Health and Quality of Life Outcomes

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Impact of immigration background on feasibility of electronic patient-reported outcomes in advanced urothelial cancer patients

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Abstract

Background Electronic patient-reported outcomes (ePROs) have been shown to enhance healthcare quality by improving patient symptom management or quality of life (QoL). However, ePROs data for urothelial cancer (UC) patients receiving systemic therapies are scarce, and the application of ePROs in this patient cohort may need specific setups. This study tested the feasibility of ePROs for UC patients receiving systemic therapies in the outpatient clinic of a tertiary care center.

Patients and Methods From January 2022 to April 2023, 30 UC patients receiving systemic cancer therapies received ePROs based on the Common Terminology Criteria for Adverse Events (CTCAE) and European Organization for Research and Treatment of Cancer Core Quality of Life questionnaires (EORTC QLQ-30) to report their symptoms and QoL during systemic therapy, in total, 125 questions for every therapy cycle. The proportion of patients adherent to the ePROs was assessed to evaluate feasibility, with a preset threshold of 50%. At least half of all treatment cycles with a minimum of two consecutive ePROs (corresponding to two successive therapy cycles) had to be completed to be counted as adherent, and a maximum of six successive therapy cycles was followed by ePROs. Descriptive statistics were calculated for clinical and demographic patient characteristics. T-test and chi-square-test analyses were performed to study the association between ePROs adherence and clinical or demographic factors. The digital process was closely monitored for procedural impediments that could occur.

Results 21 (70%) of the included 30 patients adhered to the provided ePROs, significantly higher than the predetermined threshold of 50%. Adherence remained above 70% until the end of the observation period. A significant negative effect of immigration background on ePROs compliance was observed ($p=0.006$). No other variables were significantly associated with ePROs compliance.

Conclusions In this study, ePROs were a feasible method to assess symptoms and QoL during the systemic cancer therapy of UC patients at our center. The compliance of patients with immigration backgrounds was the

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most significant barrier to using ePROs in this setting. However, the study is limited by the exclusion of patients without email access and the lack of assessment of physician compliance with the ePROs data, which may affect the generalizability and implementation of the findings.

Keywords Electronic patient-reported outcomes, urothelial cancer, feasibility study, immigration background

Background

Patient-reported outcomes (PRO) were developed as a tool to gain direct patient feedback on diverse aspects of the applied therapies, such as quality of life (QoL), symptom tracking, or functional status [1]. Electronic patient-reported outcomes (ePROs) are an innovative strategy for obtaining patient input using digital communication tools such as email, apps, or protected websites [2]. Several studies have demonstrated that measuring QoL and symptom monitoring during ongoing therapy can improve QoL, optimize symptom management, and reduce hospitalizations [3–6]. Using patient feedback to evaluate treatments provides a better understanding of the patient's overall situation in the oncological setting and improves the quality of healthcare delivery [7, 8]. A recent trial assessing the impact of utilizing ePROs during ongoing chemotherapy for solid tumors has demonstrated an improved quality-adjusted and overall survival [9–11]. The increased survival has been attributed to enhanced responsiveness to patient complaints, which might reduce unfavorable event sequences that result in mortality [10]. The Common Terminology Criteria for Adverse Events (CTCAE) is an inventory by the National Cancer Institute. It is currently considered the standard instrument for assessing adverse events (AEs) in oncology and clinical trials [12, 13]. 78 of the 838 listed AEs are symptoms and hence can be self-reported [14]. The ePROs catalog Patient-Reported Outcomes version of the CTCAE [15] comprises these self-reportable items [14]. The European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30) is a 30-item survey to measure patients' QoL during clinical trials [16]. It also offers a scoring system for a metric assessment of the QoL during therapies and in clinical practice [17–19].

Urothelial carcinoma (UC) patients experience a high frequency of adverse events during systemic therapy [20]. Little is known about the feasibility of routine ePROs utilization in this patient cohort, but could aid in improving symptom burden and quality of life during systemic treatment of UC patients. Utilizing ePROs in a specific clinical context has been suggested to provide challenges unique to that clinical environment [21–23]. A study assessing the feasibility of ePROs utilization in UC patients offered promising results in this population [24], which is, to our best knowledge, the only feasibility study in the context of UC. Potential obstacles of ePROs have been systematically addressed before [25]. They comprise among others, educational issues, usability challenges, reliance on internet access, language barriers, or user resistance. The compliance with ePROs has been reported to be influenced by various factors, including clinical factors such as ECOG or clinical status, and socioeconomic components, such as the immigration background [26]. These factors might also play a role in the utilization of ePROs in UC patients. Immigration background has been suggested to impact healthcare delivery in many ways. Besides influencing the choice of therapeutic strategies and patient-physician relationship, adherence to medical services has also been demonstrated to be lower in patients who are non-native to a culture [27]. To our knowledge, there is limited data on the influence of immigration background on the feasibility of ePROs, particularly in cancer patients. The primary aim of our study is to provide feasibility data and identify obstacles from the patients' perspective, when incorporating ePROs into routine clinical care for UC patients receiving systemic therapy at the outpatient clinic of a tertiary care center.

Methods

Between January 2022 and January 2023, a pilot study was conducted to evaluate the feasibility of electronic patient-reported outcomes (ePROs) in a uro-oncological setting. The primary objective was to identify potential barriers to the implementation of ePROs in this context. Feasibility was defined by patient adherence, while the impacts of clinical and demographic factors on ePRO implementation were analyzed within the exploratory framework of the study.

Patients

All consecutive patients starting systemic treatment for UC at our uro-oncological outpatient clinic under the same three treating physicians based on the following selection criteria were considered to be included in the study: patients were required to start treatment with chemotherapy (platin-combination), immunotherapy (pembrolizumab, nivolumab, or atezolizumab) or antibody-drug conjugates (enfortumab-vedotin), be over 18, have an adequate command of German, have an email address, and have no severe cognitive deficits. Patients were considered to have an adequate command of German if they could communicate and read in German in the clinical setting without difficulties. The study was conducted in accordance with the Declaration of Helsinki and the Ethics Committee of the Medical University

of Vienna granted official approval for the execution of this study (approval number 1972/2021). Written consent was obtained from all participating patients after providing them with detailed information on the investigation.

The sample sizes of ePROs feasibility studies vary significantly following the differences in the application methodologies and clinical settings [21, 23, 28–30]. For pilot studies in healthcare, a sample size of around 30 has been suggested as adequate by previous statistical evaluations [31–34]. Therefore, a sample size of 30 was adopted in this investigation. The recruitment period proceeded until the target of 30 inclusions was reached. The maximum number of reported cycles with ePROs was restricted to six per patient. For treatments with two-week cycle intervals, such as nivolumab, ePROs were collected every four weeks. A minimum of two consecutive cycles of ePROs evaluation for each patient was planned. The investigation continued for two months after the last patient was included, ensuring that all patients received ePROs for at least two consecutive cycles. The last ePROs were sent at the beginning of April 2023.

Electronic patient-reported outcome instruments

As the standard ePROs instruments in their respective fields, the PRO-CTCAE was utilized to assess the symptoms [35, 36], and the EORTC QLQ-C30 was employed to assess QoL [16]. Permission to use the German version of the QLQ-C30 questionnaire was acquired from the EORTC before the investigation started. No permission was required to utilize the German version of the PRO-CTCAE. German versions of the QLQ-30 and PRO-CTCAE have been validated before in clinical settings [37]. The information technology department compiled the ePROs questionnaires into digital form. A scientific data management tool, Research Documentation and Analysis (RDA), was utilized to disseminate the ePROs and document the responses. The surveys were distributed through email via an electronic order by the investigators in the RDA system. The system supplied patients with a secure URL to fill out the questionnaires. To ensure high questionnaire completeness, conditional formatting was used to hide the following questions until the current one was answered (see Fig. 1). The estimated time to complete the questionnaire was 30–40 min, depending on patients' technical skills. The RDA system automatically calculated the QoL score from the QLQ-C30 questionnaire according to the official scoring manual by the EORTC [17, 18]. Questionnaires were sent out 4–5 days after systemic treatment and had a recall period of 10 days or until the next patient visit, whichever came first. Patients who did not complete the supplied questionnaires were reminded of the ePROs evaluations at their next appointment. If patients failed to complete the provided ePROs for two consecutive cycles, they did not receive ePROs for the rest of their treatments. Investigators had immediate access to the ePROs data through the RDA system throughout the study and were able to track patient compliance as well as the operational reliability of the electronic system (Fig. 2). No alert system was installed for the ePROs system.

Patient data

The medical data and the demographic data were obtained from the medical records. The immigration

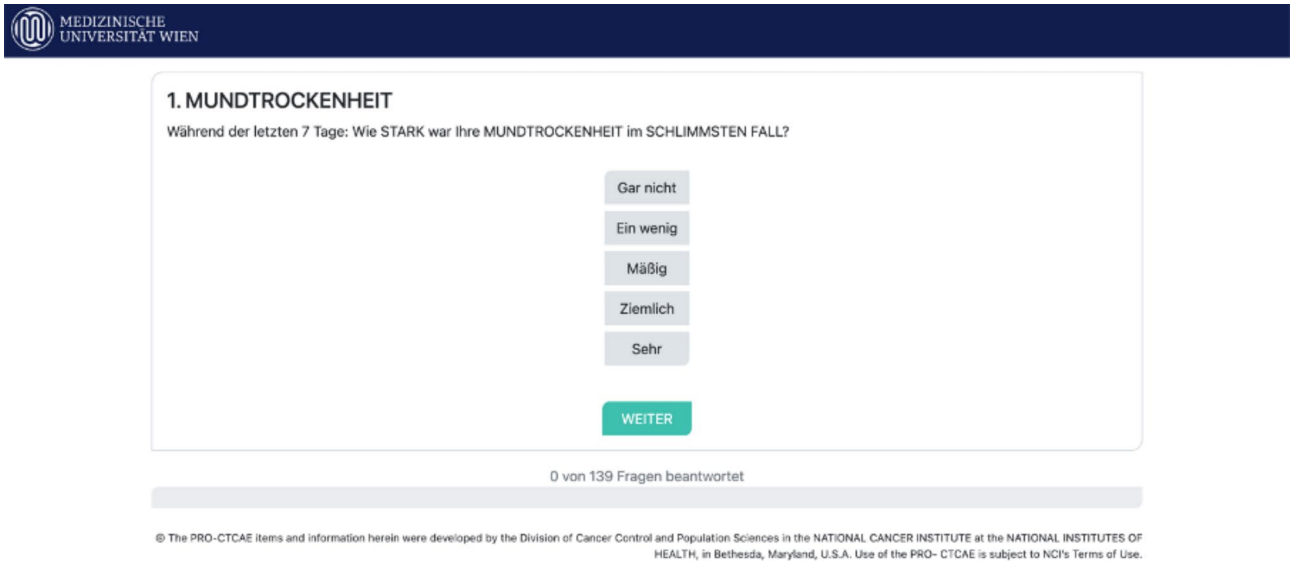

Fig. 1 The first item of PRO-CTCAE is an example of the patient's view on the secure ePROs website. Proceeding to the next item of the questionnaire is only possible after the patient has selected an answer for the question in view. At the bottom of the page, the currently answered questions and the total number of questions are listed to track progress

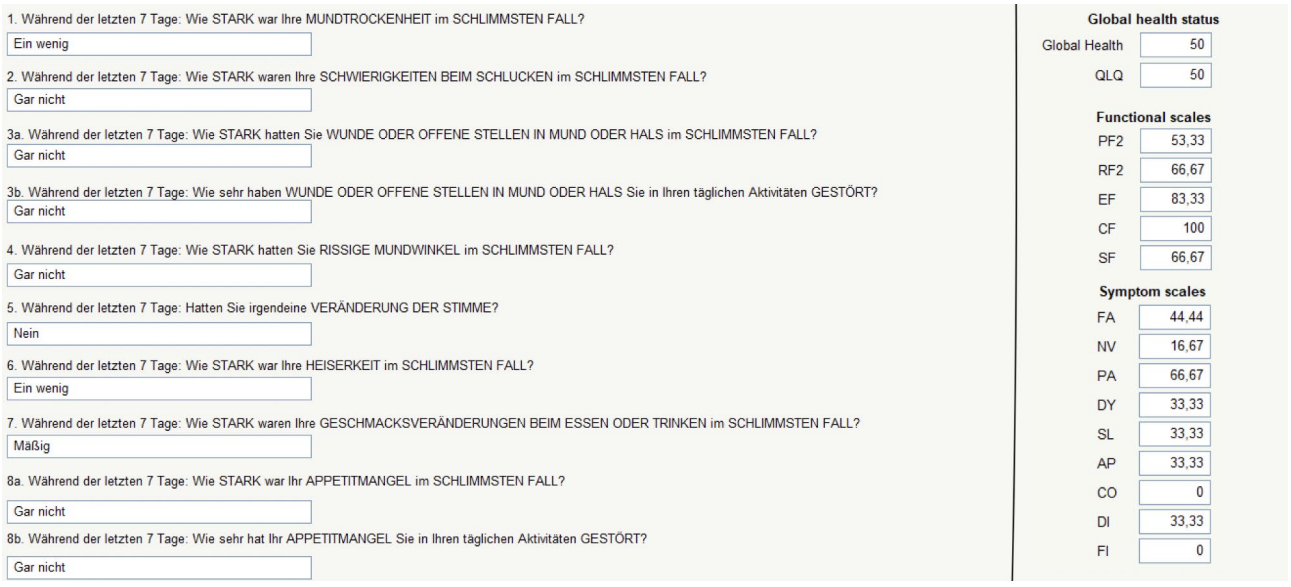

Fig. 2 Physician view of completed ePROs in the RDA system. QoL scores from the QLQ-C30 questionnaire were automatically calculated by the RDA system

status information was obtained through direct inquiry during the clinical session that followed the patient's inclusion in the study. This study adopted the European Commission's terminology on the subject, which characterizes individuals "who migrated into their present country of residence; and/or previously had a different nationality from their present country of residence; and/or at least one of their parents previously entered their present country of residence as a migrant" as persons with immigration background [38].

Feasibility assessment

The feasibility assessment comprised patient compliance and operational reliability. Patient compliance was assessed by patient adherence. Participants who completed the ePROs for at least half of their treatment cycles with a minimum of two consecutive ePROs (corresponding to two successive therapy cycles) were considered adherent. Taking into account adherence rates of other studies in this context, the feasibility threshold for patient adherence was set at 50% for the research population [24]. To increase data integrity and improve the depth of the findings, the cumulative ePROs completion rate was assessed. The cumulative ePROs completion rate aimed to determine the proportion of routine clinician visits that could be supplemented with ePROs data, which was computed by dividing the number of treatment cycles during which patients completed the ePROs by the total number of therapy cycles participants received after the study inclusion. The cumulative ePROs completion rate threshold was set to 50% to assess if the majority of the systemic therapy cycles can be supplemented with ePROs data.

Operational feasibility was assessed by closely monitoring the automated system. Before initiating the trial, investigators performed a test run with the ePROs. The technical features, such as data storage, answer transmission to RDA, and automated score calculation for the ePROs, were inspected for potential errors and proved accurate. After the test run, the created data was deleted, and the recruitment process started. Throughout the study, the first cycles of ePROs assessments for each individual patient were examined for data inaccuracies or inconsistencies. After uncompleted cycles, participants were asked if they encountered any technical issues that prevented them from completing the ePROs. The entire procedure was monitored for further unexpected operational hurdles.

Statistics

T-tests and chi-square tests were performed to assess the influence of age, gender, previous surgery, therapy modality, number of prior therapy lines, ECOG (Eastern Cooperative Oncology Group) score, and immigration background on ePROs adherence. Statistical significance was considered at $p<0.05$. All tests were two-sided. Statistical tests were performed with SPSS Statistics version 29. Moreover, a logistic regression analysis was conducted with compliance (completion of ePROs) as the dependent variable. The independent variables were age, immigration background, surgery, ECOG score, and therapy type (chemotherapy or immunotherapy).

In this study, no imputation methods were applied to address missing data. Missing data were documented as they occurred, patterns of patient dropouts were analyzed and participants who failed to complete two

Table 1 Clinical and demographic characteristics of the patient cohort. ADC: antibody-drug conjugate; BC: bladder cancer; CKI: checkpoint-inhibitor; N: number of patients; UTUC upper tract urothelial carcinoma

Variable	*N* = 30
Age (median (range))	68 (51–83 years)
Gender	
Female	4 (13.3%)
Male	26 (86.7%)
Therapeutic modality	
CKI	15 (50%)
Platin-based chemotherapy	13 (43.3%)
ADC	2 (6.7%)
Prior therapy lines	
0	15 (50%)
1	13 (43.3%)
2	2 (6.7%)
Entity	
BC	20 (66.6%)
UTUC	10 (33.3%)
ECOG	
0	22 (73.3%)
1	8 (26.7%)
Undergone previous surgery	
Yes	16 (53.3%)
No	14 (46.7%)
Immigration Background	
Yes	7 (23.33%)
No	23 (76.66%)

Table 2 *Association of patient adherence with clinical and demographic variables in UC patients receiving systemic therapy. ADC: antibody-drug conjugate; CKI: checkpoint-inhibitor; N: number of patients; UTUC upper tract urothelial carcinoma.* The cumulative questionnaire completion rate was 78% (Table 3), which was significantly higher than the threshold of 50% ($n > 15$)

Variable	Adherent	Non-adherent	*p*-value
N	21	9	
Gender			$p = 0.81$
Female	3	1	
Male	18	8	
Therapeutic modality			
CKI	11	4	
Platin-based chemotherapy	8	5	$p = 0.50$
ADC	2	0	
Number of previous therapies			$p = 0.50$
no	11	4	
one	8	5	
two	2	0	
Age (median)	70	67	$p = 0.28$
Previous surgery			
Yes	10	6	$p = 0.34$
No	11	3	
ECOG			$p = 0.21$
0	14	8	
1	7	1	
Immigration background			
Yes	2	5	$p = 0.006$
No	19	4	

consecutive cycles of electronic patient-reported outcomes (ePROs) were excluded from further adherence analysis. Non-response to ePROs was an endpoint, thus no artificial imputations were made to fill in the gaps. Adherence rates were calculated based on the completed ePRO cycles.

Results

In total, 45 patients were screened for the analysis. 5 (11%) did not have valid email addresses, and 10 (22%) were not eligible due to inclusion criteria or declined participation. 30 patients were part of the analysis, with an average age of 69 (range 51–83 years). The clinical and demographic characteristics of the cohort are shown in Table 1. The sample comprised 4 (13.3%) female and 26 (86.7%) male patients. Bladder carcinoma [39] constituted the most prevalent type of tumor, with 20 (66.6%) cases in total, followed by 10 (33.3%) patients with upper tract urothelial carcinoma (UTUC). Regarding therapy modalities, checkpoint-inhibitor (CKI) therapy was the most frequent form of treatment ($n = 15$, 50%), followed by patients receiving systemic platin-based chemotherapy ($n = 13$, 43.3%). Two (6.7%) patients were treated with the antibody-drug-conjugate (ADC) enfortumab-vedotin. On average, patients had received no or one prior therapy line. Half of the patients ($n = 15$, 50%) did not receive any prior therapies. 43.3% of the patients ($n = 13$) had received one prior therapy line, while two (6.7%) had received two. 53.3% of the patients ($n = 16$) had undergone major surgery due to UC (radical cystectomy or nephroureterectomy). 46.7% of the patients ($n = 14$) had not undergone any previous surgical interventions. Regarding the ECOG score, 22 (73.3%) patients had a score of 0, and 8 (26.7%) had a score of 1 [40]. 7 (23.3%) patients reported having an immigration background compared to 23 (76.7%) patients who stated no immigration background.

Overall, 21 (70%) patients were adherent to the ePROs, and 9 (30%) patients were non-adherent. The average compliance was thus significantly higher than the threshold of 50% ($n > 15$).

We next assessed the influence of several variables on compliance rate (Table 2). The analysis revealed that immigration background was the only variable significantly influencing compliance rates. Moreover, logistic regression analysis confirmed that only immigration background had significant effect on ePROs adherence ($p = 0.041$), while age, surgery, ECOG score, prior therapy lines, and therapy type had no significant effects. In contrast, no significant effects were observed for clinical factors, including the ECOG performance status and

Table 3 Cumulative questionnaire completion rate and association of patient adherence with therapy cycles in UC patients receiving systemic therapy

	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Total
ePROs sent out	30	30	17	8	2	2	*89*
ePROs completed	23	21	14	7	2	2	*69*
ePROs not completed	7	9	3	1	0	0	*20*
Adherence	77%	70%	82%	88%	100%	100%	*78%*

therapeutic modality, on ePROs compliance. Additionally, other assessed demographic and clinical factors did not demonstrate any significant differences or influence on the compliance rates (Table 2).

The automated data management process was completed without any errors or interruptions. The investigators observed no issues regarding the automated data management.

Discussion

In this feasibility assessment, we aimed to evaluate patient compliance and operational reliability of ePROs for UC patients receiving systemic therapies at the outpatient department of a tertiary care clinic. Overall, we observed that most patients (70%) completed the ePROs, whereas 30% did not, which aligns to prior reports on ePROs adherence rate in this population [24]. Adherence to ePROs may depend on several clinical factors, such as age or ECOG score. Data regarding age and ECOG score association with ePROs adherence is inconsistent [41]. Some studies have associated higher age or impaired clinical status with lower ePRO compliance [41–43]. Yet, several studies found no relationship between clinical status or age with ePRO compliance [44, 45]. Moreover, several studies reported that most elderly patients to be motivated to report their symptoms via ePROs, if the feasibility for this patient group is provided [46, 47]. In our study, factors associated with impaired clinical status, such as ECOG, previous surgery, or higher age, did not influence the adherence rates. Lee et al. demonstrated that amongst cancer patients, chemotherapy patients were less likely to adopt ePROs in comparison to patients receiving radiotherapy [43]. Our findings do not demonstrate a difference in ePROs compliance between chemotherapy and immunotherapy patients in the setting of UC. Notably, except the immigration background, no differences were observed between the characteristics of adherent and non-adherent patients. As a pilot study, our investigation was of exploratory nature and was not powered to investigate the impact of specific components on the feasibility of ePROs. Due to the small sample size of our cohort, it is not possible to definitely rule out the potential influence of variables that did not show a significant impact on ePROs compliance, and detection of significant differences is limited in this pilot study. Further real-world data following the implementation of ePRO instruments will be necessary to more accurately identify potential barriers and refine strategies to improve compliance across diverse patient populations.

According to reports from several clinical settings, patients with an immigration background have a lower perception of healthcare quality [48–50]. Multiple North American studies reported lower ePROs compliance rates among non-white ethnicities such as blacks and Hispanics [42, 51, 52]. The language barrier has also been suggested in the literature as a substantial challenge in providing healthcare to patients with migratory histories [53, 54]. In the current study, the participants were proficient in German, and no notable language barriers were observed when delivering or requiring clinical information to and from participants. However, patients with an immigration background demonstrated significantly lower adherence to the ePROs. We speculate that UC patients with immigration backgrounds may face various barriers regarding ePROs compliance. These could comprise difficulty in understanding medical terminology due to language barriers, differences in beliefs about illness, treatment, and symptom presentation, lower socioeconomic status leading to difficulties in affording regular and easy access to electronic devices with internet access, distrust in the healthcare system or providers, or impact of acculturation and assimilation pressures on mental and physical health that may lower an individual's commitment to complete ePROs. In future studies, a more in-depth evaluation of demographic variables, such as education and income levels, could provide valuable insights into factors influencing adherence to ePROs. In the literature, introduction of virtual tutorials or allocating time for Q&A sessions has been suggested for populations with low ePROs compliance [55]. Despite the small sample size, the substantially reduced adherence observed among patients with immigration backgrounds indicates the necessity of special attention and tailored interventions for this particular patient group. Additionally, the considerable proportion of individuals with immigration backgrounds in developed countries, such as Austria, where they constitute 25.4% of the population [56], highlights the relevance of this demographic aspect to the application of ePROs. It has been suggested in the literature that communicating with patients from migratory histories in their native language enhances the quality of interaction [57]. Most PRO instruments

are available and validated in multiple languages [58, 59]. Therefore, allowing patients to select the language of the PRO tools they receive may be a viable approach to enhance adherence. It should be noted that the challenges in caring for patients with migratory histories are not limited to the language barrier [53, 57]. Lower socioeconomic status has also been associated with lower adherence to ePROs, which was not evaluated in this study [60].

Our study has several limitations. First, study inclusion was limited to patients with access to electronic communication via email addresses. This ruled out more than 10% of potential patients. Alternative participation methods (i.e., via a tablet with access to complete the questionnaire) could be provided for these cases in future studies. Second, our study was not designed to address physician compliance to ePROs data, which is often a significant obstacle when implementing ePROs workflows [61, 62]. Engaging physicians and tracking their access to the ePROs data, education in when, where, and how results are accessed, and regular training and feedback would be needed for optimal interpreted implementation in the routine clinical workflow [63]. The study did not distinguish between first-generation and second-generation immigrants, which may be relevant since the impact of immigration could differ between generations, and should be evaluated in further studies on this topic. Moreover, the results concerning adherence per cycle should be interpreted with caution, as the majority of the patients had not completed their therapies at the time of data extraction. Nevertheless, the findings of this pilot study do not suggest a decrease in ePROs adherence throughout the course of treatment.

As reports of real-world experiences with ePROs are still limited, further research is required to better understand the limitations among different clinical and demographic contexts, especially in patients with migration background. Recently published ePROs application recommendations suggest considering demographic aspects ePROs implementation [64]. As a targeted intervention, offering patients the possibility to choose ePROs in first/second languages or providing community-specific support during the recruitment and completion process could be potential strategies to increase adherence among immigrants.

Conclusions

The application of ePROs to assess symptoms and QoL during systemic therapies for UC patients can be considered feasible. The most prominent obstacle in using ePROs in this particular setting was the compliance of patients from immigration backgrounds. Focused efforts directed at this patient population are required to optimize the ePRO application.

Abbreviations

ADC	Antibody-drug-conjugate
AEs	Adverse events
BC	Bladder carcinoma
CKI	Checkpoint-inhibitor
CTCAE	Common Terminology Criteria for Adverse Events
ECOG	Eastern Cooperative Oncology Group
EORTC	QLQ-30 European Organization for Research and Treatment of Cancer Core Quality of Life questionnaires
ePROs	Electronic patient-reported outcomes
UC	Urothelial carcinoma
UTUC	Upper tract urothelial carcinoma
PROs	Patient-reported outcomes
QoL	Quality of life
RDA	Research Documentation and Analysis

Author contributions

Conception and design: OY, MRHData collection: OY, AA, JK, SK, KG, SFS, MRHManuscript drafting: OY, MRHAll authors approved the final version of this manuscript.

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Data availability

The data for this study are available from Ozan Yurdakul and Melanie R. Hassler, but are not publicly available due to restrictions on the current study.

Declarations

Ethics approval and consent to participate

The local ethics committee approved the study (EK-Nr: 1972/2021, Ethics Committee of the Medical University of Vienna). Informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable.

Competing interests

SFS reports honoraria for lectures/consulting boards for Astellas, Astra Zeneca, Bayer, BMS, Cepheid, Ferring, Ipsen, Janssen, Lilly, MSD, Olympus, Pfizer, Pierre Fabre, Richard Wolf Roche, Sanochemia, Sanofi, Takeda, Urogen; patents: method to determine prognosis after therapy for prostate cancer granted 2002-09-06, methods to determine prognosis after therapy for bladder cancer granted 2003-06-19, prognostic methods for patients with prostatic disease granted 2004-08-05 and soluble Fas urinary marker for the detection of bladder transitional cell carcinoma granted 2010-07-20. The other authors have no competing interests to declare that are relevant to the content of this article.

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