

## ORIGINAL ARTICLE

# Prevalence of rosacea in the general population of Germany and Russia – The RISE study

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## Abstract

**Background** There is an unmet need for general population-based epidemiological data on rosacea based on contemporary diagnostic criteria and validated population survey methodology.

**Objective** To evaluate the prevalence of rosacea in the general population of Germany and Russia.

**Methods** General population screening was conducted in 9–10 cities per country to ensure adequate geographic representation. In Part I of this two-phase study, screening of a representative sample of the general population (every fifth person or every fifth door using a fixed-step procedure on a random route sample) was expedited with use of a questionnaire and algorithm based on current diagnostic criteria for rosacea. Of the subjects that screened positive in the initial phase, a randomly selected sample (every third subject) then underwent diagnostic confirmation by a dermatologist in Part II.

**Results** A total of 3052 and 3013 subjects (aged 18–65 years) were screened in Germany and Russia respectively. Rosacea prevalence was 12.3% [95%CI, 10.2–14.4] in Germany and 5.0% [95%CI, 2.8–7.2] in Russia. The profile of subjects with rosacea (75% women; mean age of 40 years; mainly skin phototype II or III, majority of subjects with sensitive facial skin) and subtype distribution were similar. Overall, 18% of subjects diagnosed with rosacea were aged 18–30 years. Over 80% were not previously diagnosed. Within the previous year, 47.5% of subjects had received no rosacea care and 23.7% had received topical and/or systemic drugs. Over one-third (35% Germany, 43% Russia) of rosacea subjects reported a moderate to severe adverse impact on quality of life.

**Conclusion** Rosacea is highly prevalent in Germany (12.3%) and Russia (5.0%). The demographic profile of rosacea subjects was similar between countries and the majority were previously undiagnosed.

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## Conflicts of interest

J. Tan, M. Berg, H. Schöfer, and E. Araviiskaia have been investigators, advisors and speakers for Galderma; J. Tan and M. Berg have been consultants for Galderma; H. Schöfer has been an advisor and speaker for Medigene, speaker for Meda, GSK/Stiefel, and Abbott; E. Araviiskaia has been an advisor and speaker for L'Oreal, La Roche Posay, Vichy, Bioderma, Pierre Fabre, Uriage, Glenmark, GSK/Stiefel and speaker for Merck Sharp & Dohme, Bayer Health Care, Mertz. F. Audibert and N. Kerrouche are full-time employees of Galderma R&D SNC.

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## Introduction

Rosacea is a chronic, inflammatory skin disorder comprising multiple signs and symptoms.<sup>1</sup> Diagnostic criteria are clinical and have been defined by the National Rosacea Society Expert

Committee (NRSEC), to comprise primary (flushing, non-transient erythema, papules and pustules and telangiectasia) and secondary features (burning or stinging, plaques, dry appearance, oedema, ocular manifestations, peripheral location and phyma-

tous changes).<sup>2</sup> The presence of one or more of the primary features with a central distribution is indicative of rosacea.<sup>2</sup> Rosacea can be divided into four subtypes of erythematotelangiectatic (ETR), papulopustular (PPR), phymatous (PR) and ocular rosacea. Patients can present with more than one subtype, but ETR and PPR are mutually exclusive.

Prior reports of rosacea prevalence range from <1% to 22%.<sup>3–18</sup> This wide variance, however, may be due to shortcomings in case finding and study design.<sup>7</sup> These studies, primarily conducted in Europe<sup>3,5,6,8,16–19</sup> and the United States,<sup>9–11</sup> largely comprised phototypes I to III. Most studies collected data from dermatologist practices or outpatient hospital dermatology clinics and even the studies conducted in broader populations had limited generalizability due to the target population studied (e.g. working population)<sup>3,5,18</sup> and/or geographical limitations (e.g. only one location).<sup>6,13,15–17</sup> Furthermore, some studies did not include the ETR subtype<sup>5,19,20</sup>, which may be more prevalent than PPR.

This study aimed to determine the prevalence of rosacea based on general population screening followed by confirmatory diagnosis by dermatologists in two European countries.

## Materials and methods

This was a multicenter, interventional, cross-sectional study conducted in Germany and Russia. Cities were selected to ensure adequate geographic representation of the respective countries. The study was approved by the local ethics committees and all data were managed in accordance with the local data privacy regulations. All subjects randomized to attend the dermatologist provided informed consent.

In Part I, a target of 3000 consenting subjects aged 18–65 years old were interviewed in the street (Germany) or at their home (Russia) using a fixed-step procedure on a random route sample (every 5th person or every 5th door). A quota sampling structure based on gender and age (census data from the German Federal Statistics Office and the Russian Federal Statistics State Service) was used to obtain a representative sample of the general population according to the region. For example, if a female subject was needed to match the quota, every fifth person would be contacted until a woman was encountered. Interviewers were non-medical professionals trained to follow a neutral predefined script to prevent selection bias. Subjects were administered a rosacea screening instrument (Rosascreen) to assess signs and symptoms of rosacea (with representative photographs), skin phototype, socio-demographic items, facial dermatoses and treatment history.

Rosascreen is comprised of a subject questionnaire and an algorithm for rosacea case finding.<sup>21</sup> Subjects were screen positive if they had at least one of the following: rhinophyma; central facial persistent erythema; facial warmth/stinging/burning for darker phototypes (i.e. IV, V and VI); previous rosacea diagnosis. Papules/pustules and ocular symptoms were not included in the algorithm due to their high prevalence in conditions not associated

with rosacea (such as acne vulgaris and conjunctivitis respectively). The questions were developed by two dermatologists (JT and MB), using the NRSEC diagnostic criteria translated into layman's language, to detect primary and characteristic features of rosacea. It was pilot tested on subjects with and without rosacea for optimization of sensitivity, specificity and clarity. Prior to implementation in this study, it was tested on a small sample of people in Germany and Russia for comprehension and acceptability.

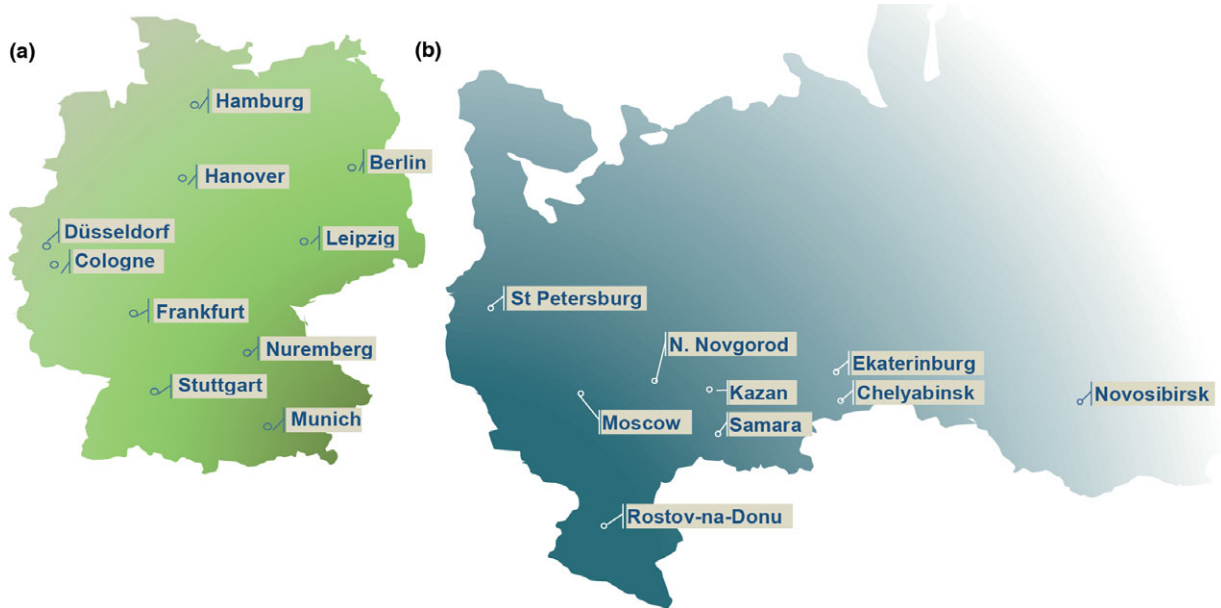
In Part II, a randomly selected population of screen-positive subjects attended a dermatologist visit (every third subject was invited until the planned number of subjects had been recruited) for diagnostic confirmation of rosacea. Information about skin care, skin characteristics, comorbidities, features of rosacea and severity of symptoms were obtained to verify or reject the diagnosis of rosacea and identify subtypes. All randomly selected subjects completed the Dermatology Life Quality Index (DLQI) questionnaire.<sup>22</sup> For those with a confirmed diagnosis, information on disease history was also collected.

Sample size calculations were based on the expected precision of the prevalence estimate accounting for variability from combining Parts I and II of the study. This calculation resulted from the product of a binomial probability law by a hypergeometric probability law. Assuming a prevalence of rosacea between 2% and 10%, a sample size of 3000 interviewed subjects in Part I and 150 subjects in Part II, the 95% confidence interval (CI) would range from 0.5–1.8%. Increasing the number of subjects visiting dermatologists would not have led to a meaningful improvement in precision.

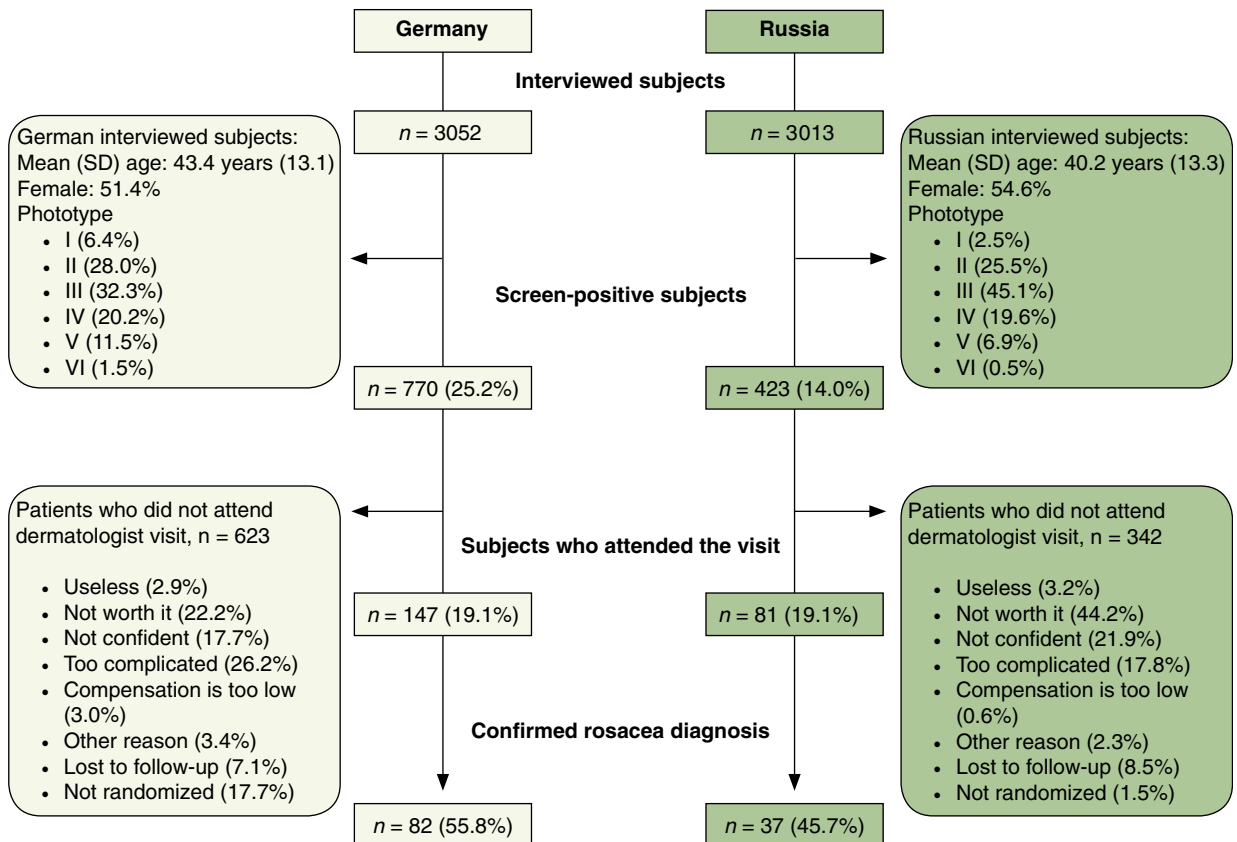
Statistical analysis was carried out using SAS software version 9.2 (SAS Institute Inc., Cary, USA). Screen-positive subjects who attended dermatologist consultations were compared to those who did not attend using a stepwise logistic regression procedure starting with all factors selected from univariate analyses. A raw estimate of prevalence was first obtained by multiplying the percentage of screen-positive subjects in Part I by the percentage of subjects with confirmed rosacea in Part II in each subcategory, defined by the combination of factors found significant in the logistic model. The variance was estimated using the variance of the product of two variables. The adjusted prevalence of rosacea was obtained by the weighted sum of all raw estimates with 95%CI (to estimate precision) using the squared weighted sum of variances.

## Results

Population surveys were conducted in 10 German cities from September 2013 to March 2014 and in nine Russian cities from November 2013 to February 2014 (Fig. 1). Of the 3052 subjects interviewed in Germany and 3013 in Russia, a total of 770 subjects (25.2%) in Germany and 423 (14.0%) in Russia were screen positive using the screening algorithm (Fig. 2 and Table 1). Screen-positive subjects were representative of the general population for age and gender. Persistent central facial erythema was the dominant criterion for initial selection (see Table 1).



**Figure 1** Location of the screening sites in Germany (a) and Russia (b).



**Figure 2** Disposition of subjects in Germany and in Russia.

**Table 1** Proportion of subjects presenting with the screening criteria for rosacea (several screening criteria could be found in the same subject)

Screening criteria (n,%)	Interviewed subjects		Screen-positive subjects	
	Germany (N = 3052)	Russia (N = 3013)	Germany (N = 770)	Russia (N = 423)
Central facial persistent erythema	704 (23.1)	343 (11.4)	704 (91.4)	343 (81.1)
Thickened skin on the nose	63 (2.1)	53 (2.5)	63 (8.2)	53 (12.5)
Prior diagnosis of rosacea or acne rosacea	61 (2.0)	19 (0.6)	61 (7.9)	19 (4.5)
Dark phototype (IV–VI) associated with facial warmth, stinging and/or burning	82 (2.7)	53 (1.8)	82 (10.6)	74 (17.5)

Following randomization of the screen-positive subjects, 147 (19.1%) in Germany and 81 (14.0%) in Russia attended confirmatory dermatologist visits. The planned sample size of 150 subjects was not reached in Russia as many screen-positive subjects refused to participate in Part II. The most common reason given for non-participation was that it was not worth it as their skin problem was not serious/disturbing (22.2% in Germany and 44.2% in Russia) (see Fig. 2).

Of subjects attending the dermatologist visit, rosacea was confirmed for 82 subjects (55.8%) in Germany and 37 subjects (45.7%) in Russia (Fig. 2). For the remaining subjects, alternate diagnoses comprised: no evident facial skin disease (39.1% Germany, 22.7% Russia); acne vulgaris (26.6% Germany, 56.8% Russia); seborrheic dermatitis (12.5% Germany, 38.6% Russia); perioral dermatitis (12.5% Germany); and facial dermatitis (11.4% Russia). Strict application of NRSEC criteria of the signs symptoms recorded by the dermatologist would have increased the number of subjects with rosacea to 90 (61.2%) in Germany and 46 (56.8%) in Russia.

Adjusted (for significant differences between screen-positive subjects in Parts I and II) rosacea prevalence was 12.3% [95%CI, 10.2–14.4] for Germany and 5.0% [95%CI, 2.8–7.2] for Russia (Table 2). Adjusted prevalence for the ETR subtype was 9.2% for Germany and 4.0% for Russia (see Table 2).

Demographics of rosacea subjects with a confirmed diagnosis were similar in Germany and Russia (Table 3). Overall, the majority (74.8%) were female, mean age was 41.8 years, skin

**Table 2** Adjusted prevalence of rosacea and rosacea subtypes in the general population of Germany and Russia

	Germany	Russia
Adjusted prevalence (%; [95%CI])	12.3% [10.2–14.4]	5.0% [2.8–7.2]
Rosacea subtypes (%; [95%CI])		
Erythematotelangiectatic	9.2% [7.2–11.2]	4.0% [1.8–6.2]
Papulopustular	3.1% [2.0–4.2]	0.9% [0.4–1.3]
Phymatous	0.5% [0.0–0.9]	0.2% [0.0–0.5]
Ocular	0.8% [0.2–1.5]	0.4% [0.1–0.7]

Subjects could have more than one subtype but erythematotelangiectatic and papulopustular subtypes were mutually exclusive.

**Table 3** Characteristics of subjects with confirmed rosacea per country and overall

Characteristics	Germany (N = 82)	Russia (N = 37)	Overall (N = 119)
Age			
Mean (SD), years	42.8 (11.8)	39.5 (11.4)	41.8 (11.8)
Age category n (%)			
<30	14 (17.1)	7 (18.9)	21 (17.6)
30–39	21 (25.6)	13 (35.1)	34 (28.6)
40–49	18 (22.0)	9 (24.3)	27 (22.7)
50–59	26 (31.7)	8 (21.6)	34 (28.6)
> 60	3 (3.7)	0 (0.0)	3 (2.5)
Gender n (%)			
Females	61 (74.4)	28 (75.7)	89 (74.8)
Skin phototype (Fitzpatrick) n (%)			
I	5 (6.1)	5 (13.5)	10 (8.4)
II	44 (53.7)	14 (37.8)	58 (48.7)
III	32 (39.0)	15 (40.5)	47 (39.5)
IV	1 (1.2)	3 (8.1)	4 (3.4)
V	0 (0.0)	0 (0.0)	0 (0.0)
VI	0 (0.0)	0 (0.0)	0 (0.0)
Sensitive facial skin n (%)			
Yes	62 (75.6)	31 (83.8)	93 (78.2)
Previous diagnosis of rosacea n (%)			
No	66 (80.5)	33 (89.2)	99 (83.2)
Yes	16 (19.5)	4 (10.8)	20 (16.8)
If yes, age of onset			
0–9 years	5 (31.3%)	1 (25.0%)	6 (30.0%)
10–19 years	2 (12.5%)	1 (25.0%)	3 (15.0%)
20–29 years	5 (31.3%)	2 (50.0%)	7 (35.0%)
30–39 years	1 (6.3%)	0 (0.0%)	1 (5.0%)
40–49 years	2 (12.5%)	0 (0.0%)	2 (10.0%)
≥ 50 years	1 (6.3%)	0 (0.0%)	1 (5.0%)
Family member(s) diagnosed with rosacea n (%)			
Missing data	17 NA	6 NA	23 NA
Yes	33 (50.8)	17 (54.8)	50 (52.1)
Subtype of rosacea n (%)			
Erythematotelangiectatic	57 (69.5)	23 (62.2)	80 (67.2)
Papulopustular	25 (30.5)	11 (29.7)	36 (30.3)
Phymatous	4 (4.9)	2 (5.4)	6 (5.0)
Ocular	6 (7.3)	7 (18.9)	13 (10.9)

phototype was mainly II or III (88.2%) and most (78.2%) had facial skin sensitivity. Less than one-fifth (16.8%) were previously diagnosed, 45% of whom reported onset of symptoms before the age of 20 years (Table 3). Overall, 23.7% of subjects had received topical and/or systemic medications within the previous year (see Fig. 3).

Relative distribution of rosacea subtypes was similar between countries except for the ocular subtype, which was twice as frequent in the Russian as the German population (18.9% vs.

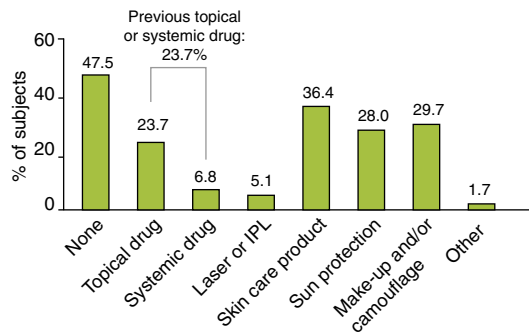
7.3%) (Table 3). Overall, 67.2% of subjects had ETR subtype, 30.3% PPR subtype and 5.0% phymatous subtype. Severity of symptoms were similar in German and Russian subjects, except for flushing, which was mostly mild in German subjects (68.4%) whereas it was moderate (50.0%) or mild (47.2%) in Russian subjects (Fig. 4).

The order of onset of clinical features was flushing first (77.0%), erythema second (61.9%), and papules and pustules appeared third (50.0%).

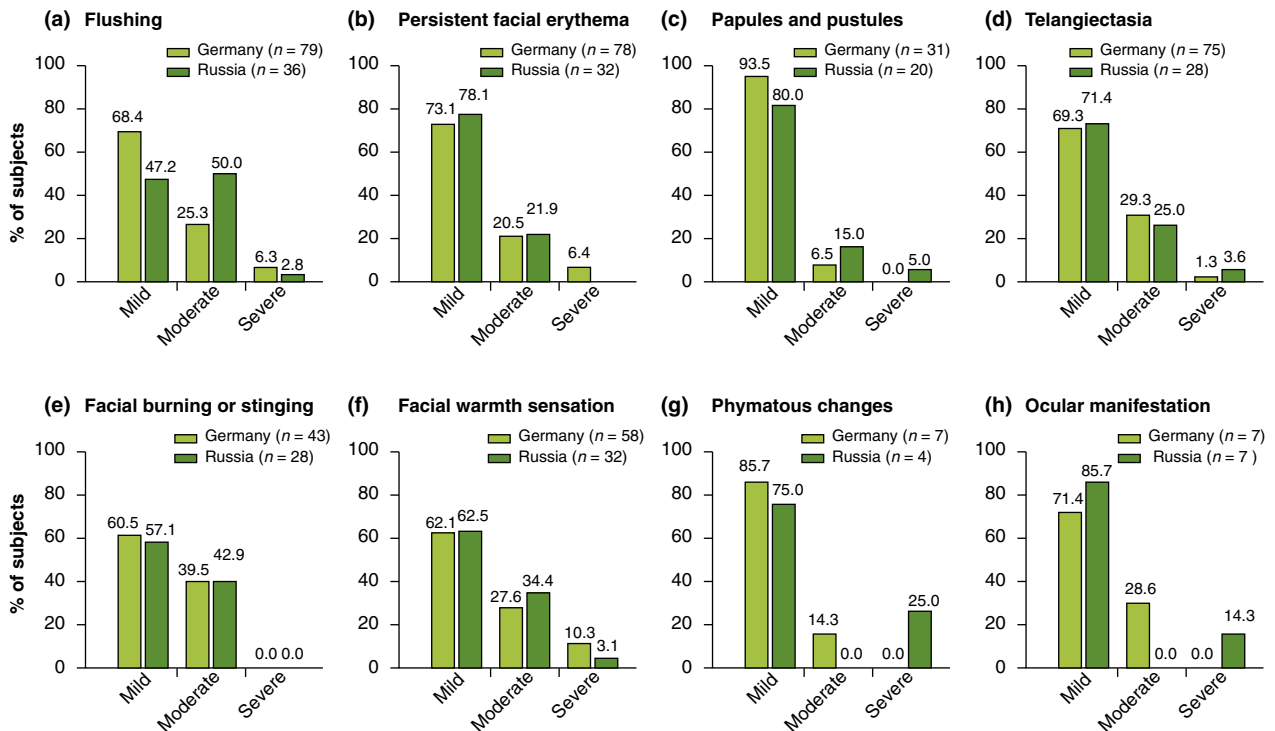
Mean DLQI scores in subjects with confirmed rosacea was 5.4 in Germany and 6.8 in Russia. The proportion of subjects in Germany and Russia reporting an adverse impact (DLQI score  $\geq 6$ ) on skin-related quality of life (QoL) were 35.4% and 43.2% respectively (Fig. 5).

## Discussion

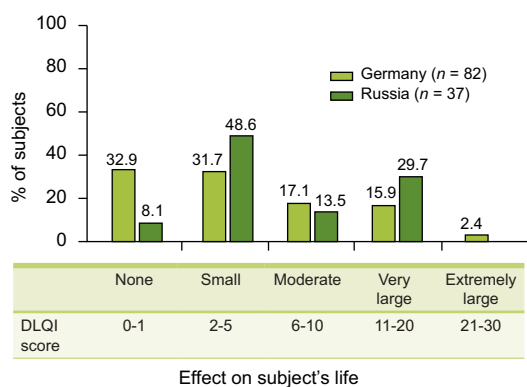
This study estimated the prevalence of rosacea in adult populations with a comprehensive approach based on screening a representative sample of the general population using a rosacea screening instrument, followed by diagnostic verification by a dermatologist. The screening instrument (Rosascreen), comprising a questionnaire and algorithm, was developed by dermatologists expert in rosacea using NRSEC diagnostic criteria.<sup>21</sup> In pilot testing, it had 100% sensitivity (i.e. true positive cases) and



**Figure 3** Rosacea care in the binational sample of 119 subjects with a confirmed diagnosis of rosacea. IPL= Intense Pulsed Light.



**Figure 4** Severity of primary (a–d) and secondary (e–h) features of rosacea in subjects with a confirmed diagnosis of rosacea. Percentages were calculated on subjects presenting the feature and several symptoms could be found in the same patient.



**Figure 5** Effect of rosacea on quality of life (QoL) in German and Russian subjects – DLQI questionnaire.

63–71% specificity. The initial screening phase, with use of Rosacreen, should therefore have detected the vast majority of rosacea cases. Indeed, as the prevalence estimates in our study exceeded those from most previous general population studies, it appears unlikely that the screening process excluded many subjects with rosacea. Furthermore, the subsequent step of confirmation by dermatologists would have excluded false-positive subjects.

Our prevalence estimates of 5% and 12% for Russia and Germany, respectively, are consistent with previous studies. The prevalence of rosacea in previous European studies generally ranged from 2% to 10%<sup>5,8,18</sup> with one study reporting 22%.<sup>3</sup> The reported prevalence in Germany of 2.2–2.3% may have been underestimated as rosacea was one of multiple potential cutaneous diagnoses based on a general skin examination, criteria for case finding were not explicitly defined and rosacea subtyping was not performed.<sup>5,18</sup> Furthermore, previous studies often did not consider the ETR subtype when assessing prevalence as it was considered only of cosmetic relevance.<sup>5,19,20</sup> Excluding the ETR subtype, the prevalence of rosacea in our study would be more in accord with previous results at 3.1%. Indeed, the ETR subtype was the most frequent in both countries involving 69.5 and 62.2% of German and Russian confirmed subjects respectively. These results are similar to the 64% previously reported in Germany<sup>16</sup>, but lower than the 78% reported in Estonia.<sup>3</sup>

Rosacea prevalence in this study was higher in Germany than Russia despite no substantive differences in skin phototype, age or gender distribution. The difference was apparent at screening with a higher screen-positive rate in Germany (25.2% vs. 14.0%), largely due to the twofold higher rate of self-reported persistent erythema in Germany (23.1% vs. 11.4%). Furthermore, there was a higher rate of diagnostic confirmation of rosacea in Germany (55.8% vs. 45.7%). Dermatologists participating in the study established a diagnosis using their clinical judgement (they were provided with diagnostic criteria based on NRSEC guidelines) and recorded the signs and symptoms

observed. It is noteworthy that a secondary analysis of these records and application of NRSEC criteria gave a higher rate (56.8% vs. 45.7%) of confirmed cases of rosacea in Russia, mainly due to slightly more cases of phymatous rosacea.

Limitations of this study include lack of representation of rural regions as the surveys were performed in cities to facilitate recruitment of subjects and dermatologists. Nevertheless, general population representation was addressed by using quotas based on demographic census data for gender and age characteristics in the selected cities. Randomization of screen-positive subjects to attend dermatology visits was undertaken to minimize selection bias during the confirmatory phase. Although a high number of subjects refused to attend the dermatologist visit, the representativeness of those attending was evaluated and the prevalence of rosacea was adjusted to compensate for any differences observed.

Our results on temporal development of clinical features support previous studies at patient<sup>23</sup> and molecular level<sup>1,24</sup> demonstrating sequential progression with episodic flushing appearing first followed by persistent erythema and then papules/pustules (insufficient data was available on the order of appearance of phymatous changes).

The demographic profile of subjects with rosacea in this study was similar in both countries and the female predominance, mean age and light skin phototype correspond to the previously established profile of subjects with rosacea.<sup>3,5,6,25</sup> Overall, 18% of rosacea subjects were younger than 30 years, which suggests that rosacea may be more common in younger subjects than previously recognized.<sup>3,8,26</sup> Clinical severity of rosacea associated signs and symptoms were predominantly mild.

Although only 16.8% of subjects with confirmed rosacea had previously been diagnosed, 25% had received drug treatments and/or 5% laser or intense pulsed light therapy. Hence, some subjects received treatment without a diagnosis and may have been misdiagnosed. This highlights that rosacea is a poorly understood disease and most subjects had received suboptimal care for their disease with about half having received no care for their rosacea within the previous year.

The mean DLQI scores reflect small to moderate effect on QoL.<sup>27</sup> However, over one-third of subjects had scores indicative of moderate to severe impact. Rosacea can significantly affect QoL manifested as embarrassment, anxiety and depression.<sup>28</sup> These findings imply that appropriate diagnosis and management may alleviate the impact of this condition and improve the QoL of this not inconsiderable proportion of the population.

In conclusion, rosacea prevalence was 12.3% in Germany and 5.0% in Russia and the majority of subjects were previously undiagnosed. We highlight the use of this methodology in surveying large populations and anticipate that future studies will provide more information on rosacea prevalence, demographic features and clinical and psychosocial impact in diverse global populations.

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