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Risk behaviour and patient preferences for an improved non-melanoma skin cancer prevention modality for organ-transplanted patients: a European, multi-country, online patient community study

Background: Immunosuppressants used in organ transplant patients increase the risk of non-melanoma skin cancer. *Objectives:* This study aimed to evaluate patient behaviours towards skin cancer prevention methods and to understand characteristics of a future prevention strategy based on patients' perspective. *Materials and methods:* Carenity, a global online patient community, enabled the recruitment of 200 adult patients with solid organ transplants from four European countries: France, Italy, Spain and Germany. *Results:* Most patients were well informed about the risk of skin cancer, but only 27% (53/200) monitored their skin. Most patients exposed themselves to intense sun exposure once a month or more. Nevertheless, more than half of patients were motivated to use additional prevention strategies and limit their sun exposure. The most appropriate prevention strategy was reported to be the use of a cosmetically attractive, water-resistant, paraben/fragrance-free cream. *Conclusion:* A one-size-fits-all approach is not an appropriate prevention strategy and an adapted approach based on patients' preferences may significantly contribute to better compliance and adherence.

Key words: non-melanoma skin cancer, NMSC, organ transplantation, keratinocyte cancer, preventive treatment, skin protection

Skin cancers account for 40-50% of all post-transplant malignancies and cause significant morbidity and mortality, as they tend to be more aggressive than skin cancers in the general population [1, 2]. Most of the cutaneous malignancies diagnosed in organ transplanted recipients (OTRs) are non-melanoma skin cancers (NMSC), such as squamous cell carcinoma (SCC) and basal cell carcinoma (BCC), along with actinic keratosis (AK), the *in-situ* precursor of SCCs [1, 2]. Of note, SCCs are more common in OTRs than BCCs [1, 2]. The risk of developing skin cancer in OTRs increases 10-100-fold and is proportional to the dose, duration, and type of immunosuppressive treatment [3-5]. Similar to the general population, ultraviolet radiation (UVR) exposure, in association with individual susceptibility (fair skin) also plays an important role in the development of skin cancer in OTRs. Other risk factors for NMSC in OTRs include age over 55 years at the time of transplantation, fair skin phototype, and a high-UV climate [6-8]. The time of development of NMSC is estimated to range from four to nine years after transplantation [9]. Per guidelines and several studies, many cases of skin cancers in OTRs can be prevented by adequate use of sun protection, retinoid for chemoprevention, skin self-examination, and physician follow-up (every 12 months for low-risk patients, every 3-6 months for patients with intermediate risk, and at least every three months for high-risk patients) [10-14]. However, in OTRs, poor compliance with advised sun protection, specifically regarding sun screens, was reported due to their oily nature, a lack of knowledge about the harmful effect of UV radiation, cosmetic unacceptability, and impracticality in a work environment [15, 16]. Furthermore, due to the cutaneous adverse events induced by immunosuppressive treatment (*i.e.* sebaceous gland hyperplasia, folliculitis, and acne), patients try to reduce the amount and frequency of an oily sunscreen [17-19]. Continuous and improved patient education is another important pillar in NMSC prevention strategies. A recent systematic review of the literature showed that there is a lack of effective patient education and adherence to recommended medical follow-up appointments [20]. Therefore, there is an urgent need to better understand factors impacting OTRs' compliance to sun protection measures. Patient perspective and satisfaction surveys have become important tools in identifying gaps in quality of healthcare, prevention, and treatment strategies [21]. We conducted a study using an online community of OTRs in several European countries to gain insight into variables that patients identify as compliance barriers to prevention measures and features that would make a future prevention strategy more acceptable and patient-friendly.

Materials and methods

This study was conducted using the Carenity platform, a free multilingual global online community (> 300,000

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members) in the USA, France, Italy, Spain, Germany and the UK. The platform facilitates discussions among patients, provides high-quality medical information, and contributes to medical research through development, initiation, and analysis of online surveys.

First, a qualitative study was conducted in France, Spain, Germany and Italy. Each country's community managers introduced and facilitated discussions on NMSC topics to collect verbatim that were analysed to identify relevant patient concerns for the survey development.

The survey contained 28 close-ended and four open-ended questions. These questions covered the following fields: patients' profile (*e.g.* what areas of your body are/were affected by the precancerous/cancerous lesions?), their perspective about living with the risk of precancerous/cancerous skin lesions (*e.g.* since your transplantation, how/when do you protect yourself? Give an example), their satisfaction about prevention strategies (*e.g.* how satisfied are you with the treatment intended to protect you from the risk of developing precancerous/cancerous lesions?), and expectations in terms of future strategies (*e.g.* in your opinion, what would be the ideal type of treatment aimed to protect you from developing precancerous/cancerous lesions?). The English version of the survey was developed in consultation with a medical review committee (*i.e.* two dermatologists) and proofread by a patient from the transplant community to ensure comprehension. The survey was then translated into local languages.

Members of transplanted communities in the above countries were invited via private e-mails to participate in the study. Patients were enrolled after providing consent with regards to processing and use of their personal health data, therefore approval from an independent ethics committee was not sought. Participation was without incentives. Only patients with solid organ transplant and under immunosuppressive drugs were enrolled.

Data was pseudonymized and surveys were checked at the end of the data collection process due to absence of pharmacovigilance signal. Data quality was verified according to: (1) response speed to the survey (estimated at 10-15 minutes); (2) coherence of answers; and (3) verbatim.

The sample size ($n = 200$) was defined considering the descriptive nature of the study and the feasibility conditions (*e.g.* size of the communities, data collection period). Minimum enrolment of 30 subjects per country was set to provide statistically meaningful data.

Excel 2013® and RStudio (v3.5.0) were used to perform descriptive, univariate, and multivariate analysis. When $n < 30$, the Shapiro-Wilk test was performed to assess the normality of the distribution. The multivariate analyses included the Student test and ANOVA test when the population was normally distributed, and the Wilcoxon test and Kruskal-Wallis test when it was not. Multivariate analysis also included the Chi-squared test and Multiple Correspondence Analysis depending on the type of data. The p value was calculated for each analysis and was categorised as $p < 0.10$; $p < 0.05$ or $p < 0.01$.

The sun exposure was defined as: (a) moderate: outdoor life; (b) intense: beach, prolonged outdoor activities, professional activities with intense sun; and (c) extreme exposure: glaciers, high mountains, tropics, professional activities with extreme sun.

Prevention satisfaction level score was defined as: (1) impact on health: effectiveness, side effects, and presence of additives in creams; (2) ease of use: ease of application and frequency of application; (3) characteristics: colour, smell, texture, aesthetic aspect of the cream post-application; and (4) cost: price and reimbursement.

Results

Patients' profile

Among 604 invited patients, 200 completed the survey and were included in the analysis (*figure 1*).

The number of respondents were distributed equally among countries (28% [$n = 58$], 26% [$n = 52$], 25% [$n = 49$], and 21% [$n = 41$] in France, Italy, Spain, and Germany, respectively) with 54% males and 46% females. The average age was 43.2 years old with younger patients in Germany and older patients in France (mean age: 36.6 and 51.1 years, respectively) (*table 1*).

The kidney was the most frequently transplanted organ, followed by the liver and heart (67% [$n = 134$], 24% [$n = 48$], and 8% [$n = 15$], respectively). On average, patients were 36.9 years old (95% CI: 35.1-38.8) when transplanted with a mean time of 6.2 years (95% CI: 5.4-7.1) since transplantation. All participants were under immunosuppressive therapy at the study start. On average, respondents were taking two treatments (mean: 1.8; 95% CI: 1.7-1.9), and among those receiving double ($n = 76$) and triple ($n = 46$) immunosuppressive treatments, calcineurin inhibitors and mycophenolate mofetil were the most prescribed.

Presence of skin cancer lesions

Since the start of their treatment, 32% of respondents developed pre-cancerous or cancerous skin lesions with the highest number in Germany (71%), followed by Italy (31%), Spain (20%), and France (16%) ($p < 0.01$). Patients receiving organ transplants at a younger age tended to develop pre-cancerous lesions and skin cancer more often than older patients (38% of OTRs < 30 years old developed skin lesions vs. 25% of OTRs > 40 years old).

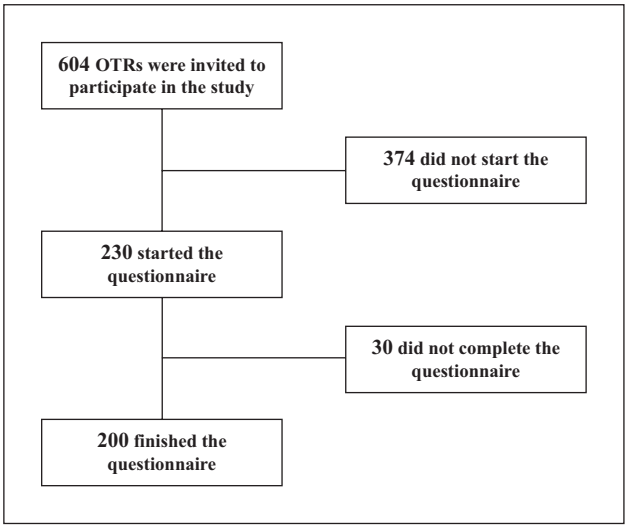

Figure 1. Flow of participation in the study.

Table 1. Distribution of respondents ($n = 200$) according to age and country.

	France		Spain		Italy		Germany	
	***n* = 58**	**%**	***n* = 49**	**%**	***n* = 52**	**%**	***n* = 41**	**%**
18-30 years	2	3%	13	27%	12	23%	15	37%
31-40 years	7	12%	20	41%	13	25%	15	37%
41-50 years	21	36%	11	22%	6	12%	3	6%
51-60 years	14	24%	4	8%	11	21%	4	10%
61-70 years	12	21%	1	2%	9	17%	4	10%
71-80 years	2	3%	0	0%	1	2%	0	0%
Mean	51.1 years		37.5 years		44.4 years		36.6 years	
95% CI	48.6 - 54.4		34.7 - 40.3		40.5 - 48.4		32.6 - 40.7	

95% CI: 95% confidence interval.

Table 2. Inconvenience related to skin cancer monitoring (score from 0-10; 0 = "not at all inconvenient" and 10 = "very convenient") in respondents ($n = 172$) monitored for their skin by a dermatologist or GP.

	Stress associated with skin cancer		Having to wait for an appointment		Out-of-pocket costs		Travel time to visit the doctor		Frequency of visits to the doctor		Duration of visits to the doctor	
	n	**%**	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**
0	18	10%	21	12%	32	19%	33	19%	40	23%	36	21%
1	20	12%	20	12%	24	14%	27	16%	22	13%	21	12%
2	10	6%	10	6%	12	7%	16	9%	22	13%	24	14%
3	13	8%	16	9%	12	7%	17	10%	13	8%	16	9%
4	18	10%	13	8%	10	6%	14	8%	10	6%	15	9%
5	13	8%	23	13%	36	21%	15	9%	22	13%	17	10%
6	18	10%	14	8%	9	5%	16	9%	11	6%	12	7%
7	17	10%	13	8%	14	8%	8	5%	15	9%	17	10%
8	15	9%	19	11%	13	8%	15	9%	6	3%	9	5%
9	8	5%	7	4%	3	2%	5	3%	6	3%	3	2%
10	22	13%	16	9%	7	4%	6	3%	5	3%	2	1%
Mean	5.0		4.7		3.8		3.6		3.4		3.3	
Q3	8.0		7.0		6.0		6.0		5.3		5.3	
Median	5.0		5.0		4.0		3.0		3.0		3.0	
Q1	2.0		2.0		1.0		1.0		1.0		1.0	

Q3: third quartile; Q1: first quartile.

Awareness and patient perception towards available prevention measures

Most respondents (90%) were informed about the risk of skin cancer lesions. Neither the presence of lesions nor the country of residence impacted awareness. In all countries, 75% of respondents were monitored for skin cancer lesions by a dermatologist, 23% by both dermatologists and general practitioners, and 27% self-monitored their skin. When comparing skin self-examination between countries, French patients were more likely to check their skin (38%) than Germans (27%), Spanish (20%), and Italians (19%) ($p < 0.10$). In terms of frequency of medical follow-up, patients were seen more often by their general practitioners (71% of patients every three months) than by dermatologists (only 36% every three months). The medical follow-up was perceived by patients as an important burden. All respondents identified "stress associated with skin cancer" (mean: 5.0/10) and "waiting time to have an appointment" (4.7/10) as important medical follow-up constraints (scale 0 to 10; 0 = "not at all inconvenient" and 10 = "very inconvenient") (*table 2*).

Sun exposure and use of sun protection

Over the past five years, patients were exposed more often to moderate sun intensity (46%) *vs.* intense (12%) or extreme

Table 3. Level of willingness of respondents without lesions (n = 136) to follow prevention strategies according to sun exposure and time to first organ transplant.

n	Score*	Years since transplant (mean)	Sun exposure (%)		
			Moderate	Intense	Extreme
136 (total)		5.9	45	21	5
28	0-3	6.8	57	32	7
35	4-6	6.5	49	23	3
73	7-10	5.3	38	16	5

**willingness to follow prevention strategies (score 0 = "not ready at all" and 10 = "totally ready").*

intensity (5%). In total, 89% of patients were exposed to moderate sun intensity at least once a month. Among patients with no lesions ($n = 136$), those with less sun exposure and recent transplantation reported greater willingness to follow prevention strategies (score 7 to 10; score 0 = "not ready at all" and 10 = "totally ready") (*table 3*).
Spanish and Italian patients were most likely to follow the prevention strategy (64% scored 7-10) *vs.* French patients (38% scored 7-10) ($p < 0.10$). Patients with skin cancer lesions ($n = 64$) were strongly convinced of the importance of using prevention strategies (53% scored 9 and 10).
In general, 65% of patients applied sunscreen (independent of sun protection factor [SPF]) all the time or if sun intensity was moderate. Moreover, approximately one third of patients (32%) always applied high-SPF sunscreen (≥ 50), but only 14% applied the cream every two hours during sun exposure.

Ideal sun protection and prevention measures

An ideal preventative treatment should be in the form of a cream (36%), followed by oral formulation (27%) and spray (22%). Less than 10% of patients preferred other forms of topical formulations (2-11% for ointment, gel, foam, or lotion). The perception of an ideal strategy varied according to respondents' age and gender. Younger patients (18-40 years old) preferred a cream (47%) while older patients (40-80 years old) preferred an oral formulation (45%). Independent of the presence of previous lesions, male patients were more inclined to use a cream (40%) *vs.* female patients (30%).
Overall, 53% of respondents were willing to apply a topical preventative treatment at a higher frequency (*i.e.* 3-6 times / twice a day). Italian patients were most likely to accept a high-frequency application (63% at least twice a day), while French patients were the least motivated (38% at least twice daily; 49% once a day).
With regards to an oral formulation, acceptance of higher treatment frequency varied according to age and country. Younger patients (18-40 years old) were more inclined to use an oral formulation at a higher frequency, at least twice a day, compared to older patients (61-80 years old) (42% *vs* 17%, respectively). German patients were more willing to accept an oral formulation at a higher frequency (49%), while French patients were the least motivated (22%).
In general, patients were more inclined to apply topical formulation at higher frequencies (53% at least twice a day) than an oral formulation (37%).
For our respondents, the ideal cream would be water-resistant (56%), non-sticky (45%), easy to spread (44%), paraben-free (35%), fragrance-free (19%), lightly textured (13%), and not shiny (11%).
With regards to applying two creams (*i.e.* one classic sunscreen and an additional one) simultaneously, most respondents (51%) identified "the risk of forgetting to apply a cream" followed by "high frequency of application" (44%) and "more side effects" (41%) as major constraints. These inconveniences were country-dependent; Italian and Spanish patients identified "forgetting the application", while French and German patients identified "time used to apply creams" and "application frequencies", respectively, as major concerns.
Patients with previous skin lesions expressed a need for additional support (6/10; $n = 38$), including support from healthcare professionals or family (18/38), financial support (11/38), and improvement of prevention and treatment strategies (8/38).

Discussion

To our knowledge, this is the first study that provides real-world perspectives on the behaviour of transplanted patients with regards to available NMSC prevention strategies and patient-preferred features of an improved prevention strategy using an online community of organ transplanted patients in Europe.
Our solid organ-transplanted study population, with a mean age of 43.2 years, was slightly younger than those in previous studies (average age of 51.7 ± 9.97 years [22]). Our study did not include the time from transplantation as an inclusion criterion in order to allow patients without lesions to participate, as the appearance of NMSC is directly related to the elapsed time from transplantation.
Overall, 32% of respondents reported the presence of NMSC lesions, with a mean time of 6.2 years since transplantation. Although we cannot define the speed with which NMSC developed in OTRs based on this study, the observed time since transplantation and percentage of OTRs developing NMSCs within six years in each country is similar to previously reported data [8, 23-26]. We also found a higher rate of lesion appearance among German respondents, perhaps due to their fair skin or to our finding that these patients exposed themselves to the sun more within the last five years and/or they used more classic sunscreens as opposed to high-protection ones, *versus* other respondents. In our study, as patients self-reported NMSC diagnosis, the risk of incorrect reporting due to patient misunderstanding of the type of skin

cancer or failure to correctly recall the diagnosis cannot be excluded.

Surprisingly, NMSC lesions were reported at a higher frequency in our younger participants. This is unexpected since it is well documented that the risk of NMSC increases with age at transplantation [16]. Perhaps this discrepancy is a selection bias due to an increased willingness of young patients with previous skin lesions to participate in the study. Furthermore, it might indicate a shift in the risk of NMSC development in the younger population, potentially due to a lack of appropriate educational programmes. Considering that this population comprises avid internet/mobile users, further integration and use of these tools in the delivery of prevention messages might be warranted.

Participants were well informed about the risk of skin cancer. They were regularly monitored by a dermatologist, a general practitioner, or both, and used sun protection strategies (sunscreens, sun avoidance, and sun-protective clothing). However, our respondents continued to adopt risky behaviour, *i.e.* most were exposed to moderate sun intensity at least once a week and only a small percentage applied sunscreen every two hours during sun exposure, in line with data reported in previous studies [27, 28]. We obtained similar results in patients who had already developed lesions. Although these patients were more willing to use prevention strategies versus patients without lesions, they were not more compliant regarding sun protection behaviours. The reason for this non-compliance was not investigated in this study but may reflect a gap within the quality of information provided, education, and available strategies, warranting a need for alternative strategies.

Furthermore, most patients identified medical follow-ups as a major burden because of the stress related to skin cancer and delay for appointments. To the best of our knowledge, this is a new finding with an important impact on OTR compliance, since, as shown previously, providing effective and repetitive sun protection education during medical follow-up increases compliance [20, 29].

Interestingly, our results show that despite low compliance, most of our respondents were eager to try a new prevention strategy, indicating that available strategies are not sufficient or patient-friendly.

In our respondents' opinion, the most appropriate form of prevention (other than sunscreen) is the use of a cream followed by oral and spray formulation. The preference is age-dependent, *i.e.* younger patients (18-45 years) prefer a cream formulation while older patients prefer an oral formulation (61-80 years). Patients were more inclined to apply a topical formulation at least twice a day than take an oral formulation at the same frequency. Independent of the formulation, patients younger than 60 years old were willing to use a product at higher frequency. From a patient's perspective, the ideal cream should be water-resistant, non-sticky, easy to spread, and paraben-free. The most important risk factors identified by respondents with regards to the application of two creams (one classic sunscreen and an additional one for preventive treatment) were the risk of forgetting to apply one of the creams followed by high frequency of application and more side effects. In addition, respondents with previous skin lesions expressed a need for additional preventive support including support from healthcare professionals and family, financial support, and improvement of prevention and treatment strategies.

We acknowledge some limitations inherent in the design of our study. As respondents were members of an online patient community, young, computer-literate, and highly educated patients regarding the risk of skin cancer may have been over-represented. However, based on recent surveys showing that 71% of European people use the internet on a daily basis, with 60% searching for health-related information, we estimate that our population closely represented the general population [30, 31]. As is the case with any self-reported study, NMSC may have been incorrectly reported due to patients' misunderstanding of the type of skin cancer or incorrect recall. Considering that 61% of patients with NMSC lesions in our study reported a visit to dermatologists at least once every three months versus 22% of patients without lesions, we consider that NMSCs were well reported in our study. In addition, we did not collect information on skin phenotype which could have provided additional insight into data interpretation. Furthermore, patients invariably related such a NMSC prevention strategy to sunscreen, despite specifying that our survey focused on the use and features of a new preventative product other than sunscreen. Patient educational level was not evaluated in our study which may impact patient awareness of skin cancer risk and use of prevention strategies [32].

In conclusion, the present study demonstrates a need for improved educational and prevention strategies for OTRs, specifically for a younger patient population. These results point to the fact that, as for other diseases, a one-size-fits-all approach is not an appropriate prevention strategy and an adapted approach based on the patients' expectations and preferences may significantly contribute to better compliance and adherence. ■

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