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Reliability of the electronic patient reported outcome measures for assessing xerostomia, dysphagia and quality of life in Spanish patients with head and neck cancer: a randomised crossover design

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Abstract

Purpose To analyse reliability in terms of concordance (agreement) and equivalence of the Patient Reported Outcome Measures (PROM) with an electronic modality (ePROM) of the recognised questionnaires assessing of xerostomia, dysphagia and quality of life (QoL) in Spanish patients with head and neck cancer (HNC). We hypothesised notable reliability and equivalence between the two modalities.

Methods A total of 24 patients (median age 63.00 years, undergone radiotherapy, either alone or in combination with surgery and/or chemotherapy, and suffering xerostomia) were randomised to either paper-based (PROM) or ePROM in a two-arm crossover design with a within-subject comparison of the two modalities (washout period 90 min). Outcome measures of interest were xerostomia: severity itself (Xerostomia Inventory, XI), perceived xerostomia (visual analogue scale, VAS), regional oral dryness (Regional Oral Dryness Inventory, RODI) and dry mouth/sticky saliva (specific head and neck module European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Head and Neck Module, EORTC QLQ-H&N35 and updated EORTC QLQ-H&N43); dysphagia: swallowing burden (Eating Assessment Tool-10, EAT-10) and swallowing (EORTC QLQ-H&N35 and EORTC QLQ-H&N43); and QoL: global health (EORTC QLQ-Core 30, EORTC QLQ-C30). Data concerning the concordance between modalities was evaluated using Spearman correlation coefficients, intraclass correlation coefficients (ICCs) and Bland Altman plots with limits of agreement. In addition, a two one-sided test to check equivalence with clinical importance changes. Finally, 1-week time span separated test and retest of ePROM (only electronic modality) using Wilcoxon test and ICCs.

Results There was excellent concordance (PROM versus ePROM 0.79–0.96) with most differences fell within the limits of agreement. The equivalence analysis showed that the difference between both modalities was not more than a tolerably small amount ($P < 0.05$), except for dysphagia and QoL. Analysis over time exhibited from good to excellent (0.81–0.93) test–retest stability for the majority of outcome measures.

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Conclusion The newly developed ePROMs embedded into LAXER application have showed high level of reliability that supports their implementation in clinical practice, offering a convenient and efficient alternative to paper-based questionnaires. This study shows that electronic adaptations are possible despite the challenging older target population.

Trial registration The study is part of the LAXER study (2021-11-04 / ClinicalTrials.gov: NCT05106608).

Keywords Deglutition Disorders, Electronic Health Records, Head and Neck Neoplasms, Patient Reported Outcome Measures, Quality of Life, Xerostomia

Introduction

Patients with head and neck cancer (HNC) frequently suffer from symptoms that significantly impact their quality of life (QoL) so effective monitoring and management of these symptoms are crucial, and can be achieved through well-known Patient Reported Outcome Measures (PROMs) [1]. PROMs are standardized and validated questionnaires filled out by patients to measure relevant symptoms, function, or health status information [2], without the need for clinical interpretation [3]. Paper-based questionnaires have traditionally been preferred by researchers/clinicians for face-to-face surveys because they allow: to produce reliable data with high completion rates, to clarify possible misunderstandings, and to suit to responders with reading or writing difficulties [4]. Conversely, this modality has geographical limitations, loss of anonymity that may discourage honest responses to personal questions, and the potential for interviewer bias that may influence answers [4]. Ultimately, paper-based questionnaires may remain labour-intensive and time-consuming, both for patients and researchers. Despite their weaknesses, the paper-based questionnaires continue to be valuable tools for obtaining high-quality data when resources and conditions permit.

In recent years, particularly due to the latest pandemic, the use of PROMs through electronic modalities (ePROMs) has increased, as we are more dependent on remote mobile Health devices (mHealth) [5]. This has led to obvious benefits that complement traditional healthcare [6, 7] such as facilitating patient-professional communication, implementation of treatment, symptom assessment and follow-up, and access to healthcare information [8–10]. Moreover, the integration of ePROMs in patients with HNC is particularly relevant due to specific characteristics of this group: HNC affects a smaller population compared to other types of cancer, they tend to be older [11], and most mHealth tools target cancer symptoms rather than tumour specific ones [12]. All of this added to common barriers such as low mHealth literacy [13] often result in fewer digital resources and support options available to them [12].

In contrast to these limitations so far, emerging evidence indicates that older adults are increasingly becoming adept at using mobile technologies [14]. A recent review gathers the research on digitalized health in HNC population and their caregivers [15], highlighting all of them high satisfaction with the tools in early detection of symptoms and patient's management, self-confidence and communication, and at the same time being time- and cost-effective. Kristensen et al. have assessed the effect of telehealth on management of swallowing and nutritional sequelae during and after treatment [16]. Similarly, a remote monitoring application for physical symptoms during the SARS-CoV-2 pandemic aimed at patients with HNC displayed good usability by means of a qualitative analysis, however authors did admit that reliability of patient-monitoring in comparison to face-to-face one should be studied in the future [17]. In fact, a systematic review in 2021 has found that regarding PROMs in these patients, some tools are limited when they have to precisely reflect patient's issues [1]. Also, there is scarce evidence on the impact of the reliability and adoption of ePROMs by means of mHealth apps to record other oral health symptoms, in particular xerostomia.

This troublesome side effect is one of the most prevalent after overcoming oncological treatment and is present in 39–100% of cases [18–20], and which can become chronic [21]. Older age [22], current smoking, female sex, and having a high school level of education or less have been shown to be risk factors for moderate-to-severe xerostomia among long-term survivors [23]. Also, related to the characteristics/location of tumour and oncological treatment, among others: primary tumour localization, more advanced tumours (likely due to the larger radiotherapy, RT fields required), bilateral involvement of lymph nodes [22] and higher mean radiation doses to the parotid glands [24] are also linked to a higher incidence of xerostomia. Equally concerning are the figures for dysphagia (54.9%) [25] with patient (advanced age, pretreatment malnutrition, rural location, among others), tumour (recurrence, advanced T and N stage, and hypopharyngeal subsite) and treatment factors (tracheostomy, chemoradiotherapy and multimodality treatment) as predictors of dysphagia [26]. Consequently, patients require life-long strategies for continuous monitoring and care. These challenges underscore the importance of

Fig. 1 Outline of crossover design of PROM versus ePROM and 1-week delay test–retest (ePROM). Abbreviations: ePROM: electronic Patient Reported Outcome Measures; PHP: hypertext preprocessor; PROM: Patient Reported Outcome Measures; SQL: structured query language

developing innovative solutions beyond standard face-to-face management to effectively monitor and address xerostomia, dysphagia and QoL in patients with HNC, driving the aim of this study.

Methods

Study design and aim

This study was a randomised, single-blinded, two-arm crossover design to carry out a comprehensive reliability analysis of ePROM embedded into LAXER application (https://www.laxer.es) compared to its original PROMs about xerostomia, dysphagia and QoL. The study is reported in accordance with the STROBE guideline [27] and is part of the LAXER study (2021-11-04 / ClinicalTrials.gov: NCT05106608) [28].

Eligible patients

Patients meeting the following inclusion criteria were enrolled: 1) 18 years or older diagnosed with HNC, 2) experiencing chronic xerostomia (> 3 months) [29] due to RT, 3) finished oncological treatment and achieved complete remission, and 4) possessing access to mobile applications or residing with someone who does.

Exclusion criteria comprised: 1) metastases, 2) cognitive impairment, and 3) a Karnofsky Performance Status Scale score < 60. All patients provided written informed consent, and the study received approval from the Andalusian Biomedical Research Ethics Portal (2402-N-21 CEIM/CEI Provincial de Granada).

Randomisation and setting

Patients were referred from the Departments of Radiation Oncology, Virgen de las Nieves University Hospital (Granada), and HLA Inmaculada Hospital (Granada) between September to December 2023. To control the order of modality (PROM or ePROM) administration in the crossover design, a random allocation was done by the principal investigator (NGC), based on a computer list-generated 1:1. The clinical staff was not blinded to the result of the randomisation; neither did patients but where to the study hypothesis. Therefore, only statistician conducting the analysis was blinded to group allocation (MLL).

For the main analysis, answers from each patient were gathered with a PROM or ePROM. After 90 min of the first assessment, they changed modality. To dilute the memory of their answers to the questions from the first modality patients received a health education lecture [30] during the washout time. Together with this, patients also completed the paper-based questionnaires (PROMs) in randomised order, when appropriate. Both modalities were completed in a unique appointment lasting 150 min. For the test–retest analysis, one week later, patients at home completed once again ePROM without clinical staff supervision (Fig. 1). All questionnaires used in the LAXER app follow both the validated written format and Spanish language version and the ePROMs have identical content to the PROM administration and were adapted in terms of layout and assisted functions via the Moodle platform.

Outcome measures

Xerostomia

The severity of xerostomia was assessed using the Spanish version of the Xerostomia Inventory (XI), a reliable questionnaire (Cronbach's alpha 0.87–0.89) that consists of 11 items (score range 1–5) with a total score ranging from 11 to 55 points. A higher scores indicate more severe xerostomia [31]. A minimal important difference (MID) for the XI was established as a change ≥ 6 points [32]. On the other hand, the perceived xerostomia, a numeric visual analogue scale (VAS) was used, with a grade ranging from 0 (no symptoms) to 10 (the worst possible symptoms) [33]. For VAS, due to the lack of a MID established, a 1 point was taken.

Regional oral dryness was assessed with the Regional Oral Dryness Inventory (RODI). This questionnaire quantifies the severity of dryness at nine different locations in the oral cavity using a 5-point Likert scale (1 = none, 5 = severe) [34]. As described above, for RODI, due to the lack of a MID established a 1 point was taken.

Finally, the specific head and neck module European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Head and Neck Module 35 (EORTC QLQ-H&N35) was used [35]; this module comprises 7 scales and 11 single items scored from 0 to 100. However, only items related to xerostomia were taking into account, that is, dry mouth and sticky saliva items, as selected in previous studies [36, 37]. Higher scores indicate more symptoms. This tool has also been shown to be reliable (Cronbach's alpha > 0.70) [38]. MID for these single items were a change of 15.73 for dry mouth and lastly, a change of 15.18 for sticky saliva [39]. Recently, an updated specific head and neck module 43 appeared EORTC QLQ-H&N43. Evidence supports the reliability and validity of the EORTC QLQ-H&N43 as a measure of QoL (Cronbach's alpha was > 0.70) [40]. For the dry mouth and sticky saliva scales the rule of 10% of the total score have been chosen to represent MID, for that, a change in 10 points could be clinically important [41].

Dysphagia

Swallowing burden was measured using the Eating Assessment Tool-10 (EAT-10), a validated and reliable questionnaire (Cronbach's alpha 0.96) [42], that consists of 10 items related to swallowing difficulties (score range 0–4, 0 = no problem, 4 = severe problem) scored from 0 to 40. A total score of 3 or higher indicates dysphagia. A minimal clinically important difference (MCID) on the EAT-10 score was assumed as a change > 3 points [43]. Along this, scales related to swallowing from EORTC QLQ-H&N35 and EORTC QLQ-H&N43 questionnaires mentioned before were taken [44]. For EORTC QLQ-H&N35, swallowing scale was selected and a MID was a change of 8.04 points. As mentioned earlier, scale reflecting the outcome of interest was selected [36, 37]. Meanwhile a MID of 10 points in swallowing scale in EORTC QLQ-H&N43 has been proposed [44].

Quality of life

The EORTC QLQ—Core 30 (EORTC QLQ-C30) V.3.0 was used for QoL assessment [45]. Despite the EORTC QLQ-C30 comprising 30 items, only the global health scale [46], assessed by a 7 -point Likert scale with a total score ranging from 0 to 100, was utilized. Higher scores on the global health scales indicate better QoL. This is a validated and reliable questionnaire widely used in the oncology population (Cronbach's alpha > 0.70) [47]. A MID in HNC population was establish as a change in 5.41 points [48].

Description of LAXER app and data collection

The LAXER application has been described in detail elsewhere [28]. Regarding design, this app is a hybrid development for web technology as well as being available on iOS and Android platforms to cover the vast majority of smartphones at the user level. The programming languages used for the creation of both applications are Objective-C for iOS and Java for Android. This application is technologically based on the free software Moodle platform in its version 3.9. This system has PHP in its version 7.0 for logical development, mustache for the frontend part and SQL for the database part.LAXER app (ID: IPR-1053 Website register: https://n9.cl/rycfux). At the end of the whole ePROM set, patients can even verify if any questionnaire or item remains unfilled.

Sample size

The sample size calculation was based on detecting a significant difference in the intraclass correlation coefficient (ICC) for the reliability analysis of between modalities. With an expected ICC of 0.90 and an unacceptable ICC of 0.60 [49], a sample size of 24 patients was required to achieve 90.8% power at a 5% significance level. Considering possible dropouts, an initial recruitment target of 30 patients was set to ensure a robust sample size. This approach is consistent with established methodologies for reliability studies, which often recommend sample sizes that can provide sufficient power to detect meaningful differences in ICC values, ensuring the validity and reliability of the results [50, 51].

Statistical analysis

Sociodemographic and clinical characteristics as well as descriptive statistics for the distribution of scores on the PROM and ePROM for all outcome measures. On this point, floor and ceiling effects occur when a considerable

proportion of respondents endorse the best or worst score (≥ 15% as a significant floor or ceiling effect) [52].

The concordance between PROM and ePROM was evaluated using Spearman correlation coefficients, mean differences and ICC (two-way random effects model) for all the individual items, scales and total scores selected. For ICC interpretation the criteria proposed by Bartko et al. [53] and Stokdijk et al. [54] was assume. The Bland–Altman analysis was employed to assess the agreement between the PROM and ePROM scores. The agreement of scores between the paper-based (PROM) and the electronic (ePROM) modalities was assessed at the individual patient level. Percentage Exact Agreement (PEA) referred to patients who provided the same responses to individual questions on both modalities, whereas Percentage Global Agreement (PGA) was defined as the proportion of agreement within one adjacent response category in either higher or lower direction [55].

A Two One-Sided Test procedure was employed to assess equivalence between the two modalities [56]. Unlike conventional methods such as the independent t-test, which primarily aim to detect differences, equivalence testing focuses on determining whether the difference between modalities is within a tolerably small range. In our analysis, we utilized a MCID or MID for each item, scale or total score as the acceptable threshold to evaluate equivalence and were specified above.

Finally, a test–retest reliability of ePROM at two time points, separated by a one-week period, was assessed using mean differences (with 95% CI), Wilcoxon test (with corresponding *p*-values), and ICCs [57].

Results

Patients

Of the patients referred from corresponding hospitals, 24 who met the eligibility criteria were randomised to either paper-based (PROM) or electronic (ePROM) modalities to control for possible order effects. Of those participating in the study, only 20 completed all tasks. The flow chart is shown in Fig. 2. No value was missing due to staff supervision and verification of the app itself.

The median age was 63.00 (55.75–65.75) years, 58.33% were male, most completed higher education, and only 8.33% were smokers. Most of them (70.80%) declared as use preference ePROM modality (Table 1).

Regarding the clinical characteristics (see Table 2), primary tumour localization following the American Joint Committee on Cancer/Union for International Cancer Control (AJCC/UICC) [58] and National Comprehensive Cancer Network (NCCN) Guidelines for HNC [59] was highly heterogeneous. The most common cancer was nasopharynx (25%). All patients received RT, either alone or in combination with surgery and/or chemotherapy (CT). The total RT dose administered was 66.62 ± 4.07 Gray (Gy), with the most common method being volumetric modulated arc therapy (VMAT) with image-guided radiation therapy (IGRT). Finally, patients were treated according to standard concomitant CT regimen with cisplatin (100 mg/m^2 3-weekly); those patients with contraindication (comorbidity) to aforementioned regimen were treated according to carboplatin (1.5 to 2 mg/m^2 weekly) or cisplatin (40 mg/m^2 weekly). In the cases of nasopharynx as primary tumour, concomitant CT regimen with cisplatin and adjuvant CT regimen with cisplatin and 5-fluorouracil (5FU) (cisplatin 100 mg/m^2 3-weekly followed by three cycles of cisplatin 80 mg/m^2 on day 1 and 5FU 1000 mg/m^2/d on days 1 to 4, every four weeks, respectively) were administered. All patients undergone these regimes were monitored, with appropriate adjustments (medical oncological-decision making) to each regimen based on their progress and toxicity recorded during the treatment.

Descriptive statistics for the distribution of scores on the PROM and ePROM are provided in Table 3.

The Spearman correlations coefficients were very strong association (r ≥ 0.80) for the comparison between PROM and ePROM in the XI, VAS, 2 out of 9 RODI items, sticky saliva (EORTC QLQ-H&N35), the EAT-10, swallowing problems (EORTC QLQ-H&N35), swallowing (EORTC QLQ-H&N43) and global health (EORTC QLQ-C30). Dry mouth (EORTC QLQ-H&N35) and dry mouth and sticky saliva (EORTC QLQ-H&N43) showed a strong correlation coefficient, as well as six items of the RODI. Nevertheless, the correlation of anterior tongue (RODI) was moderate between modalities. The ICCs showed excellent concordance for all outcome measures (PROM versus ePROM: 0.79–0.96), except for anterior tongue (RODI) that reported a good coefficient (0.72). The highest ICCs were obtained for VAS (ICC: 0.95, 95% CI: 0.88; 0.98), the EAT-10 (ICC: 0.93, 95% CI: 0.82; 0.97) and swallowing (EORTC QLQ-H&N43) (ICC: 0.96, 95% CI: 0.90; 0.98) (Table 4). Bland–Altman plots were also generated for all items, scales and total scores, as appropriate (Fig. 3a-c), as a graphical representation to depict the difference and limits of agreement between PROM and ePROM. The results indicated that most differences fell within the limits of agreement, demonstrating that the discrepancies between the PROM and ePROM were minor and did not show any systematic bias. Most of the differences between both modalities were scattered closely around the mean difference, with very few points lying outside the limits of agreement. This indicates a high level of concordance between the two modalities studied. Additionally, there was no apparent trend or pattern in the differences, reinforcing

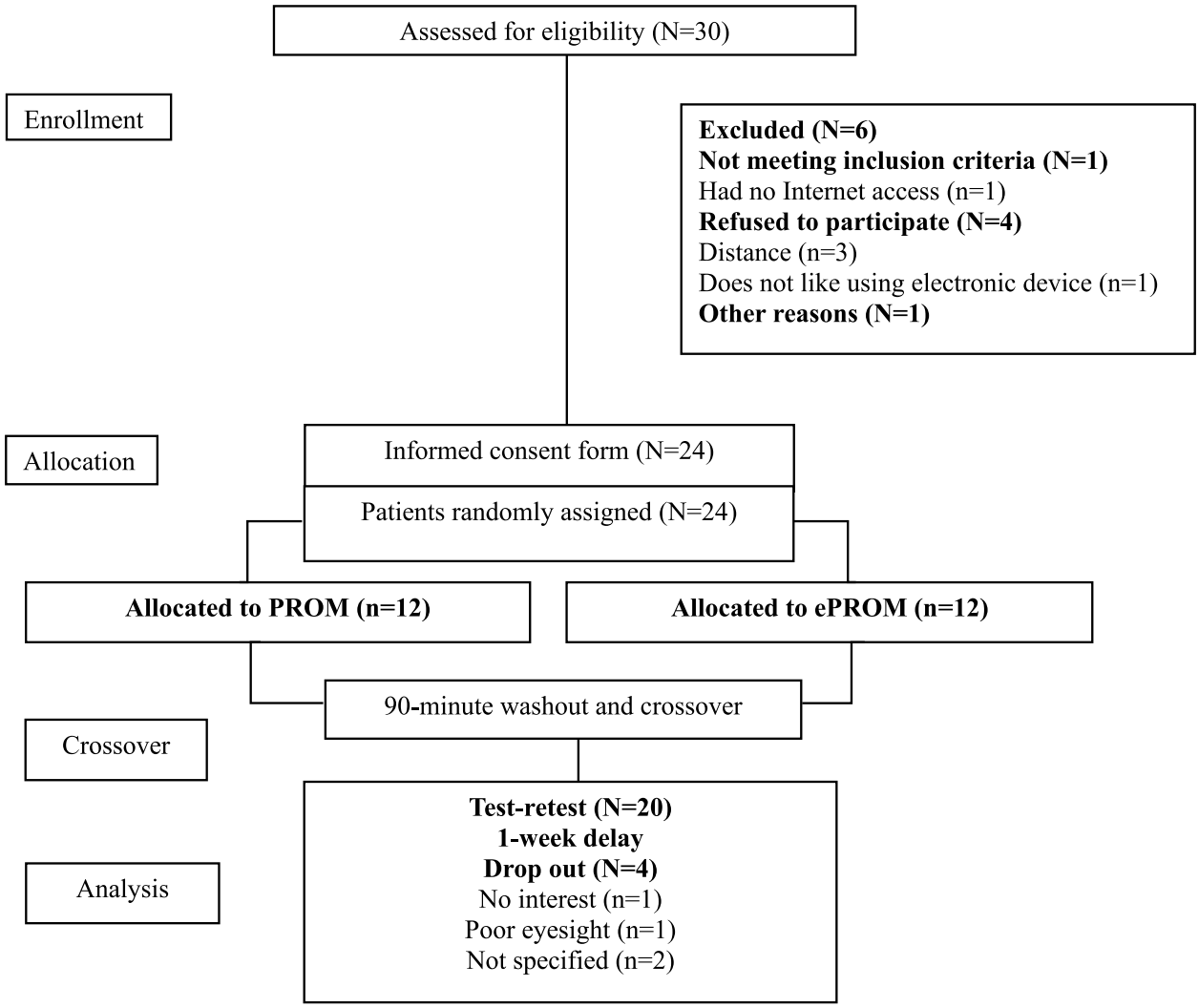


Fig. 2 Flow diagram for crossover design of PROM versus ePROM in patients with HNC. Abbreviations: ePROM: electronic Patient Reported Outcome Measures; HNC: head and neck cancer; PROM: Patient Reported Outcome Measures

the consistency and reliability of the ePROM as an alternative to the paper-based questionnaires.

Table 5 shows the PEAs and PGAs for each outcome measures between modalities. Our results showed that the PEAs for all outcome measures ranged from 54 to 83% and the PGAs ranged from 79 to 100%. For that, all outcome measures directly related to xerostomia (except VAS) exhibited a PEA exceeding 60% and a PGA exceeding 89% (Table 5).

Table 6 shows the results of equivalence test between modalities based on the MCID or MID. The results showed the means between modalities were equivalent for all outcome measures except for dysphagia (EAT-10) and global health (EORTC QLQ-C30) (Table 6).

The XI and EAT-10 indicated an excellent reliability (ICC > 0.90) (Table 7). VAS xerostomia and three items of the RODI presented good reliability as well as all items and scales in EORTC. Nevertheless, the rest of items of the RODI indicated moderated reliability. The mean differences were non-significant throughout all analyses.

Discussion

This randomised crossover design showed the equivalence of scores between PROM and ePROM with near perfect agreement reached for 16 out of 18 items, scales and/or total scores. Any observed differences were not clinically significant in Spanish patients with HNC. In line with these results, the observed mean differences between modalities were small with excellent ICC for the

Table 1 Sociodemographic characteristics of study patients ($N = 24$)

Age (years), median (range)	63.00 (55.75–65.75)
Gender, n (%)	
Male	14 (58.33)
Female	10 (41.67)
Education level, n (%)	
Primary studies	7 (29.17)
Secondary studies	8 (33.33)
Higher education	9 (37.50)
Tobacco consumption, n (%)	
Yes	2 (8.33)
No	8 (33.33)
Ex-smoker	14 (58.33)
Use preference, n (%)	
PROM	7 (29.20)
ePROM	17 (70.80)

Data are presented as median (range) or n (%), as appropriate

Abbreviations: ePROM electronic Patient Reported Outcome Measures, *PROM* Patient Reported Outcome Measures

Table 2 Clinical characteristics of study patients ($N = 24$)

Primary tumour localization, n (%)	
Oral cavity	2 (8.33)
Oropharynx	5 (20.83)
Larynx	5 (20.83)
Hypopharynx	1 (4.17)
Nasal cavity and paranasal sinuses	2 (8.33)
Salivary glands	2 (8.33)
Nasopharynx	6 (25.00)
Occult primary cancer	1 (4.17)
Treatment received, n (%)	
Surgery and RT	7 (29.17)
RT	1 (4.17)
Surgery, RT and CT	8 (33.33)
RT and CT	8 (33.33)
Type of RT, n (%)	
RT3D	6 (25.00)
IMRT_IGRT	1 (4.17)
VMAT_IGRT	15 (62.50)
Proton therapy	2 (8.33)
Dose of RT, mean ± SD	
Total, Gy	66.62 ± 4.07
Time since RT, mean ± SD	
Months	24.09 ± 17.40
Type of CT, n (%)	
Concomitant (cisplatin)	9 (37.50)
Concomitant (carboplatin)	1 (4.17)
Concomitant and adjuvant (cisplatin and 5FU)	6 (25.00)

Data are presented as mean ± SD or n (%), as appropriate

Patients were treated with radiation therapy methods using IMRT or VMAT, both with IGRT. These methods can provide more conformal dose coverage for the treatment area and reduce the dose to organs at risk (OAR) in anatomically complex disease sites such as head and neck cancer; that is why, radiation therapy stands out as the main treatment choice for this tumour currently

Abbreviations: 5FU 5-fluorouracil, *CT* chemotherapy, *IGRT* Image-guided radiation therapy, *IMRT* Intensity modulation radiation therapy, *RT* radiotherapy, *RT3D* Three-Dimensional Conformal Radiotherapy, *SD* standard deviation, *VMAT* Volumetric modulated arc therapy

vast majority of outcome measures indicating high concordance. As to test–retest LAXER application, reliability ranged from moderate to excellent. Finally, the PGAs in all outcome measures were greater than 79% and close to 71% patients preferred the ePROM using LAXER application. It is worth noting that patients, staff and oncologists were involved in its co-design framework which could be partly the reason of high agreement of the ePROM embedded itself [60].

The XI and VAS revealed clinical values indicative of chronic xerostomia in our study population with no floor/ceiling effects for the XI. Although some degree of floor and ceiling effects is usually expected for any measure [61], as might be expected, a greater sample size may give us more details concerning how to interpret these findings. The most significant effects in this sense have been associated to the novelty RODI, a questionnaire that assess regional dryness [34] but it has not been tested yet in terms of Spanish validity. Up to now, RODI seems capable of discriminate between xerostomia patient groups [62], but according to our findings, it displays some uncertainty in its ability to detect changes in future clinical trials.

Based on the ICCs and the numerically small mean differences, PROM are comparable with the same modality on a mobile application (LAXER). These results are also consistent with the results from a systematic review with metanalysis of 72 studies conducted between 2007 and 2013 in different population (cancer, back pain, mental health, etc.) with 434 correlations a pooled ICC of 0.88 [63]. More recently in 2023, a paper and electronic versions of the Integrated Palliative care Outcome Scale, a 17-item questionnaire that measures symptoms and concerns of those receiving palliative care, was also considered equivalent (all ICCs ≥ 0.95) [64]. All this linked also to high PGA, (except VAS that ranges 0–10 could explain lower agreement) may be indicative that both modalities are equivalent to measure what they intend to assess. This is also consistent with previous HNC literature assessing swallowing, nutrition and distress status undergoing chemoradiotherapy, where a web-based screening tool called ScreenIT also showed acceptable agreement (80% PEA/PGA) between ePROM and clinician judgement for most scores [65]. Taking into consideration

Table 3 Sample statistics for PROM versus ePROM ($N = 24$)

Outcome measures		PROM				ePROM			
		Mean (SD)	Median	% floor	% ceiling	Mean (SD)	Median	% floor	% ceiling
Xerostomia	The XI	36.21 (9.05)	36.50	0.00	0.00	33.00 (8.20)	32.50	0.00	0.00
	VAS	6.71 (2.66)	7.00	0.00	16.67	6.75 (2.45)	7.00	0.00	12.50
	Upper lip (RODI)	2.21 (1.25)	2.00	41.67	4.17	2.21 (1.18)	2.00	33.33	4.17
	Anterior palate (RODI)	2.33 (1.24)	2.00	33.33	4.17	2.29 (1.08)	2.00	29.17	0.00
	Inside cheeks (RODI)	2.33 (1.20)	2.00	33.33	0.00	2.00 (0.98)	2.00	37.50	0.00
	Posterior palate (RODI)	3.21 (1.28)	3.00	12.50	16.67	2.88 (1.26)	3.00	20.83	8.33
	Lower lip (RODI)	2.75 (1.26)	3.00	20.83	12.50	2.42 (1.18)	2.00	25.00	4.17
	Floor of the mouth (RODI)	2.42 (1.14)	3.00	29.17	4.17	2.38 (1.06)	2.00	25.00	0.00
	Posterior tongue (RODI)	2.79 (1.41)	3.00	29.17	12.50	2.75 (1.26)	3.00	25.00	8.33
	Anterior tongue (RODI)	2.92 (1.35)	3.00	25.00	8.33	2.54 (1.10)	2.50	20.83	0.00
	Pharynx (RODI)	3.08 (1.38)	3.00	20.83	16.67	2.83 (1.43)	3.00	29.70	12.50
	Dry mouth (35)	61.11 (33.57)	66.66	8.33	33.33	29.72 (29.46)	66.67	4.17	25.00
	Sticky saliva (35)	50.00 (35.44)	50.00	20.83	20.83	48.61 (35.41)	33.33	20.83	20.83
	Dry mouth and sticky saliva (43)	59.72 (30.26)	66.67	0.00	20.83	56.95 (26.43)	50.00	0.00	16.67
Dysphagia	EAT-10	13.25 (9.50)	11.50	8.33	0.00	11.25 (7.93)	12.50	12.50	0.00
	Swallowing problems (35)	21.87 (17.69)	20.84	12.50	0.00	22.22 (16.97)	16.67	16.67	0.00
	Swallowing (43)	20.83 (17.72)	16.67	16.67	0.00	19.79 (14.71)	20.84	16.67	0.00
Quality of life	Global health (30)	68.75 (18.07)	66.67	0.00	12.50	65.97 (20.98)	66.67	0.00	8.33

Non-parametric data due to small sample size

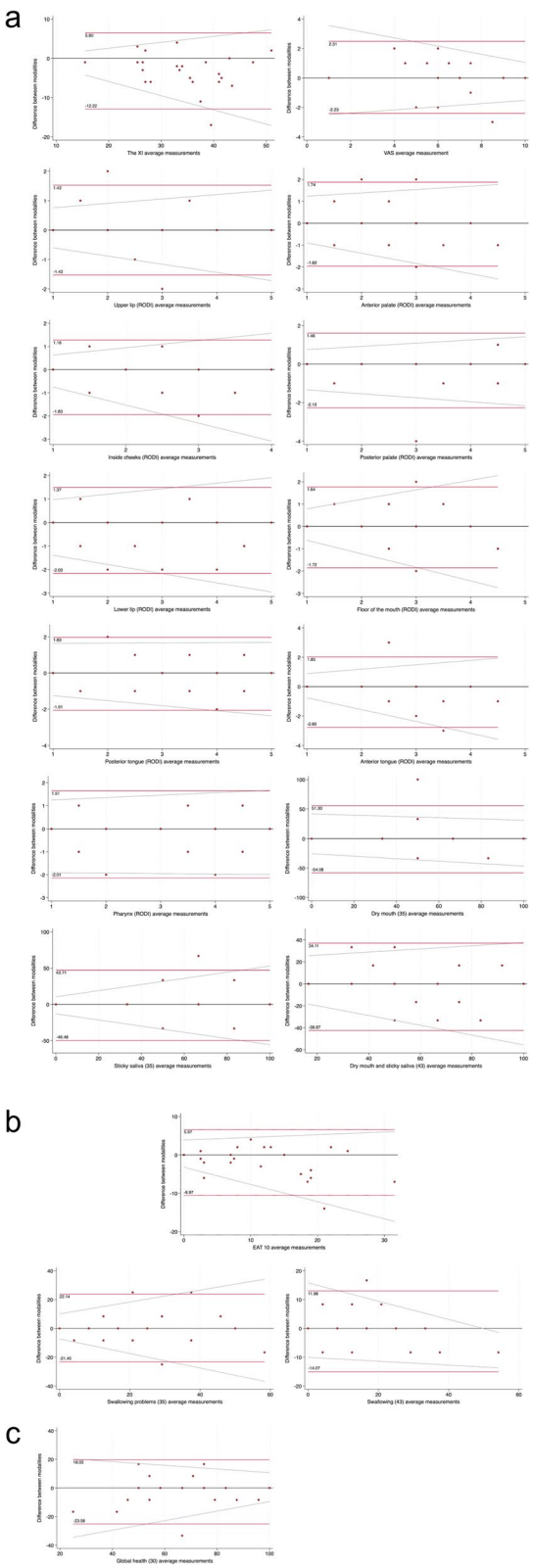
Abbreviations: EAT-10 Eating Assessment Tool-10, *ePROM* electronic Patient Reported Outcome Measures, *PROM* Patient Reported Outcome Measures, *RODI* Regional Oral Dryness Inventory, *SD* standard deviation, *VAS* Visual Analogue Scale for xerostomia, *XI* Xerostomia Inventory, *30* EORTC QLQ-C30, *35* EORTC QLQ-H&N35, *43* EORTC QLQ-H&N43

Table 4 Spearman correlations, mean differences (with 95% confidence interval), intraclass correlation coefficients for the concordance between PROM and ePROM ($N = 24$)

Outcome measures		r_s	M_{diff} (95% CI)	ICC (95% CI)
Xerostomia	The XI	0.81	3.21 (1.27; 5.15)	0.89 (0.63; 0.96)
	VAS	0.87	-0.04 (-0.53; 0.45)	0.95 (0.88; 0.98)
	Upper lip (RODI)	0.81	0.00 (-0.31; 0.31)	0.91 (0.78; 0.96)
	Anterior palate (RODI)	0.71	0.04 (-0.34; 0.43)	0.83 (0.60; 0.93)
	Inside cheeks (RODI)	0.79	0.33 (-0.01; 0.65)	0.85 (0.63; 0.93)
	Posterior palate (RODI)	0.75	0.33 (-0.05; 0.72)	0.84 (0.63; 0.93)
	Lower lip (RODI)	0.75	0.33 (-0.03; 0.70)	0.84 (0.63; 0.93)
	Floor of the mouth (RODI)	0.68	0.04 (-0.32; 0.40)	0.83 (0.59; 0.92)
	Posterior tongue (RODI)	0.75	0.04 (-0.36; 0.44)	0.86 (0.67; 0.94)
	Anterior tongue (RODI)	0.56	0.38 (-0.10; 0.85)	0.72 (0.36; 0.88)
	Pharynx (RODI)	0.80	0.25 (-0.13; 0.63)	0.88 (0.73; 0.95)
	Dry mouth (35)	0.65	1.39 (-9.96; 12.74)	0.79 (0.50; 0.91)
	Sticky saliva (35)	0.81	1.39 (-8.33; 11.11)	0.89 (0.74; 0.95)
	Dry mouth and sticky saliva (43)	0.79	2.78 (-5.17; 10.73)	0.88 (0.72; 0.95)
Dysphagia	EAT-10	0.92	2.00 (0.28; 3.72)	0.93 (0.82; 0.97)
	Swallowing problems (35)	0.85	-0.35 (-5.04; 4.35)	0.89 (0.74; 0.95)
	Swallowing (43)	0.94	1.04 (-1.76; 3.85)	0.96 (0.90; 0.98)
Quality of life	Global health (30)	0.85	2.78 (-1.70; 7.26)	0.92 (0.82; 0.97)

Spearman correlation coefficients: < 0.19 very weak, 0.20 to 0.39 deemed weak, 0.40 to 0.59 moderate, 0.60 to 0.79 strong, ≥ 0.80 very strong. Intraclass correlation coefficients: < 0.40 poor concordance, 0.40 to 0.59 moderate, and 0.60 to 0.75 good, and > 0.75 excellent concordance

Abbreviations: CI confidence interval, *EAT-10* Eating Assessment Tool-10, *ePROM* electronic Patient Reported Outcome Measures, *ICC* intraclass correlation coefficients, *Mdiff* mean difference, *PROM* Patient Reported Outcome Measures, *RODI* Regional Oral Dryness Inventory, *rs* Spearman's rank correlation coefficient, *VAS* Visual Analogue Scale for xerostomia, *XI* Xerostomia Inventory, *30* EORTC QLQ-C30, *35* EORTC QLQ-H&N35, *43* EORTC QLQ-H&N43



◀ **Fig. 3** **a** Bland–Altman plot for reliability in Xerostomia Outcome Measures. The two horizontal maroon lines indicate the 95% Limits of Agreement (LoA), calculated as the mean difference ± 1.96 * SD, showing the range within which 95% of the differences between the measurements are expected to lie. Abbreviations: XI: The Xerostomia Inventory; VAS: Visual Analogue Scale; RODI: Regional Oral Dryness Inventory; 35: EORTC QLQ-H&N35; 43: EORTC QLQ-H&N43. **b** Bland–Altman plot for reliability in Dysphagia Outcome Measures. The two horizontal maroon lines indicate the 95% Limits of Agreement (LoA), calculated as the mean difference ± 1.96 * SD, showing the range within which 95% of the differences between the measurements are expected to lie. Abbreviations: EAT-10: Eating Assessment Tool-10; 35: EORTC QLQ-H&N35; 43: EORTC QLQ-H&N43. **c** Bland–Altman plot for reliability in Quality of life Outcome Measure. The two horizontal maroon lines indicate the 95% Limits of Agreement (LoA), calculated as the mean difference ± 1.96 * SD, showing the range within which 95% of the differences between the measurements are expected to lie. Abbreviations: 30: EORTC QLQ-C30

only EORTC questionnaires, the use of the updated EORTC QLQ-H&N35 (QLQ-H&N43) is essential for a more accurate and comprehensive assessment of the QoL in patients with HNC [66]; especially for the inclusion of new scales, such as those directly related to oral health. Notwithstanding this upgrade, dry mouth and sticky saliva assessed in both EORTC questionnaires, may not be optimal for capturing the specific nuances of these symptoms in light of our confusing descriptive statistics. Other modules as EORTC QLQ-PR25 (prostate cancer) [67] and EORTC CIPN20 (peripheral neuropathy in breast cancer) [61] did show that the data obtained from electronic modality were equivalent in comparison with PROM (ICCs ranged 0.45–0.78 and ICC > 0.91 for its matching scales, respectively) along with PGAs (> 85%) for those with prostate cancer slightly lower than ours (94–100%).

Last but not least, test–retest reliability for LAXER application demonstrates that even the insignificant observed variation between ePROM with 1-week delay, may be due to random variation across two different administrations over time rather than to mode of administration. In consequence, it is reinforced its utility in longitudinal studies and routine clinical assessments. Similarly, Huang et al. demonstrated in a newly randomised crossover study of an electronic versus paper-based questionnaire based on oropharyngeal dysphagia excellent test–retest reliability (ICC = 0.96) showing likewise robustness in its temporal stability [68]. Only caution should be taken our results from RODI (ICC ranged 0.51–0.79).

The eighty-four percentage of Belgian healthcare providers who have in radiation oncology [69] considered ePROMs beneficial for patients' health and symptom

Table 5 Percentages exact and global agreements between PROM and ePROM (*N* = 24)

Outcome measures		PEA[a]	PGA[b]
Xerostomia	The XI (11 items)	164/264 (62%)	244/264 (92%)
	VAS (1 item)	13/24 (54%)	19/24 (79%)
	RODI (9 items)	130/216 (60%)	192/216 (89%)
	Dry mouth (1 item) (35)	17/24 (71%)	23/24 (96%)
	Sticky saliva (1 item) (35)	16/24 (67%)	23/24 (96%)
	Dry mouth and sticky saliva (2 items) (43)	31/48 (65%)	47/48 (98%)
Dysphagia	EAT-10 (10 items)	152/240 (63%)	214/240 (89%)
	Swallowing problems (4 items) (35)	71/96 (74%)	96/96 (100%)
	Swallowing (4 items) (43)	80/96 (83%)	96/96 (100%)
Quality of life	Global health (2 items)	32/48 (67%)	45/48 (94%)

Number of total pairs = number of subjects × number of items – number of missing pairs

Abbreviations: EAT-10 Eating Assessment Tool-10, *ePROM* electronic Patient Reported Outcome Measures, *PROM* Patient Reported Outcome Measures, *RODI* Regional Oral Dryness Inventory, *VAS* Visual Analogue Scale for xerostomia, *XI* Xerostomia Inventory, *30* EORTC QLQ-C30, *35* EORTC QLQ-H&N35, *43* EORTC QLQ-H&N43

[a] PEA: Percentage Exact Agreement (in %): number of same response pairs/number of total pairs

[b] PGA: Percentage Global agreement (in %): number of within one-difference response pairs/number of total pairs

Table 6 Equivalence analysis between PROM and ePROM (*N* = 24)

Outcome measures		PROM	ePROM	Equivalence test*		
		Mean (SD)	Mean (SD)	95% CI of mean difference	Left tail [a] *p* value	Right tail [b] *p* value
Xerostomia	The XI	36.21 (9.05)	33.00 (8.20)	1.27; 5.15	0.0034	< 0.001
	VAS	6.71 (2.66)	6.75 (2.45)	-0.53; 0.45	< 0.001	< 0.001
	Upper lip (RODI)	2.21 (1.25)	2.21 (1.18)	-0.31; 0.31	< 0.001	< 0.001
	Anterior palate (RODI)	2.33 (1.24)	2.29 (1.08)	-0.34; 0.43	< 0.001	< 0.001
	Inside cheeks (RODI)	2.33 (1.20)	2.00 (0.98)	-0.01; 0.65	< 0.001	< 0.001
	Posterior palate (RODI)	3.21 (1.28)	2.88 (1.26)	-0.05; 0.72	< 0.001	< 0.001
	Lower lip (RODI)	2.75 (1.26)	2.42 (1.18)	-0.03; 0.70	< 0.001	< 0.001
	Floor of the mouth (RODI)	2.42 (1.14)	2.38 (1.06)	-0.32; 0.40	< 0.001	< 0.001
	Posterior tongue (RODI)	2.79 (1.41)	2.75 (1.26)	-0.36; 0.44	< 0.001	< 0.001
	Anterior tongue (RODI)	2.92 (1.35)	2.54 (1.10)	-0.10; 0.85	0.0064	< 0.001
	Pharynx (RODI)	3.08 (1.38)	2.83 (1.43)	-0.13; 0.63	< 0.001	< 0.001
	Dry mouth (35)	61.11 (33.57)	29.72 (29.46)	-9.96; 12.74	0.007	0.002
	Sticky saliva (35)	50.00 (35.44)	48.61 (35.41)	-8.33; 11.11	0.004	< 0.001
	Dry mouth and sticky saliva (43)	59.72 (30.26)	56.95 (26.43)	-5.17; 10.73	0.036	0.002
Dysphagia	EAT-10	13.25 (9.50)	11.25 (7.93)	0.28; 3.72	0.120	< 0.001
	Swallowing problems (35)	21.87 (17.69)	22.22 (16.97)	-5.04; 4.35	< 0.001	< 0.001
	Swallowing (43)	20.83 (17.72)	19.79 (14.71)	-1.76; 3.85	< 0.001	< 0.001
Quality of life	Global health (30)	68.75 (18.07)	65.97 (20.98)	-1.70; 7.26	0.118	< 0.001

Abbreviations: CI confidence interval, *EAT-10* Eating Assessment Tool-10, *ePROM* electronic Patient Reported Outcome Measures, *MCID* Minimal Clinically Important Differences, *MID* Minimal Important Difference, *SD* standard deviation, *PROM* Patient Reported Outcome Measures, *RODI* Regional Oral Dryness Inventory, *VAS* Visual Analogue Scale for xerostomia, *XI* Xerostomia Inventory, *30* EORTC QLQ-C30, *35* EORTC QLQ-H&N35, *43* EORTC QLQ-H&N43

[a] Left tail significance indicates µPROM – µePROM > MCID or MID

[b] Right tail significance indicated µPROM – µePROM < MCID or MID

[*] Based on the equivalence test using the score MCID or MID as the tolerably difference

Table 7 Mean differences (with 95% confidence interval) and intraclass correlation coefficients for the test–retest reliability of electronic modality, ePROM ($N=20$)

Outcome measures		M_{diff} (95% CI)	*p* value*	ICC (95% CI)
Xerostomia	The XI	0.18 (-1.95; 2.31)	0.99	0.91 (0.79; 0.96)
	VAS	-0.41 (-1.20; 0.38)	0.38	0.83 (0.59; 0.93)
	Upper lip (RODI)	0.18 (-0.34; 0.71)	0.69	0.72 (0.32; 0.88)
	Anterior palate (RODI)	0.09 (-0.36; 0.54)	0.92	0.75 (0.38; 0.89)
	Inside cheeks (RODI)	0.18 (-0.32; 0.69)	0.54	0.57 (-0.03; 0.82)
	Posterior palate (RODI)	0.00 (-0.47; 0.47)	1.00	0.79 (0.48; 0.91)
	Lower lip (RODI)	-0.18 (-0.80; 0.44)	0.43	0.51 (-0.19; 0.80)
	Floor of the mouth (RODI)	0.00 (-0.56; 0.56)	0.85	0.51 (-0.22; 0.80)
	Posterior tongue (RODI)	-0.18 (-0.77; 0.41)	0.37	0.65 (0.14; 0.85)
	Anterior tongue (RODI)	0.32 (-0.12; 0.76)	0.19	0.79 (0.50; 0.91)
	Pharynx (RODI)	-0.23 (-0.79; 0.34)	0.64	0.69 (0.26; 0.87)
	Dry mouth (35)	1.52 (-6.99; 10.02)	0.69	0.88 (0.71; 0.95)
	Sticky saliva (35)	-1.52 (-12.19; 9.16)	0.89	0.86 (0.66; 0.94)
	Dry mouth and sticky saliva (43)	-3.79 (-12.89; 5.31)	0.39	0.81 (0.54; 0.92)
Dysphagia	EAT-10	1.59 (-0.45; 3.63)	0.20	0.93 (0.83; 0.97)
	Swallowing problems (35)	-2.65 (-8.28; 2.98)	0.33	0.84 (0.63; 0.93)
	Swallowing (43)	1.89 (-2.80; 6.59)	0.42	0.89 (0.73; 0.95)
Quality of life	Global health (30)	0.76 (-6.26; 7.78)	0.40	0.81 (0.54; 0.92)

Intraclass correlation coefficients: < 0.5 poor reliability, 0.5 to 0.75 moderate reliability, 0.75 to 0.9 indicate good reliability, and values exceeding 0.90 indicate excellent reliability under these conditions **p* value calculated with Wilcoxon test. Non-parametric data due to small sample size

Abbreviations: CI confidence interval, *EAT-10* Eating Assessment Tool-10, *ePROM* electronic Patient Reported Outcome Measures, *ICC* Intraclass correlation coefficients, *Mdiff* mean difference, *RODI* Regional Oral Dryness Inventory, *VAS* Visual Analogue Scale for xerostomia, *XI* Xerostomia Inventory, *30* EORTC QLQ-C30, *35* EORTC QLQ-H&N35, *43* EORTC QLQ-H&N43

knowledge, symptom self-management and active participation in care. Additionally, Salz et al. [70] suggest that incorporating ePROM into clinical practice for patients with HNC can be valuable due to little work so far. The implementation of ePROM may offer several advantages to patients with HNC, especially when fully integrated within a mobile application as LAXER: 1) missing data were reduced by requiring completion of an item before the patient can change to next item; 2) unclear data were also avoided by allowing patient to only select one option on the screen; 3) real-time clinical feedback had an relevant role in symptom management; 4) administering PROM on a mobile application like this has the potential to improve patient compliance and reduce the scoring process burden on staff; and 5) the validity, reliability and sensitivity to change have been demonstrated in the PROM used.

As opposed, limitations of LAXER app have been also described: 1) potential difficulties that some patients may had have in interacting with mobile application; 2) senior patients could have explained partly lower correlations (concordance and test–retest reliability) and mean differences not close to zero despite efforts to make the interface user-friendly, such as adapting font sizes; 3) the timing of assessments and selecting the appropriate washout and test–retest periods were a challenge but we did believe that a fast-changing symptom burden specifically in a chronic symptom as xerostomia was not expected in our population; 4) psychometric properties cannot be assumed stable across modalities, necessitating a careful electronic adaptation of paper-based questionnaires; and 5) the analysis was conducted using a small sample ($N=24$) and in a heterogeneous patient population thus, the results are preliminary and cannot be generalized to other populations.

It should be underscored that the mHealth is not intended as a replacement for the researcher/clinician; rather, its intended value would be in providing additional information that is appropriate to the care of the patient and the specific symptoms in real time using a simple and secure mobile application. Our results support the reliability with temporal stability (test–retest) of ePROMs for xerostomia, dysphagia and QoL in clinical practice. In fact, they are already being used in an ongoing randomised controlled trial (NCT05106608) where their use enables more efficient patient assessment and facilitates large-volume data collection. All in all, the most compelling argument in favour of implementing of the ePROM into oncology practice is that it allows patients to actively participate in their own care

[71]. A larger and less heterogeneous sample size could enhance the generalizability of our preliminary findings. Furthermore, future studies should replicate our design based on senior population to further substantiate our conclusion. Lastly, upcoming LAXER updates should consider incorporating additional languages to broaden the accessibility to other speakers.

This study shows that electronic adaptations of outcome measures are possible despite the challenging older target population. Furthermore, it aligns with a patient-centred approach to healthcare, recognizing the importance of a mobile application for reporting timely and accurate clinical information, and experienced symptoms thus empowering patients in the management of their conditions through accessible and user-friendly digital tool.

Abbreviations

5FU	5-Fluorouracil
AJCC/UICC	American Joint Committee on Cancer/Union for International Cancer Control
CIPN20	Chemotherapy-Induced Peripheral Neuropathy Module of the EORTC QLQ
CT	Chemotherapy
EAT-10	Eating Assessment Tool-10
EORTC	European Organisation for Research and Treatment of Cancer
ePROM	Electronic Patient-Reported Outcome Measure
Gy	Gray
HNC	Head and Neck Cancer
ICC	Intraclass Correlation Coefficient
IGRT	Image-guided radiation therapy
IMRT	Intensity Modulation Radiation Therapy
LoA	Limits of Agreement
MCID	Minimal Clinically Important Differences
MID	Minimal Important Difference
NCCN	National Comprehensive Cancer Network
OAR	Organs at risk
PGA	Patient Global Assessment
PEA	Percentage of Exact Agreement
PROM	Patient-Reported Outcome Measure
QLQ-H&N35	Quality of Life Questionnaire Head and Neck Module 35
QLQ-H&N43	Quality of Life Questionnaire Head and Neck Module 43
RODI	Regional Oral Dryness Inventory
RT	Radiotherapy
RT3D	Three-Dimensional Conformal Radiotherapy
SD	Standard Deviation
VAS	Visual Analogue Scale
VMAT	Volumetric Modulated Arc Therapy
XI	Xerostomia Inventory
QoL	Quality of Life

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Authors' contributions
ITM and NGC contributed to the study conception, design and funding acquisition. Material preparation and data collection were performed by PCG, PPM, CFL, ITM, and NGC. Analysis was performed by MLL and MLG. The first draft of the manuscript was written by MLL, MLG, PCG, PPM, and CFL and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Andalusian Biomedical Research Ethics Portal (2021-12-02 / No 2402-N-21 CEIM/CEI Provincial de Granada). Informed consent was obtained from all individual participants included in the study.

Consent for publication
Patients provided informed consent for the publication of their data. No identifying information has been included to ensure patient anonymity.

Competing interests
The authors declare no competing interests.

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