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Operational feasibility of implementing electronic patient-reported outcomes in routine head and neck cancer care: a prospective pilot study

Hiroto Ishiki

ishiki-tky@umin.ac.jp

National Cancer Center Hospital https://orcid.org/0000-0002-0800-2161

Tomomi Kobayashi

National Cancer Center Hospital: Kokuritsu Gan Kenkyu Center Chuo Byoin

Hisayo Doi

Kobe University Hospital: Kobe Daigaku Igakubu Fuzoku Byoin

Sayaka Arakawa

National Cancer Center Hospital: Kokuritsu Gan Kenkyu Center Chuo Byoin

Koji Amano

National Cancer Center Hospital: Kokuritsu Gan Kenkyu Center Chuo Byoin

Eriko Satomi

National Cancer Center Hospital: Kokuritsu Gan Kenkyu Center Chuo Byoin

Yoshitaka Honma

National Cancer Center Hospital: Kokuritsu Gan Kenkyu Center Chuo Byoin

Mitsumi Terada

National Cancer Center Japan: Kokuritsu Gan Kenkyu Center

Junki Mizusawa

National Cancer Center Japan: Kokuritsu Gan Kenkyu Center

Yuichiro Kikawa

Kansai Medical University: Kansai Ika Daigaku

Yoshinori Imamura

Kobe University Hospital: Kobe Daigaku Igakubu Fuzoku Byoin

Taiji Koyama

Kobe University Hospital: Kobe Daigaku Igakubu Fuzoku Byoin

Kayoko Nakano

Kobe University Hospital: Kobe Daigaku Igakubu Fuzoku Byoin

Susanne Singer

Rostock University Medical Center: Universitatsmedizin Rostock

Gerhard Rumpold

Medical University of Innsbruck: Medizinische Universitat Innsbruck

Bernhard Holzner

Medical University of Innsbruck: Medizinische Universitat Innsbruck

Naomi Kiyota

Kobe University Hospital: Kobe Daigaku Igakubu Fuzoku Byoin

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Abstract

Background

The EORTC QLQ-HN43 (HN43) is validated for head and neck cancer (HNC) patients, but evidence regarding its feasibility for electronic data capture is limited. We investigated the feasibility of using the EORTC QLQ-C30 and HN43 as electronic patient-reported outcome measures (ePROMs) via the Computer-Based Health Evaluation System (CHES) in clinical and home settings.

Methods

In this multicenter, prospective study, HNC outpatients completed questionnaires via CHES at a visit (T1) and one week later at home (T2), with a reminder if needed. The primary outcome was the T1 completion rate (≥ 90% items answered).

Results

Forty patients enrolled. The T1 completion rate was 98% (95% CI: 86.8–99.9), meeting the primary objective. Median completion time was 10 minutes. At T2 (home), the pre-reminder completion rate was 38%. After reminders (issued to 63%), the final T2 rate was 88% (95% CI: 73.2–95.8). Missing data were infrequent, mostly concerning Sexuality, Social Eating, and Financial Difficulties.

Conclusions

Online Quality of Life (QOL) assessment via CHES is highly feasible in supervised clinical settings for Japanese HNC patients. While remote assessment achieved high completion rates, adherence heavily depended on active reminders, highlighting the necessity of implementing effective reminder systems for routine practice.

Introduction

Head and neck cancers (HNCs) constitute a heterogeneous group of malignancies originating in anatomically complex and functionally critical regions such as the oral cavity, nasal cavity, paranasal sinuses, nasopharynx, oropharynx, hypopharynx, larynx, and salivary glands. In Japan, HNC accounts for approximately 2.3% of all cancer-related deaths [1]. Due to the anatomical location where sensory organs are concentrated, and multimodal treatment approaches often involving surgery, radiotherapy, and chemotherapy, patients with HNC frequently experience profound impacts on essential physiological functions including vision, hearing, olfaction, gustation, swallowing, and phonation.

The unique challenges faced by patients with HNC extend beyond disease control and survival. Treatment often results in long-term sequelae [2] affecting social interaction, communication, and nutritional intake, leading to significant declines in health-related quality of life (HRQOL). HRQOL encompasses physical, emotional, social, and spiritual dimensions of well-being [3, 4]. As such, it is widely accepted that HRQOL should be a key endpoint in the treatment planning and evaluation for HNC patients [5–7].

Patient-reported outcome measures (PROMs) have gained increasing importance as reliable tools to capture patients' subjective experiences of disease burden and treatment effects [8–10]. Among several instruments used in oncology, the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Core Questionnaire 30 (QLQ-C30) [11, 12], a standardized, cancer-generic HRQOL instrument, is applied worldwide in multiple clinical studies [13]. To address site-specific issues, it is typically supplemented with tumor-specific modules. For HNC, the original EORTC QLQ-HN35 was developed in the 1990s and validated for assessing HRQOL in HNC patients [14]. In 2019, this module was revised to better reflect modern treatment modalities and patient needs, resulting in the updated EORTC QLQ-HN43, which contains 43 items designed to be administered alongside the 30-item core questionnaire [15].

To date, much of the existing HRQOL data using these instruments has been collected via paper-based formats during clinical visits. However, the increasing availability of digital technologies presents opportunities to collect PROMs electronically via electronic patient-reported outcomes (ePRO) platforms [16, 17]. The Computer-based Health Evaluation System (CHES) platform is a specialized software dedicated to the assessment, storage and processing of ePRO. It is a product of the software company ESD - Evaluation Software Development [18] and facilitates the development of the PROM of the EORTC Quality of Life Group (QLG), their use for research activities as well as the dissemination of computer adaptive measures. The CHES is already in use for clinical trials and routine care [19–22]. Previous studies on paper-based administration of the EORTC QLQ-HN35 found a full response rate of approximately 66–92%, with the highest rate of missing values observed in questions related to sexuality [23]. Data on EORTC QLQ-HN43 response rates remain scarce, although preliminary validation studies report that 94% of patients can complete both EORTC QLQ-HN43 and EORTC QLQ-C30 within 20 minutes, with a proportion of missing items of only 6% on sexuality-related questions [15].

Digital PROMs have shown additional clinical benefits in recent randomized controlled trials. Symptom monitoring using an ePRO system during routine cancer treatment not only improved HRQOL but also extended overall survival and reduced emergency visits [24, 25]. These findings highlight the clinical relevance and potential utility of integrating PROMs into daily oncology practice. However, there is conflicting evidence on whether the time needed for assessing HRQOL is longer when using ePROM or paper-based PROM [26].

In Japan, internet penetration continues to rise, with a reported proportion of 84.9% in 2022 and increasing smartphone ownership with currently 88.6% [27]. Nevertheless, the feasibility of using web-

based HRQOL assessments specifically in HNC patients has not yet been systematically evaluated. Given the physical impairments (i.e. speech impairment due to laryngectomy) and treatment-related limitations (i.e. dysphagia after chemoradiotherapy) frequently experienced by this population, it is particularly important to determine whether electronic HRQOL surveys are tolerable and acceptable in this clinical context. Therefore, we designed a multicenter observational study to evaluate the feasibility of electronic HRQOL assessments using the EORTC QLQ-HN43 and EORTC QLQ-C30 in Japanese HNC patients receiving outpatient care. This study investigated the completion rates and data quality when patients respond via web-based platforms and assess whether such an approach is viable for broader implementation in both clinical practice and future clinical trials.

Patients and Methods

Study Design

This is a multicenter, prospective, observational study aimed at evaluating the tolerance and data completeness of electronic HRQOL assessment using EORTC questionnaires in patients with HNC. Patients were recruited at the head and neck medical oncology outpatient clinics of two comprehensive cancer centers (National Cancer Center Hospital and Kobe University Hospital).

Participants

Eligible participants included adult patients (≥ 20 years) with a confirmed histological or clinical diagnosis of HNC (including oral cavity, pharynx, larynx, nasal cavity, and salivary gland cancers), who were receiving outpatient treatment, had access to the internet via smartphone or personal computer (PC), and were expected to survive for at least three months. All participants provided written informed consent. Patients with cognitive impairments or those deemed inappropriate by their attending physician were excluded.

Data Collection Procedure

After confirming eligibility, patients were asked to complete the C30 and HN43 questionnaires using the electronic format during an outpatient visit as part of the baseline assessment (T1 survey). One week after the T1 survey, patients were asked to access the online response platform and complete the C30 and HN43 again (T2 survey). If no response was received by day 10 after T1, a single reminder was issued by phone or e-mail. The researchers confirmed whether responses had been submitted by 14 days after the initial T1 survey. The observation period was defined as 14 days following T1, and it ended once this period had elapsed.

All data collection was conducted through CHES. Medical professionals entered the medical information of registered patients, and patients entered their own patient information and PROs using their own smartphones. The time it took to complete the QOL questionnaire was recorded by CHES.

Questionnaires

The EORTC QLQ-C30 and EORTC QLQ-HN43 were used in this study. Both paper-based and electronic versions (via an online response platform) were available; in this study, data was collected using the electronic version. Although responses were anonymized, each participant got a registration number that was pseudonymized in a manner allowing linkage to clinical data via the CHES system [19].

EORTC QLQ-C30

The EORTC QLQ-C30 is a 30-item questionnaire capturing five functional domains (physical, role, emotional, cognitive, social), nine cancer symptoms (fatigue, pain, nausea/vomiting, dyspnea, insomnia, appetite loss, constipation, diarrhea) plus global health/QoL and financial impact [11]. Items refer to the past week and use a 1–4 Likert scale (global health 1–7); scores are linearly transformed to 0-100, where higher values denote better function or worse symptoms. The EORTC QLQ-C30 is reliable and valid. Thresholds for clinically meaningful differences across cancer populations are established [11, 28].

EORTC QLQ-HN43

The EORTC QLQ-HN43 is a 43-item module complementary to the C30. The items were presented as a single consecutive battery: EORTC QLQ-C30 items were numbered #1–30, immediately followed by EORTC QLQ-HN43 items #31–73. The EORTC QLQ-HN43 covers 12 multi-item domains—pain, swallowing, senses, speech, social eating/contact, body image, sexuality, dental problems, dry/sticky saliva, shoulder function and skin issues—and eight single-item symptoms such as trismus, hoarseness, neck swelling and fear of progression [15]. Items use a 1–4 Likert scale (past week); scores are transformed to 0-100 following EORTC guidelines [29], higher values denote worse symptoms. The instrument shows robust reliability and validity internationally [15].

Outcomes

Primary outcome of this study was the response completion rate, which is defined as the proportion of patients who complete ≥ 90% of items on both the C30 and the HN43 at T1. In other words, when the patients completed both 27 or more items of the C30 and 39 or more items of the HN43, it was defined as sufficiently complete.

Secondary outcomes included response completion rate at T2, total number of completed items at T1 and T2 (out of 73), number and type of missing items, and QOL scores calculated based on the EORTC scoring manual [29].

Sample Size and Statistical Analysis

In 23 previous studies using the HN35 questionnaire, the complete response rate was 66% [23]. Therefore, we expected a completion rate of at least 70% at T1. The sample size was determined based on the desired precision of the estimated questionnaire completion rate.

To ensure sufficient precision, we assumed a point estimate of 80% and calculated that enrolling 40 patients would yield a lower bound of approximately 69% for the one-sided 90% exact confidence interval (equivalent to the lower bound of a two-sided 80% CI). This precision was considered adequate to judge feasibility relative to the expected threshold of 70%.

Data Management and Confidentiality

All data were anonymized using study IDs. CHES ensures secure storage of data, and each participating site maintained a separate ID linkage table under strict security measures.

Ethical Considerations

The study protocol was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Boards of both participating institutions (approval number: 2020 − 130 in National Cancer Center Hospital and B200371 in Kobe University Hospital). All participants provided written informed consent prior to enrollment.

This study was registered in the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) (UMIN000042936).

Results

Between July 2021 and October 2021, 99 outpatient HNC patients were screened, and 50 patients receiving chemotherapy were eligible. A total of 40 patients were enrolled in the study and completed the baseline (T1) assessment (Fig. 1). Of these, 35 patients (88%) also completed the follow-up assessment at day 7 (T2).

The median age of the patients was 64 years (range 42–75), and most were male (35/40, 88%). Primary tumor sites were distributed across oral cavity (30%), oropharynx (25%), hypopharynx (20%), nasopharynx (15%), larynx (5%), nasal/paranasal sinus (3%) and salivary gland (3%). The majority presented with recurrent or metastatic disease (83%), while seven patients (18%) had locoregional disease. Fifteen patients (38%) were receiving chemotherapy and 23 (58%) were receiving immunotherapy, and 2 (5%) received both chemotherapy and immunotherapy. Thirty-six (90%) patients had their own smartphone and 26 (65%) patients had PCs. Half of the patients used PCs more than one time per week (Table 1).

At the initial assessment (T1), the response completion rate was 100% for the C30 (40/40 patients answering ≥ 27 items) and 98% for the HN43 (39/40 patients answering ≥ 39 items). The respective 95% and 80% CIs were 91.2–100.0 and 94.4–100.0 for the C30, and 86.8–99.9 and 90.6–99.7 for the HN43.

At the second assessment (T2), the completion rate before the reminder was 38% (15/40). Twenty-five (63%) of the patients received a reminder, and the final response completion rate was 88% (35/40) for both questionnaires, with 35 patients meeting the completion criteria for each. The 95% and 80% CIs of both the C30 and the HN43 at T2 were 73.2–95.8 and 78.0-93.8, respectively. The combined overall response completion rate was 97.5% at T1 and 87.5% at T2 (Table 2).

A completion time analysis revealed that at the first assessment (T1), the median time required to complete the EORTC QLQ-C30 was 5 minutes 10 seconds (range 1 min 54 s − 24 min 52 s), while the EORTC QLQ-HN43 took a similar 5 min 08 s (2 min 21 s − 32 min 58 s). At the second assessment (T2), completion times decreased for both instruments: 3 min 38 s (1 min 38 s − 48 min 44 s) for the C30 and 3 min 17 s (1 min 48 s − 8 min 15 s) for the HN43 (Table 3).

In the item-level missing-data analysis (Table 4), T1 showed very few omissions. The greatest non-response frequency was for #61 (Sexuality), with three missing values (3/40; 7.5%). Two responses were missing (5.0%) for #28 (Financial difficulties), #53 (Social eating), and #68 (Weight loss). Single omissions (2.5%) were noted for #2 and #17 and #37, 40, 55, 57, 59, 60, 66, and 69. At T2, missing data were minimal: only one response (1/35; 2.9%) was absent for each of items 40, 53, 60, and 61, and every other item was fully completed.

Discussion

Summary of the Results

This study evaluated the response acceptability of the EORTC QLQ-C30 and EORTC QLQ-HN43 with internet devices in patients with HNC. Observed completion rates were high at both assessment points (97.5% at T1 and 87.5% at T2). As the lower limit of the 80% CI exceeded the pre-defined feasibility threshold of 70%, the primary objective was met. In addition, total median completion time was 10 minutes at T1 and 7 minutes at T2, indicating shorter at-home completion, and brief enough for routine evaluation, indicating a high level of adherence to web-based self-reporting. Item-level analysis revealed an overall missing data rate as low as 0.87% at T1 and 0.27% at T2 across all QLQ-HN43 items. Questions concerning sexual function and dietary issues were identified as those most prone to missing data.

These low missing rates suggest good acceptability and feasibility of the electronic patient-reported outcomes (ePRO) system using the CHES platform among HNC patients. The completion rates and minimal missing data support the potential integration of web-based HRQOL assessment into routine clinical care and research settings for this patient population.

Comparison to Previous Evidence

A previous review of 23 studies using the HN35 reported a full completion rate of 66%. Furthermore, item nonresponse was noted in questions regarding sexuality, with a missing rate of 11.5% (range: 0–29%).

Based on this, we defined questionnaire completion as responding to more than 90% of the items. The questionnaire completion rates for HN43 were 97.5% at T1 and 87.5% at T2. Considering confidence intervals for both timepoints, questionnaire completion rate would be expected to surpass 80% in QOL assessment using the CHES for patients with HNC. More recently, the international validation study of the EORTC QLQ-HN43 [15], which primarily used paper-based administration, reported a high completion rate of 94%. Our study achieved comparable completion rates (97.5% at T1 and 87.5% at T2) using an ePRO platform. Regarding administration time, ePRO is not inherently faster than paper-based assessments. Prior research indicates completion times can be longer for ePRO, particularly among patients with emotional distress [26]. The mode sequence can also create a learning effect, influencing the recorded duration [30]. Although this study did not directly compare paper and ePRO, the response time was less than 10 minutes, which is considered short enough to assess QOL using ePRO in HNC patients.

These results suggest that electronic administration via CHES does not negatively impact the completion rate compared to traditional paper-based methods.

The high completion rate at T2 (87.5%) demonstrates the potential for remote ePRO collection; however, it should be interpreted with caution. Notably, 62.5% of patients required a reminder to complete the assessment, and the pre-reminder completion rate was only 37.5%. This suggests that while patients are capable of completing ePROs at home, maintaining adherence in routine clinical practice may depend on effective reminder systems or support structures. Future implementation strategies should therefore focus on optimizing patient engagement and minimizing the need for manual reminders.

The maximum item-level missingness observed for a single HN43 item was low (T1: 7.5%, T2: 2.9% across HN43 items). Items within the Sexuality scale and Social Eating showed comparatively higher non-response, consistent with previous reports [23].

Strengths

This prospective, multicenter study enrolled outpatients receiving systemic anticancer therapy. Although HNC comprises a heterogeneous set of disease entities, the sample contained a well-balanced distribution of patients across these entities, supporting the representativeness of the cohort for the broader HNC population. Moreover, patients completed T1 during their outpatient visit and subsequently completed T2 at home. In cases where no T2 response was received, reminders were sent to confirm whether the patient had responded. This design allowed us to evaluate the feasibility of remote ePRO collection at home, including the necessity and effectiveness of a reminder strategy.

Limitations

A key limitation of this study is that enrolment was confined to two comprehensive cancer centers, introducing possible institutional bias and precluding broad generalizability. In addition, this study required participants to have internet access and their own devices, inherently selecting a population with a certain level of digital literacy. This selection bias, often referred to as the digital divide, limits the

generalizability of our findings. Furthermore, this study focused primarily on quantitative feasibility (completion rates and times) and did not include a formal assessment of usability or qualitative interviews regarding patient acceptability of the CHES platform. Understanding patient-perceived barriers and the ease of use is crucial for successful implementation in routine care.

Conclusion

Even with these limitations, this study meaningfully demonstrates the feasibility of collecting quality-of-life data via electronic patient-reported outcomes (ePROs) in HNC patients. ePRO-based data capture will become increasingly important in future research and routine care. In conclusion, quality-of-life assessment by ePRO is achievable in this population.

Declarations

Competing interests:

The authors have no competing interests to declare that are relevant to the content of this article.

Ethics approval:

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Institutional Review Boards of the National Cancer Center Hospital (approval number: 2020 – 130) and Kobe University Hospital (approval number: B200371).

Consent to participate:

Written informed consent was obtained from all individual participants included in the study.

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Data availability:

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

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Tables

Table 1 to 4 are available in the Supplementary Files section.

Figures

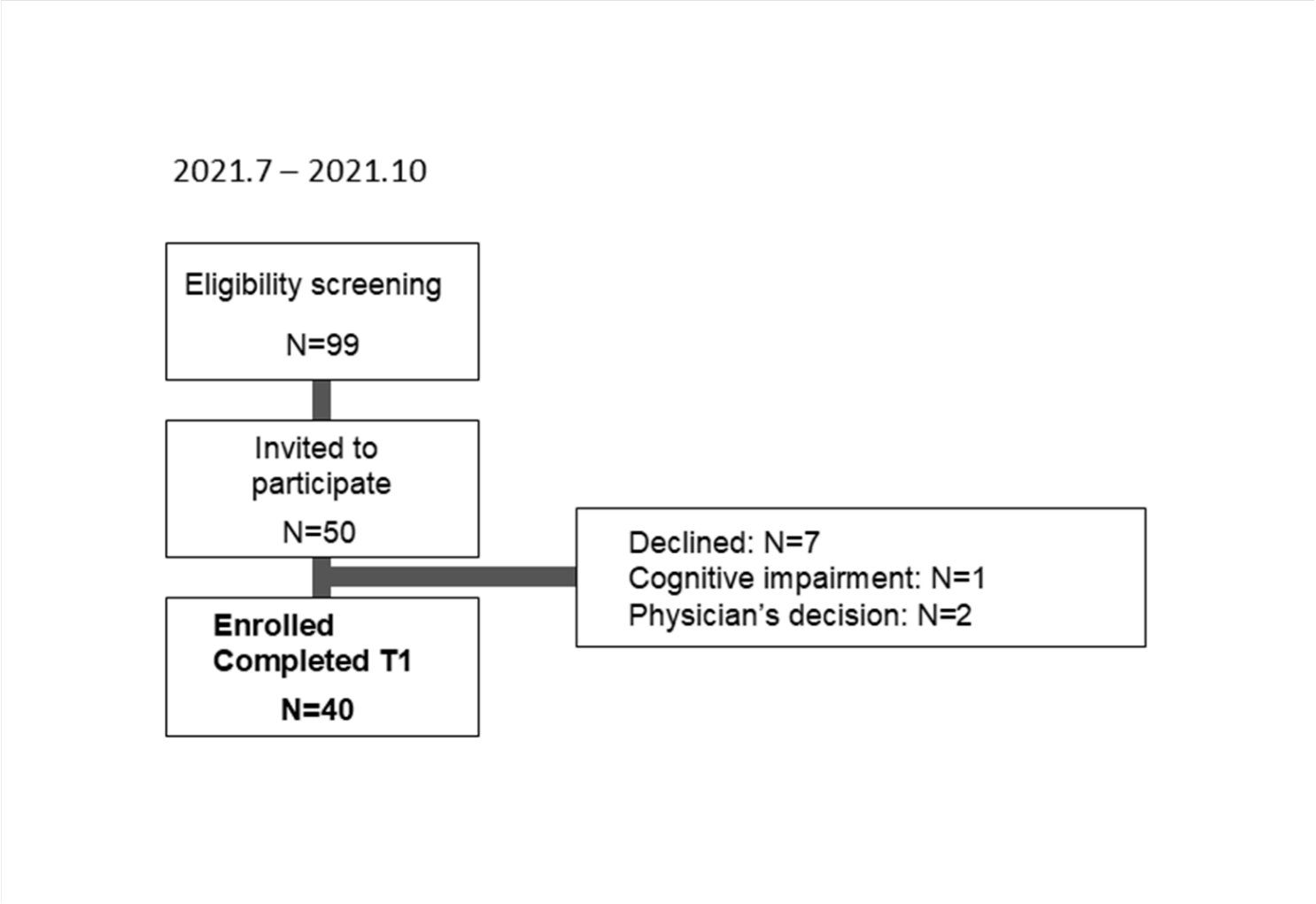

Figure 1

Patient flow diagram. Between July and October 2021, 99 outpatients with head and neck cancer were screened and 50 were invited to participate; 40 patients were enrolled and completed the baseline (T1) assessment

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- tablesIJCO.xlsx