UNMET MEDICAL NEED OF PRURIGO NODULARIS

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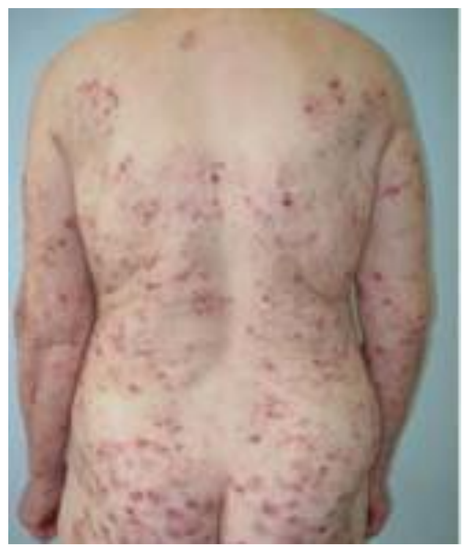
INTRODUCTION

The severity and chronic nature of itch of the dermatological condition prurigo nodularis (PN) **drastically impacts quality of life** (QoL) and there is **no currently approved, effective treatment.** Despite its severity, the prevalence of PN is unknown. To evaluate unmet medical need we will estimate the prevalence and assess the impact of PN on QoL



OBJECTIVES

- Estimate the prevalence of PN
- Summarise the impact of PN on quality of life

MATERIALS AND METHODS

Prevalence: the German claims database **WIG2 Benchmark** covers 4.5 million enrolled patients. *Incident cases* with PN were identified in 2012 among 2.7m enrolees at 1/1/12. To ensure that cases were new, any patients with code of PN in the previous two years were excluded. Furthermore, all patients had to have a second code for PN in a later quarter; this removes those with working diagnoses and ensures high specificity. Using the median age at diagnosis we estimated the life-expectance of these patients. Given the chronic nature of PN, life-expectancy therefore represents the duration of PN. The prevalence is thus the product of incidence and the median duration of PN

Quality of life: a broad literature search was conducted: from 730 publications on PN 11 provide some data on QoL or severity

RESULTS

Prevalence

In 2012, the Benchmark database provided 186 new diagnoses of PN out of 2.7 million enrolees giving an incidence of 0.68/10,000 person-years.
Median age at diagnosis was 59 years. Assuming a life-expectancy of 24 years, prevalence is 16.3/10,000.

***Table 1**: Epidemiological data on prurigo nodularis in Germany*

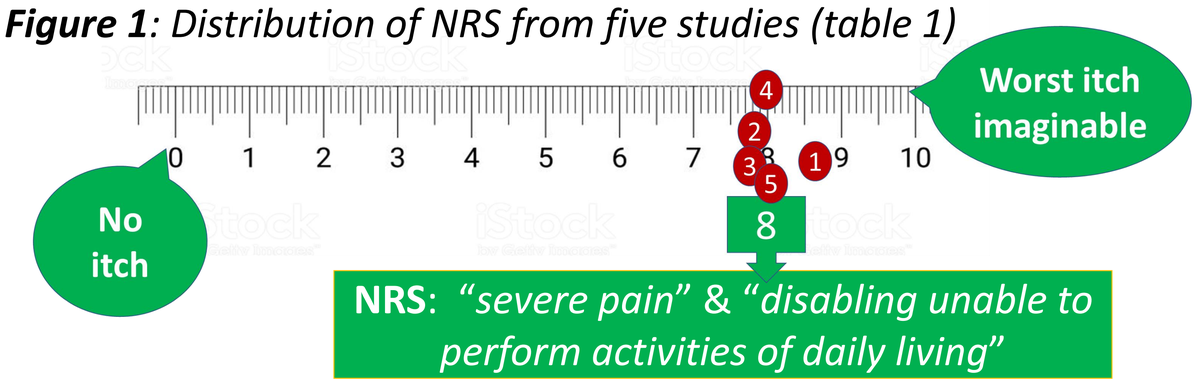
	Result
Study population*	2,736,276
New cases in 2012	186
Incidence	**0.68/10,000**
Median age at diagnosis	59
Life-expectancy	24 years
Prevalence	**16.3/10000**

**at 1/1/12*

Quality of life

Four observational studies and one clinical trial provided suitable quantification of severity or QoL (table 2). The Numerical Rating Scale (NRS) in these PN patients (0: no itch; 10: worst itch) ranged from 7.8 to 8.7 (figure 1)

***Figure 1**: Distribution of NRS from five studies (table 1)*



A recent study of PN (Brenaut) reported an **EQ-VAS** of 57.4 and was the third worst skin disease in terms of QoL and showed a DLQI (dermatologic life quality index) of 12.4 (>11: "large impact") and a **suicide ideation rate of 15% due to PN**

***Table 2**: Impact of prurigo nodularis on quality of life: NRS and VAS (10="worst itch imaginable)*

	key in fig.1	Year	N	NRS*	VAS†
Mollanazar	*1*	2016	35	8.7	
Pereira	*2*	2018	30‡	7.8	
Stander	*3*	2019	96	7.6	8
Iking	*4*	2013	108	8	8
Hammes	*5*	2011	22	8	

**numerical rating scale; †visual analgue scale; ‡physician responders*

CONCLUSIONS

- An NRS of 8 implies "disabling, unable to perform activities of daily living" and the reported DLQI corresponds to a **"very large" impact on QoL**.
- This quantifies the narrative of experts that PN "dramatically impairs patients' quality of life" and is a "heavy burden" which may affect **16/10,000 people**.
- Given the impact on patient life, **there is an unmet need for effective treatment**.

References: Mollanazar NK et al. *J Am Acad Dermatol*, 2016, 842-843; Pereira MP, et al. J Eur Acad Dermatol Venereol. 2018 Dec;32(12):2224-9; Stander S, et al. *J Am Acad Dermatol*. 2019 May;80(5):1395-1402; Iking, et al. *JEADV* 2013, 27, 550–7; Hammes S et al *J Eur Acad Dermatol Venereol*. 2011 Jul;25(7):799-803; Brenaut E, et al. *J Eur Acad Dermatol Venereol*. 2019 Jan;33(1):157-162