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Data Article

Health-related quality of life (EuroQol 5D-5L) in patients with autoimmunity in the context of immunotherapy: A large dataset comprising cancer patients after cessation of checkpoint inhibitor therapy and patients with autoimmune diseases



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ABSTRACT

This dataset contains demographic, clinical, and health-related quality of life (HRQoL) data from 2905 patients including 200 cancer patients after immune checkpoint inhibitor (ICI) cessation and 2705 patients with a wide variety of autoimmune diseases.

Within this multicenter, cross-sectional survey study data were collected questionnaire-based in cancer patients (ICI-patients) ≥ 18 years of age who had received at least one dose of ICI with ≥ 12 weeks since ICI discontinuation. Patients with autoimmune diseases (AI-patients) were ≥ 18 years, had at least one autoimmune disease and had never received ICI. ICI-patients were recruited in three skin cancer centers and via support groups. AI-patients were recruited in an outpatient clinic for internal medicine and via support groups.

Specific questionnaires for ICI-patients/AI-patients were provided paper-based for patients from outpatient clinics and online for patients from support groups. Both questionnaires contained sections with demographic information, clinical data, and the standardized patient-reported outcome measure EuroQol 5D-5L (EQ-5D-5L) to assess HRQoL. Clinical data focused on autoimmunity and therapy of autoimmunity in (1) ICI-patients referring to particularly persistent immune-related adverse events (persistent irAEs) and in (2) AI-patients referring to respective autoimmune diseases. Additionally, specific items on cancer and cancer therapy were included in ICI-patients, and AI-patients were asked about the presence of acute exacerbations of autoimmune diseases. This dataset contains the raw data for ICI-patients and AI-patients, analyzed data on patient demographics, clinical characteristics and HRQoL scores among ICI-patients with/without persistent irAEs and among AI-patients.

The data provide a basis for further investigations within the cohort of ICI-patients after ICI cessation and/or for AI-patients with different autoimmune diseases with regard to HRQoL, autoimmunity and therapy of autoimmunity.

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Specifications Table

Subject	Immunology
Specific subject area	Clinical data and health-related quality of life in patients with persistent immune-related adverse events or autoimmune diseases
Type of data	Table
How the data were acquired	Data were collected using questionnaire-based surveys. Questionnaires comprised the standardized patient-reported outcome measure EuroQol 5D-5L, items on demographic data, and items on clinical data relevant for autoimmunity.

(continued on next page)

Data format	Raw Analyzed
Description of data collection	From April to October 2021, surveys were conducted paper-based in outpatient clinics (LMU Klinikum, Munich; University Hospital Schleswig-Holstein, Kiel; Hospital Bremerhaven Reinkenheide, Bremerhaven) and online via support groups. Patients in outpatient clinics were identified by weekly review. Support groups were contacted and asked to inform their members about the survey via an online link. Eligible cancer patients were ≥ 18 years of age and had received at least one dose of ICI with ICI cessation ≥ 12 weeks ago. Eligible patients with autoimmune diseases were ≥ 18 years of age, had at least one autoimmune disease, and had never received any ICI.
Data source location	<ul style="list-style-type: none"> • Institution: Department of Dermatology and Allergy, University Hospital, LMU Munich • City/Town/Region: Munich • Country: Germany
Data accessibility	Repository name: Mendeley Data Data identification number: 10.17632/jvs782kvw8.2 Direct URL to data: https://dx.doi.org/10.17632/jvs782kvw8.1
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Value of the Data

- Data on ICI-patients provide a broad base of cancer survivors after ICI discontinuation for further investigation on clinical parameters and HRQoL.
- Data on AI-patients offer data of numerous autoimmune diseases, related therapies, and implications on HRQoL.
- Researchers in the field of oncology can mainly benefit from the data of ICI-patients as data include a broad sample with relevant parameters.
- Researchers from various medical disciplines may benefit from the data of AI-patients as a broad variety of autoimmune disease is covered.
- The data on ICI-patients give detailed information about persistent/chronic irAEs and related therapies which is – until now – a largely unexplored field.
- The data on AI-patients can be used to investigate specific autoimmune diseases, their impact on HRQoL and their therapies.

1. Objective

This dataset was generated to investigate persistent irAEs in cancer patients ≥ 12 weeks after cessation of ICI therapy, to assess the prevalence of persistent irAEs, and to analyze the impact of persistent irAEs on HRQoL [1]. As persistent irAEs mimic non-ICI-induced autoimmune diseases, patients with autoimmune diseases were included in the study to identify commonalities and differences regarding autoimmune symptoms, related therapies, and implications on HRQoL.

2. Data Description

The dataset contains demographic data, clinical data and data on HRQoL from 200 ICI-patients and 2705 AI-patients (Table 1) [2].

The distribution of gender and age in the sample of ICI-patients, who mainly had a melanoma with 96.5%, was consistent with the usual distribution among patients with melanoma [3]. The

Table 1
ICI-patients and AI-patients: demographics, clinical characteristics, and recruitment cohorts.

	ICI-patients n = 200 (6.9%)	AI-patients n = 2705 (93.1%)	Total n = 2905 (100.0%)
Gender, n (%)			
Female	98 (49.0)	2391 (88.4)	2489 (85.7)
Male	102 (51.0)	314 (11.6)	416 (14.3)
Age at time of survey, years			
Mean (SD)	60 (14.6)	47 (11.6)	48 (0.2)
Median (range)	60 (23.0-91.0)	48 (18.0-84.0)	49 (18.0-91.0)
Marital status, n (%)			
Partnered	152 (76.0)	1989 (73.6)	2141 (73.7)
Not partnered	48 (24.0)	716 (26.5)	764 (26.3)
Education, n (%)			
Low qualification	46 (23.0)	303 (11.2)	349 (12.0)
Middle qualification	76 (38.0)	1134 (41.9)	1210 (41.7)
High qualification	78 (39.0)	1268 (46.9)	1346 (46.3)
Recruitment cohort, n (%)			
Outpatient clinics	147 (73.5)	9 (0.3)	156 (5.4)
Support groups	53 (26.5)	2696 (99.7)	2749 (94.6)

ICI, immune checkpoint inhibitor; AI, non-ICI-induced autoimmune disease.

Table 2
ICI-patients (n = 200): types of persistent irAEs.

	Outpatient ICI-patients n = 147 (73.5%)	Support group ICI-patients n = 53 (26.5%)	Total ICI-patients n = 200 (100.0%)
Persistent irAEs, n (%)			
Patients without persistent irAEs	86 (58.5)	14 (26.4)	100 (50.0)
Patients with persistent irAEs	61 (41.5)	39 (73.6)	100 (50.0)
Type of persistent irAE, n (%) ^a			
Arthralgia	24 (16.3)	17 (32.1)	41 (20.5)
Myalgia	20 (13.6)	18 (34.0)	38 (19.0)
Hypothyroidism	16 (10.9)	20 (37.7)	36 (18.0)
Hypophysitis	12 (8.2)	3 (5.7)	15 (7.5)
Diabetes mellitus	2 (1.4)	2 (3.8)	4 (2.0)
Adrenal insufficiency	2 (1.4)	2 (3.8)	4 (2.0)
Xerostomia	12 (8.2)	6 (11.3)	18 (9.0)
Polyneuropathy	3 (2.0)	7 (13.2)	10 (5.0)
Neuropathy (CN VIII)	1 (0.7)	0 (0.0)	1 (0.5)
Vitiligo	14 (9.5)	6 (11.3)	20 (10.0)
Dermatitis/pruritus	4 (2.7)	4 (7.5)	8 (4.0)
Leukotrichia	4 (2.7)	4 (7.5)	8 (4.0)
Lichen ruber	4 (2.7)	0 (0.0)	4 (2.0)
Pneumonitis/respiratory distress	7 (4.8)	9 (17.0)	16 (8.0)
Colitis	5 (3.4)	6 (11.3)	11 (5.5)
Pancreatitis	1 (0.7)	1 (1.9)	2 (1.0)
Hepatitis	1 (0.7)	0 (0.0)	1 (0.5)

^a Multiple responses are possible. ICI, immune checkpoint inhibitor; irAE, immune-related adverse event; CN, cranial nerve.

sample of AI-patients was mainly derived from patients in support groups. AI-patients were more likely to be female, younger, and more highly educated compared to ICI-patients. This is consistent with studies showing that particularly young and educated women take advantage of help in support groups [4,5]. Moreover, the high proportion of female participants in our sample reflects the target group of AI-patients described in literature: approximately 78% of patients affected by autoimmune diseases are women [6]. In particular hormonal and/or genetic factors [7] are responsible for this imbalance and for the about 2.7 higher risk of autoimmune diseases in women compared to men [8].

Table 3

AI-patients (n = 2705): types of autoimmune diseases.

	Non-exacerbated AI-patients n = 1837 (67.9%)	Exacerbated AI-patients n = 868 (32.1%)	Total AI-patients n = 2705 (100.0%)
Type of AI, n (%) ^a			
Addison's disease	141 (7.7)	36 (4.1)	177 (6.5)
Ankylosing spondylitis	55 (3.0)	58 (6.7)	113 (4.2)
Autoimmune gastritis	9 (0.5)	3 (0.3)	12 (0.4)
Autoimmune hematological disorders	19 (1.0)	9 (1.0)	28 (1.0)
Autoimmune hepatitis	69 (3.8)	23 (2.6)	92 (3.4)
Autoimmune hyperthyroidism	132 (7.2)	41 (4.7)	173 (6.4)
Autoimmune hypothyroidism	299 (16.3)	146 (16.8)	445 (16.5)
Bullous pemphigoid	2 (0.1)	3 (0.3)	5 (0.2)
Collagenosis (others)	6 (0.3)	9 (1.0)	15 (0.6)
Crohn's disease	88 (4.8)	47 (5.4)	135 (5.0)
Dermatomyositis	18 (1.0)	9 (1.0)	27 (1.0)
Diabetes mellitus type 1	150 (8.2)	21 (2.4)	171 (6.3)
Giant cell arteritis	5 (0.3)	2 (0.2)	7 (0.3)
Hypophysitis	14 (0.8)	4 (0.5)	18 (0.7)
Idiopathic pulmonary fibrosis	4 (0.2)	5 (0.6)	9 (0.3)
Lichen ruber	40 (2.2)	31 (3.6)	71 (2.6)
Lichen sclerosus	7 (0.4)	4 (0.5)	11 (0.4)
Multiple sclerosis	49 (2.7)	17 (2.0)	66 (2.4)
Myasthenia gravis	64 (3.5)	36 (4.1)	100 (3.7)
Myositis	28 (1.5)	18 (2.1)	46 (1.7)
Neurodermatitis	29 (1.6)	12 (1.4)	41 (1.5)
Pemphigus vulgaris	17 (0.9)	6 (0.7)	23 (0.9)
Polymyalgia rheumatica	42 (2.3)	16 (1.8)	58 (2.1)
Polymyositis	26 (1.4)	16 (1.8)	42 (1.6)
Polyneuropathy: CIDP	8 (0.4)	7 (0.8)	15 (0.6)
Polyneuropathy: GBS	4 (0.2)	1 (0.1)	5 (0.2)
Primary biliary/sclerosing cholangitis	47 (2.6)	22 (2.5)	69 (2.6)
Psoriasis vulgaris	137 (7.5)	87 (10.0)	224 (8.3)
Psoriatic arthritis	134 (7.3)	127 (14.6)	261 (9.6)
Rheumatoid arthritis	107 (5.8)	94 (10.8)	201 (7.4)
Sarcoidosis	185 (10.1)	85 (9.8)	270 (10.0)
Sjogren's syndrome	215 (11.7)	154 (17.7)	369 (13.6)
Systemic sclerosis	66 (3.6)	50 (5.8)	116 (4.3)
Systemic lupus erythematosus	181 (9.9)	78 (9.0)	259 (9.6)
Ulcerative colitis	79 (4.3)	48 (5.5)	127 (4.7)
Vasculitis (others)	68 (3.7)	38 (4.4)	106 (3.9)
Vitiligo	204 (11.1)	74 (8.5)	278 (10.3)

^a Multiple responses are possible. AI, non-ICI-induced autoimmune disease; CIDP, chronic inflammatory demyelinating polyneuropathy; GBS, Guillain-Barré syndrome.

The data shows persistent irAEs in 41.5% of ICI-patients (Table 2) and a broad variety of autoimmune-diseases in AI-patients (Table 3).

All patients filled the EQ-5D-5L to assess HRQoL. The EQ-5D-5L includes five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) rated by five ordinal levels (no, slight, moderate, severe, or extreme problems). Based on the ratings and on a value set for the German population, the EQ-Index score was determined for each patient. The EQ-Index score ranks on a scale from -0.661 (extreme problems in all five dimensions) to 1 (no problems in any dimension). Moreover, the EQ-5D-5L comprises a visual analogue scale indicating subjective HRQoL on a scale from 0 (worst imaginable health state) to 100 (best imaginable health state) which corresponds to the EQ-VAS score.

To evaluate internal consistency of EQ-Index scores and EQ-VAS scores in ICI-patients and in AI-patients respectively, standardized Cronbach's alpha was calculated for each group showing good internal consistency among ICI-patients (0.751) as well as among AI-patients (0.742) [9].

The dataset comprises the following files, available on Mendeley Data [2]:

- 1_Questionnaires: This file contains the questionnaire for ICI-patients after immunotherapy and the questionnaire for AI-patients with autoimmune diseases in English.
- 2_Data_AI-patients: This file contains the raw data of the survey among AI-patients extended by a legend. Raised data comprised recruitment, case, gender, age, education, marital status, onset of autoimmune disease, state of exacerbation, type of autoimmune disease and related burden, therapy of autoimmune disease and related burden, EQ-5D-5L dimensions, EQ-Index score, and EQ-VAS score.
- 2_Data_ICI-patients: This file contains the raw data of the survey among ICI-patients extended by a legend. Raised data comprised recruitment, case, gender, age, education, cancer type, cancer stage, metastatic status, response to therapy, type of ICIs administered, time since last ICI dose, burden before/during/after ICI, reversible irAEs, therapy of reversible irAEs, persistent irAEs, burden of persistent irAEs, therapy of persistent irAEs, burden of therapy of persistent irAEs, EQ-5D-5L dimensions, EQ-Index score, EQ-VAS score, patients' retrospective evaluation of ICI therapy, previous cancer therapies, and current cancer therapies.
- 3_AI-Patients_demographics & clinical characteristics: This file contains analyzed demographics and clinical characteristics of AI-patients as total and divided by exacerbation status.
- 3_ICI-Patients_demographics & clinical characteristics: This file contains analyzed demographics and clinical characteristics of ICI-patients as total and divided by recruitment type.
- 4_Autoimmunity_HRQoL and burden: This file contains EQ-Index scores, EQ-VAS scores, burden of symptoms and burden of therapies in ICI-patients/AI-patients with persistent irAEs/autoimmune diseases divided by recruitment cohort/exacerbation status.

3. Experimental Design, Materials and Methods

After obtaining approval from the ethics committee (LMU Munich; 21-0499 KB), this multi-center cross-sectional study was conducted from April to October 2021.

ICI-patients were recruited at three outpatient clinics of skin cancer centers (Department of Dermatology and Allergy, LMU Klinikum in Munich; Department of Dermatology, University Hospital Schleswig-Holstein in Kiel; Department of Dermatology, Allergology and Phlebology, Hospital Bremerhaven-Reinkenheide in Bremerhaven) by weekly review of outpatient lists. In parallel, support groups for cancer patients were contacted and asked to forward an online link to their members. The same procedure was used to recruit AI-patients, except that an internal medicine outpatient clinic (Department of Internal Medicine IV, LMU Klinikum in Munich) recruited the patients and support groups for patients with a wide variety of autoimmune diseases were contacted. Questionnaires in outpatient clinics were paper-based and questionnaires in support groups were conducted using an online survey tool. Patients in the outpatient clinics had the option of handing in the paper-based questionnaires with a prepaid envelope or via an on-site drop-off box. Eligible ICI-patients were ≥ 18 years of age, had received at least one dose of ICI with the last dose ≥ 12 weeks ago. Eligible AI-patients were ≥ 18 years of age, had at least one autoimmune disease and had never received any ICI before. Participation in this study was voluntary for all respondents. Participants were informed at the beginning of the survey that all data would be collected, analyzed, and published anonymously.

Specific questionnaires were created for ICI-patients and AI-patients, with certain sections of the questionnaires resembling each other. To detect misconceptions and reduce measurement errors, the questionnaires were pretested on selected groups of participants and revised accordingly. Both questionnaires included sections with demographic information (gender, age, highest educational level, and marital status) and the standardized patient-reported outcome measure EQ-5D-5L to assess HRQoL [10] after obtaining permission from EuroQol Group.

(1) Additionally, ICI-questionnaires recorded the following self-reported data: type of cancer, metastatic status, previous ICI therapy, date of last ICI administration, burden of cancer before/during/after ICI therapy indicated on a VAS from 0 (not at all) to 100 (very much), reversible irAEs, therapy of reversible irAEs, persistent irAEs as well as their burden within the last week indicated on a VAS from 0 (not at all) to 100 (very much), therapy of persistent irAEs as well as its burden within the last week indicated on a VAS from 0 (not at all) to 100 (very much), and the assessment of ICI therapy and patient education, respectively indicated on a VAS from 0 (I don't agree) to 100 (I agree). Before issuing ICI-questionnaires to patients in outpatient clinics, physicians completed a section on type of cancer, current stage of cancer, previous drug-based anti-cancer therapies, current drug-based anti-cancer therapies, and date of last ICI administration. For patients reached via support groups, this section was omitted and supplemented with a question about current cancer stage and current drug-based anti-cancer therapy.

(2) AI-questionnaires contained further self-reported information on type of autoimmune disease as well as burden of autoimmunity within the last week indicated on a VAS from 0 (not at all) to 100 (very much), onset of autoimmune disease, presence of acute exacerbation, and therapy of autoimmune disease) as well as its burden within the last week indicated on a VAS from 0 (not at all) to 100 (very much).

All collected questionnaires were entered into a data set and merged. If values were missing or inclusion criteria were not met, the entire case was deleted from the data set. Nominal, ordinal and metric variables were summarized by means, medians and/or percentages. Standardized Cronbach's alpha was calculated for EQ-Index scores and EQ-VAS scores among ICI-patients and AI-patients respectively. Statistical analyses were conducted using SPSS Statistics (IBM®, version 28.0).

Ethics Statements

The Ethics Committee at the Medical Faculty of LMU Munich approved the clinical study as anonymized collection and analysis of patient data (21-0499 KB). Informed consent has been obtained from all participants. The research has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

CRedit Author Statement

Thomas U. Schulz: Conceptualization, Methodology, Formal analysis, Investigation, Data Curation, Writing – original draft, Writing – review & editing. **Sarah Zierold:** Conceptualization, Investigation, Writing – review & editing. **Michael M. Sachse:** Investigation, Writing – review & editing. **Giulia Pesch:** Investigation, Writing – review & editing. **Dirk Tomsitz:** Investigation, Writing – review & editing. **Katharina Schilbach:** Investigation, Writing – review & editing. **Katharina C. Kähler:** Investigation, Writing – review & editing. **Lars E. French:** Investigation, Writing – review & editing, Supervision. **Lucie Heinzerling:** Conceptualization, Methodology, Investigation, Writing – review & editing, Supervision.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: S. Zierold has received speaker fees and/or travel grants from BMS, Sun Pharma and MSD. M. M. Sachse reports speaker honoraria from Novartis and advisory board honoraria from Sanofi Genzyme. D. Tomsitz reports consultancy, speaker fees

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Data Availability

[Health-related quality of life \(EuroQol 5D-5L\) in patients with autoimmunity in the context of immunotherapy: a large dataset comprising cancer patients after cessation of checkpoint inhibitor therapy \(Original data\)](#) (Mendeley Data).

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.dib.2022.108676](https://doi.org/10.1016/j.dib.2022.108676).

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