

Exploring the Natural and Treatment History of Vitiligo in Europe: Findings From the Global VALIANT Study

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Background

- Vitiligo is a chronic autoimmune disease characterized by the destruction of melanocytes, resulting in pale or white patches of skin¹
- It is estimated that vitiligo affects 0.5% to 2% of the global population, with rates varying geographically^{2,3}
 - In Europe, reported prevalence rates range from 0.4% to 1.6%^{2,3}
- Vitiligo affects adults and children of both sexes equally⁴; disease onset commonly occurs by 30 years of age, although initial manifestations later in life are also common^{5,6}
- Extensive body surface area (BSA) involvement, darker skin types, and the presence of visible lesions have been associated with greater patient burden⁷
- There is a need to understand the experiences among patients with vitiligo from different countries in Europe and with different disease characteristics

Objective

- The population-based Vitiligo and Life Impact Among International Communities (VALIANT) study sought to understand the natural history of vitiligo among patients in Europe as well as the patient journey with vitiligo

Methods

Study Design and Patients

- This cross-sectional online survey recruited adult patients (aged ≥18 years) diagnosed with vitiligo by a healthcare professional
- Patients were recruited using a general population sampling approach from a network of potential participants in Africa/Middle East (Egypt, Saudi Arabia, South Africa), Asia (China, India, Japan, Philippines, Thailand), Australia, Brazil, Canada, Europe (France, Germany, Italy, Spain, United Kingdom), and the United States
 - Here we present findings from Europe
- Patients completed a self-administered online screener designed to capture high-level demographics, confirm diagnosed vitiligo, and obtain consent before continuing to the 25-minute survey
- Clinical characteristics were solicited to understand the time since diagnosis of vitiligo, the diagnostic process, and the rate at which vitiligo is spreading
 - Family history of vitiligo, self-reported factors influencing vitiligo, and the type of management the patient was currently receiving were also probed
- Treatment history was examined to reflect on the use of various treatments and management strategies
- The extent of vitiligo was assessed using the validated Self Assessment Vitiligo Extent Score (SA-VES) tool,⁸ which uses an array of validated images for the patient to self-select, indicating how many lesions on each location on the body are affected with vitiligo, and estimates the affected BSA

Statistical Analyses

- Data were analyzed using descriptive statistics, with mean (SD) and median (range) for continuous variables, and percentages for discrete variables
- Statistical comparisons were made between subgroups (eg, countries, fair vs dark skin) using the chi-square test for categorical variables and t test for continuous variables, with significance conferred at the level of $P<0.05$; no corrections were made for multiple testing

Results

Patient Demographics and Disease Characteristics

- Of 284,111 participants invited to the survey in Europe, 68,840 clicked on the link, and 1554 reported a vitiligo diagnosis that directed them to the complete survey
 - Of these, 1289 (82.9%) completed the survey, and 1151/1289 (89.3%) were included in the analysis (**Table 1**)
- Among the 1151 included patients from Europe, median (range) age was 38 (18–93) years
 - More than half of the patients (57.3%) were male
 - More patients reported Fitzpatrick skin types I–III (fairer skin types, 64.7%) compared with types IV–VI (darker skin types, 35.3%)

Table 1. Patient Demographics

Characteristic	All Participants (N=1151)
Age, median (range), y	38 (18–93)
Age range, n (%), y	
18–34	414 (36.0)
35–54	489 (42.5)
≥55	248 (21.5)
Male, n (%)	659 (57.3)
Country, n (%)	
France	250 (21.7)
Germany	250 (21.7)
Italy	200 (17.4)
Spain	200 (17.4)
United Kingdom	251 (21.8)
Fitzpatrick skin type,* n (%)	
I	114 (9.9)
II	424 (36.8)
III	207 (18.0)
IV	229 (19.9)
V	150 (13.0)
VI	27 (2.3)

* Fitzpatrick skin types are defined as follows: type I, pale white skin; type II, white skin; type III, light brown skin; type IV, moderate brown skin; type V, dark brown skin; type VI, deeply pigmented dark brown to black skin.

Disease Characteristics

- Median (range) BSA affected by vitiligo was 3.8% (0%–73.9%), as estimated by the SA-VES (**Table 2**)
- Mean (SD) time between first noticing lesions and achieving a formal diagnosis was 2.5 (4.0) years
- Most patients reported slow progression (38.5%) or rapid progression (31.5%) of vitiligo, whereas only 10.6% reported no progression since the first appearance of lesions

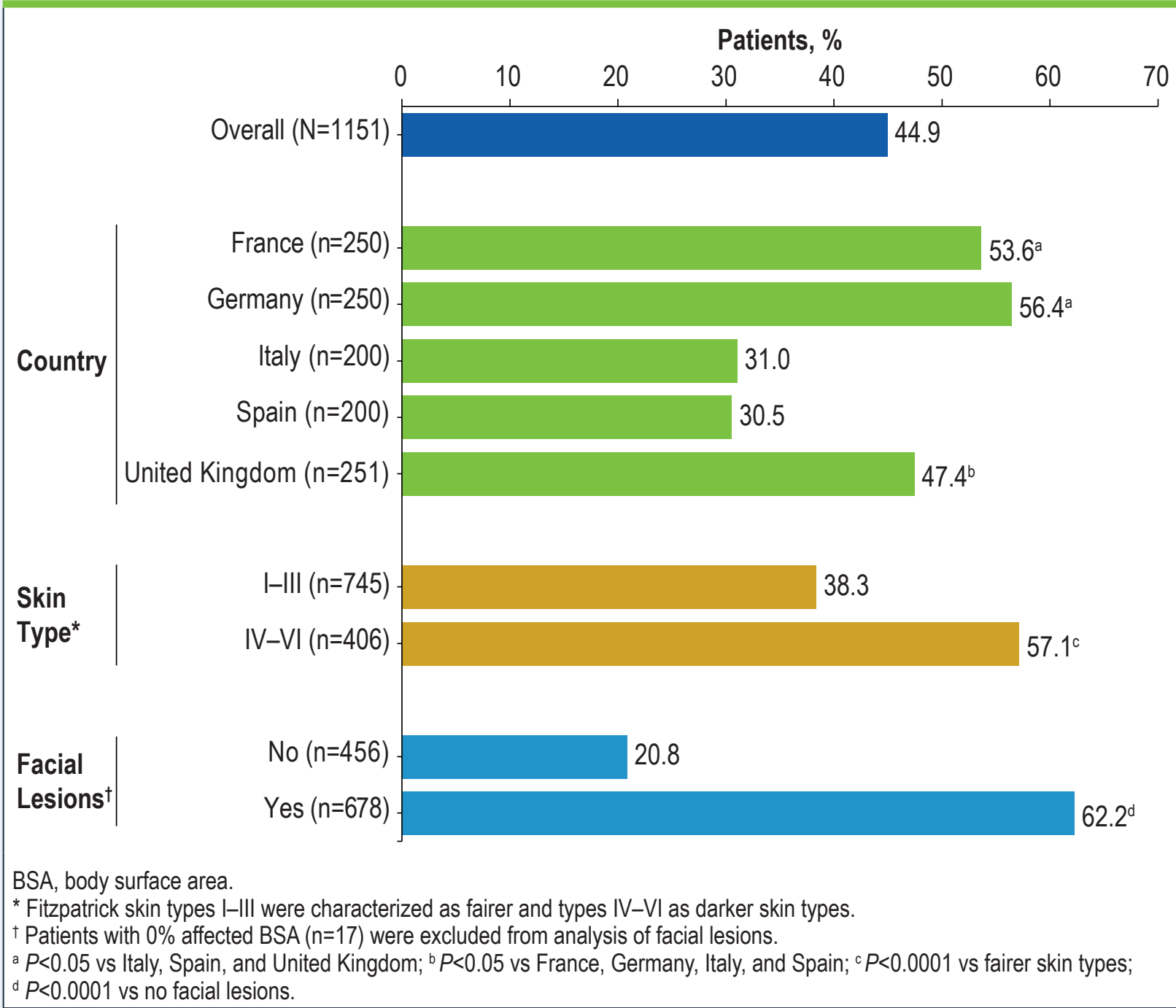
Table 2. Disease Characteristics

Characteristic	All Participants (N=1151)
Age at diagnosis, median (range), y	27 (0–74)
Time before diagnosis, mean (SD), y	2.5 (4.0)
Disease duration, mean (SD), y	14.3 (12.9)
Affected BSA, median (range), %	3.8 (0–73.9)
Affected BSA range, n (%)	
<1%	308 (26.8)
1%–5%	326 (28.3)
>5%	517 (44.9)
Disease progression, n (%)	
No progression	122 (10.6)
Slow progression	443 (38.5)
Stable, then rapid	216 (18.8)
Rapid, no stabilization	132 (11.5)
Rapid at first, then stabilized	146 (12.7)
Rapid, short bursts separated by stabilization	84 (7.3)
Other	8 (0.7)
Stress-induced vitiligo flares, n (%)	749 (65.1)
Itch before or during flares, n (%)	708 (61.5)
Family history, n (%)	579 (50.3)

BSA, body surface area.

- Nearly half (44.9%) of patients had >5% affected BSA, with significantly ($P<0.05$) higher rates in Germany (56.4% of 250 patients) vs the United Kingdom (47.4% of 251 patients), Italy (31.0% of 200 patients), and Spain (30.5% of 200 patients; **Figure 1**)
 - Patients with darker skin types (57.1% vs 38.3% for fairer skin) or facial lesions (62.2% vs 20.8% for no facial lesions) had significantly ($P<0.0001$) greater rates of >5% affected BSA

Figure 1. Patients With >5% Affected BSA



BSA, body surface area.

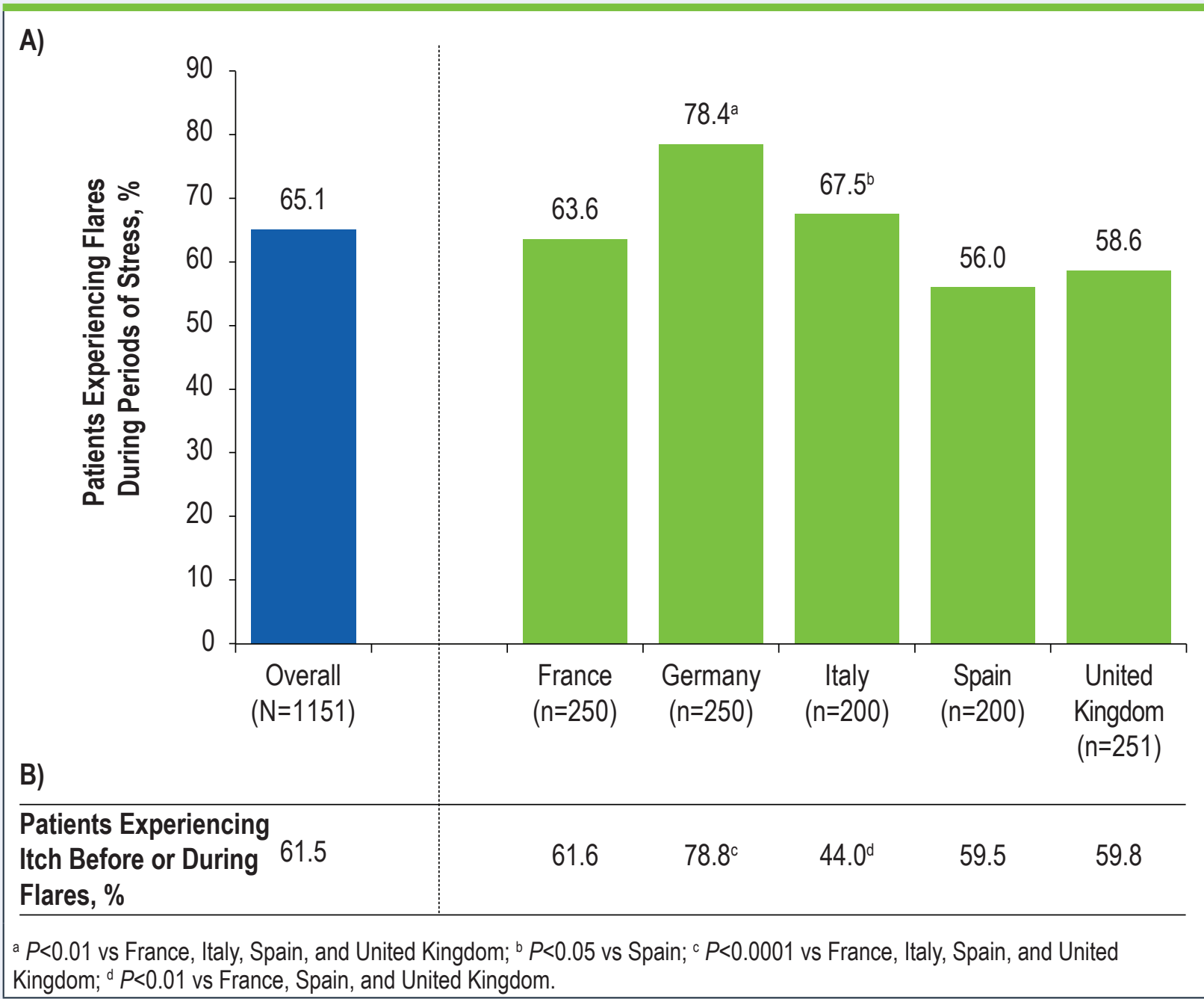
* Fitzpatrick skin types I–III were characterized as fairer and types IV–VI as darker skin types.

† Patients with 0% affected BSA (n=17) were excluded from analysis of facial lesions.

* $P<0.05$ vs Italy, Spain, and United Kingdom; * $P<0.05$ vs France, Germany, Italy, and Spain; * $P<0.0001$ vs fairer skin types; † $P<0.0001$ vs no facial lesions.

- Patients from Germany were significantly ($P<0.05$) younger at the time of first noticing lesions (mean [SD], 24.0 [11.7] years) than those from the United Kingdom (30.8 [15.3] years), Spain (29.0 [12.8] years), Italy (28.6 [13.9] years), and France (26.6 [14.0] years)
 - Patients with >5% affected BSA were significantly ($P<0.0001$) younger at the time of first noticing lesions (mean [SD], 25.0 [12.7] years) than those with 1%–5% (28.8 [14.0] years) or <1% affected BSA (31.0 [14.4] years)
- Approximately half of patients (50.3%) noted a family history of vitiligo, with the highest rates observed among patients from France (66.4%) and Germany (58.8%)
 - Family history of vitiligo was most common among patients with >5% affected BSA (66.0% vs 40.2% for 1%–5% and 34.7% for <1% affected BSA; both $P<0.0001$), darker skin types (73.4% vs 37.7% for fairer skin; $P<0.0001$), and facial lesions (60.8% vs 32.9% for no facial lesions; $P<0.0001$)
- Nearly two-thirds (65.1%) of patients noted experiencing flares during periods of stress, and 61.5% noticed itching before or during a flare; rates in Germany (78.4% and 78.8%, respectively) were significantly higher than in the other countries surveyed (**Figure 2**)
 - Significantly ($P<0.0001$) higher rates of flares during periods of stress were reported by patients with >5% affected BSA (82.4% vs 56.1% for 1%–5% and 45.5% for <1% affected BSA), darker skin types (78.6% vs 57.7% for fairer skin), or facial lesions (73.3% vs 51.5% for no facial lesions)
 - Similarly, significantly ($P<0.0001$) higher rates of experiencing itch before or during a flare were reported by patients with >5% affected BSA (76.4% vs 57.1% for 1%–5% and 41.2% for <1% affected BSA), darker skin types (74.1% vs 54.6% for fairer skin), or facial lesions (69.0% vs 48.9% for no facial lesions)

Figure 2. Patient Experiences of (A) Flares During Periods of Stress and (B) Itching Before or During Vitiligo Flares

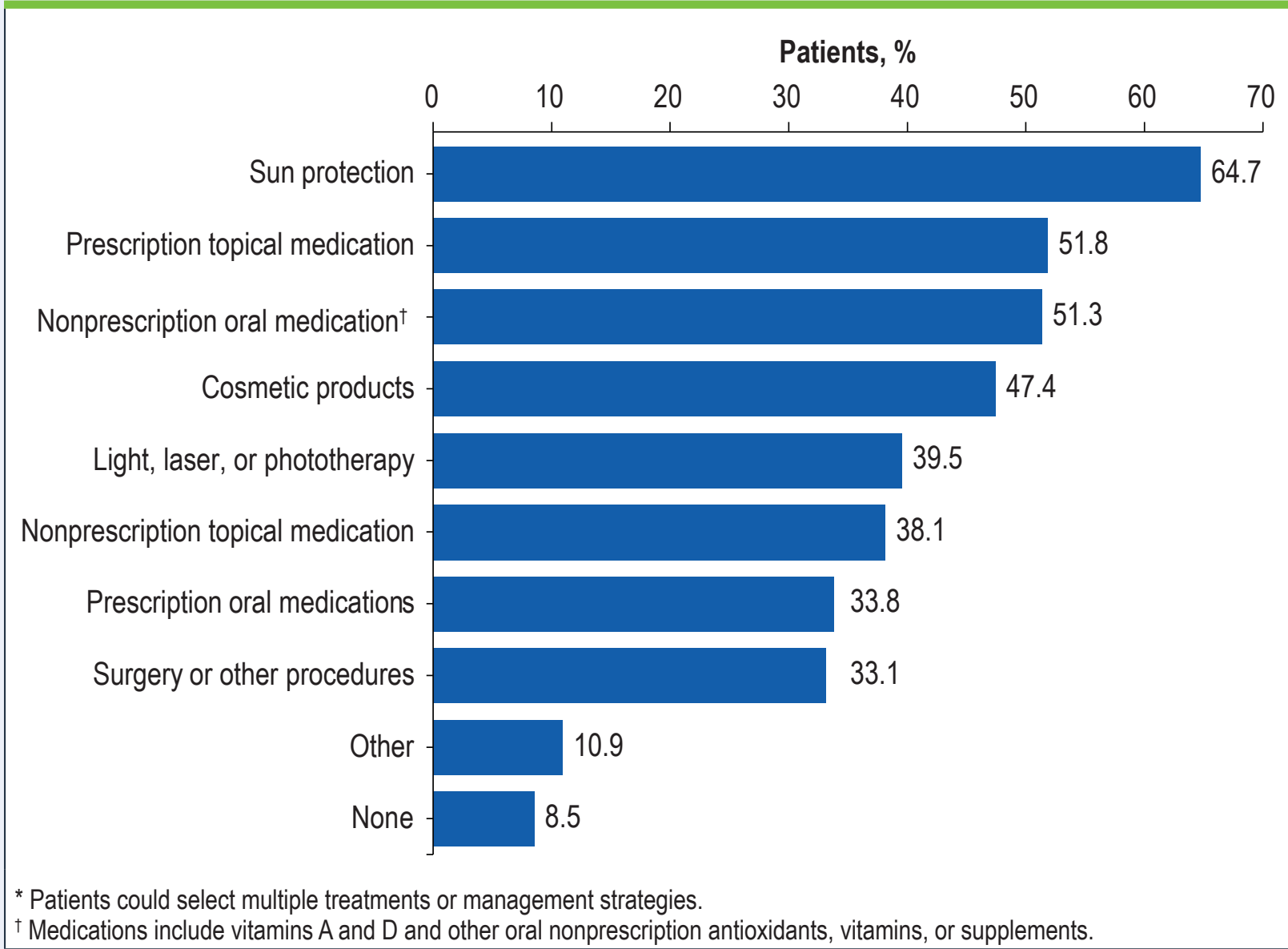


* $P<0.01$ vs France, Italy, Spain, and United Kingdom; * $P<0.05$ vs Spain; * $P<0.0001$ vs France, Italy, Spain, and United Kingdom; † $P<0.01$ vs France, Spain, and United Kingdom.

Treatment History and Satisfaction

- Patients had used a mean (SD) of 5.0 (4.4) treatments to manage their vitiligo
 - A significantly ($P<0.0001$) greater number of treatments were used by patients from Germany (mean [SD], 6.5 [5.5]) vs those from the United Kingdom (4.9 [4.0]), France (4.6 [4.2]), Spain (4.1 [3.7]), and Italy (4.7 [3.8])
 - Use of a significantly greater number of treatments was reported by patients with >5% affected BSA (mean [SD], 5.9 [5.0] vs 4.8 [3.8] for 1%–5% and 3.7 [3.4] for <1% affected BSA; $P<0.001$ / $P<0.0001$), darker skin types (5.9 [5.0] vs 4.5 [3.9] for fairer skin; $P<0.0001$), or facial lesions (5.7 [4.8] vs 3.9 [3.4] for no facial lesions; $P<0.0001$)
- Among prescription treatment options, the use of topical creams or ointments (51.8%) was more common than oral treatments (33.8%; **Figure 3**)
 - 8.5% of patients were treatment-naïve

Figure 3. Current and/or Previous Treatments or Management Strategies*

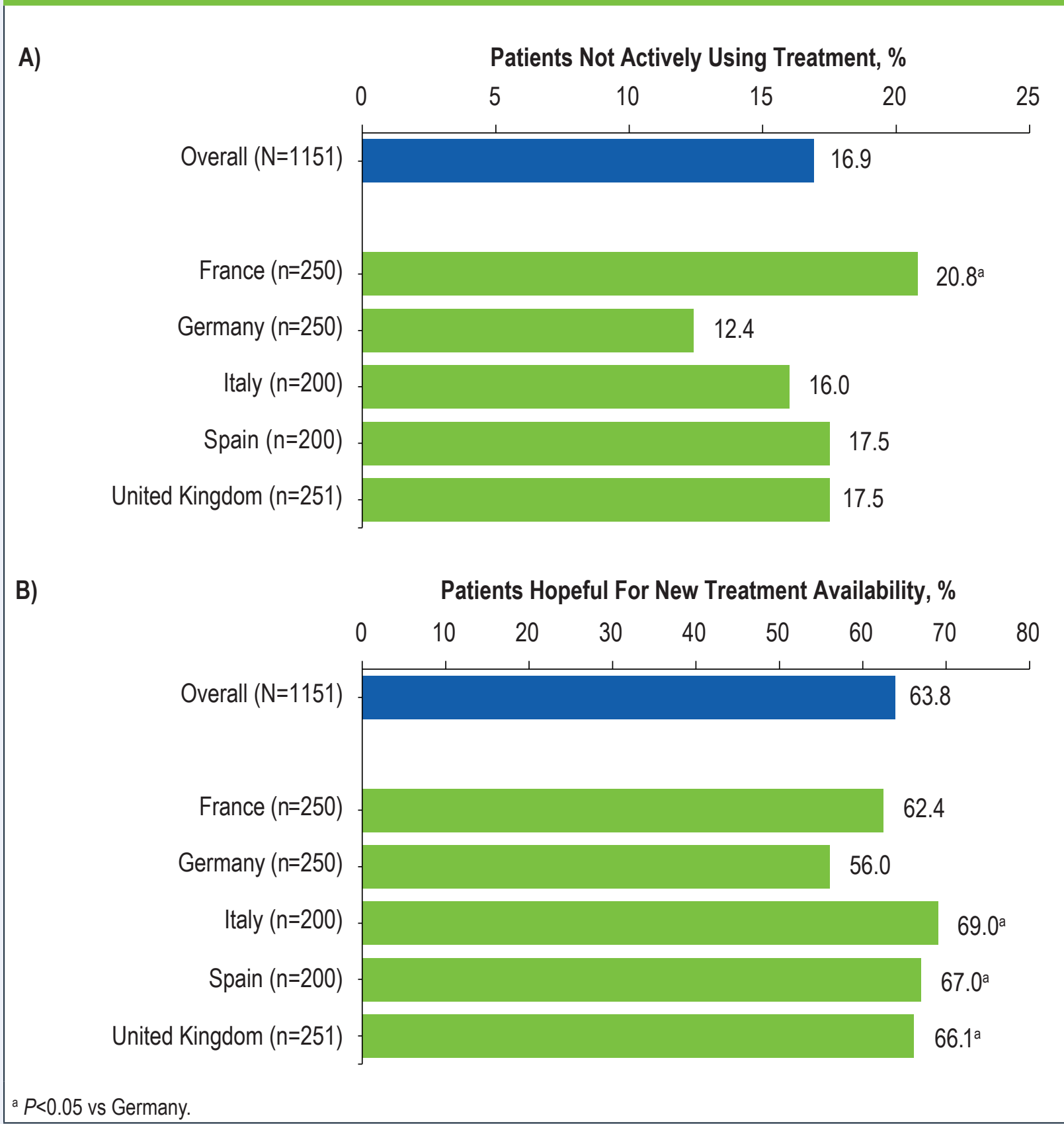


* Patients could select multiple treatments or management strategies.

† Medications include vitamins A and D and other oral nonprescription antioxidants, vitamins, or supplements.

- Overall, 16.9% of patients were not actively using treatment, with significantly ($P<0.05$) higher rates in France (20.8% of 250 patients) vs Germany (12.4% of 250 patients); 17.5% of 251 patients in the United Kingdom, 17.5% of 200 patients in Spain, and 16.0% of 200 patients in Italy were also not actively using treatment (**Figure 4A**)
- Most patients (63.8%) were hopeful that a new treatment will become available, with the greatest proportion in Italy (69.0% of 200 patients) and the lowest in Germany (56.0% of 250 patients; **Figure 4B**)

Figure 4. Patients (A) Not Actively Using Treatment and (B) Hopeful That a New Treatment Will Become Available



* $P<0.05$ vs Germany.

Limitations

- Limitations associated with an online survey, including restriction of participants to those with internet access
 - Efforts were made to conduct in-person interviews in populations with limited internet access if needed to reach desired sample size
- Potential errors in measurement that are inherent in patient-reported outcomes studies

Conclusions

- On average, it took patients 2.5 years to achieve a formal diagnosis of vitiligo after appearance of their first lesions
- Patients from Germany generally reported higher rates of >5% affected BSA, used a greater number of treatments, had earlier disease onset, and were less hopeful about the availability of new treatments compared with patients from France, Italy, Spain, and the United Kingdom
- Patients with >5% affected BSA, darker skin types, and facial lesions often had earlier disease onset, a family history of vitiligo, and used a greater number of treatments than other patients
- These findings provide a new perspective on the diagnosis and treatment journey for patients with vitiligo in Europe

Disclosures

NvG is a consultant and/or investigator for AbbVie, Incyte Corporation, Merck/MSD, Pfizer, and Sun Pharma; and is chair of the Vitiligo Task Force for the European Academy of Dermatology and Venerology (EADV). JEH has served as a consultant for AbbVie, Aclaris Therapeutics, BiologicsMD, EMD Serono, Genzyme/Sanofi, Janssen, Pfizer, Rheos Medicines, Sun Pharmaceuticals, TeVido BioDevices, The Expert Institute, 3rd Rock Ventures, and Villarix Therapeutics; has served as an investigator for Aclaris Therapeutics, Celgene, Dermira, EMD Serono, Genzyme/Sanofi, Incyte, LEO Pharma, Pfizer, Rheos Medicines, Stiefel/GlaxoSmithKline, Sun Pharmaceuticals, TeVido BioDevices, and Villarix Therapeutics; holds equity in Aldena Therapeutics, NIRA Biosciences, Rheos Medicines, TeVido BioDevices, and Villarix Therapeutics; is a scientific founder of Aldena Therapeutics, NIRA Biosciences, and Villarix Therapeutics; and has patents pending for IL-15 blockade for treatment of vitiligo, JAK inhibition with light therapy for vitiligo, and CXCR3 antibody depletion for treatment of vitiligo. IHH has served as an advisory board member for AbbVie; a consultant for Boehringer Ingelheim, Galderma Laboratories LP, Incyte, Pfizer, and UCB; a principal investigator for Avita, Bayer, Estée Lauder, Ferndale Laboratories, Incyte, Lencicura, L'Oréal, Pfizer, and Unigen; a subinvestigator for Arcutis; president of the HS Foundation; and a board member of the Global Vitiligo Foundation. KB, JG, and HR are employees and shareholders of Incyte. KE is a consultant for AbbVie, Incyte, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Viela Bio.

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