



Original article

Quality of life in patients with long-standing chronic non-pathological pancreatic hyperenzymemia



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ABSTRACT

Background: Chronic non-pathological pancreatic hyperenzymemia is a benign condition characterized by the persistent elevation of serum pancreatic enzymes without morphological alterations of the pancreas. No information is available regarding the quality of life of these subjects.

Aim: To evaluate the physical, mental and psychological status of these subjects using SF-12 Health Survey questionnaire and the 12-item General Health Questionnaire.

Methods: Fifty-one consecutive subjects having long-standing chronic non-pathological pancreatic hyperenzymemia (duration: 11.0 years, range 5–21) were studied. The Italian version of the SF-12 questionnaire and the General Health Questionnaire were compiled by the subjects studied.

Results: Regarding the SF-12 questionnaire, the physical component scores and the mental component scores were 50.1 ± 8.0 and 44.7 ± 11.7 , respectively and these figures were not statistically different from those of reference Italian population. Regarding the psychological status, seven subjects (13.7%) had non-psychotic-psychiatric problems. No statistical differences in the physical component score, mental component score and general health questionnaire were found between patients having non-familial or familial chronic non-pathological pancreatic hyperenzymemia.

Conclusions: Subjects with long-standing chronic non-pathological pancreatic hyperenzymemia had a quality of life no different from that of the Italian population. The explanation provided by the physician regarding the benignity of long-standing chronic non-pathological pancreatic hyperenzymemia is enough to reassure this type of patient.

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Introduction

Chronic non-pathological pancreatic hyperenzymemia (CNPH) is characterized by a chronic, abnormal increase in the serum concentrations of the pancreatic enzymes, including amylase, pancreatic isoamylase, lipase and trypsin, without abdominal pain of pancreatic origin and morphological alterations of the pancreatic gland at imaging techniques [1–3]. As for diagnosing irritable bowel syndrome, symptoms and their severity are only part of the picture, and other causes need to be ruled out. In similar manner, subjects having an increase in pancreatic enzyme serum levels

usually undergo a thorough diagnostic work-up prior to establishing the existence of CNPH. In fact, we have previously reported that at least 50% of subjects seen for asymptomatic increased levels of pancreatic enzymes may have non-pancreatic digestive diseases or may develop pancreatic diseases within five years after the first appearance of pancreatic hyperenzymemia [3]. Our data have been also confirmed by others who found that alterations of the pancreatic duct system at secretin-magnetic resonance cholangiopancreatography in subjects with chronic asymptomatic pancreatic hyperenzymemia can be observed in 50% of the subjects and are clinically relevant in 14.4% of cases [4]. A proper diagnosis of long-standing CNPH is also important because it reassures the subject having this biochemical anomaly that the syndrome is benign and that she/he does not have pancreatic disease [5,6]. Finally, the well-being of subjects with chronic diseases has been recognized as an important outcome of possible medical treatment and the impact of long-standing CNPH on the well-being of these

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subjects has never been assessed; thus, the aim of this study was to evaluate the physical, mental and psychological status of these subjects using the SF-12 and the GHQ-12 questionnaires.

Material and methods

All consecutive subjects having long-standing CNPH defined according to our criteria [3] and diagnosed at our Department were enrolled into the study from June 2013 to January 2014. CNPH was defined as persistent hyperenzymemia exclusively of pancreatic origin without pancreatic disease or non-pancreatic diseases [3]. A patient with persistent hyperenzymemia exclusively of pancreatic origin without pancreatic disease with at least one member of the family having the same enzyme alteration [3] was diagnosed as having familial hyperenzymemia. Subjects with macroamylasemia defined as the presence of an abnormal complex in which amylase is bound to globulin without manifesting pancreatic or extrapancreatic diseases were excluded from this study [3].

The study was approved by the Senior Staff Committee of the Department of Digestive Diseases and Internal Medicine of the University of Bologna and was carried out in accordance with the Helsinki Declaration of the World Medical Association. All study participants gave informed consent.

The Italian versions of the SF-12 Health Survey (SF-12) and the 12-item General Health Questionnaire (GHQ-12) were used for the purpose of the study.

The SF-12 questionnaire had previously been developed and tested on the Italian population in general [7]. It consists of 12 items which generate two summary scales capable of evaluating the physical and mental components of well-being. High scale scores of the SF-12 physical (PCS) and mental (MCS) component summaries represent a good quality of life. The Italian normative population tested with the SF-12 questionnaire included 61,434 subjects randomly sampled from the electoral lists, regardless of their health status [7]. The values of this group represented the average of the health-related quality of life of the general Italian population. The stratified mean \pm standard deviation (SD) values of the PCS-12 and the MCS-12 referring to 51 sex- and age-matched Italian subjects of this population were used as a normative group.

The GHQ-12 is an instrument commonly used for detecting psychiatric disorders, and it measures current mental health [8]; it has been translated into the Italian language and has been tested on the Italian population [9,10]. The scale asks whether the respondent has recently experienced a particular symptom or behaviour, and each item is rated on a four-point scale (less than usual, no more than usual, slightly more than usual or much more than usual). The score ranges from 0 to 12; subjects with a score from 0 to 4 have a greater than 80% probability of having non-psychotic psychiatric disorders, and they are generally considered cases of interest while those subjects with a score greater than 4 should be considered as not affected by non-psychotic psychiatric disorders [11].

All patients included in our study were fluent in the Italian language and the questionnaires were administered according to the recommendations suggested by the user manuals [7,12].

The sample size necessary for evaluating statistical differences between the mean of the study population and the normative group is reported in the Italian version of the manual [7]. In order to find 5 points of difference using the SF-12 questionnaire with an α level equal to 0.05, using a two-tailed t-test and a statistical power of 80%, 32 subjects are needed for the study.

The descriptive statistics applied were mean, standard deviation and range as well as absolute and relative frequencies. The Kolmogorov–Smirnov test was carried out to evaluate the distribution of the individual values of amylase and lipase; these data were not normally distributed even after log and arithmetic transformation;

thus, non-parametric tests were applied for these two parameters. Three-way ANOVA, one-way ANOVA and the Fisher exact test were applied where appropriate. The Mann–Whitney test was also applied to analyze the data regarding amylase and lipase serum activity. All statistical evaluations were carried out by running SPSS version 13.0 for Windows. Two-tailed P values less than 0.05 were considered statistically significant.

Results

Fifty-one consecutive subjects having long-standing CNPH (25 males and 26 females, mean age 56.7 years, range 22–90) were enrolled in the studies. The CNPH duration was 11.0 years with a range of 5–21 years. Twenty-nine subjects (56.9%) were light alcohol drinkers (less than 40 gr of pure alcohol per day) with a duration of alcohol drinking ranging from 9 to 60 years (mean \pm SD year alcohol drinking duration 35.5 \pm 13.4; 31 subjects (60.8%) were smokers with a duration of smoking ranging from 3 to 46 years (mean \pm SD year smoke duration 25.1 \pm 12.5). Regarding their educational level, four subjects (7.8%) had finished elementary school, 9 (17.6%) middle school, 24 (47.1%) had a high school diploma and 14 (27.5%) had a university degree. Regarding job status, 22 subjects were retired (43.1%) while 29 (56.9%) were still working.

The mean body mass index (BMI) of the population studied was 24.6 \pm 3.0 kg/m²; (mean \pm SD); in particular, according to the World Health Organization (WHO) criteria [13], 27 subjects (52.9%) had a normal weight (BMI between 18.5 and 24.9 kg/m²) and 24 (47.1%) were pre-obese (BMI between 25.0 and 30.0 kg/m²). Thirty-three subjects (64.7%) had arterial hypertension and they took 3 drugs on average for their illnesses. None of the subjects studied had undergone surgery during their lives.

Three subjects (5.9%) had a family history of pancreatic cancer and seven (13.7%) had at least one family member having CNPH. All subjects had undergone to at least one imaging examination the time of the first finding of increased serum values of serum pancreatic enzymes. All subjects had undergone abdominal ultrasonography, 26 (51.0%) contrast enhanced computed tomography, 28 (54.9%) magnetic resonance plus cholangio-pancreatography and 2 subjects (3.9%) endoscopic ultrasonography. Eight subjects (15.7%) had undergone one imaging study, 31 (60.8%) two imaging studies, 11 (21.6%) three imaging studies and only one (2.0%) four imaging studies. The results of all these imaging studies did not reveal any morphological alteration of the pancreatic gland in subjects with long-lasting CPNH.

Serum amylase activity (normal values less than 100 IU/L) at the time of the study was 364 \pm 414 IU/L (mean \pm SD) and serum lipase activity (normal values less than 60 IU/L) was 241 \pm 217 IU/L.

Both serum amylase and lipase activities were similar (amylase: $P = 0.073$; lipase: $P = 0.862$) in subjects having non-familial pancreatic hyperenzymemia (amylase 223 \pm 392 IU/L, lipase 241 \pm 217 IU/L) as compared to subjects with familial pancreatic hyperenzymemia (amylase: 618 \pm 490 IU/L, lipase: 234 \pm 233 IU/L). Regarding alcohol consumption, drinkers had amylase activity (327 \pm 435 IU/L) similar to that of non-drinkers (327 \pm 435 IU/L; $P = 0.154$) whereas serum lipase activity was significantly lower in drinkers (178 \pm 123 IU/L) as compared to non-drinkers (327 \pm 282 IU/L; $P = 0.047$). Smokers had amylase serum activity (348 \pm 456 IU/L) similar to that of non-smokers (387 \pm 350 IU/L; $P = 0.095$) whereas serum lipase activity was significantly higher in non-smokers (326 \pm 2850 IU/L) than in smokers (186 \pm 139 IU/L; $P = 0.043$).

Considering the BMI classes, patients having a normal BMI had serum amylase (447 \pm 484 IU/L) and lipase (281 \pm 273 IU/L) activity similar to that of pre-obese subjects (amylase: 270 \pm 300 IU/L;

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