclusions

Poor nutrition and sedentary living are associated with a constellation of risk factors, some of which have been identified in the metabolic syndrome, and all of which are known to be linked to ED. It

is possible to achieve an improvement of erectile function in men at risk by means of nonpharmacological intervention. It is also critically important that individuals limit their overall caloric intake, improve their nutrition, and become physically active to help maintain a healthy body weight.

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Statement of Authorship

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