

Assessment of chronic pain and access to pain therapy: a cross-sectional population-based study

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Background: Chronic pain (CP) has been shown as an important public health problem, and several studies emphasize the need to strengthen the health care and social systems to reduce its marginalization. This study aimed to: evaluate the epidemiology of CP in the general population in an Italian area; and assess the awareness of a specific law, unanimously approved in Parliament, which provides citizens the right to access pain management (Italian Law 38/2010).

Methods: A cross-sectional population-based study carried out during the spring of 2014 at Narni, Umbria, Italy. All the citizens residing in that area, aged >18, were enrolled in the study. Outcome measures were: prevalence of CP and therapies. The awareness of the Italian Law 38/2010 was also recorded.

Results: Data of 1293 questionnaires were analyzed. The prevalence of CP was 28.4%. In 51.5% of cases, pain was severe, with higher prevalence in females ($p < 0.001$). Moreover, pain was generally increasing with age ($p < 0.001$). The risk of suffering from severe pain was modeled using logistic regression. Significant predictors were female gender (OR 2.59; 95% CI: 1.77–3.79), living in an urban area (OR 0.63; 95% CI 0.45–0.88), and age (OR 1.06; 95% CI: 1.04–1.08). Among people with CP, 77.9% were receiving therapy; the proportion of individuals in therapy for severe pain significantly increased with age (OR 1.03; 95% CI: 1.02–1.05) and was smaller in individuals with light pain (OR 0.21; 95% CI: 0.07–0.66). The majority of subjects (61.9%) are not aware of the existence of a specific law stating their rights to receive pain management.

Conclusion: CP, at least in the rural part of the community investigated in Italy, is not perceived as a chronic disease in its own right. A socio-cultural transformation in patients and in the health care system seems necessary.

Keywords: cross-sectional study, chronic pain, palliative care, pain therapy, pain control

Introduction

Chronic pain (CP) is a major health care problem. It occurs at all ages and in any kind of population, and has been reported either in concomitance with other pathologies, or alone. CP should be looked at as a "chronic condition in itself", a disease in its own right.¹

Therefore, according to this definition, CP should be looked at as a chronic disease with characteristics and symptoms, which are mostly independent from the trigger disease/injury and with several consequences in terms of costs and morbidity/mortality. This definition of CP imposes a reflection for the health care systems worldwide considering that chronic diseases are the major cause of disability and death worldwide,³ and the capacity to prevent and treat chronic diseases has recently been assessed by the World

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Health Organization (WHO).^{2,4} From a public health perspective, CP has a major impact on quality of life, may cause other medical conditions, and imposes severe financial burden, at least in Europe. Nonetheless, in the common clinical practice, CP is often overlooked and undertreated with evident clinical, psychological, and socio-economic consequences.^{5,9,11,20} Marginalization of CP in the health systems deserves a robust effort in order to achieve “global access to pain control”.¹⁶ This requires a “cultural transformation” in how medical professionals, in general, understand and approach CP.²²

In the last few years, Italy has made some efforts to obtain such a change, simplifying the access to pain care and, at political level, demanding a better approach to patients with pain. Therefore, it would be necessary to understand how such efforts have modified the situation. At the moment, to the best of our knowledge, studies focusing on the epidemiology of CP in Italy are lacking.

On March 15th, 2010, Italy adopted the Law number 38 “Dispositions to guarantee access to Palliative Care and Pain Management”, (Italian Parliament; available from: <http://www.parlamento.it/parlam/leggi/100381.htm>; 2010) (Italian Law 38/2010). This law provides citizens the right to access palliative care and pain therapy, and compels the health care systems to create dedicated structures to achieve these goals. Moreover, the current model of CP management in Italy is centered on an important aspect of the patient–doctor relationship, based on the dignity and autonomy of the patient in the process of care. Nevertheless, the public awareness of this right has not been investigated so far.

We implemented a cross-sectional study, focusing on individuals aged over 18 years, in a small Italian city. This study aimed to: i) evaluate the epidemiology of CP in the general population in an Italian area; and ii) assess the awareness of the Italian Law 38/2010.

Material and methods

Study community

A cross-sectional study was carried out during the spring of 2014 in Narni, Italy, a municipality of 8790 inhabitants. The study covered both urban and rural areas. A questionnaire was mailed to all the citizens aged 18 and over (8140 the recipients of the questionnaire; participation rate 15%). The home addresses of the individuals were obtained from the Registry Office of the Municipality according to the most recent census of the population (2011).

We calculated the sample size needed to estimate the proportion of the population suffering from CP (18% in other epidemiological studies) with a 95% CI of absolute length

equal to 0.05, obtaining a sample size of 907 individuals. Pain was recorded on a scale between 0 and 10, and recoded into a 3-level variable as follows: (0–5), light pain; (5–7), moderate; and (7–10), severe.

The statistical analysis was performed in two steps. First, we assessed the univariate association between the presence of severe CP and each of the available predictors. To measure association between severe CP and risk factors, age was categorized based on empirical quartiles, while all other variables were intrinsically categorical. Standard chi-square test was used for these exploratory analyses.

Second, we implemented logistic regression models to predict the probability of severe CP, and, separately, the chance of pain reduction, and the proportion of individuals using therapy for CP; further, we modeled the proportion of individuals who were aware of the Italian Law 38/2010. Using regression models allowed us to measure the effect of covariates, adjusting for potential confounding. Different covariates have been used for different outcome variables. Age, gender, and civil status were always included. In the tables, we report logistic regression coefficients with their asymptotic standard errors and the associated two-sided *p*-value for the null hypothesis that the coefficient is equal to zero. To measure a possible departure from linearity of the effect of age, we repeated the analysis using restricted cubic splines with two internal knots. Using splines permits achieving any desired flexibility. The effect of age was then represented graphically. R statistical software (www.r-project.org) was used in data analysis. Statistical significance for all outcomes was set at $p < 0.05$.

Questionnaire

Questionnaires with different colors were used for people living in rural or urban areas. This was to simplify successive stratifications of the city's inhabitants from the ones living in the rural areas. The reason for this choice is justified by the possibility that the inhabitants of the countryside may have a different esteem and consideration on pain versus the inhabitants of the cities.¹⁴ The questionnaire was prepared with simple and easily comprehensible questions. It contained questions about pain experience during the last 3 months, localization of pain, duration and frequency of pain symptoms, ongoing therapy, and clinical outcomes. The questions evaluated the following items: intensity and site of pain (your pain is a continuous/chronic pain? yes/no; Which part of your body is usually affected by pain? joints/muscles/back/abdomen/pelvis/others; Please try to express how severe your pain can be: light/tolerable/moderate/severe/extremely severe/

unbearable); types of pain (pang/pin/dagger/weight/burn/electric shock); ongoing therapy and clinical outcome (how the treatment helps you to reduce the pain? highly/modestly/poorly, which drug[s] would you take to treat your pain?).

Lastly, we investigated the awareness of the interviewees about the Italian Law 38/2010 which provides citizens the right to access palliative care and pain therapy, and compels the health care system to organize the network for palliative care and pain management (Are you aware that there is a Law of the Italian Government, which guarantees access to pain therapy [Italian Law 38/2010]?). Checklists were also used to record the associated chronic diseases (ADs), such as diabetes, hypertension, cardiovascular diseases, asthma, and their therapies. All categories of pain treatments were carefully assessed.

Definition and grading

To detect individuals with CP and to grade CP itself, structured questions were used: experience, duration, frequency, localization, and characteristics of CP. To clearly define duration and frequency of CP, we used methods widely used in other epidemiological studies and in clinical settings.^{10,19} CP was defined as pain lasting for at least 3 months. CP severity was measured with a numeric scale ("no pain" = 0, to "the worst imaginable pain" = 10).

Ethics committee

The survey was anonymous and the questionnaire was completed by participants anonymously, no informed consent was required. The study was approved by the Regional Committee for Medical Research Ethics (Umbria, Italy).

Results

Participants

Data of 1293 participants were analyzed: 57.2% were females, 42.1% males. The median age was 58 years; 67.4% had a partner, 53% were from an urban area, and 34.5% had ADs (Table 1).

Prevalence of CP

The prevalence of CP was 28.4% and was lower in men than in women (males, 21%; females, 34.1%). Among all participants, a higher prevalence of CP was found in older people. Among participants suffering from CP, 51.5% reported severe pain, 42.8% reported moderate pain, and 4.4% light pain. The prevalence rates of severe pain increased with age. Among individuals who suffer from CP, 77.9% were receiving therapy. The prevalence of CP was not different in relation to the areas where they were living and the civil status (Table 1).

Table 1 Characteristics of the respondents in the study population (N=1293)

Variables	Number (%)
Gender, n (%)	
male	544 (42.1)
female	739 (57.2)
nr	10 (0.8)
Age, years	
mean (SD)	55.8 (18.4)
median (IQR)	58 (43–70)
nr (%)	47 (3.6)
Age groups, years, n (%)	
<44	326 (25.2)
44–58	313 (24.2)
59–70	313 (24.2)
>70	294 (22.7)
nr	47 (3.6)
Civil status, n (%)	
with a partner	872 (67.4)
single	391 (30.2)
nr	30 (2.3)
Residence area, n (%)	
urban	685 (53)
rural	608 (47)
CP, n (%)	366 (28.4)
males	114 (21.0)
females	252 (34.1)
CP according to age groups, n (%)	
<44	31 (9.5)
44–58	67 (21.4)
59–70	105 (33.5)
>70	150 (51.0)
CP according to civil status, n (%)	
with a partner	243 (27.9)
single	117 (29.9)
CP according to residence areas, n (%)	
urban	192 (52.3)
rural	175 (47.7)
Severity of CP, n (%) *	
light	16 (4.4)
moderate	157 (42.8)
severe	189 (51.5)
nr	5 (1.4)
Severe CP according to age groups, n (%) *	
<44	15 (48.4)
44–58	30 (44.8)
59–70	53 (51.0)
>70	87 (59.6)
Individuals with ADs, n (%)	
with ADs	446 (34.5)
no ADs	847 (65.5)
Therapies for CP, n (%) *	286 (77.9)
Therapies for ADs, n (%)	288 (22.3)
Awareness of Italian Law 38/2010	495 (38.1)

Note: * % computed among individuals with CP.

Abbreviations: IQR, interquartile range; CP, chronic pain; ADs, associated chronic diseases; nr, not reported.

Risk of severe CP

The following predictors were considered in the statistical analysis: area (urban vs rural), gender, age, and civil status. We used chi-square test to describe the association between the considered factors and the binary indicator of severe pain. For the exploratory analysis, age was categorized based on its quartiles. The risk of suffering from severe CP was higher in females than in males ($p<0.001$) and was found to be an increasing function of age ($p<0.001$), while no significant association with the other predictors was detected (Table 2). The univariate results, however, are likely to have been affected by severe confounding. For example, the partnership status was strongly associated with age, and the age structure was not the same in rural and urban areas. We improved our analysis by fitting a logistic model to jointly evaluate the effect of the selected predictors on pain. The OR associated with female gender was 2.62 (95% CI; 1.79–3.83) and that associated with living in an urban area was 0.63 (95% CI; 0.45–0.89). Having a partner did not appear to affect the risk of severe CP (Table 3). To achieve a higher flexibility, we included age (which is the only continuous predictor) by means of a natural cubic spline (Figure 1). No significant deviation from linearity was detected.

Therapies for CP and ADs

The analysis of prescribed drugs showed the following results: 46% of the individuals receive nonsteroidal anti-inflammatory drugs; 22% take paracetamol; 7% glucocorticoids; 3% weak opioids; 2% pregabalin; and 1% gabapentin; while 19% do not follow any therapy. As shown in Table 2, older people were more likely to be on a therapy ($p<0.001$), and females appeared to be more frequently receiving drugs also for ADs ($p=0.023$). For patients with CP we used a logistic regression to predict the proportion of individuals

receiving therapy for pain (Table 3), which significantly increased with age ($p<0.001$) and with the intensity of pain. To test linearity of age, we also modeled its effect by means of a natural cubic spline (Figure 1C, D). However, no significant deviation from linearity was detected. In Table 3, we considered individuals with CP who were currently receiving therapy for CP. We then defined the binary variable indicating whether the reduction of pain after the therapy was high, and predicted it using a logistic regression. As shown in Table 3, only age was a significant predictor ($p=0.035$).

Awareness about the Italian law regarding the right to access palliative care and pain therapy

Five years after its promulgation (March 15, 2010), the majority of individuals were not aware of the existence of that law (Table 1). The logistic regression for the proportion of individuals who were aware of the Italian law shows a strong association with residence in urban area, OR 1.52 (95% CI: 1.20–1.93) and with female gender, OR 1.31 (95% CI: 1.03–1.67), while neither civil status nor the presence of CP appeared to be associated with the awareness of the law (Table 4). By including age in the model through a 3-dimensional natural cubic spline, the fit displayed in Figure 1B shows that there is increasing awareness of the law until the age of 65–70 years, after which it decreases rapidly.

Discussion and conclusion

The need for pain awareness, as well as CP treatment, is a clear imperative, and access to pain control is currently grossly inequitable.^{17,23,25}

The present study shed light on the Italian scenario of CP as a non-communicable disease. Several surveys were

Table 2 Association between severe CP, therapies, and demographic variables

Variables	Severe pain (%)	p-value	Therapies for CP (%)*	p-value	Therapies for ADs (%)	p-value
Gender						
males	9		76		19	
females	19	<0.001	79	0.730	25	0.023
Civil status						
with a partner	14		77		25	
single	16	0.429	81	0.436	17	0.003
Residence area						
urban area	13		77		21	
rural area	17	0.075	79	0.592	24	0.177
Age groups (years)						
<44	5	ref	58	ref	6	ref
44–58	10	0.021	69	0.188	19	0.090
59–70	17	<0.001	80	0.008	33	0.012
>70	30	<0.001	85	<0.001	34	0.011

Notes: * % computed among individuals with CP. Bold figure indicates $p<0.05$.

Abbreviations: CP, chronic pain; ref, reference group; ADs, associated chronic diseases.

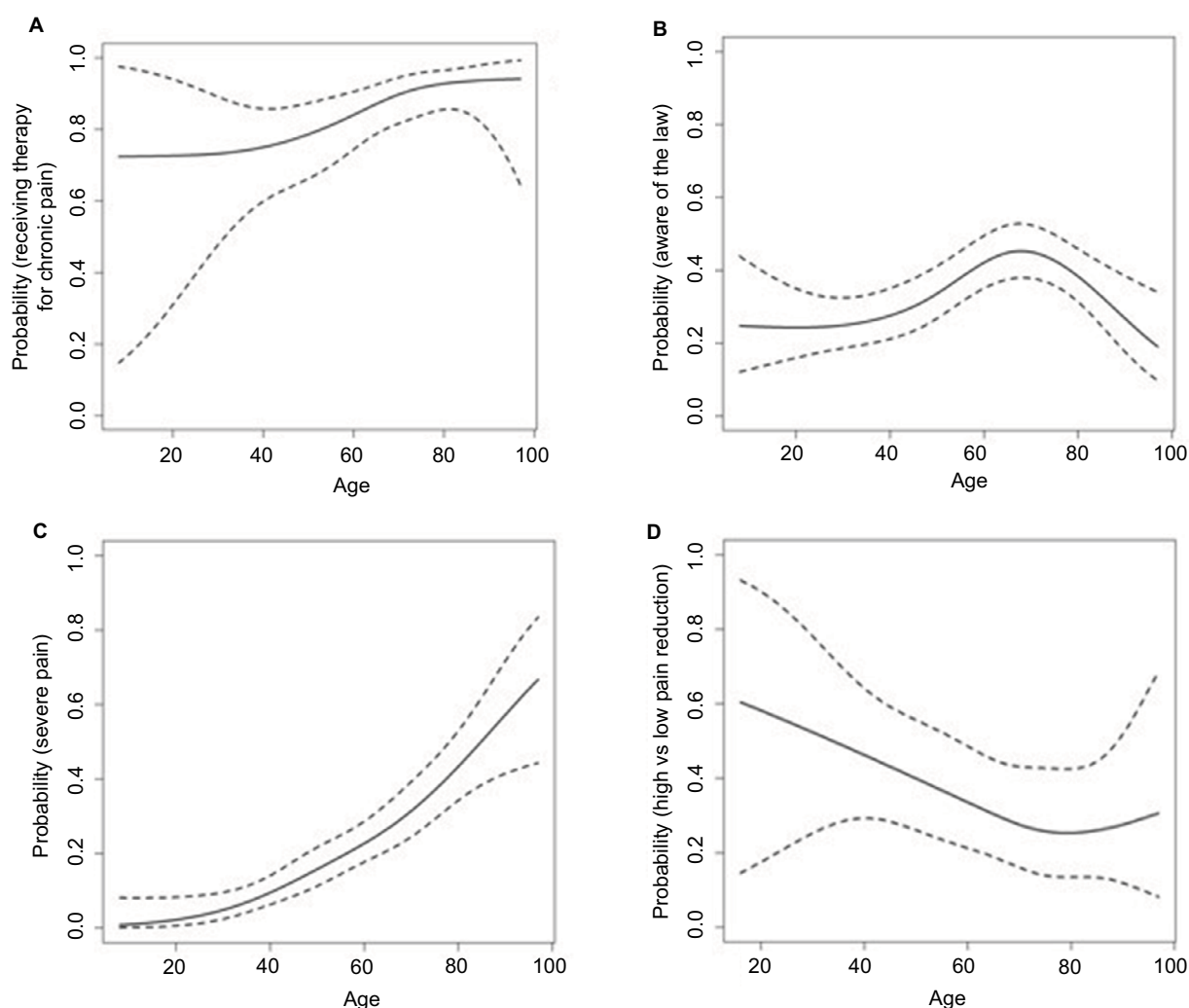


Figure 1 Estimated effects of age on different outcomes.

Notes: Effect of age estimated through a natural cubic spline with 3 degrees of freedom which has been used to include age in models summarized in Table 3, A, B, C, and in Table 4, D. Dashed lines represent pointwise 95% CI. (A) was adjusted for residence area, gender, civil status; (B–D) were adjusted for no associated chronic diseases and moderate/severe chronic pain. A significant ($p < 0.001$) deviation from linearity was found in (B), where the awareness of the law is increasing until the age of 65–70 years, and falls rapidly afterwards.

conducted in Europe to define the epidemiology of CP and Italy took part in one of them.⁵ Surprisingly, there have been no Italian surveys on general population, focusing on CP, until now.

In this study the findings of CP prevalence are in line with those of previous surveys on the general population.^{5,10} A considerable proportion of the study population had CP. This study indicates that 28% of this Italian sample population presented this condition. The prevalence of CP increased with age, which is one of the possible reasons why half of participants with pain were older than 58 years. To assess the clinical significance of CP, pain was graded by intensity, as done in other large surveys.²⁶ A striking result is that individuals reporting CP suffered most frequently from moderate-severe pain (80%). Age- and gender-specific rates had peculiar patterns. These results are in agreement

with epidemiological population study on gender and illness orientation.¹³ Women exhibit CP more frequently than men, and its rates increased with age. The response rate of females was higher than that of males, which may partly be explained by a higher prevalence of CP in females.

As assessed in the multivariate analysis, the probability of suffering from severe CP is higher in females than in males. Moreover, females with ADs are more frequently receiving therapy for these diseases. From an epidemiological perspective, we can present different evidence to explain such gender differences. Findings shown that women are more sensitive to perceive symptoms and have a better perceive symptoms as well as have a better self-perceived health status on non-communicable diseases.²⁴ On the other hand, from a heuristic epidemiological perspective, a fascinating explanation is biopsychosocial and arises from social and cultural differences.³

Table 3 Summary of the logistic regressions for different outcomes

	OR (95% CI)	p-value
Probability of severe chronic pain		
area = urban	0.63 (0.45–0.89)	0.008
gender = female	2.62 (1.79–3.83)	<0.001
civil status = single	1.11 (0.76–1.62)	0.587
age	1.05 (1.04–1.06)	<0.001
Probability of receiving therapy for chronic pain		
area = urban	0.67 (0.38–1.19)	0.168
gender = female	1.13 (0.63–2.03)	0.692
civil status = single	1.39 (0.74–2.62)	0.311
pain = light	0.21 (0.07–0.66)	0.007
pain = severe	1.71 (0.96–3.06)	0.070
age	1.03 (1.02–1.05)	<0.001
Probability of having high pain reduction		
area = urban	0.98 (0.57–1.67)	0.930
gender = female	0.78 (0.44–1.40)	0.404
civil status = single	1.02 (0.57–1.83)	0.940
no ADs	1.06 (0.61–1.81)	0.845
severe pain	0.88 (0.51–1.49)	0.626
age	0.98 (0.96–1.00)	0.035

Notes: Probability of receiving therapy for CP is computed using only subjects with CP. Probability of having high pain reduction is computed using only subjects with CP, receiving treatment. Bold figure indicates $p < 0.05$.

Abbreviations: CP, chronic pain; ADs, associated chronic diseases.

Table 4 Logistic regression for the proportion of individuals who are aware of the Italian Law 38/2010

	OR (95% CI)	p-value
area = urban	1.52 (1.20–1.93)	0.001
gender = female	1.31 (1.03–1.67)	0.028
civil status = single	1.00 (0.77–1.31)	0.986
chronic pain	0.94 (0.71–1.25)	0.686
age	1.01 (1.01–1.02)	<0.001

Note: Bold figure indicates $p < 0.05$.

Italians and other Mediterranean people are emotional and overreact to pain, compared with, for example, people from Northern Europe with higher tolerance to pain.²⁹

In contrast to earlier surveys,^{18,27} we could not identify marital status as a predictor of pain. We strive to elucidate if the residence area can influence differences in terms of prevalence and intensity of pain, and in medication intake. Based on logistic regression, the probability of suffering from severe pain was smaller among people living in urban areas ($p = 0.007$). Few studies have investigated the relationship between the area where subjects live and CP.^{6,7} In these studies, residence area indices are composite measures which include several indicators of socio-economic status.⁷ Overall, these studies indicated an inverse relationship between CP and area-level measures, with higher proportion and increasing pain in low-income areas, e.g., rural areas.⁸ These

studies, however, are mostly focused on musculoskeletal pain.²⁰ The significance of our study is that it permits drawing similar conclusions using the concept of CP as a disease per se, and not a symptom of other diseases.

About three quarters of people with CP reported current use of a medication to treat CP. We improved our analysis with a logistic regression model for the association between demographic factors and medications used for CP. The proportion of individuals receiving therapy for severe pain significantly increased with age and level of pain. Overall, only 30% of individuals reported high satisfaction rate on pain management. The chance of a significant pain reduction is a decreasing function of age.

The recognition of pain control and palliative care is an essential part of a health system and a priority of investments in health care worldwide. In 2010 the Italian Parliament passed a law (Italian Law 38/2010) which states the right to access palliative care and pain therapy. This law is framed in the novel initiatives of global health agenda as promoted by the WHO Secretariat to integrate palliative care and pain therapy, recognizing it as a human right.²⁸ The Italian law “Dispositions to guarantee access to Palliative Care and Pain Management” is based on the recognition that pain relief is a human right and to provide adequate treatment is an institutional duty. With this law, a network between hospital and home for the continuity of care was established, through the creation of multidisciplinary teams (general practitioners, physicians specializing in palliative care, psychologists, nurses) with specific guidelines for the health care professionals involved.

Less than half of the participants were aware of this law, with a higher proportion being female, older individuals, and living in urban areas. These results confirmed findings of other studies showing that gender and socio-economic level are associated with different perceptions of chronic illness, care seeking, and utilization of health care.¹ The proportion of those who are aware of this law is not significantly higher in individuals with CP. As recently assessed by the Harvard Global Equity Initiative–Lancet Commission on Global Access to Pain Control and Palliative Care (GAPCPC),¹² the enormous global divide in access to pain control and palliative care constitutes an ongoing crisis, and despite the Italian Law 38/2010 in Italy there is still not adequate awareness about CP.

Progress toward adequate palliative care and therapy for CP probably remains a challenge, at least for the moment. A socio-cultural transformation in both patients and physicians is mandatory, as invoked worldwide.⁸ A solution to this matter may be represented by a multilevel approach, bringing together researchers, stakeholders, practitioners,

and the general population. The key may be represented by strengthening health communication: patients with CP deserve better treatment and care, everywhere.

We have to acknowledge the following study limitations. First, our study is based on observational data, therefore we cannot be sure that unmeasured confounders did not contribute to the associations found. Second, a low participation rate (about 15%) was found. Participation rates are generally low in southern Europe, compared with Nordic Countries (e.g., Sweden, Finland) and are also associated with the outcomes the survey was designed to measure.¹⁵ Much higher participation rates, are observed in surveys on different diseases such as cancer, HIV, and cardiovascular diseases. We suppose that this finding could be related to a poor collective consciousness of CP in the general population, as confirmed by a poor awareness of the Italian law that states the right to access palliative care and pain therapy. This result suggests that the real incidence and prevalence of CP in Italy may be highly underestimated. Raising awareness represents an important step to investigate the epidemiology of CP, to prevent it, and to implement adequate treatments.

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Author contributions

RDG and SC developed the study concept and oversaw research. RDG, SC, and PF managed, checked, and analyzed data. RDG, SC, AP, and GV wrote the paper and prepared tables and figures. All authors contributed toward data analysis, drafting and revising the paper and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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