

Quality of Life and Disease Severity in Patients With Vitiligo: 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
- Severity and extent of vitiligo are associated with significant quality-of-life impairment in routine activities, employment, and psychosocial health^{2,3}
- There is a need to further investigate and understand the severity, extent, and impact of vitiligo from the perspective of patients

Objective

- The population-based Vitiligo and Life Impact Among International Communities (VALIANT) study sought to understand the severity, extent, and impact of vitiligo on patients worldwide

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 17 countries from the following geographic regions: 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
- 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
- Patient responses in the Patient Global Assessment (PtGA) were solicited to understand the severity (PtGA severity: not severe at all, mild, moderate, severe, very severe), extent (PtGA extent: no vitiligo anymore, limited, moderate, extensive, very extensive), and impact of vitiligo on their daily lives (PtGA impact: none, mild, moderate, high, very high)⁴
- The affected area of vitiligo was assessed using the validated Self Assessment Vitiligo Extent Score (SA-VES) tool,⁵ 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 body surface area (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, fair vs dark skin) using the chi-square test, with significance conferred at the level of $P<0.05$; no corrections were made for multiple testing

Results

Patient Demographics and Disease Characteristics

- Of 881,522 participants invited to the survey, 197,858 clicked on the link, and 5859 reported a vitiligo diagnosis that directed them to the complete survey
 - Of these, 3919 (66.9%) completed the survey, and 3541 (60.4%) were included in the analysis (**Table 1**)
- Among the 3541 included patients, median age was 38 (18–95) years
 - More than half of the patients (54.6%) were male
 - More patients reported Fitzpatrick skin types I–III (fairer skin types, 59.2%) compared with types IV–VI (darker skin types, 40.8%)
 - 29.0% of patients had ≥10% affected BSA

Table 1. Patient Demographics and Disease Characteristics

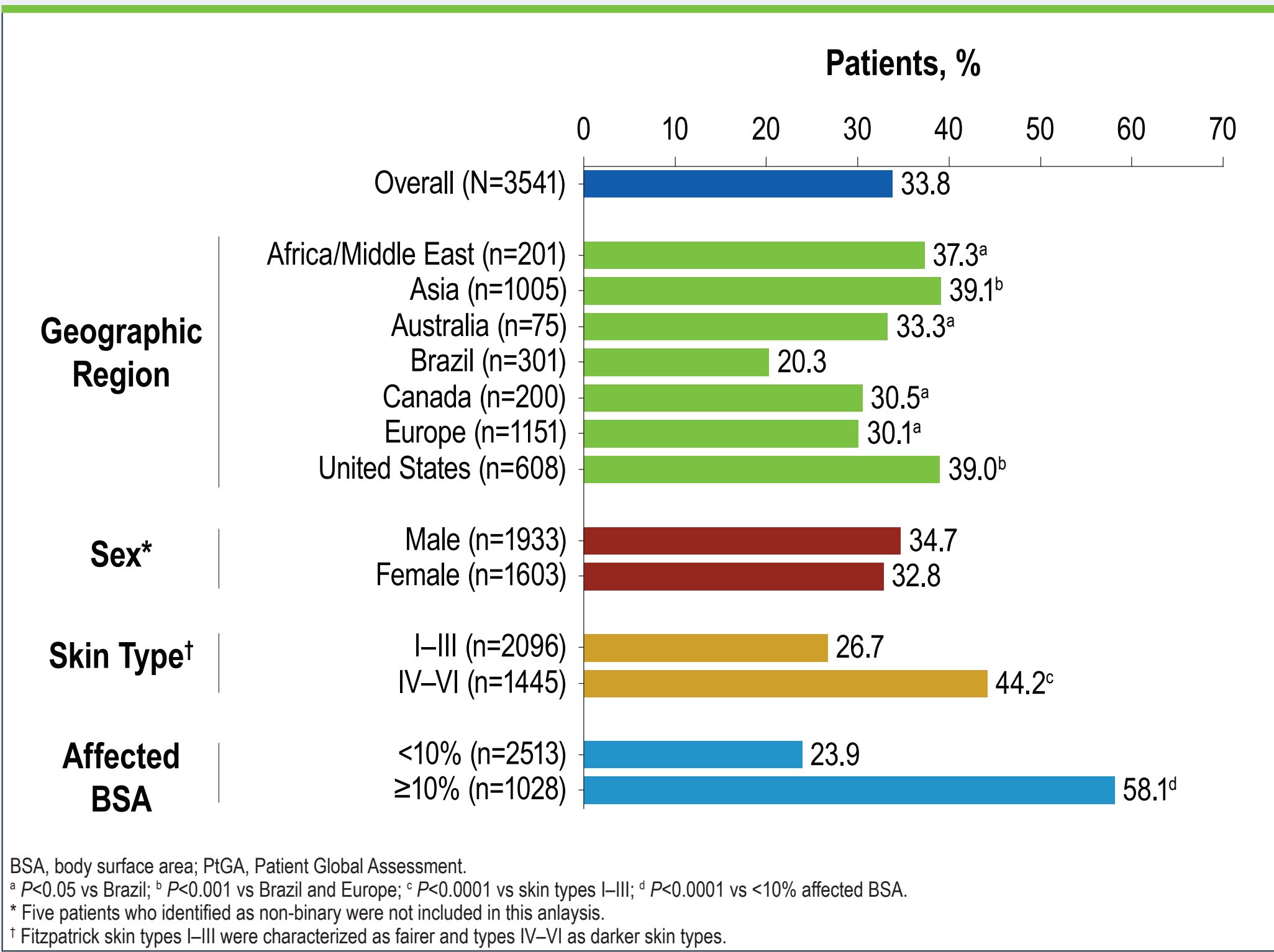
Characteristic	All Participants (N=3541)
Age, median (range), y	38 (18–95)
Male, n (%)	1933 (54.6)
Race,*† n (%)	
White	1555 (51.1)
Black	283 (9.3)
Asian	929 (30.5)
Other	287 (9.4)
Fitzpatrick skin type,‡ n (%)	
I–III	2096 (59.2)
IV–VI	1445 (40.8)
Geographic region, n (%)	
Africa/Middle East	201 (5.7)
Asia	1005 (28.4)
Australia	75 (2.1)
Brazil	301 (8.5)
Canada	200 (5.6)
Europe	1151 (32.5)
United States	608 (17.2)
Age at diagnosis, median (range), y	30 (1–95)
Time before diagnosis, mean (SD), y	2.4 (4.1)
Disease duration, mean (SD), y	12.7 (12.6)
Affected BSA, median (range), %	4.0 (0–73.9)
≥10% affected BSA, n (%)§	1028 (29.0)

BSA, body surface area; SA-VES, Self Assessment Vitiligo Extent Score.
* Multiple answers for race were accepted.
† Race was not solicited in France (n=250) or Germany (n=250).
‡ 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.
§ BSA was estimated using the SA-VES tool.

PtGA Severity of Vitiligo

- Globally, 33.8% of patients reported severe/very severe disease (**Figure 1**)
 - Percentages of patients reporting severe/very severe disease were highest in Asia (39.1%) and the United States (39.0%) and lowest in Brazil (20.3%) and Europe (30.1%)
 - Significantly greater percentages of patients with darker vs lighter skin (44.2% vs 26.7%; $P<0.0001$) and ≥10% vs <10% affected BSA (58.1% vs 23.9%, $P<0.0001$) reported severe/very severe disease

Figure 1. Severe/Very Severe Disease as Assessed by the PtGA in Patients With Vitiligo

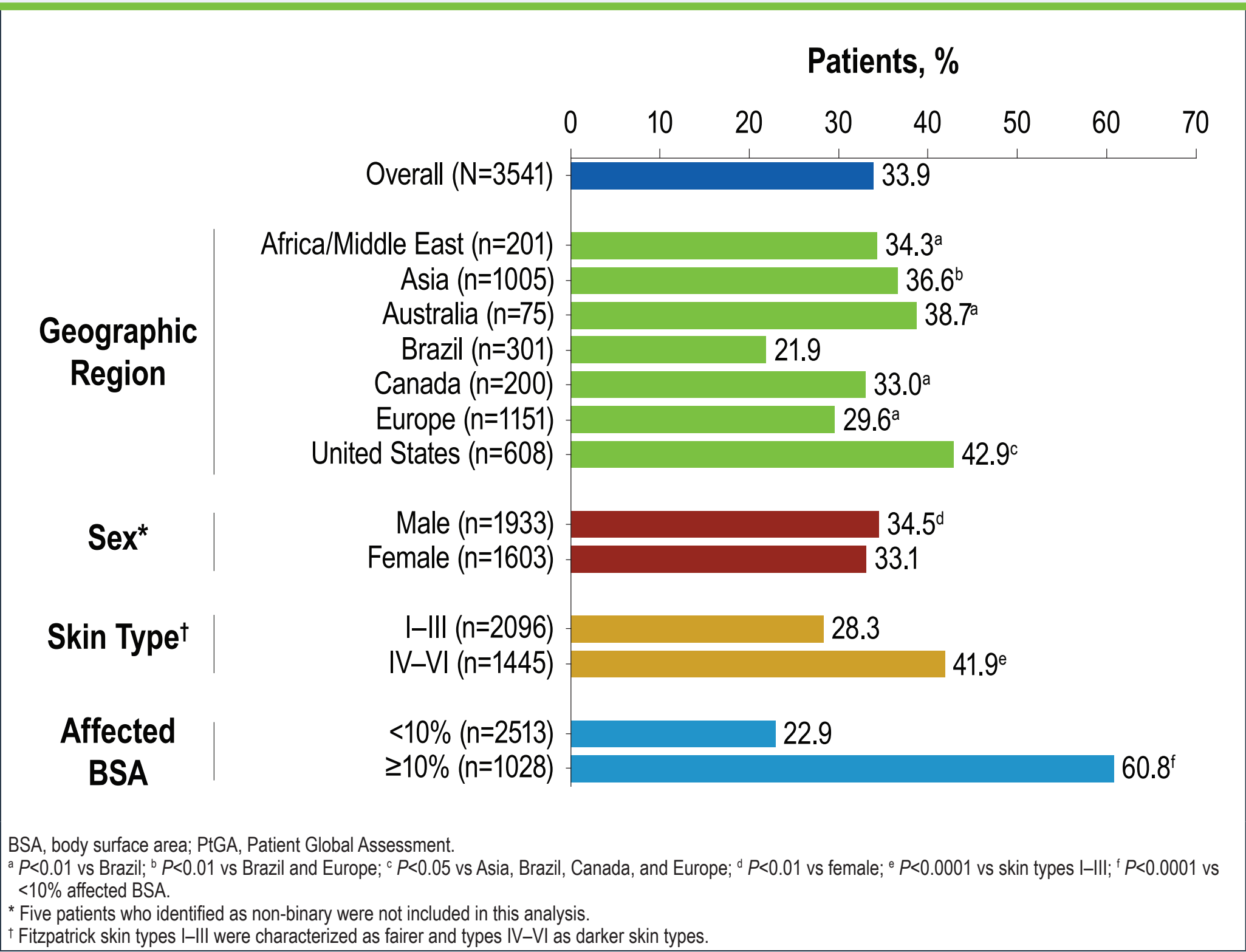


BSA, body surface area; PtGA, Patient Global Assessment.
^a $P<0.05$ vs Brazil; ^b $P<0.001$ vs Brazil and Europe; ^c $P<0.0001$ vs skin types I–III; ^d $P<0.0001$ vs <10% affected BSA.
* Five patients who identified as non-binary were not included in this analysis.
† Fitzpatrick skin types I–III were characterized as fairer and types IV–VI as darker skin types.

PtGA Extent of Vitiligo

- Extensive/very extensive disease was reported in 33.9% of patients globally (**Figure 2**)
 - The United States (42.9%) and Australia (38.7%) had the highest percentages of patients reporting extensive/very extensive disease, and Brazil (21.9%) and Europe (29.6%) had the lowest
 - Extensive/very extensive disease was reported in significantly greater percentages of patients with darker skin (41.9% vs 28.3% for fairer skin; $P<0.0001$) and ≥10% affected BSA (60.8% vs 22.9% for <10% BSA, $P<0.0001$)
 - The difference in extent of disease between male and female patients was significant ($P=0.0041$)

Figure 2. Extensive/Very Extensive Disease as Assessed by the PtGA in Patients With Vitiligo

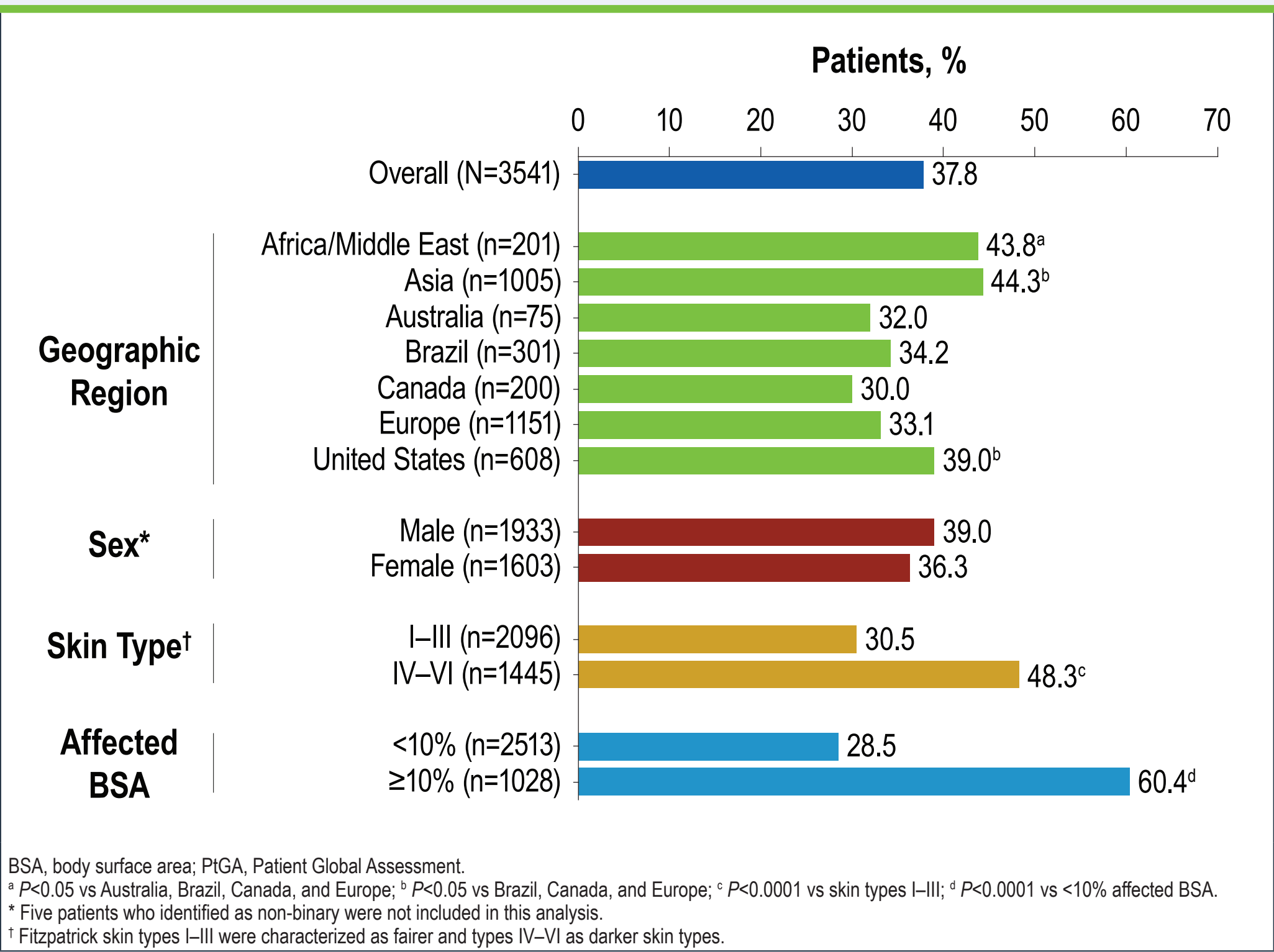


BSA, body surface area; PtGA, Patient Global Assessment.
^a $P<0.01$ vs Brazil; ^b $P<0.01$ vs Brazil and Europe; ^c $P<0.05$ vs Asia, Brazil, Canada, and Europe; ^d $P<0.01$ vs female; ^e $P<0.0001$ vs skin types I–III; ^f $P<0.0001$ vs <10% affected BSA.
* Five patients who identified as non-binary were not included in this analysis.
† Fitzpatrick skin types I–III were characterized as fairer and types IV–VI as darker skin types.

PtGA Impact of Vitiligo on Daily Life

- Vitiligo had a high/very high influence on the lives of 37.8% of patients globally (**Figure 3**)
 - Impact was highest in Asia (44.3%) and Africa/Middle East (43.8%) and lowest in Canada (30.0%) and Australia (32.0%)
 - Influence of vitiligo was high/very high in a significantly greater percentage of patients with darker skin (48.3% vs 30.5% for fairer skin; $P<0.0001$) and ≥10% affected BSA (60.4% vs 28.5% for <10% BSA; $P<0.0001$)

Figure 3. Severe/Very Severe Influence of Vitiligo on Daily Life of Patients as Assessed by the PtGA



BSA, body surface area; PtGA, Patient Global Assessment.
^a $P<0.05$ vs Australia, Brazil, Canada, and Europe; ^b $P<0.05$ vs Brazil, Canada, and Europe; ^c $P<0.0001$ vs skin types I–III; ^d $P<0.0001$ vs <10% affected BSA.
* Five patients who identified as non-binary were not included in this analysis.
† Fitzpatrick skin types I–III were characterized as fairer and types IV–VI as darker skin types.

Limitations

- The current study is limited by selection bias associated with its online nature (ie, only available to patients with internet access), although 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 inherent to patient-reported outcomes studies may have occurred

Conclusions

- **Substantial proportions of patients with vitiligo globally report severe/very severe disease and extensive/very extensive disease and are highly impacted in their daily lives per the PtGA**
- **Patients with darker skin types (ie, types IV–VI) and ≥10% affected BSA reported significantly greater severity, extent, and impact of vitiligo on their daily lives than patients with fairer skin types (ie, types I–III) and <10% affected BSA**
 - **The severity, extent, and impact of vitiligo on patients with skin types I–III and <10% affected BSA should, however, not be underestimated; approximately one-quarter of patients meeting these criteria perceived their disease as severe/extensive**

Disclosures

NvG is a consultant and/or investigator for AbbVie, Incyte, Merck/MSD, Pfizer, and Sun Pharma; and is Chair of the Vitiligo Task Force for the European Academy of Dermatology and Venereology (EADV). PG has served as a consultant for Aclaris Therapeutics, Clarify Medical, DermaForce, Incyte, Proctor & Gamble, and Versicolor Technologies; and a principal investigator for Aclaris Therapeutics, Allergan/SkinMedica, Clinuvel Pharmaceuticals, Incyte, Johnson & Johnson, L'Oréal, Merz Pharma, Pfizer, Thync Global Inc., and VT Cosmetics. KB, AL, JGao, and HR are employees and shareholders of Incyte. JEJH 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 Villarís 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 Villarís Therapeutics; holds equity in Aldena Therapeutics, NIRA Biosciences, Rheos Medicines, TeVido BioDevices, and Villarís Therapeutics; is a scientific founder of Aldena Therapeutics, NIRA Biosciences, and Villarís 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, Lenicura, L'Oréal, Pfizer, and Unigen; a subinvestigator for Arcutis; president of the HS Foundation; and a board member of the Global Vitiligo Foundation. DP has served as an expert or primary investigator for Incyte, Pfizer, and Sun Pharmaceuticals. MT has no conflicts of interest to disclose. JGardner has served as a consultant for AbbVie, Avita Medical, Concert Pharmaceuticals, Incyte, Mitsubishi Tanabe Pharma Corporation, and Pfizer. YV is CEO of the Vitiligo Research Foundation, has served as a scientific advisor at Temprian Therapeutics, and as an invited professor at Guglielmo Marconi University. GTM is the founder of Beyond Vitiligo South Africa and cofounder of Beyond Vitiligo Botswana. KE is a consultant for AbbVie, Incyte, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Vela Bio.

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