

Erectile Dysfunction in Patients in a Cardiac Rehabilitation Program

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Introduction and objectives. Erectile dysfunction is common in patients with coronary heart disease. The aim of this study was to investigate the incidence of, etiological factors associated with, and treatment results obtained in this condition in patients participating in a cardiac rehabilitation program.

Methods. The study included 420 male patients with heart disease who were taking part in a multicomponent therapeutic program that involved physical exercise, psychological techniques, and risk factor reduction.

Results. Overall, erectile dysfunction was present in 216 patients (52.6%) and there were clear associations with age ($P < .001$), diabetes mellitus ($P < .001$), arterial hypertension ($P = .029$), cigarette smoking ($P = .044$), and treatment with angiotensin-converting enzyme inhibitors ($P = .003$) and diuretics ($P < .001$). However, there were no links to treatment with beta-blockers, calcium antagonists, statins, or antiplatelet agents. There were direct associations with trait anxiety ($P = .009$) and state anxiety ($P = .006$) and with depression ($P = .003$). The final multivariate analysis model included diabetes mellitus, smoking, diuretic use, state anxiety and age as significant variables. Only 59 patients agreed to treatment with a phosphodiesterase-5 inhibitor, with positive results in 45 (76.27%). Treatment was contraindicated in 41 patients because they were taking nitrates for myocardial ischemia. The remaining patients expressed no interest, had relationship problems, or were worried about complications.

Conclusions. The incidence of erectile dysfunction was substantial. The condition was directly associated with risk factors for atherosclerosis, treatment, and psychological disorders (ie, anxiety and depression).

Relationship problems and the fear of complications may explain why many patients refused to take phosphodiesterase-5 inhibitors.

Key words: *Erectile dysfunction. Cardiac rehabilitation. Risk factors. Relationship problems. Phosphodiesterase-5 inhibitors.*

Disfunción eréctil en pacientes incluidos en un programa de rehabilitación cardíaca

Introducción y objetivos. La disfunción eréctil es frecuente en pacientes con cardiopatía. Analizamos la incidencia, los factores etiológicos y los resultados obtenidos en el tratamiento de esta afección en pacientes incluidos en un programa de rehabilitación cardíaca.

Métodos. Se estudió a 420 varones cardiopatas sometidos a una terapia multifactorial de entrenamiento físico, actuación psicológica y control de factores de riesgo.

Resultados. Tuvieron disfunción eréctil 216 (52,6%) pacientes, en clara relación con edad ($p < 0,001$), diabetes mellitus ($p < 0,001$), hipertensión arterial ($p = 0,029$), tabaquismo ($p = 0,044$) y tratamientos con inhibidores de la enzima de conversión de la angiotensina ($p = 0,003$) y diuréticos ($p < 0,001$). No así con bloqueadores beta, antagonistas del calcio, estatinas y antiagregantes. Estuvo en conexión directa con la ansiedad rasgo ($p = 0,009$) y estado ($p = 0,006$) y con la depresión ($p = 0,003$). El modelo final del análisis multivariable incluyó como variables significativas diabetes mellitus, tabaquismo, diuréticos, ansiedad estado y edad. Sólo 59 pacientes aceptaron tomar un inhibidor de la fosfodiesterasa, con resultados positivos en 45 (76,27%). En 41 estaba contraindicado, pues recibían tratamiento con nitratos por isquemia miocárdica demostrada. Los demás adujeron falta de interés, problemas de pareja y miedo a las complicaciones.

Conclusiones. La incidencia de disfunción eréctil es muy significativa. Se relaciona con los factores de riesgo de aterosclerosis, con el tratamiento y con anomalías psicológicas (ansiedad y depresión). El miedo a las complicaciones y las malas relaciones de pareja puede favorecer que muchos pacientes declinen tomar inhibidores de la fosfodiesterasa.

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ABBREVIATIONS

CRP: cardiac rehabilitation program

ED: erectile dysfunction

PDE: phosphodiesterase

INTRODUCTION

The incidence of erectile dysfunction (ED) in the healthy population and in different diseases is well documented. Its etiology is varied, occasionally coexisting with a different situations: advanced age, relationship problems, organic and psychological diseases, medical treatments, lack of information, fear of possible complications, etc.

Variable percentages have been described (38%-78%) in cardiac patients, fundamentally after an acute myocardial infarction (AMI).¹

Several oral pharmaceutical products have appeared in recent years, including phosphodiesterase inhibitors (PDE-5), which have been shown to be effective in the treatment of this condition. However, a noticeably small percentage of patients accept taking these drugs.

Several explanations of this negative attitude have been suggested, among which the fear of complications predominates, this being an effect that seems to be more prominent among cardiac patients because of the sensational news published in daily newspapers.

Meanwhile, cardiologists and patients who have suffered from acute coronary events do not usually talk about matters of a sexual nature. The study by Bedell et al² showed that 97% of men and 82% of women did not feel they received sufficient information in this respect.

Cardiac rehabilitation programmes (CRP) can be effective for the treatment of ED. This would result from an improvement in the psychological deterioration common in these patients, thanks to the effects of daily exercise, more information, and a closer doctor-patient relationship in the weeks of attending the multi-disciplinary action plan.

Based on this, we thought it would be interesting to know the response of cardiac patients with erectile dysfunction to the treatment proposed by the group of healthcare professionals in our CRP, providing daily care during a period ranging between 2 and 3 months.

TABLE 1. Etiological Diagnosis of the Patients Included in the Study

	Revascularisation			
	No	Percutaneous	Surgery	Total
ACS without infarction	23	43	46	112
ACS with infarction	86	179	33	298
Dilated cardiomyopathy				9
NOHCM				1

ACS: acute coronary syndrome; NOHCM: non-obstructive hypertrophic cardiomyopathy.

METHODS

In a prospective study, 420 male patients included in the cardiac rehabilitation programme were studied consecutively. The predominant condition was ischemic heart disease (acute myocardial infarction or after coronary surgery) presented by 410 patients, another 9 had been diagnosed with dilated cardiomyopathy (5 idiopathic cardiomyopathy and 4 with coronary etiology) and 1 patient presented non-obstructive hypertrophic cardiomyopathy (Table 1).

In the inclusion time period (October 1, 2004 to April 30, 2006), 62 women were also rehabilitated (58 with ischemic heart disease and 4 after valve surgery). Two women requested a consultation with the sexual dysfunction unit, and both considered the disorder was secondary to relationship problems.

When considered necessary, the diagnostic and therapeutic management of the male patients' sexual activity was analysed.

All the patients gave their written consent to being included in the CRP, as usual in the unit, and the study was approved by the hospital ethics committee.

The CRP described above³ is started between 10 and 15 days after discharge from hospital in patients with acute coronary syndromes, and at 6 weeks when the patient has undergone revascularisation surgery.

The multidisciplinary programme, with an average duration of 2-3 months, includes: *a)* supervised, personalised physical training; *b)* psychological action with behaviour modifying techniques, group therapy and relaxation sessions; *c)* educational programme on modifying lifestyle and controlling risk factors; and *d)* social and vocational advice.

The physical training, predominantly aerobic, was carried out 5 days a week. The training heart rate (THR) was calculated individually, based on the results of the stress test, maximum or limited by the symptoms seen at the beginning and end of the programme.

The psychological programme consists of an initial assessment with a study of the psychological profile, by conducting an interview and completing questionnaires to evaluate anxiety (STAI)⁴ and depression (Beck),⁵ and

intervention through relaxation techniques and group therapy.

The educational programme is implemented through weekly lectures/discussions aimed at the patients and their close relatives, during which they receive information and advice about the disease and the need to modify harmful risk factors and lifestyle habits.

A variable percentage of patients, based on uncontrolled conditions, are included in specific sub-units of the CRP: tobacco smoking, lipids, and sexual dysfunction.

The latter comprises a cardiologist, a psychiatrist, a urologist (andrologist), and a nurse.

The male patients were advised to fill in an erectile dysfunction study questionnaire (SHIM)⁶ 4 weeks after starting the CRP. The waiting period was based on the experience that the patient had stabilised, physically and mentally, at this time.

The SHIM (Sexual Health Inventory for Men) analyses the sexual capacity to achieve and maintain an erection and complete coitus. It consists of 5 questions, and in each of them, the patient makes a self-evaluation on a scale ranging from 0 to 5 points. Erectile dysfunction was considered to exist when the score was 20 or lower.

Those not reaching these scores are seen in a specific consultation managed by a cardiologist. The healthcare professional questions the patient about the subjective feeling of dysfunction. If the response confirms the ED, and the patient accepts the possibility of receiving treatment, the studies begin.

The analysis includes data about the heart disease, added conditions, the results of the stress test and psychological questionnaires, as well as the treatment administered.

If there are clinical data of significant depression, the specialised management of this condition is prioritised. It is unlikely that these patients are not already receiving treatment after previous psychological and psychiatric studies.

If physical capacity, measured in the stress test at the beginning of the programme, is above 6 METs and there is no ischemia below these levels, the possibility of treatment may be considered, as it has been shown that the energy used in coitus, with a regular partner, is between 3 and 5 METs⁷ and that the incidence of arrhythmia is similar to those presenting during daily activities.⁸

We start the treatment with average doses of phosphodiesterase 5 (PDE-5) if there are no medical contraindications (treatment with nitrates).

If this is not possible, other types of actions (oral apomorphine, vacuum systems, intracavernosal injections, prosthesis) are considered, provided that there is no evidence of intractable myocardial ischemia at low stress levels. In these cases they are seen by the andrologist.

In spite of the high incidence of ED in the population, more than 152 million people in the world in 1995,⁹ the percentage of individuals receiving treatment is extremely low.

Based on this final statement, it has been considered of interest to know the response of cardiac patients with erectile dysfunction to the study proposals and treatment administered by a group of professionals treating them every day for a period spanning several weeks, which whom they generally have excellent relationships.

In the cardiac patients included in the CRP we have analysed, as basic objectives, the incidence of erectile dysfunction, the reasons given by the patients when accepting or rejecting the different therapies advised and the results obtained with the use of PDE-5 inhibitors.

In a secondary manner, the existence and value of the coronary risk factors, the psychological disorders and the medication are possible triggers of the dysfunction.

From a statistical standpoint, the continuous variables are expressed as mean and standard deviation, and the discrete with absolute frequency and relative frequency.

The univariate analysis of the data was carried out using χ^2 tests for the categorical variables and the Student *t* test for continuous variables (after checking the assumption of normality with the Kolmogorov-Smirnov test).

For the multivariate analysis, a logistic regression model was created. The maximum model comprises the variables considered statistically significant in the univariate analysis and those that are considered to be classic risk factors. The strategy used was stepwise backward elimination.

In order to evaluate the predictive capacity of the model, the area under the ROC curve was calculated.

The contrasts were bilateral with a level of significance below 0.05 ($P < 0.05$).

The entire analysis was carried out with SPSS 12.0.1.

RESULTS

The incidence of risk factors and conditions of an atherosclerotic nature in the study patients was: diabetes 16.19%, tobacco smoking 87.64%, dyslipidemia diagnosed prior to admission 17.91%, arterial hypertension 39.19%, lower limb arterial disease 4.98%.

The percentage of patients treated with different drugs is shown in Table 2.

The mean age of patients with ED (60.61 [8.7]) was significantly older than those in the group without dysfunction (52.78 [9.4]) with $P < .001$.

We found a clear relationship between the incidence of ED and the existence of diabetes, arterial hypertension, and those treated with ACEI and diuretics. There was no relationship when peripheral arterial disease was analysed, or in the case of treatment with beta-blockers, calcium channel blockers, statins, and antiplatelet drugs. (Tables 3 and 4).

The group of patients diagnosed with dyslipidemia before arriving at the hospital was very low (17.91%), the great majority of them being unaware of their cholesterol and triglycerides. No direct connection was

TABLE 2. Drug Treatment Followed by the Patients

Treatment	Patients, No. (%)
Beta-blockers	331 (78.8)
ACEIs	210 (50)
Calcium channel blockers	92 (21.9)
Diuretics	51 (12.14)
Statins	360 (85.71)
Antiplatelet drugs	383 (91.19)

TABLE 3. The Incidence of Erectile Dysfunction With Regard to Other Risk Factors for Atherosclerosis

	Erectile Dysfunction		
	No, No. (%)	Yes, No. (%)	P
Diabetes	18 (26.5)	50 (73.5)	<.001
Arterial hypertension	69 (41.8)	96 (58.2)	.029
Peripheral vascular disease	6 (28.6)	15 (71.4)	.061
Tobacco smoking	172 (46.6)	197 (53.4)	.044

TABLE 4. Incidence of Erectile Dysfunction With Regard to Drug Treatment

	Erectile Dysfunction		
	No	Yes	P
Beta-blockers	167 (50.5)	164 (49.5)	.137
ACEIs	87 (41.4)	123 (58.6)	.003
Calcium channel blockers	46 (50.0)	46 (50.0)	.756
Diuretics	13 (25.5)	38 (74.5)	<.001
Statins	178 (49.4)	182 (50.6)	.381
Antiplatelet drugs	189 (49.3)	194 (50.7)	.306

found with the presence of ED; 21 patients suffered from this and 22 did not.

Psychological disorders had a significant influence on the sexual area, as shown in the questionnaires analysing state-trait anxiety (STAI) and depression (Beck) (Table 5). We considered scores above 80 in the state-trait (STAI) and 16 in the Beck to be abnormal values.

In the multivariate analysis, the maximum model included the variables of diabetes mellitus, arterial hypertension, peripheral vascular disease, tobacco smoking, β -blockers, ACEIs, diuretics, Beck, STAI (trait), STAI (state), and age.

The final model included the variables of diabetes mellitus, tobacco smoking, diuretics, STAI (state) and age (Table 6). The Nagelkerke's R^2 was equal to 0.288. The predictive capacity of the model was analysed with the area under the ROC curve, which was equal to 0.77.

The analysis of the SHIM questionnaire showed that 216 patients (52.6%) scored below 20, the limit for considering the possibility of erectile dysfunction. A total

TABLE 5. Erectile Dysfunction and Psychological Disorders

	Erectile Dysfunction		
	No, No. (%)	Yes, No. (%)	P
Beck	6 (21.4)	22 (78.6)	.003
STAI (trait)	15 (31.2)	33 (68.8)	.009
STAI (state)	22 (33.3)	44 (66.7)	.006

TABLE 6. Multivariate Analysis of the Relationship Between Different Coronary Factors and the Treatment and Incidence of Erectile Dysfunction

	Exp(B)	95% CI
Age	1.094	1.067-1.122
Diabetes	2.746	1.448-5.207
Tobacco smoking	2.104	1.057-4.187
Diuretics	2.563	1.220-5.385
STAI (state)	3.341	1.639-6.811

CI: confidence interval.

of 17.9% had between 15 and 19 points, 14.9% from 10 to 14, and the rest (18.7%) from 0 to 9.

Six patients with more than 20 points asked for a consultation with the ED unit, 4 presented premature ejaculation and another 2 had lack of desire but not dysfunction. Sixteen patients with scores below 20 were not considered as having ED.

There were contraindications against treatment with PDE-5 inhibitors in 41 coronary patients, due to ischemia at low stress levels in 16 cases and to the need to take nitrates in all of them since they presented clinically and/or electrically positive stress tests. After the consultation, only 3 agreed to be seen by the urologist.

Fifty five were not interested in having treatment. The reasons given were one or more of the following: lack of desire, advanced age (some aged 60), and fundamentally (52 of them) due to a poor relationship with their partners.

The rest of the patients, 104, were interviewed during the consultation. In spite of the advice given, only 4 of them attended with their partners. After the interview, 6 of them said they would think about the possibility of receiving treatment, while 98 of them agreed to take a PDE-5 inhibitor.

In the subsequent consultation for the results, 39 had not taken the product for a variety of reasons, the most common of which was fear of taking it, in spite of the explanations given, and the refusal of the partner, in 35 of them. In 3 cases, they did not take it after a consultation with their family doctor or cardiologist. The product had a positive effect in 45 (76.27%) of the 59 patients who had taken the medication. Three of the patients who were not considered to have obtained good

results, had undergone radical prostate cancer surgery. Four went to the andrology department.

DISCUSSION

Sexual disorders have a very negative effect on the quality of life of patients with heart diseases it has been described in over 50% of males, and although there is less information on female sexuality, an even larger proportion seems to be involved.¹⁰⁻¹²

The subjective reason for the sexual dysfunction described by the 2 women in our programme was the deterioration of the relationship with the partner, similar to that described by Abramov¹¹ many years ago and by Yildizh¹² in 2000.

The existence of a stable relationship signified greater sexual activity, 73% in men and 57% in women, decreasing to 30% and 5% when it did not exist.¹³ On the other hand, if the emotional relationship had already deteriorated, the disease could be the justification for not recommencing it.

We believe that relationship problems have a definitive effect on the management of sexual dysfunction in our patients. Perhaps it is anecdotic that in 3 patients it was fundamental that their doctor (2 cardiologists and 1 family physician) advised them not to take the PDE-5 inhibitor prescribed at the unit, even though they admitted there were no contraindications at all.

Sexual disorders, until very recent times, were to have a mainly psychological etiology and have been described up to 80% in severe depressive syndromes. However, over time, organic disorders become more frequent, comprising 80% in moles aged over 70 years, as opposed to 20% of psychological origin.¹⁴

Some authors considered that ED and ischemic heart disease have endothelial dysfunction as a common substrate, explaining the high incidence of sexual disorders in the coronary patient.¹⁵ The evidence of the greatest percentage of ED in our patients with AHT and tobacco smoking, risk factors for atherosclerosis, supports this theory. We believe that the dyslipidemia data in our patients is unreliable, owing to lack of control data. The small number of patients with peripheral vascular diseases means that there are no statistically significant differences, in spite of the high percentage of ED in these patients (71.4% with sexual disorders and 28.6% without them).

The great majority of drugs used (beta-blockers, hypotensive drugs, diuretics, hypolipidemic agents, etc) in cardiac patients may increase the incidence of ED but, paradoxically, may have a positive influence if they control angina, heart failure, etc. In these patients, we have found a higher incidence of ED in those treated with ACEIs and diuretics, but not with the rest of the products analysed.

It is perhaps interesting that it is not present in the 331 patients receiving beta-blockers. The explanation could lie in the fact that atenolol has been described as

being the least negative of this therapeutic family and in the recently described fact that the knowledge of the product and their possible negative effects on sexuality have a significantly negative effect in the presentation of the disorders.¹⁶

The absence of sexual activity in the couple after a myocardial infarction, in the presence of normal personal relations, is usually the consequence of fear of the complications which might present. The medical information may have a positive effect in this respect or, on the other hand, a very negative effect, as occurred in 3 of our patients.

There is sufficient evidence that the severe complications, death or risk of infarction during coitus, are extremely low. Muller et al,¹⁷ in 858 sexually active patients before the AMI, consider that the sexual intercourse increases the absolute risk in such an insignificant percentage as a chance in a million.

The energy expenditure is around 5 METS during orgasm, and 3.7 in the pre- and post orgasmic phase.⁷ Heart rate and arrhythmia during sexual activity have been described in similar percentages to those of daily activities, although it must be taken into account that there are wide variations based on multiple factors: the physical characteristics of the patient, those of the partner, the emotional situation, having eaten a large meal, extramarital relations, etc.¹

Our study, after a univariate and multivariate analysis, seems to show that sexual dysfunction in cardiac patients is a complex phenomenon relating to different variables such as age, risk factors for atherosclerotic heart disease, medication, and psychological disorders. All these factors must be taken into account when it comes to managing this condition.

The information is of the utmost importance. It is necessary to talk to the patient's partner, in order to deal with the fear of coital death, before release from hospital or when the diagnosis is made.

CRP have positive effects in this respect, as a result of the actions mentioned above. Of 180 post-infarction patients, divided randomly into 2 groups, we found a lower percentage of impotence in the short and long term ($P<.02$) in the rehabilitated group, in a period of time in which we did not have oral substances for its treatment.¹⁸

The management of erectile dysfunction has greatly improved since the appearance on the market of phosphodiesterase 5 (sildenafil, vardenafil, tadalafil).

They have proven very effective and provide optimum results in around 80%, 75.27% in our patients, and do not cause complications of any type. By perfecting planning its use, the risks are reduced to a minimum.

Their administration is absolutely contraindicated in patients treated with nitrates or nitric oxide donors (NO) in any form. These patients present raised NO levels in blood, and these drugs can strengthen the vasodilator effect of the exogenous NO as they inhibit the

phosphodiesterase enzyme present in the cells of the vascular smooth muscle cells, leading to a significant reduction in blood pressure.

PDE-5 inhibitors and any other sexual treatments (vacuum systems, intracavernosal injections, etc) should be viewed with caution when it comes to advising sexual activity in patients with angina when doing on medium or low effort or uncontrolled conditions such as arrhythmia, heart failure, and arterial hypertension.

We believe this study can be used to draw important conclusions for managing ED in cardiac patients. The following are worth noting: *a)* there is an incidence of over 50%; *b)* the etiology depends on the existence of risk factors for atherosclerosis, the treatment followed and psychological problems; *c)* it is probable that a good relationship with the partner may have a positive effect on solving the problem; *d)* it is essential for the healthcare professionals to provide enough, good information; *e)* when there are not contraindications, the use of PDE-5 inhibitors gives excellent results.

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