ORIGINAL ARTICLE

European academy of dermatology and venereology European prurigo project: expert consensus on the definition, classification and terminology of chronic prurigo

M.P. Pereira,[1] S. Steinke,[1] C. Zeidler,[1] C. Forner,[1] C. Riepe,[1] M. Augustin,[2] S. Bobko,[3] F. Dalgard,[4] J. Elberling,[5] S. Garcovich,[6] U. Gieler,[7] M. Gonçalo,[8] J.A. Halvorsen,[9] T.A. Leslie,[10] M. Metz,[11] A. Reich,[12] E. Şavk,[13] G. Schneider,[14] E. Serra-Baldrich,[15] H.F. Ständer,[16] M. Streit,[17] J. Wallengren,[18] K. Weller,[11] A. Wollenberg,[19] P. Bruland,[20] I. Soto-Rey,[20] M. Storck,[20] M. Dugas,[20] E. Weisshaar,[21] J.C. Szepietowski,[22] F.J. Legat,[23] S. Ständer,[1,*] for the EADV Task Force Pruritus group members[†]

[1]Department of Dermatology, Competence Center for Chronic Pruritus, University Hospital Münster, Münster, Germany
[2]Competence Center for Healthcare Research in Dermatology (CVderm), Institute for Healthcare Research in Dermatology and Nursing (IVDP), University Hospital of Hamburg-Eppendorf, Hamburg, Germany
[3]Moscow Scientific and Practical Center of Dermatovenerology and Cosmetology, Moscow, Russia
[4]Department of Dermatology and Venereology, Skåne University Hospital, Lund University, Malmö, Sweden
[5]Department of Dermatology, University Hospital Gentofte, Copenhagen, Denmark
[6]Institute of Dermatology, Catholic University of the Sacred Heart, Rome, Italy
[7]Justus Liebig University, Giessen, Germany
[8]Department of Dermatology, University Hospital and Faculty of Medicine, University of Coimbra, Coimbra, Portugal
[9]Department of Dermatology, Oslo University Hospital, University of Oslo, Oslo, Norway
[10]Department of Dermatology, Royal Free Hospital, London, UK
[11]Department of Dermatology and Allergy, Charité – Universitätsmedizin Berlin, Berlin, Germany
[12]Department of Dermatology, University of Rzeszow, Rzeszow, Poland
[13]Department of Dermatology, Adnan Menderes University, Aydın, Turkey
[14]Department of Psychosomatics and Psychotherapy, Münster University Hospital, Münster, Germany
[15]Department of Dermatology, Cutaneous Allergy Unit, Hospital Sant Pau, Universitat Autònoma Barcelona, Barcelona, Spain
[16]Dermatological Practice, Bad Bentheim and Department of Dermatology, Klinikum Dortmund GmbH, Dortmund, Germany
[17]Department of Dermatology, Kantonsspital Aarau, Aarau, Switzerland
[18]Department of Dermatology and Venereology, Skåne University Hospital SUS Lund, Lund University, Lund, Sweden
[19]Department of Dermatology and Allergology, Ludwig Maximilian University, Munich, Germany
[20]Institute of Medical Informatics, University of Münster, Münster, Germany
[21]Department of Social Medicine, Occupational and Environmental Dermatology, University of Heidelberg, Heidelberg, Germany
[22]Department of Dermatology, Venereology and Allergology, Wroclaw Medical University, Wroclaw, Poland
[23]Department of Dermatology, Medical University of Graz, Graz, Austria
*Correspondence: S. Ständer. E-mail: sonja.staender@uni-muenster.de

Abstract

Background The term prurigo has been used for many decades in dermatology without clear definition, and currently used terminology of prurigo is inconsistent and confusing. Especially, itch-related prurigo remains unexplored regarding the epidemiology, clinical profile, natural course, underlying causes, available treatments and economic burden, although burdensome and difficult to treat.

Objective To address these issues, the multicentre European Prurigo Project (EPP) was designed to increase knowledge on chronic prurigo (CPG). In the first step, European experts of the EADV Task Force Pruritus (TFP) aimed to achieve a consensus on the definition, classification and terminology of CPG. Additionally, procedures of the cross-sectional EPP were discussed and agreed upon.

Methods Discussions and surveys between members of the TFP served as basis for a consensus conference. Using the Delphi method, consensus was defined as an agreement ≥75% among the present members.

Results Twenty-four members of the TFP participated in the consensus conference. Experts consented that CPG should be used as an umbrella term for the range of clinical manifestations (e.g. papular, nodular, plaque or umbilicated types). CPG is considered a distinct disease defined by the presence of chronic pruritus for ≥6 weeks, history and/or signs of repeated scratching and multiple localized/generalized pruriginous skin lesions (whitish or pink papules, nodules and/or plaques). CPG occurs due to a neuronal sensitization to itch and the development of an itch-scratch cycle.

Conclusion This new definition and terminology of CPG should be implemented in dermatology to harmonize communication in the clinical routine, clinical trials and scientific literature. Acute/subacute forms of prurigo are separated entities, which need to be differentiated from CPG and will be discussed in a next step. In the near future, the cross-sectional EPP will provide relevant clinical data on various aspects of CPG leading to new directions in the scientific investigation of CGP.

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Conflicts of Interest

MPP, SS, CZ, CF, CR, MA, SB, FD, JE, SG, UG, JAH, TL, EŞ, GS, ES-B, JW, KW, PB, IS-R, MS, MD, FJL declare that they have no conflicts of interest. MG is advisor for Novartis.
MM has received honoraria as a speaker and/or advisor for Bayer, Beiersdorf, Menlo Therapeutics, Merz, Moxie, Nerre, Novartis, Pierre Fabre, Roche, Sanofi.
AR is investigator and/or advisor for Abbvie, Amgen, Eli Lilly, Janssen-Cilag, LEO Pharma, Novartis, Pierre Fabre Medicament, Regeneron.
HFS is investigator or advisor for AbbVie, Janssen, Novartis, Leo and Beiersdorf. MS is or has been an advisor of Almirall, Celgene, MSD, Novartis, Pfizer.
AW is investigator, lecturer or advisor for Almirall, Anacor, Astellas, Basilea, Beiersdorf, Bioderma, Celgene, Chugai, Galderma, Glaxo-Smith-Kline, Hans Karrer, LEO, L'Oreal, Maruho, MEDA, MedImmune, Merck-Sharp-Dohme, Merz, Novartis, Pierre Fabre, Pfizer, Regeneron, Sanofi, Sienna, Stiefel, Ziarco.
EW is investigator in clinical trials of Tigercat, Menlo Therapeutics, Trevi Therapeutics.
JCS is consultant and advisor for AbbVie, Celgene, Dignity Sciences, Leo Pharma, Novartis, Pierre-Fabre and Sandoz; investigator for AbbVie, Actelion, Amgen, GSK, Janssen, Merck, Novartis, Regereron and Trevi; speaker for AbbVie, Actavis, Astellas, Janssen, Leo Pharma, Novartis, SunFarm, Sandoz, Eli Lilly.
SST is investigator and advisor for Almirall, Astellas, Beiersdorf, Celgene, Chugai Pharma, Creabilis, Daiichi Sankyo, Dermasence, Galderma, Helsinn, Kiniska, Kneipp, Maruho, Menlo Therapeutics, Merz, Nerre, Novartis, Pierre Fabre, Sienna, Trevi Therapeutics, Ziarco, Vanda Pharmaceuticals.

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Introduction

Chronic pruritus has gained substantial research attention in recent years resulting in a more comprehensive understanding of this condition.[1] However, prurigo, which occurs along with chronic pruritus and presents with symmetrically distributed intensively itchy papules, nodules and/or plaques, remains relatively unexplored.[2] Prurigo is difficult to treat[3] and entails a high disease burden for the affected individuals.[2]

Introduced over 200 years ago by Robert Willian to describe itchy papules, the term prurigo has been used without clear criteria to name a variety of entities.[4] Due to the plethora of possible clinical presentations of prurigo conditions,[5] a multitude of terms (e.g. prurigo ferox, prurigo Hebra, prurigo nodularis Hyde, prurigo mitis and prurigo Besnier) has been associated with prurigo. Additionally, inflammatory dermatoses that are not primarily induced by pruritus have been named with prurigo-associated terms (e.g. prurigo actinica and prurigo pigmentosa) leading to confusion among dermatologists and other specialists.[4] There is thus need for an expert consensus on the definition and classification of prurigo-associated terms for a harmonized use of the terminology in dermatology.

Single-centre analysis indicated that prurigo has a common clinical appearance but potentially heterogeneous origin, arising from dermatological, systemic, neurologic or psychiatric diseases or resulting from a combination of these different conditions or from an unknown origin.[6,7] Atopy seems to play an important role, as estimates show that approximately half of the prurigo patients have an atopic disposition.[6] As prurigo is a rare medical condition, single-centre studies are not appropriate for providing robust data on various aspects of the disease. There is thus a need for a large multicentre study to gain insight into these matters. The multicentre cross-sectional European Prurigo Project (EPP) is designed to address these issues. Aims of the study were (i) to gather epidemiology data on the frequency and prevalence of prurigo in participating centres of involved countries, (ii) to establish a clinical profile of prurigo diseases, including its

†Further members of the Task Force Pruritus group: in Appendix 1.

demographic background, underlying causes, symptoms, associated comorbidities and disease burden, (iii) to survey currently used therapies and their effectiveness across European centres and (iv) to gain insight into the quality of life as well as the economic burden for the affected individuals. This study aims ultimately to provide further evidence on prurigo eventually leading to better treatment and care as well as to the development of management strategies by health authorities. The first step of the EPP was to achieve an expert consensus on the clinical definition, diagnostic criteria and terminology. The next step is to implement the consented definitions into daily practice of dermatologists and routine care of patients.

Materials and Methods

The Task Force Pruritus (TFP) of the European Academy of Dermatology and Venereology (EADV) met for the first time on 28 September 2016 at the 25th EADV Annual Meeting in Vienna. Here, the EPP was presented and considered a priority. A steering committee was formed to facilitate the project (M. Augustin, C. Forner, F. Legat, M. Pereira, C. Riepe, S. Ständer, S. Steinke, J. Szepietowski, J. Wallengren, E. Weisshaar, C. Zeidler). The steering committee prepared the scientific background including a discussion on the frame of the terminology, clinical images and questions of the cross-sectional study (September 2016 to January 2017). The first meeting of the EPP group aiming to achieve formal consensus on terminology and definition of prurigo was held on 3 February 2017, in Münster, Germany (Fig. S1).

Preconference survey

To facilitate the discussion during the consensus conference and based on previous extensive literature search[4] and a discussion within the steering committee, two preconference surveys were organized by the steering committee.

The first survey took place between 3 December 2016 and 19 December 2016 and was performed by Navigant Consulting Inc. and funded by Menlo Therapeutics Inc. It consisted of a total of 29 items focusing on various aspects of prurigo, including pathogenic concepts and classification. Members of the TFP as well as external experienced clinicians were invited to participate. In total, 30 respondents (22 TFP members, eight external clinicians) completed the survey. In this paper, we present the results regarding pathogenesis of prurigo and classification of prurigo as a disease.

Following a discussion on current and historical terms within the steering committee, a second survey on the understanding of the currently used terminology was performed among the TFP members. Participants were presented clinical images of patients selected from the Münster Center for Chronic Pruritus, Germany. Participants were asked to answer the question "Which term would you use in your daily routine?" and could select from the possible answers: 'prurigo nodularis', 'prurigo papulosa', plaque-type prurigo', 'prurigo', 'prurigo simplex', 'prurigo simplex subacuta', 'prurigo simplex acuta' and 'scratch-induced prurigo'. Additionally, by choosing the option 'other', participants were allowed to freely write the diagnosis they considered more appropriate. The survey was conducted in the period between 5 January 2017 and 19 January 2017 and was programmed by the Institute of Medical Informatics at the University of Münster (Germany) using the software LimeSurvey. In total, 39 TFP members (all task force members) responded; of these, 32 participants completed the survey (Fig. 1).

Consensus conference

All members of the TFP were invited to participate in the consensus conference with the aim of achieving consensus on definitions of the terms related to prurigo. At the beginning of the meeting, participants introduced themselves. An independent chair, Bettina Pfleiderer, MD, Professor for Radiology at the University of Münster, moderated the conference. In the first part, an overview on the historical development, existing terms and results of the surveys were presented and discussed. In the second part, a consensus of the terminology was pursued using the Delphi method.[8] Consensus was defined as an agreement of 75% or more of the present members. Each definition was discussed in plenum, and amendments were made before voting. For each item, participants could vote anonymously 'Yes', 'No' or 'Abstain' via a televoting system (turning point used for presentation; local audience response system for voting). If consensus was not reached, there were further discussions and amendments, followed by a second vote.

After a consensus on the definition of prurigo was reached, the protocol and detailed questions to be answered by patients in the planned upcoming cross-sectional EPP study were discussed. Consensus on this matter was obtained using the Delphi method. Questions needing adjustments and/or those which could not be discussed during the meeting were agreed upon using a postmeeting paper-based Delphi method (8 March 2017 to 15 March 2017; Fig. 1).

Role of the industry

To follow the scientific discussion, several companies were invited. Members of Menlo Therapeutics Inc., Menlo, USA, Galderma International, La Défense, France and Kiniska Pharmaceuticas, Wellesley, USA, joined the consensus conference and two of them (Menlo and Galderma) provided an unrestricted grant to the University Hospital Münster, Department of Dermatology, Münster. These participants had no influence on the consensus process at any time. All financial transactions (e.g. reimbursement of travel costs of TFP members) were processed through the finance department of the Department of Dermatology, Münster.

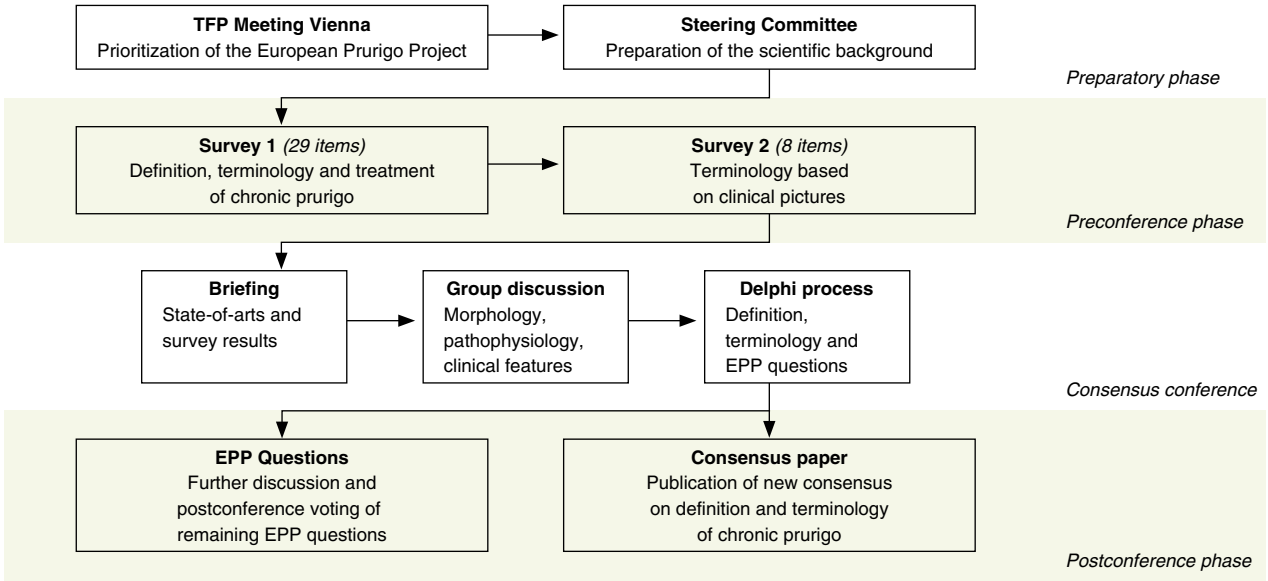

Figure 1 Flow chart of the consensus process in the European Prurigo Project.

Results

Preconference survey

In the first preconference survey, experts considered that chronic pruritus leading to prolonged scratching is essential in the pathogenesis of prurigo. Additionally, there was a consensus that prurigo is a disease. Prurigo nodularis or prurigo are terms used most regularly in clinical practice and teaching by respondents. The second survey revealed that the use of the terms varied across experts. Prurigo and prurigo nodularis were the most accepted terms while a proposed new term *scratch-induced prurigo* was not a popular response and was rejected. In free text sections, participants suggested *chronic prurigo* as a term in five of seven questions.

Consensus conference

A total of 25 participants (24 dermatologists, one specialist for psychosomatics and psychotherapy) from 12 countries participated in the consensus conference (Fig. S1). Of these, one abstained to vote, because being a specialist for psychosomatics and psychotherapy this participant did not feel qualified enough to vote on the clinical definition and terminology of prurigo (in total, 65% of all TFP members attended the meeting and voted).

Prevoting discussion During the debate prior to the voting, based on the results of the survey, the term prurigo was discussed, and the typical morphological elements were defined. It was agreed that prurigo is characterized by papules, nodules and/or plaques induced by scratching due to chronic pruritus. The underlying aetiology of pruritus cannot be discerned by the clinic, and some patients develop prurigo whereas others do not, despite having the same underlying aetiology for the pruritus. All TFP members agreed that a novel terminology should be simple and include the aspects of chronic pruritus and scratching into the definition. It was agreed to focus on defining chronic prurigo types and to put aside the definitions of acute/subacute prurigo. It was agreed that defining prurigo as chronic should be based mainly on the clinical presentation and not on

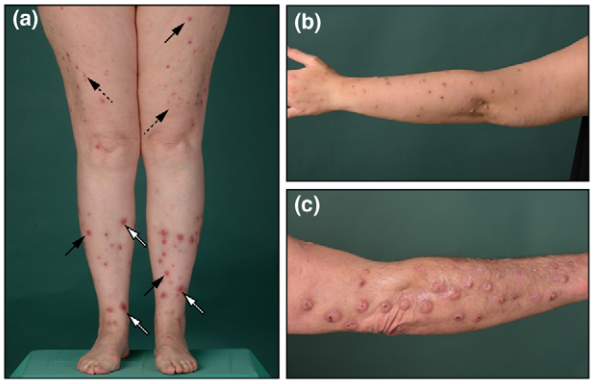

Figure 2 Clinical presentations of chronic prurigo. (a) 58-year-old female patient with an atopic disposition showing chronic prurigo of papular (dashed arrows), nodular (black arrows) and umbilicated (white arrows) type. (b) Chronic prurigo – papular type. (c) Chronic prurigo – nodular type.

the duration of the condition. The term 'chronic prurigo' (CPG) was suggested as an umbrella term for chronic prurigo conditions, because this term reflects the presence of chronic pruritus (≥6 week duration)[9] and the development of prurigo lesions. As this term includes all the manifestations of the disease, it is appropriate to refer to patients who present with more than one type of CPG (Fig. 2a). Finally, the terms 'pruritic' and 'pruriginous lesions' were differentiated. While 'pruritic' refers to the itchy nature of the lesion, 'pruriginous' refers to an elevated lesion (papule, nodule or plaque).

Delphi process A vast majority of the participating members considered prurigo a distinct disease (83%, Table S1) and agreed on 'chronic prurigo' as an umbrella term including the variants of prurigo as papular (Fig. 2b), nodular (also known as prurigo nodularis Hyde, Fig. 2c), plaque and umbilicated prurigo and other prurigo manifestations (92%). Consensus was also achieved regarding the core symptoms of CPG, namely the presence of chronic pruritus (≥6 weeks),[9] history and/or signs of repeated scratching (e.g. excoriations and scars) and the localized or generalized presence of multiple pruriginous lesions (75%). All members consented on the proposed definition of pruriginous lesions as 'excoriated, scaling and/or crusted papules and/or nodules and/or plaques, often with a whitish or pink center and hyperpigmented border'. Further consensus was reached on associated criteria for CPG (signs, symptoms, function, emotion and pathophysiology). Based on these voting results, CPG was defined as 'a distinct disease defined by the presence of chronic pruritus and multiple localized or generalized pruriginous lesions (Table 1). CPG occurs due to a neuronal sensitization to itch, i.e. an amplification of pruritic signaling in the peripheral and central nervous system,[10] and the development of an itch-scratch cycle (Fig. 3). CPG can be of dermatological, systemic, neurologic, psychiatric/psychosomatic, multifactorial or undetermined origin'. All voting members agreed on this definition (Table S1).

Discussion

In this consensus conference, a novel terminology of pruritus-related prurigo was developed and agreed among European experts. This new definition has several implications; one is that it clarifies that the expert group considers CPG as a disease. In the past decades, there was much debate on the nature of CPG and still no clear biomarker has been identified that explains the pathophysiology. However, it can be deduced from the comprehensive clinical experience of the involved experts that independently of the aetiology of the underlying pruritus, predisposed patients with chronic pruritus and prolonged scratching develop specific and easily to diagnose pruriginous lesions which have a similar appearance across patients. It is a common experience that from the clinical picture of pruriginous lesions observed in CPG patients, the underlying aetiology or trigger factors cannot be defined and a similar diagnostic work up is necessary in every patient. In contrast to chronic pruritus, there is no evidence that the initial underlying aetiology has an influence on the clinics, severity or course of CPG. The experts agreed on the concept that the itch-scratch cycle is a critical event promoting neuronal sensitization leading to CPG (Fig. 3). In other words, the presence of CPG should prompt a search for the underlying aetiology of chronic pruritus but this can be considered just as trigger of CPG. Once established, CPG necessitates an own therapeutic approach and does not resolve if the underlying aetiology is cured or treated (Fig. 3).

Another implication is the use of the novel terminology. The term CPG has already been used previously in the literature[11] condensing in one term the various presentations of CPG. The experts agree to this concept. Although CPG can present with a wide range of manifestations, the authors consider that these entities belong to the same disease sharing common (obligatory) core symptoms and (optional) associated criteria (Table 1). The best-known type of CPG is prurigo nodularis. Looking into the literature, this term was used to name different types of CPG including the papular and nodular types. Also, as some patients present with different prurigo lesions simultaneously, the umbrella term CPG has the advantage to avoid artificial separations. Additionally, the different clinical manifestations may represent different stages of the disease. Often papular prurigo evolves into nodular prurigo, which in turn may evolve into plaque prurigo. The authors consider it unreasonable to use different terms for each stage of the disease. Thus, the experts recommend the use of an umbrella term is a prerequisite to bring clarity and propose implementing this new terminology in dermatology to facilitate communication in clinical routine, clinical trials and scientific work.

There are still open issues related to other diseases using the term prurigo. There was a discussion among experts regarding the spectrum of the so-called prurigo simplex – acute and subacute. It was noted that there is no clear definition of these two terms. There was a general agreement that CPG should be separated from these diseases. In future discussions, the terms acute and subacute prurigo simplex should be clarified.

Now that the terminology of CPG was agreed upon, the future cross-sectional EPP study can be initiated. Patients will be identified from databases of the clinical centres and asked to participate. So far, centres from 18 different European countries form the EPP agreed to participate. In the second part of the consensus meeting, the wording of the questions to be included in a patient electronic survey that will form the basis of the study has been discussed and formulated. The questionnaire will be divided into subsections, including general information (demographics, comorbidities, atopic disposition, current presence of pruritus and/or pruriginous lesions), clinical profile (pruritus intensity, concomitant sensory symptoms, quality of life and the underlying disease leading to CPG), treatment and economic burden to the affected individuals.

Table 1 Definition and diagnostic criteria of chronic prurigo (CPG)

Parameter	Term	Comment
Definition	Chronic prurigo (CPG) is a distinct disease defined by the presence of chronic pruritus and multiple localized or generalized pruriginous lesions. CPG occurs due to a neuronal sensitization to itch and the development of an itch-scratch cycle. CPG can be of dermatological, systemic, neurologic, psychiatric/psychosomatic, multifactorial or undetermined origin.	
Diagnosis	Chronic prurigo (CPG)	• Umbrella term for all stages and manifestations of CPG. • `Chronic` points to chronicity as an important part of the pathophysiology (peripheral and central neuronal sensitization)
State	Disease	Indicates an own state and distinction from the underlying aetiology
Core symptoms (Major criteria)	(1) **Chronic pruritus (≥6 weeks)** (2) **History and/or signs of repeated scratching** (e.g. excoriations and scars) (3) **Localized or generalized presence of multiple pruriginous* lesions**	• All core symptoms must be present to make a diagnosis of chronic prurigo. • Pruritus must be present and should be the initial sign. • Localized: an area such as the lower leg or lower arm. Initial presence of singular lesions does not fulfill the diagnostic criteria.
Range of Manifestations	(1) Papular type (2) Nodular type (3) Plaque type (4) Umbilicated type	Patients may present with one or more than one clinical manifestation of chronic prurigo. It is sufficient to diagnose the patients as chronic prurigo without mentioning the subtype.
Associated criteria (Frame the disease in more detail)	(1) **Signs** • Pruriginous lesions are distributed on areas of the skin accessible to scratching • Pruriginous lesions are usually symmetrically distributed • Normal or lichenified skin between pruriginous lesions • Other scratch-induced lesions may be associated: e.g. excoriations and scars • Face and palms are rarely affected • Pruriginous lesions are persistent (2) **Symptoms** • Pruritus precedes development of skin lesions • Pruritus might be accompanied by burning, stinging, pain and other sensations • Signs of chronicity: continuous pruritus of high intensity, alloknesis, hyperknesis, spreading of pruriginous skin lesions (3) **Function** • Impaired quality of life • Sleep loss due to disease • Days of absence from work • Obsessive-compulsive behaviour (4) **Emotions** • Depression • Anxiety • Anger • Disgust • Shame • Helplessness (5) **Pathophysiology** • Neuronal sensitization towards itch induced by chronic pruritus and development of a chronic itch-scratch cycle • Aetiology of chronic pruritus might be of dermatological, systemic, neurological, psychiatric/psychosomatic, multifactorial aetiology or idiopathic • Presence of other specific skin lesions may point to a concomitant skin disease	

*Definition of pruriginous lesion: Excoriated, scaling and/or crusted papules and/or nodules and/or plaques, often with a whitish or pink centre and hyperpigmented border.

Conclusion

The first consensus conference of the EPP provided a simple and consistent definition and terminology of CPG, which should be implemented in the future to harmonize communication in the clinical routine and scientific work. The multicentre cross-sectional EPP study shall provide clinically relevant data on various aspects of CPG in Europe, which is much needed for this rare but burdensome and often refractory medical condition. With the expected information on the nature and course of CPG gathered from the different countries across Europe, we will be

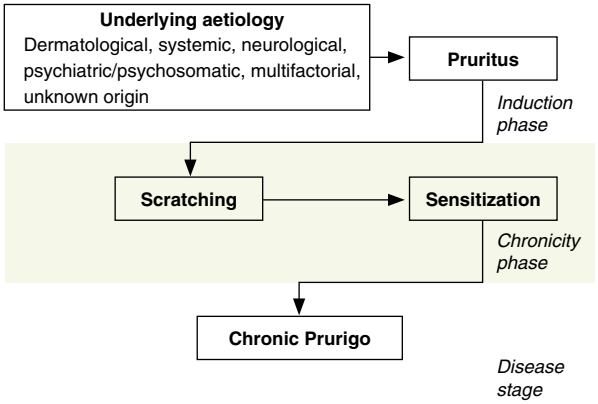

Figure 3 Evolution of chronic prurigo. Different etiologies might trigger pruritus (induction phase), which leads to scratching. With time, this leads to sensitization processes (chronicity phase) and the development of papules, nodules, plaques and/or umbilicated lesions (disease stage). The clinical picture is depending on scratching but not on the initial aetiology.

able to follow new directions in the scientific investigation of CPG as well as in new treatments for this impairing disease.

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Appendix 1

E. Brenaut[a], A.W.M. Evers[b], N. Kluger[c], J. Kupfer[d], J. Lambert[e], A. Lvov[f], L. Misery[a], A. Mittal[g], K. Nordlind[h], E. Tschachler[i]

a. Department of Dermatology, University Hospital of Brest, Brest, France.
b. Department of Health, Medical and Neuropsychology, Institute of Psychology, Leiden University, Leiden, The Netherlands.
c. University of Helsinki and Helsinki University Central Hospital, Departments of Dermatology, Allergology and Venereology, Meilahdentie 2, PO Box 160 FIN-00029 HUS, Finland.
d. Justus Liebig University, Giessen, Germany.
e. Department of Dermatology, University Hospital of Antwerp, Antwerp, Belgium.
f. Moscow Scientific and Practical Center of Dermatovenerology and Cosmetology, Moscow, Russia.
g. Department of Dermatology, Venereology and Leprosy, RNT Medical College, Udaipur, Rajasthan, India.
h. Dermatology and Venereology Unit, Department of Medicine, Karolinska University Hospital, Solna, Sweden.
i. Department of Dermatology, Medical University Vienna, Austria.

Supporting information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Member group on the consensus conference in February 2017.
Table S1. Results of the Delphi process on the terminology of prurigo.