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Epidemiology and Severity of Prurigo Nodularis in Europe: A Literature Review with an Application to Italian Data

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ABSTRACT

Introduction: Prurigo nodularis is a chronic inflammatory skin disease with recent definition and relatively low prevalence. Information on prurigo nodularis, including its epidemiology, severity, and burden of disease, is still scanty.

Objectives: We sought to review and summarize recent quantitative data on prurigo nodularis in Europe and to estimate the burden of disease in Italy, with a focus on moderate-to-severe prurigo nodularis.

Methods: We conducted a systematic literature review of recent studies on the epidemiology of prurigo nodularis in Europe, using PubMed/MEDLINE and EMBASE. The study selection process was conducted independently by two reviewers. Articles focusing on the severity of prurigo nodularis were also searched (non-systematically), and relevant information was extracted. Synthetic results were combined to population data to derive the best estimate of the burden of prurigo nodularis in Italian adults.

Results: Five articles reporting data on incidence and/or prevalence of prurigo nodularis in European populations were identified. The prevalence of prurigo nodularis ranged from 6.5 to 111.0 cases per 100,000, with a median estimate of 32.7 cases per 100,000, the incidence ranging between 2.88 and 20 per 100,000 person-years. Five other studies reported data on the severity of prurigo nodularis, measured through pruritus scores, quality-of-life indexes and/or percentage of non-response to treatment. We estimated a total of 16,280 prevalent prurigo nodularis cases in Italy, of whom 6,073 had moderate-to-severe to very severe disease. Among the latter, 1,798 estimated cases were not controlled by standard treatments.

Conclusions: We retrieved and summarized recent epidemiological data on prurigo nodularis, evidencing a high burden of disease in Italy and other European countries.

Introduction

Prurigo nodularis (PN) is a chronic inflammatory skin disease characterized by highly pruritic, dome-shaped hyperkeratotic nodules, most commonly on extensor surface of arms and trunk [1,2]. PN is among the most frequent phenotypes of chronic prurigo, a polymorphous skin condition that is usually difficult to treat and is associated with a considerable burden on patients' quality of life [3,4]. Chronic prurigo was thoroughly defined and classified during 2016–2017, after decades of unclear and inconsistent use of the term "prurigo", which was applicable to many distinct clinical conditions [5,6], by expert members of the European Academy of Dermatology and Venereology (EADV) within the framework of the multicenter European Prurigo Project [6]. The new definition and terminology may help to improve the accuracy of diagnosis of this disease and may facilitate the development of treatments specifically targeted to each distinct subtype of chronic prurigo. In consideration of its recent definition and relatively low prevalence, information on PN, including epidemiology, severity and burden of disease, is still rather scanty. Following the European Prurigo Project results, however, the interest and investigation of several aspects of PN has increased in Europe as well as in the US, with improved scientific evidence promoted by the common disease definition and terminology. A number of recent studies examined clinical characteristics and disease burden [7-11], epidemiological aspects [12-15], the presence of comorbidities [16,17], and the management of PN [7,14], thus providing relevant up-to-date information on this disease. Furthermore, international guidelines for the diagnosis and treatment of chronic prurigo and PN were published in year 2020 [18].

Objectives

With the aim of summarizing recent quantitative data on PN, we conducted a literature review of disease epidemiology and severity in the European population. Furthermore, we tried to estimate the burden of disease in Italy, with a focus on moderate-to-severe PN cases, by applying European data to the Italian population setting.

Methods

On 22 February 2024, we systematically searched for studies on the prevalence and/or incidence of PN in Europe using PubMed/MEDLINE and EMBASE and following the indications of the PRISMA statement [19]. We explored epidemiological data published from 2017 onwards, i.e., after online publication of the landmark definition of chronic prurigo by the EADV study group [6]. Included were papers reporting original data on the prevalence and/or incidence of PN in Europe, whereas we excluded case-reports, case-series, and review articles, studies focused on other dermatological diseases (e.g., atopic dermatitis), those focused on PN but considering aspects other than its epidemiology, and those conducted outside of Europe. Figure 1 shows the flow diagram of the identification of literature studies and their selection process. The search string used in PubMed/MEDLINE focused on high-income European countries and was structured as follows: "(prurigo OR pruritus nodularis OR pruritus nodular OR nodular pruritus) AND (epidemiology[MeSH Terms] OR epidemiol* OR prevalence OR incidence OR cohort OR prospective OR retrospective OR cross-sectional OR registry OR real-world OR real-life OR observational) AND (italy OR germany OR uk OR united kingdom OR england OR france OR spain OR sweden OR denmark OR norway OR finland OR netherlands OR switzerland OR belgium OR austria OR ireland OR portugal)". The same terms and logic structure were used to conduct the search in EMBASE. The study selection process was conducted independently by two reviewers. Any disagreement in results between reviewers was discussed and resolved. Firstly, scientific articles were examined on the basis of title and abstract only, excluding papers clearly not relevant to the analysis (e.g., studies conducted on other continents or focusing on diseases other than PN or with aims unrelated to the epidemiology of disease). During this phase, after the selection based on exclusion parameters and deletion of duplicate articles identified in both PubMed and EMBASE, 34 papers were kept for further consideration. The scientific articles selected during the first step of the process were examined on the basis of their full text to identify whether epidemiological information on PN in Europe was present. During this step, 29 articles

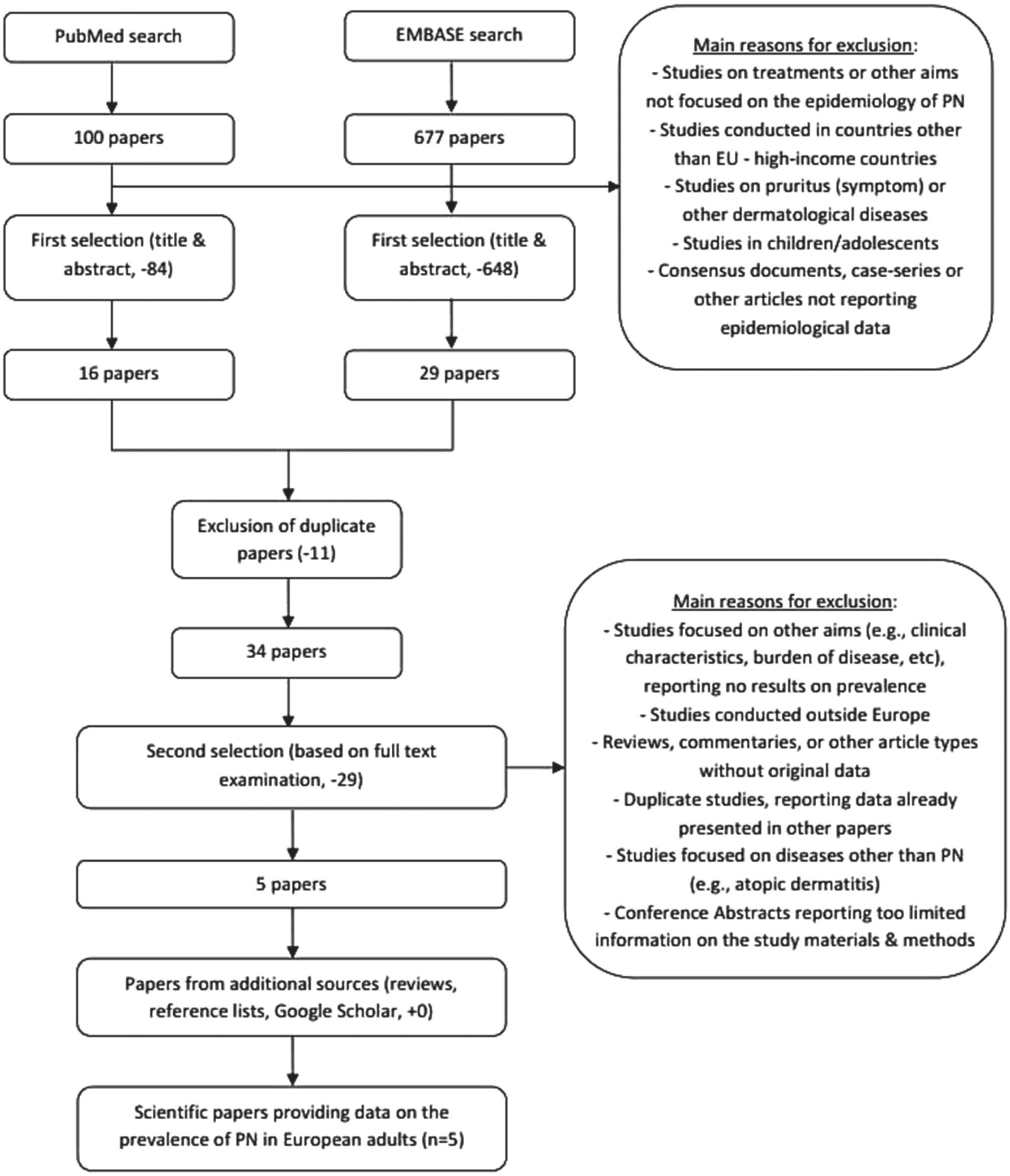

Figure 1. Flow diagram reporting the search and selection process of epidemiological articles on prurigo nodularis.

were excluded, mainly because they focused on other aims and did not report epidemiological data or were reviews or other article types providing no original data or focused on other skin disorders; two potentially relevant Conference Abstracts [20, 21] were excluded due to the limited available information on the materials and methods used in the corresponding studies. A total of five articles reported data on incidence and/or prevalence of PN in European populations and were thus included in our review. Additional searches for articles eventually missed by our strategy were performed by i) checking the lists of references of reviews, commentaries and of the epidemiological studies selected for inclusion; ii) exploring Google Scholar through ad hoc searches based on combinations of the keywords “prurigo nodularis”, “chronic prurigo”, “incidence”, “prevalence”, “epidemiology”, although no additional, relevant articles were retrieved. The articles selected for inclusion were subsequently examined in-depth to extract relevant information on period of investigation, geographic area, study design, age (all patients vs. adult patients only), data source, population, prurigo subtype (PN vs other prurigo), and main results on prevalence and incidence of disease. This was summarized in recapitulatory tables to facilitate the analysis and interpretation of findings. Assessment of the risk of bias was conducted using a tool specifically developed for prevalence studies [22]. The second part of the literature review, focused on the severity of

PN, was conducted in a non-systematic manner and is therefore informative but not exhaustive. With reference to PN severity measures, we included both observational studies that considered indexes of pruritus (e.g., Numerical Rating Scale [NRS], Verbal Rating Scale [VRS], Worst Intensity Numerical Rating Scale [WI-NRS], etc.) and quality of life (e.g., Dermatology Life Quality Index [DLQI], 5-Pruritus Life Quality [5-PLQ], etc.) as well as indirect/proxy measures of disease severity (e.g., response to treatment, treatment satisfaction, et cetera). Population data used to derive the best estimate of the burden of PN in Italian adults were retrieved from the Italian National Institute of Statistics (ISTAT, http://dati.istat.it/, last accessed on 20 February 2024) and refer to year 2023. The median prevalence estimate identified in the systematic review was used to calculate the number of prevalent cases in Italy. The proportion of moderate-to-severe cases was derived from a multicenter EU study involving 12 countries, including Italy (% of cases with NRS ≥7) [8] combined with a survey of clinical experts of PN (% of cases with ≥20 lesions) [5]. The proportion of patients with uncontrolled disease was derived by averaging specific results from two European studies [7,23].

Results

Table 1 gives the basic characteristics of the five studies retrieved that presented data on the epidemiology of PN in Europe. Two studies were conducted in Germany, based on different health insurance databases, and one each in Poland, France (Brittany Region), and England. All the analyses considered data from 2008 onwards, with three studies from Poland, France and England providing the latest prevalence estimates in the year 2018. The results on the prevalence and incidence of PN in Europe, extracted from the five studies retrieved, are shown in Table 2. All studies reported PN prevalence. Three studies also provided PN incidence data, while three provided additional data on other prurigo subtypes (International Classification of Diseases [ICD]-10: L28.2) and/or total prurigo (ICD-10: L28.1 and L28.2). The risk of bias was low-to-moderate in all studies. The prevalence of PN ranged from 6.5 cases per 100,000 in the Polish study to 111.0 per 100,000 in a German study. The median estimate was from the English analysis, which reported a prevalence of PN of 32.7 cases per 100,000. The incidence of PN was 2.88 per 100,000 in the English study and 20 per 100,000 in two German studies based on health insurance databases. Prevalence results from two recent Conference Abstracts—not considered in the systematic analysis due to scanty available methodological information—were in line with the reported prevalence range, i.e., they were equal to 14 per 100,000 in Denmark [21] and 88 per 100,000 in England [20]. We also collected findings on the severity of PN cases in recent European studies (Table 3). Three analyses were from an EU 12-country multicenter study and two others were from Germany. Various direct scores and indirect (proxy) measures of disease severity were used. In the multicenter EU study, 50.2% of patients had NRS ≥7 and 48.2% had VRS ≥3 points. Two analyses reported median WI-NRS equal to 6.0 (multicenter EU study) and 8.5 (Germany). As for quality of life, two studies addressed it using DLQI or 5PLQ and found that a consistent percentage of PN patients had moderate-to-severe impact on quality of life. More specifically, the median DLQI was 13.0 (95% confidence interval (CI): 11.0-15.5) in an analysis from Germany. The proportion of non-responders to standard PN treatments was similar in the multicenter EU study (28.7%) and in a German analysis (30.5%). In an additional Conference Abstract based on a French study of 141 cases, according to the 5-D itch scale score, 64.5% of PN patients had ≥6 itchy areas [24]. The estimation of the burden of PN in Italy on 1 January 2023 was obtained through an application of relevant European epidemiological information to the Italian adult population (Figure 2). We estimated a total of 16,280 prevalent PN cases, of whom 6,073 with moderate-to-severe or very severe disease according to itch intensity and number of lesions. Among the latter, 1,798 cases were estimated to have PN not controlled by standard treatments.

Conclusions

Our bibliographic review of European studies on PN available after the publication of a clear-cut disease definition in 2017 retrieved and summarized several greatly needed epidemiological data published recently. Findings on PN prevalence were heterogeneous among the studies, with a median estimate of 32.7 per 100,000 reported by an investigation from England, broadly consistent with other recent data from the US [13]. Such estimates, if confirmed by more stable future data, would place PN among rare diseases according to both the EU definition (i.e., any disease affecting no more than 1 person in 2,000) and the US Orphan Drug Act [25]. Incidence results also varied, ranging between 2.88 and 20 per 100,000 person-years. The review of studies on clinical characteristics of PN consistently showed a high impact of the disease, with a large proportion of cases reporting moderate-to-severe disease, high itch scores, and a major effect on patients' quality of life. Furthermore, about 30% of PN patients did not respond to the available treatments. Given these results, a total of over 16,000 prevalent PN cases are estimated in Italy, of whom around 1,800 with a high burden of disease that is not controlled by therapy. PN prevalence and incidence varied greatly among the studies taken into consideration, from 6.5 to 111.0 per 100,000, i.e., a 17-fold variation, for prevalence and from 2.9 to 20 per

Table 1. Main Characteristics of the Studies Reporting Data on the Epidemiology of Prurigo Nodularis in Europe.

Study Reference	Period	Area	Data source	Population	Notes
Ryczek et al., 2020 [30]	2016-18	Poland	National Health Fund (clinical activities) plus data from the University Hospital of Rzeszow	Polish population, i.e. about 38.5 M inhabitants	
Ständer et al., 2020 [31]	2012-15	Germany	German Statutory Health Insurance Database	About 2.8 M inhabitants	Comparison to patients with psoriasis
Augustin et al., 2021 [32]	2010-11	Germany	DAK-G Health Insurance Database	About 2 M inhabitants	Comparison to patients with pruritus
Misery et al., 2021 [14]	2009-18	Brittany (France)	French Healthcare Database and outpatient data from the Brest itch expert center	Not reported [a]	
Morgan et al., 2022 [12]	2008-18	England	Clinical Practice Research Datalink Aurum	The database covers about 40 M patients	

[a] Brittany has about 3.3 M inhabitants.

Table 2. Main Results on the Prevalence and Incidence of Prurigo Nodularis in Europe.

Study Reference	Age	Types of Prurigo Examined (ICD-10)	Prevalence per 100,000	Incidence per 100,000
Ryczek et al., 2020 [30]	All patients, including <18 y	L28.1 (PN) L28.1+L28.2 (PN + other prurigo)	2016: 5.82 2017: 5.85 2018: 6.52 2016: 9.04 2017: 8.69 2018: 9.26	Incidence was not available in this study
Ständer et al., 2020 [31]	All patients, including <18 y	L28.1 (PN)	111.0 Men: 93.1 [a] Women: 131.2 [a]	20
Augustin et al., 2021 [32]	Adult patients	L28.1 (PN) L28.2 (Other prurigo) L28.1+L28.2 (PN + other prurigo)	40 180 210	20 110 130
Misery et al., 2021 [14]	Adult patients	L28.1 (PN) L28.1+L28.2 (PN + other prurigo)	8.4 46.7	Incidence was not available in this study
Morgan et al., 2022 [12]	All patients, including <18 y	L28.1 (PN)	32.7 Men: 25.4 Women: 40.1	2.88

Abbreviations: ICD = International Classification of Diseases; PN = prurigo nodularis. [a]Adjusted for age

100,000 person-years, i.e., a 7-fold variation, for incidence. This large heterogeneity may be explained by a number of factors, including study design, data source (e.g., administrative vs clinical data source), and period of data recruitment, along with the real differences in risk of PN across European populations. Interestingly, US prevalence estimates were also heterogeneous across studies, ranging from 13 to 72 cases per 100,000 [15,26]. This evidence underlines the difficulties in extrapolating data for PN, even in the presence of clear clinical definitions. It is therefore hard to synthesize the results. The most important European findings are likely those recently provided by the English study from Morgan et al. [12]. In fact, the latter analysis was specifically aimed at filling the gap of epidemiological knowledge and was thus

Table 3. Severity Distribution of Cases of Prurigo Nodularis in Recent European Observational Studies.

Study Reference	Area	Type of Measure of PN Severity	Severity Level	Main Results	Notes
Gründel et al., 2020 [7]	Germany	Degree of response to treatment, measured as DPS change	Non-responder (Δ<30%) Weak responder (30≤Δ<50%) Good responder (50≤Δ<70%) Very good responder (Δ≥70%)	30.5% 5.2% 17.8% 46.5%	Main treatments used in the study were: antihistamines (32.3%) gabapentinoids (24.0%) immunosuppressants (22.8%)
Pereira et al., 2020 [8]	12 EU countries	Worst itch intensity in the past 24 h, assessed using NRS and VRS; impact of PN on QoL, assessed using 5PLQ	No itch (NRS=0) Low (NRS=1-2) Moderate (NRS=3-6) Severe (NRS=7-8) Very severe (NRS=9-10) Median NRS No itch (VRS=0) Low (VRS=1) Moderate (VRS=2) Severe (VRS=3) Very severe (VRS=4) Median VRS 5PLQ, median (IQR)	0.8% 9.2% 39.9% 32.1% 18.1% 7 (severe) 0.7% 15.7% 35.3% 31.8% 16.4% 2 (moderate) 2.4 (1.6-3.0)	
Pereira et al., 2021 [23]	12 EU countries	Satisfaction in the response to recent treatments (last 6 months)	No recent treatment Not satisfied Rather not satisfied Rather satisfied Very satisfied No treatment was effective:	9.8% 31.1% 25.8% 28.0% 5.3% 28.7%	Main treatments used were: emollients (84.0%) Topical steroids (51.7%) antihistamines (43.3%) UV therapy (20.4%) antidepressants (20.2%) immunosuppressants (17.2%)
Zeidler et al., 2021 [10]	Germany	WI-NRS (24h) AI-NRS (24h) DLQI Sleep hours lost	Median (95% CI) Median (95% CI) Median (95% CI) Mean (SD)	8.5 (8.5-9.0) 6.5 (6.0-7.0) 13.0 (11.0-15.5) 3.2 (2.0)	
Pereira et al., 2022 [11]	12 EU countries	WI-NRS (24h)	Median (IQR)	6.0 (4.0-8.0)	No significant differences between distinct Fitzpatrick skin types

Abbreviations: 5PLQ: 5-Pruritus Life Quality; AI-NRS: Average Intensity Numerical Rating Scale; CI: confidence interval; DLQI: Dermatology Life Quality Index; DPS: Dynamic Pruritus Score; IQR: inter-quartile range; NRS: Numerical Rating Scale; QoL: quality of life; SD: standard deviation; VRS: Verbal Rating Scale; WI-NRS: Worst Intensity Numerical Rating Scale.

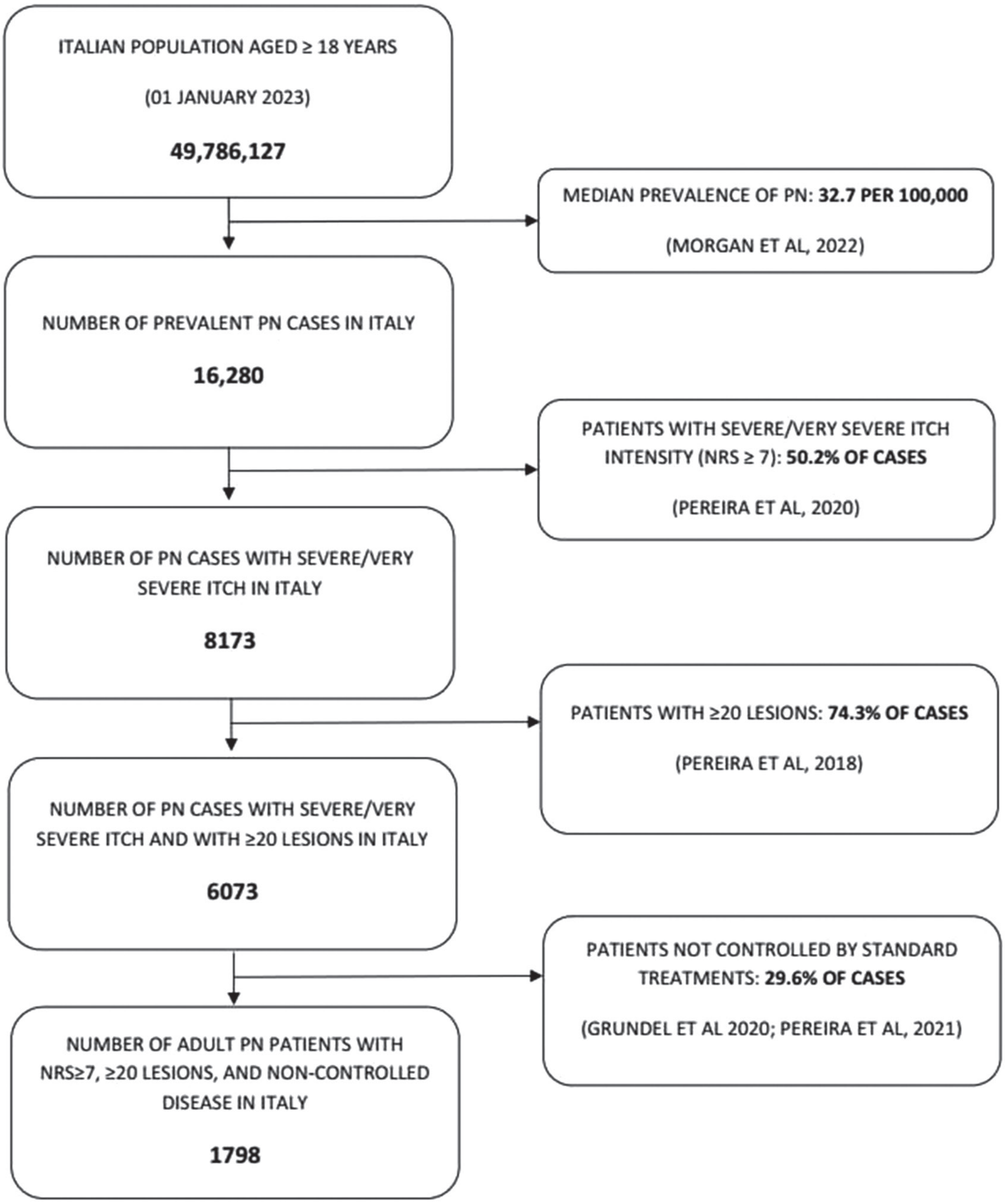

Figure 2. An application of European epidemiological information on prurigo nodularis to estimate the Italian burden of disease.

conducted using multiple (linked) data sources involving a large and representative population through a specific coding system. Furthermore, a robust methodology was applied, including several sensitivity analyses. This estimated a prevalence of 32.7 per 100,000 (which, of note, corresponds to the median European prevalence estimate), with a range of 22.4–69.8 per 100,000 in sensitivity analyses [12]. This information, being the most statistically robust, was therefore adopted in our calculation of the Italian burden of PN. Several data on the frequency distribution of severe PN cases derived from the multicenter cross-sectional study conducted in 12 countries by the European Prurigo Project study group [8,11,23], including more than 400 PN patients. According to this study, between 48% and 50% of patients (according to the rating scale used) present a high burden of PN [8]. An additional, relevant measure of disease severity is represented by the number of lesions. In a US survey of 231 PN patients, 90.6% of them reported 10 or more pruritic nodules [9]. On the other hand, no recent European observational study provided results according to this measure, and the only information derives from a survey of EADV physician experts (mostly from Europe) reporting that 74.3% of patients present 20 or more lesions [5]. The high burden of PN is also well represented by the calculation of quality of life indexes: a median DLQI of 13 points – indicating a very large effect of PN on most patients' life – was reported in a German study [10]. The impact on quality of life was somewhat more moderate in the European Prurigo Project

(5-PLQ median score of 2.4 points) [8]. With further reference to disease severity, two studies provided (proxy) information on the proportion of cases that are not controlled by treatment, showing similar findings (i.e., around 30% of patients are not controlled) [7,23].

The heterogeneous measures used to assess PN severity complicate quantitative summarization. Nonetheless, all indicators used in different studies consistently showed that a large proportion of patients have moderate-to-severe PN, with a considerable burden of illness. Limitations of our analysis are related to the large heterogeneity of epidemiological estimates and of the severity measures retrieved. This issue may also affect the estimation of the burden of disease in Italy, given the uncertainty of various measures. We tried to overcome this limit either by using median values or by combining the most reliable and comparable indexes. The overall analysis focused on European data alone. Relevant differences in the occurrence of PN, however, emerged across ethnic groups in a US study of over 900 PN patients, with African American patients reportedly at 3.4 times higher risk of PN than white patients [27]. Considering the different distribution of race and ethnic groups in the USA and Europe [28], along with the heterogeneity in the terminology and definition of PN [5,29], and in order to limit the (already high) heterogeneity of the results, we decided a priori to restrict the review to European populations. Furthermore, we excluded from the analysis all the papers published before 2017, i.e., before the release of the consensus definition of chronic prurigo [6]. This may have led to the exclusion of relevant studies that could have provided valuable insights, especially if consistent definitions were used. European data on the epidemiology of prurigo published before 2017 are, in any case, scarce, and the results should thus not be notably affected by the adoption of such exclusion criteria. On the other hand, the increasing scientific interest in PN in Europe since 2017 and the systematic review approach are among the strengths of the study. Moreover, although our estimation of the epidemiological numbers in Italy has several limitations, nonetheless it provides useful, currently lacking data to inform health policymakers and improve the overall management of PN at a public health level.

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