

Treatment Burden Among 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
- Historically, standard-of-care vitiligo treatment options, including off-label topical corticosteroids and calcineurin inhibitors, provide suboptimal repigmentation and may have safety limitations²
 - Adherence to these treatments is low and is largely driven by patient satisfaction³
- There is a need to further investigate and understand the treatment burden of vitiligo among patients

Objective

- The population-based Vitiligo and Life Impact Among International Communities (VALIANT) study sought to understand the treatment burden for vitiligo among patients worldwide

Methods

Participants and Study Design

- This cross-sectional online survey recruited adult participants (aged ≥18 years) diagnosed with vitiligo by a healthcare professional
- Participants 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
- Participants 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
- Treatment burden was assessed using a 19-item questionnaire that assessed the difficulty and frustration with getting appointments, applying topical products (treatment, makeup, sunscreen), phototherapy, costs associated with treatment, and psychosocial burden
 - Participants were asked if they agreed, strongly agreed, slightly agreed, or disagreed with each statement in the questionnaire⁴

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), with significance conferred at the level of $P<0.05$; no corrections were made for multiple testing

Results

Patient Demographics and Disease Characteristics

- Among 881,522 general population consumers invited to the survey, 197,858 clicked the link; 5859 participants reported a vitiligo diagnosis that directed them to the complete survey
- A total of 3919 (66.9%) participants completed the survey, and 3541 (60.4%) were included in the analysis after 378 respondents were excluded for data quality issues
- The 3541 patients with diagnosed vitiligo had a median age of 38 (18–95) years at the time of the survey (Table 1)
 - 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%)

Treatment Burden of Vitiligo by Demographics and Disease Characteristics

- Treatment burden was significantly greater ($P<0.0001$) among patients with darker (Fitzpatrick skin types IV–VI) vs fairer (skin types I–III) skin for all items in the questionnaire (Figure 1)
- Similarly, treatment burden was significantly greater ($P<0.0001$) among patients with affected BSA ≥10% vs <10% for all items in the questionnaire (Figure 2)
- Significantly more female vs male patients agreed or strongly agreed that consequences of treatments on their physical appearance caused stress (56.3% vs 52.9%), that they choose to protect themselves from the sun with sunscreen (58.3% vs 54.8%), and that cosmetics and self-tanners are expensive (62.3% vs 56.5%; $P<0.05$ for all 3 items; Figure 3)

Treatment Burden of Vitiligo by Geographic Region

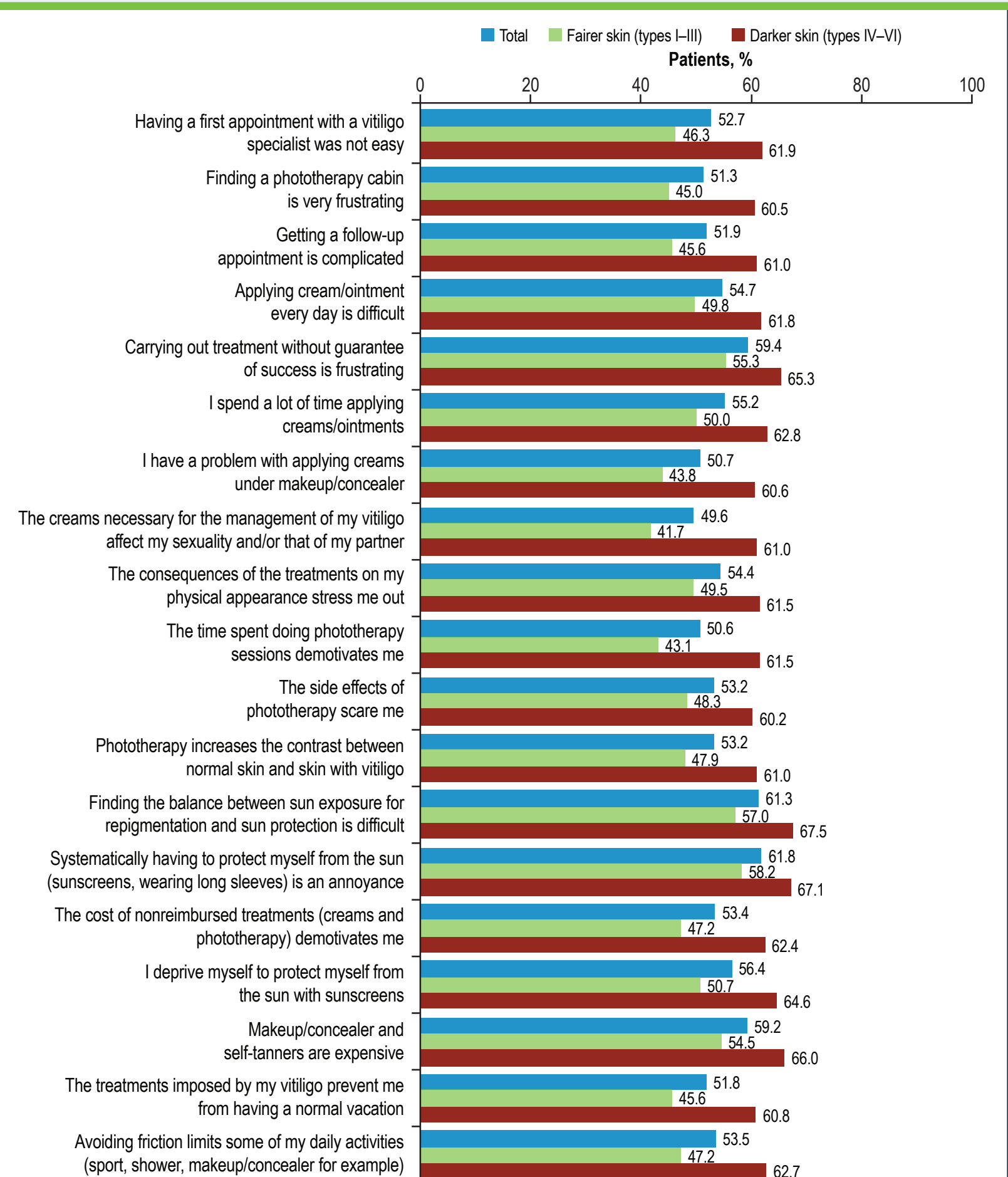
- Treatment burden was generally lowest in Europe and Canada and highest in the United States, Australia, and Africa/Middle East (Figure 4)
- Approximately half of patients agreed or strongly agreed on the following:
 - It was not easy having a first appointment with a vitiligo specialist (range across regions, 44.0% [Europe]–62.0% [United States])
 - Continuing treatment with no guarantee of success was frustrating (51.6% [Europe]–69.4% [Brazil])
 - The cost of nonreimbursed therapies was demotivating (44.5% [Europe]–66.2% [Africa/Middle East])
 - Applying topical therapy every day was difficult (44.3% [Europe]–64.0% [United States])
 - Consequences of treatment on patients' physical appearance caused stress (42.2% [Europe]–65.3% [Australia])

Table 1. Patient Demographics and Disease Characteristics

Characteristic	All Patients (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)

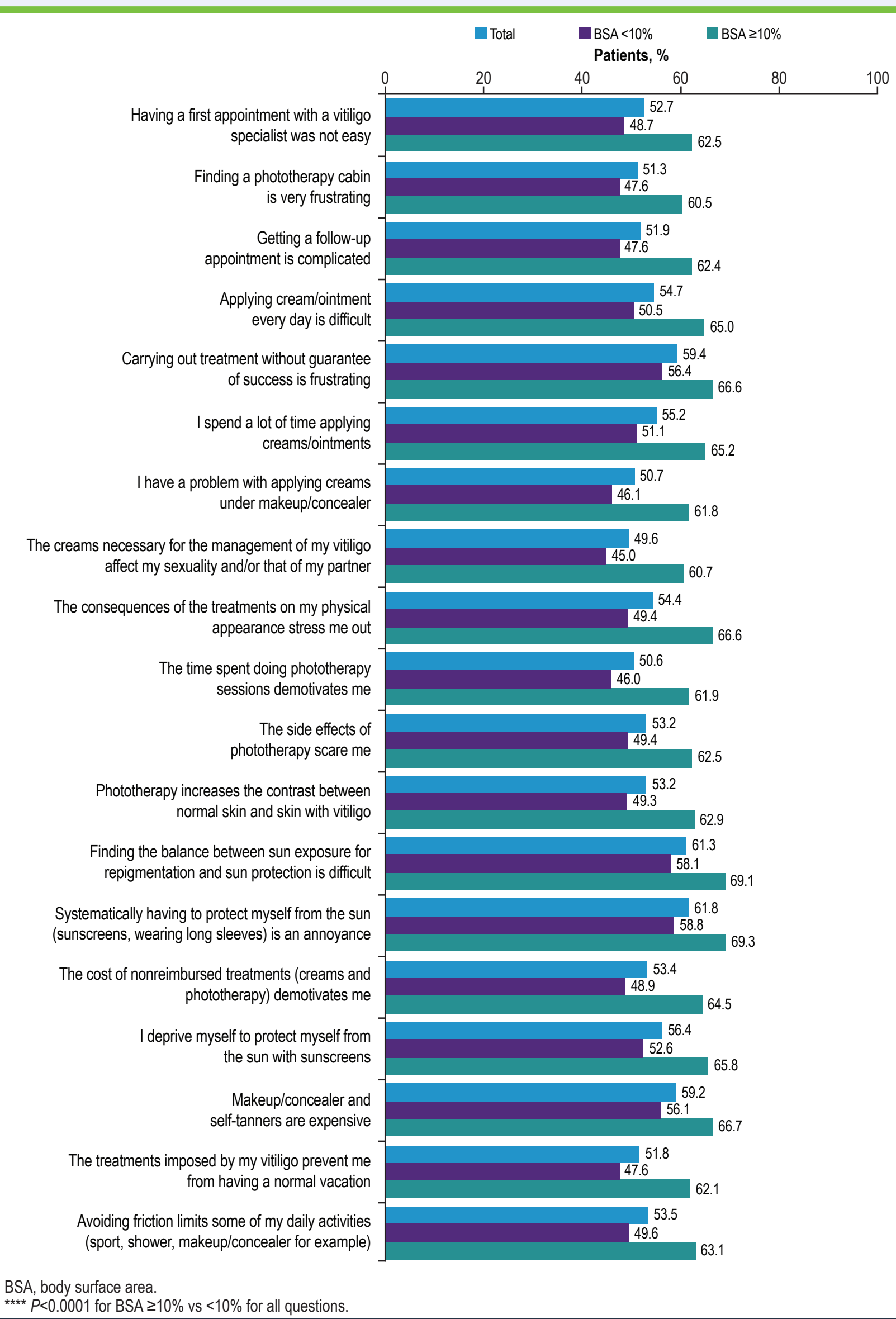
BSA, body surface area; SA-VES, Self Assessment Vitiligo Extent Score.
[†] Multiple answers for race were accepted.
[‡] Race was not solicited in France (n=250) or Germany (n=250).
[§] Fitzpatrick skin types are defined as follows: type I, pale white skin; type II, white skin; type III, light brown skin; 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.

Figure 1. Treatment Burden of Vitiligo by Fitzpatrick Skin Type****



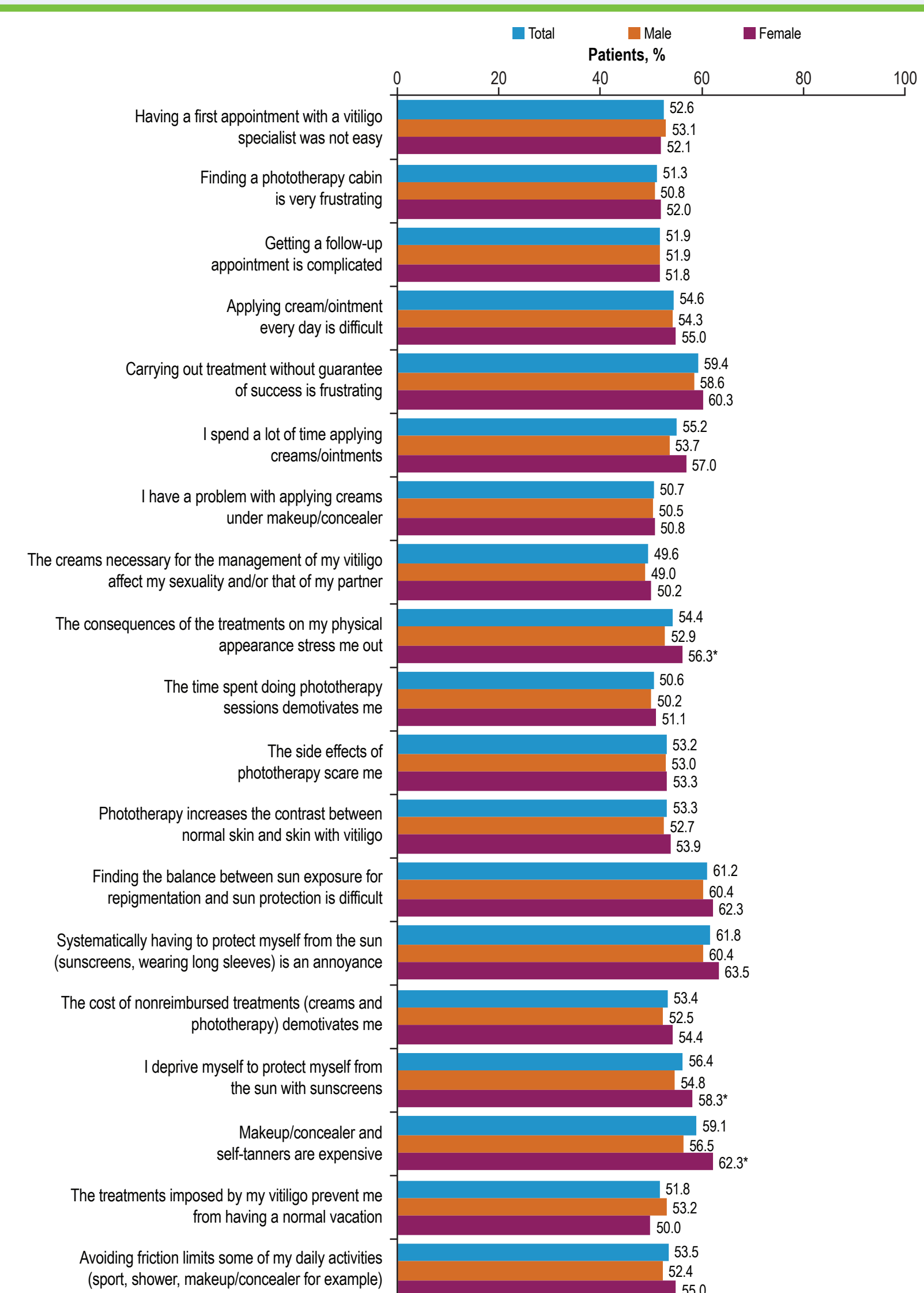
**** $P<0.0001$ for darker vs fairer skin for all questions.

Figure 2. Treatment Burden of Vitiligo by Affected BSA****



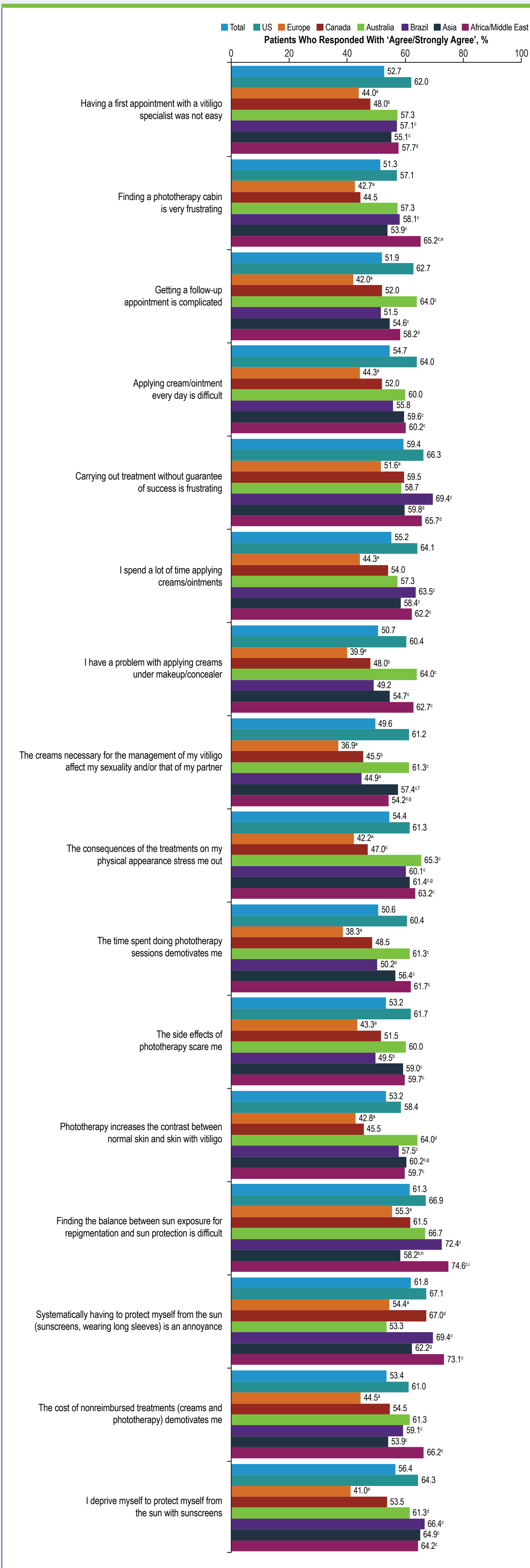
BSA, body surface area.
**** $P<0.0001$ for BSA ≥10% vs <10% for all questions.

Figure 3. Treatment Burden of Vitiligo by Sex



[†] $P<0.05$ for male vs female.

Figure 4. Treatment Burden of Vitiligo by Geographic Region



[†] $P<0.0001$ vs US; [†] $P<0.001$ vs US; [†] $P<0.0001$ vs Europe; [†] $P<0.001$ vs Europe; [†] $P<0.0001$ vs Canada; [†] $P<0.001$ vs Brazil; [†] $P<0.001$ vs Canada; [†] $P<0.0001$ vs Brazil; [†] $P<0.0001$ vs Asia.

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Limitations

- Limitations are those 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
- Other limitations include potential errors in measurement that are inherent in patient-reported outcomes studies

Conclusions

- Patients with darker Fitzpatrick skin types (IV–VI) or ≥10% affected BSA reported a higher treatment burden across items in the online questionnaire
- Treatment burden varied across geographic regions and was generally lowest in Europe and Canada and highest in the United States, Australia, and Africa/Middle East
- These findings highlight the high burden that patients with vitiligo endure with regard to starting and continuing treatment, difficulty finding therapy, and frustration with treatment outcomes, which may lead patients to stop treatment

Disclosures

KE is a consultant for AbbVie, Incyte Corporation, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Viela Bio. 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. KB, JGao, and HR are employees and shareholders of Incyte. 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. 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). 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. 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.

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