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Original article

Stable Angina in Spain and its Impact on Quality of Life. The AVANCE Registry

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ABSTRACT

Introduction and objectives: Mortality from acute coronary syndrome has fallen but a substantial number of chronic patients remain symptomatic. The present study was designed to determine the clinical characteristics and therapeutic treatment of patients with stable angina and its impact on their quality of life.

Methods: A cross-sectional, multicenter, observational study of 2039 patients with stable angina attended in outpatient clinics was performed. Data were collected on clinical variables and on the subjective perception of the severity of angina and the resulting limitations. Patients completed questionnaires on their perception of severity and quality of life.

Results: We analyzed data on 2024 patients; 73% were men (mean age 68 [10] years). Some 50.3% were asymptomatic (<1 angina attack per week in the previous 4 weeks), 39.2% reported 1-3 attacks per week and 10.5% reported >3 attacks per week; 66% had previously undergone revascularization, and 59% of these developed recurrent angina. Patients rated the severity of their condition higher than did their physicians (4.5 [2.5] vs 4.3 [2.3]; *P*=.002). Physicians' and patients' perceptions of the repercussions of angina showed little concordance (kappa <0.3). The patients believed their condition was much more severe, more debilitating, and had a greater negative impact on their quality of life.

Conclusions: A high proportion of patients with stable angina remains symptomatic and their quality of life is impaired. Their perception of the condition is worse than that of their physicians.

Estudio de la angina estable en España y su impacto en la calidad de vida del paciente. Registro AVANCE

Palabras clave:
Angina estable
Calidad de vida
Tratamiento antianginoso
Cardiopatía isquémica crónica

RESUMEN

Introducción y objetivos: La mortalidad por cardiopatía isquémica aguda se ha reducido, pero los pacientes crónicos persisten sintomáticos en una proporción importante. Se pretende conocer las características clínicas y la terapéutica del paciente con angina estable y el impacto de esta enfermedad en la calidad de vida.

Métodos: Estudio observacional, multicéntrico y de corte transversal, sobre 2.039 pacientes con angina estable en control ambulatorio. Además de variables clínicas, el investigador recogió su valoración subjetiva sobre la gravedad de la angina y la limitación causada por ella. Los pacientes contestaron sobre percepción de gravedad y calidad de vida con cuestionarios específicos.

Resultados: Se analizó a 2.024 pacientes. El 73% eran varones (media de edad, 68 ± 10 años). El 50,3% estaba asintomático (menos de una crisis de angina por semana en las últimas 4 semanas), el 39,2% había tenido entre una y tres crisis por semana, y el 10,5% declaró más de tres crisis por semana. El 66% había sido revascularizado, y de ellos el 59% volvía a tener angina. Los pacientes puntuaron la gravedad de la enfermedad más que los médicos (4,5 ± 2,5 frente a 4,3 ± 2,3; p = 0,002). Las percepciones del médico y del paciente sobre la repercusión de la angina tuvieron poca concordancia (índice kappa < 0,3), pues los pacientes consideraron que su enfermedad era más grave, más invalidante y con mayor disminución de la calidad de vida.

Conclusiones: Persiste una elevada proporción de pacientes sintomáticos y con reducción de la calidad de vida. La percepción del paciente sobre la enfermedad es peor que la del médico.

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◇ A list of the AVANCE study researchers is included in the appendix.

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Abbreviation

CVRF: cardiovascular risk factors

INTRODUCTION

The early recognition of acute coronary syndrome and prompt reperfusion techniques have reduced in-hospital and short-term mortality.[1] There have also been changes in chronic ischemic heart disease: more patients undergo revascularization, medical treatment and control of cardiovascular risk factors (CVRF) have been intensified, and new treatments have appeared on the market. Nonetheless, in Spain, angina pectoris has not disappeared. The prevalence of angina is estimated to be 2%-4% in most European countries, with an annual mortality of 0.9%-1.4% and an incidence of nonfatal myocardial infarction of 0.5%-2.6%.[2,3] A significant number of patients with angina pectoris cannot be efficiently controlled; these patients have disabilities and their quality of life deteriorates, as shown in the RITA-2[4] and COURAGE[5] studies. The Euro Heart Survey reports that, at diagnosis, 60% of patients with angina are moderately/severely limited in their daily activities.[6] Angina pectoris frequently causes permanent disability and patients' quality of life deteriorates markedly at a younger age than in patients with heart failure.[7,8] The World Health Organization considers ischemic heart disease to be the second cause of disability-adjusted life years lost[9] after depression.

In Spain, knowledge of patients with stable angina is scarce. Subjectively, the issue appears to be of little relevance given improvements in the treatment of acute coronary syndrome. We consider it important to learn about standard cardiologic practice in patients with stable angina and to study physicians' and patients' perceptions of its impact on quality of life and of the general efficacy of treatment.

METHODS

We designed a cross-sectional, multicenter, observational study based on unrestricted, noninfluenced, single routine visits to clinical cardiologists in Spain. Given the difficulty of conducting a nationwide randomized study with measurement of quality of life, we decided to substantially increase the number of researchers—distributed proportionately throughout Spain's autonomous regions—and to limit the number of patients to 5 per researcher so as to avoid any individual selection bias that might affect the series.

Our principle objective was to determine the clinical characteristics of patients with stable angina and the treatment they receive. Furthermore, we designed the study to identify how patients and cardiologists perceive the condition and to determine its impact on patients' quality of life.

Our inclusion criterion was "patient with a previous diagnosis of angina pectoris secondary to chronic ischemic heart disease attending a routine follow-up visit" at an outpatient cardiology clinic. Specifically, a confirmed clinical diagnosis of stable chronic angina (previous diagnoses of acute coronary syndrome, myocardial infarction or unstable angina) or chest pain with positive exercise testing were required. Patients aged <18 years, those included in clinical trials, and those who did not give their informed consent to the construction of the registry were excluded. The cardiologists recorded demographic, clinical and treatment variables. Using a questionnaire and a linear scale, they also reported subjective impressions of the severity of the disease and its resulting limitations.

After giving written consent and in the absence of the researcher, patients reported their perception of their condition in terms of its severity and their degree of disability. They completed two questionnaires: the Seattle Angina Questionnaire (SAQ),[10] specifically about angina pectoris and validated in Spanish, and the SF-12 (12-Item Short-Form Health Survey),[11] short form general quality of life questionnaire.

Justification of Sample Size and Method of Selecting Researchers

The sample size was calculated assuming maximal indifference (p=q=0.5) in relation to the therapeutic management of patients and, to achieve a data precision of 2.3% (normal 95% 2-tailed distribution), a sample of 1800 valid patients was calculated. Assuming a 20% loss to follow-up, we began with an initial sample of 2250 patients. To avoid individual selection bias or systematic errors, we set the number of patients per physician at 5. The preestablished number of cardiologists was 450, distributed proportionately in relation to the Spanish population. The study's scientific committee used the Spanish Society of Cardiology Clinical Cardiology Section census to select 50 coordinators from different centers, chosen in proportion to their distribution across the country. After special training, the 50 coordinators each recruited 8 cardiologists working in general cardiology outpatient clinics in their area. The 450 cardiologists selected were instructed that the data collection period was strictly limited and that patients had to be consecutive or—if this was not possible—chosen using random criteria such as being the first patient of the morning diagnosed with stable angina or a similar disorder, to avoid any selection bias toward young or cooperative patients.

The study was approved by the principal researcher's clinical trial committee and, later, in each participating center.

The protocol and inclusion variables were developed by the scientific committee. A company independent of the project management and researchers was responsible for designing and producing the data collection folder, guaranteeing researcher anonymity, and conducting the preliminary analysis of the results.

Statistical Analysis

Categorical variables are described as frequencies and percentages; continuous variables as mean (standard deviation) or median [interquartile range], according to the distribution. Categorical variables were compared with Fisher's exact test; dichotomous continuous variables with the Student *t*-test, and variables with >2 categories with ANOVA. If assumptions of applicability were not met, we used the nonparametric Mann-Whitney U or Kruskal-Wallis tests. Correlations between variables were studied with the Pearson or Spearman correlation coefficients if parametric applicability was not met. Researcher-patient concordance in the subjective perception of severity of angina and the degree of its associated disability was measured with the kappa statistic. Statistical significance was set at a two-tailed 5%. Data were analyzed with SAS 9.1.3 (SAS Institute Inc., Cary, North Carolina, United States).

RESULTS

A total of 419 cardiologists participated in the study and 2039 patients were enrolled; 15 failed to meet the inclusion/exclusion criteria and were excluded, leaving 2024. All patients were attended in cardiology outpatient clinics; 68% of these were