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Dietary habits and genetic factors associated with the alleviation of cancer therapy-related adverse events: a protocol for a prospective observational cohort study

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ABSTRACT

Introduction Despite substantial research investments aiming to prevent cancer and develop therapeutic interventions, cancer remains a formidable challenge. In view of the persistent rise in cancer prevalence, the condition should also be recognised as a chronic disease. Such an approach can enhance the quality of life of patients with cancer, inhibit treatment-related adverse events and prevent recurrence via comprehensive post-treatment management. The core objective of this study is to investigate the association between dietary factors and treatment-related adverse events in patients with cancer, with the aim of providing individualised dietary recommendations to reduce adverse events and enhance quality of life.

Methods and analysis The study cohort will include 600 participants aged ≥20 years. The participants will be assessed for dietary intake, cancer therapy-related adverse events and single-nucleotide polymorphisms using genomic DNA extracted from saliva. In addition, general and clinical information, lifestyle patterns and general/biochemical data of the blood will also be collected. The primary outcome is dietary factors that mitigate chemotherapeutic adverse events, and the secondary outcome is the association between nutritional status and survival in Korean patients with cancer. Considering the potential impact of dietary habits on the adverse events of cancer treatment, the findings of this study can be used as a basis for the establishment of new dietary guidelines for patients with cancer.

Ethics and dissemination The Institutional Review Board of Severance Hospital, Yonsei University Health System, Seoul, Korea, approved the study protocol (4-2021-1110). Further, all participants provided a written informed consent prior to the study. The findings will be shared via publications.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Prospective cohort design including patients undergoing cancer therapy.
⇒ Comprehensive data collection covering clinical data, dietary intake, adverse events data and genetic data.
⇒ Inclusion of multiple cancer types allowing identification of dietary characteristics across different tumour categories.
⇒ Inclusion of multiple cancer types leading to heterogeneity and limited statistical power within specific subgroups.
⇒ Variability from patient-reported outcomes and uncontrolled treatment factors may influence consistency and interpretation of results.

INTRODUCTION

Cancer remains one of the foremost challenges in modern medicine. In South Korea, it is the leading cause of mortality, with its prevalence steadily increasing.[1] In response, cancer-related research is continuously expanding, with efforts focused on the development of novel medications, treatments and prevention strategies.

Managing potential adverse events during cancer treatment is essential due to several reasons. First, it is important for maintaining and improving the quality of life (QoL) of patients with cancer. Cancer treatments can often be physically and emotionally burdensome, and patients can maintain their daily activities and functions with the proper management of adverse events. This can increase patient adherence to treatment and, consequently, enhance treatment outcomes.[2 3] Second, adverse event management is important for preventing treatment discontinuation. If the adverse events are severe or uncomfortable, patients may find it difficult to continue with treatment.[4] This can compromise treatment efficacy and inhibit progress. Therefore, it is vital to manage adverse events to help patients continue with their treatments. Finally, the management

of adverse events is crucial for preventing major complications that may develop during the treatment process. Some adverse events can progress into severe complications that seriously threaten a patient's health. The proper management of adverse events can decrease the occurrence of these complications.[5]

In particular, the importance of dietary management during cancer treatment cannot be overstated. Cancer treatments such as chemotherapy and radiation therapy can take a toll on the body, thereby affecting appetite, digestion and nutrient absorption. With proper dietary management, patients can receive adequate nutrition to support their overall health and help in the recovery process. Further, good nutrition helps patients maintain their strength and energy levels,[6 7] which are essential for coping with the physical and emotional demands of cancer treatment. Adequate intake of calories, protein, vitamins and minerals supports muscle function and overall vitality.[8] Cancer treatment can weaken the immune system, making patients more susceptible to infections.[9] A well-balanced diet rich in fruits, vegetables, lean proteins and whole grains provides essential nutrients and antioxidants that support immune function and help the body fight off infections.[10 11] Numerous studies have also suggested that dietary factors may influence treatment outcomes and the body's ability to tolerate and respond to cancer therapy.[12 13] By following a healthy diet tailored to their individual needs, the overall well-being of the patients may improve, and the efficacy of their treatment can be enhanced. Most importantly, certain foods and dietary strategies can help alleviate the common adverse events of cancer treatment such as nausea, vomiting, diarrhoea and mouth sores.[14 15] For example, bland, easily digestible foods may be recommended during periods of digestive discomfort. Meanwhile, cold or soft foods can soothe mouth sores.[15–17]

With consideration of factors such as the patient's health status, cancer type and stage, treatment plan and adverse events, individualised dietary adjustments can be made to support the patient's health and optimise treatment outcomes. Moreover, personalised dietary recommendations, such as offering individualised meal plans, can provide psychological comfort to patients. If patients feel that their diet is helping in their treatment, they are more likely to maintain a positive attitude towards their therapy.[18]

Single-nucleotide polymorphisms (SNPs) are small variations in an individual's genome that can influence their susceptibility to certain diseases and their response to specific nutrients due to their impact on metabolism or absorption.[19 20] Therefore, analysing SNPs allows for the understanding of a patient's genetic profile and enables the customisation of dietary plans tailored to their individual needs. For example, specific SNP variants may affect the metabolism of antioxidant vitamins such as vitamin C, thereby potentially affecting responsiveness to cancer treatment and the risk of adverse events.[21] In addition, other SNP variations can alter the activity of drug-metabolising enzymes involved in cancer therapy, potentially reducing drug efficacy.[22 23] Thus, by evaluating the genetic profile of patients with cancer via SNP analysis, treatment outcomes can be optimised, and adverse events can be reduced. This approach is considered an important strategy in the cancer treatment process.

To address this issue, a cohort study was initiated to investigate the association between cancer treatment-related adverse events and dietary factors among patients with cancer. This study will evaluate the types and severity of adverse events experienced by patients during treatment and examine the association between these adverse events and dietary habits. Further, clinical information and SNP data will be collected from patients to examine the association of genes with dietary patterns and the alleviation of cancer therapy-associated side effects. This research aimed to provide dietary advice to patients to alleviate the adverse events of cancer treatment and enhance their QoL. These findings can contribute to the understanding of the impact of dietary factors on cancer treatment outcomes.

METHODS AND ANALYSIS

Study design

A two-site, prospective observational cohort study was designed to examine the correlation of cancer therapy-related adverse events and dietary intake. Further, this research would like to identify whether there are any changes in their association based on the genetic characteristics of individuals. The study protocol (V.1.0) and informed consent forms were approved by the Institutional Review Board (IRB) of Severance Hospital, Yonsei University Health System, Seoul, Korea (IRB No.: 4-2021-1110). The study commenced in 2022 and is ongoing. Over a period of 5 years, annual follow-up examinations will be conducted to collect information from the participants, including cancer therapy-related adverse events, clinical data and dietary records (figure 1). Patients and the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Eligibility criteria

Inclusion criteria

1. Adult men and women aged ≥20 years undergoing radiation therapy and/or chemotherapy.
2. Individuals with conditions such as breast, lung and gastric cancer.

Exclusion criteria

1. Patients with severe cancer (a European Cooperative Oncology Group Performance Status score of 3).
2. Patients with cognitive impairment or psychiatric disorders.
3. Female patients who are pregnant.

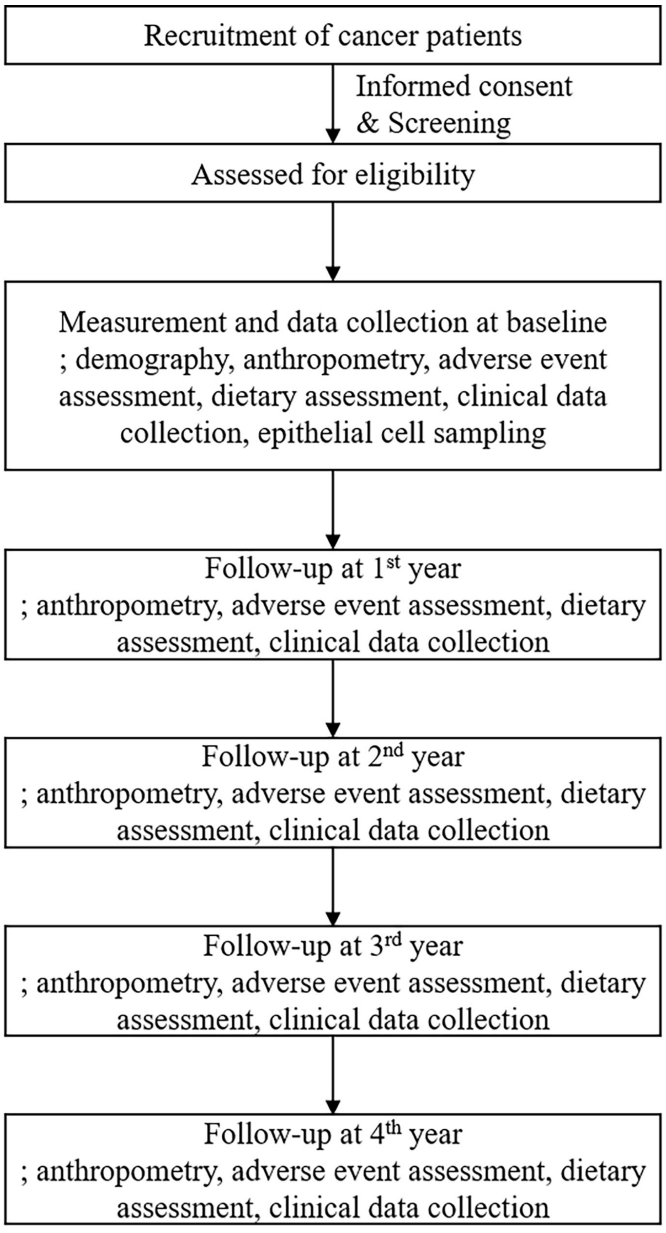

Figure 1 Cohort flow diagram.

Study population, recruitment, engagement, consent and withdrawal

Patient enrolment will take place at Shinchon Severance Hospital and Yongin Severance Hospital, and the target number of participants will be 600. Patients who visit the radiation oncology outpatient clinic and who meet the inclusion and exclusion criteria will be informed about the purpose and procedures of the study in a private setting. After obtaining the written consent from the patients, screening will be conducted to enroll candidates suitable for the study. Clinical research nurses will provide sufficient explanation about the study to the participants, and consent will be collected on the same day. The patient will sign the final consent form. Patients will be ensured that the withdrawal of consent implies discontinuation of providing information for the collected data. Only data with consent from the participants will be used for research, and data from patients who withdrew their consent will be discarded.

Sample size

This study is designed to investigate the severity of adverse events over time and to identify the dietary and genetic factors associated with their alleviation. For a continuous outcome like severity, a small-to-medium effect size (Cohen's d=0.20) was considered clinically relevant, as defined by Cohen.[24] Detecting this effect would require about 787 participants in a single-time design. Our study is a longitudinal design with five repeated measurements (baseline plus four follow-ups), which increases statistical power to detect changes over time. To account for this, we incorporated the efficiency of repeated measures using a mixed-effects regression model. Based on a previous study, we conservatively assumed an intraclass correlation coefficient (ICC) of 0.75. This relatively high ICC reflects the expectation that an individual's adverse event severity remains fairly stable over time, thereby necessitating a larger sample to detect a true effect. Under these assumptions, the minimal sample size required to maintain 80% power (α=0.05) was calculated to be approximately 197 participants.[25 26] Considering a 30% dropout rate over the study period, the recruitment target needed to be about 282 participants to ensure sufficient statistical power at the final follow-up. To provide sufficient power for our primary analysis as well as planned exploratory gene–diet interaction and subgroup analyses by cancer type, we set our baseline recruitment target at 600 participants. This number significantly exceeds the minimal requirement, enabling us to detect smaller effect sizes and providing sufficient power for more detailed analyses. A target sample size of 600 ensures a robust study with high statistical power and increases the generalisability and clinical relevance of our findings.

Patient and public involvement

Patents or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Measurement and data collection

The data that should be measured and collected by this study, along with its frequency, are as follows (table 1):

Self-assessment of the adverse events in cancer therapy

At the time of registration and then annually until the end of the study in 2026, information on adverse events will be collected. The current adverse events and their severity will be assessed by the attending physician using the Common Terminology Criteria for Adverse Events (CTCAE) version 5. The patient-reported outcomes (PROs) for adverse events will be evaluated using the NCI PROs version of the CTCAE (PRO-CTCAE) Items-Korean version 1. In total, 20 of 78 items will be selected for the survey based on their relevance to the study. These included (1) anxiety, (2) arm/leg swelling, (3) constipation, (4) decreased appetite, (5) dry mouth, (6) fatigue, (7) hair loss, (8) headache, (9) insomnia, (10) loose

Table 1 Measurement items and data collection time points

Items	Subcategories	Follow-up				
		Baseline	1 year	2 years	3 years	4 years
Informed consent	–	x				
Eligibility assessment	–	x				
Demographic characteristics	General characteristics	x				
	Lifestyle habits	x	x	x	x	x
Anthropometric measurement	Height, weight and blood pressure	x	x	x	x	x
Adverse event assessment	CTCAE V.5.0	x	x	x	x	x
	PRO-CTCAE V.1.0	x	x	x	x	x
Dietary assessment	FFQ for patients with cancer	x	x	x	x	x
	Dietary habits	x	x	x	x	x
Clinical data collection	Medical history	x	x	x	x	x
	Drug and dietary supplement history	x	x	x	x	x
	Surgical treatment status	x	x	x	x	x
	Chemotherapy status	x	x	x	x	x
	Radiation therapy status	x	x	x	x	x
	Laboratory data collection	x	x	x	x	x
Epithelial cell sampling	SNP analysis	x				

SNP, single-nucleotide polymorphismCTCAE, Common Terminology Criteria for Adverse Events; FFQ, food frequency questionnaire; PRO-CTCAE, patient-reported outcomes version of the CTCAE.

stools, (11) mouth or throat sores, (12) nausea, (13) numbness/tingling in the hands or feet, (14) pain, (15) issues with concentration, (16) problems with tasting food/drink, (17) rash, (18) sad or unhappy feelings, (19) shortness of breath and (20) vomiting.

Dietary assessment

Annually, information on the dietary intake of the participants will be collected using two methods. First, the food frequency questionnaire (FFQ) will be used to conduct an assessment of long-term dietary intake over the course of 1 year. We will use the FFQ that was developed to assess the dietary characteristics of patients with cancer.[27] The FFQ comprises 109 food items. Based on the responses, analysis will be conducted on the patients' food intake lists, frequencies and average annual nutritional intake. In addition, dietary records and patient-reported adverse event assessment will be conducted at 4-month intervals during the baseline visit. From the second year onwards, patients will undergo annual follow-up for 4 years, during which the FFQ, dietary records and adverse event data will be collected. Patients will be encouraged to record all the foods that they consume as comprehensively as possible during the survey period. Based on these data, the analysis of nutritional intake during that period and the derivation of food lists will be possible. In addition, a survey was conducted to assess the patients' usual dietary habits, including meal frequency, snack and eating-out experiences, meal size and food preferences, as well as their experiences with foods that helped alleviate adverse events. No additional dietary restrictions will be applied.

Clinical data

In this study, various items will be collected via medical records and clinical visits once at the registration point and annually until the study's conclusion in 2026. The collected clinical data are as follows:

1. Current cancer and related disease status: cancer type and stage, treatment status and recurrence status.
2. Surgical treatment status: type and date of surgery.
3. Chemotherapy status: current or previous chemotherapy types, medication used and treatment duration.
4. Radiation therapy status: radiation treatment area, dose, number of sessions, treatment modalities and date.
5. Blood test results: complete blood count test (such as white cell count, red cell count and platelet count) and routine chemistry test (such as albumin and creatinine levels).
6. Chemotherapy and radiation adverse events and scores: fatigue, weight loss, weight gain, anorexia, diarrhoea, constipation, nausea, vomiting, abdominal pain, taste disturbance, dysphagia, mucositis, dry mouth, oral pain, oesophageal pain, dyspnoea, cough, joint pain, peripheral neuropathy, chest pain, hypertension, dermatitis, rash and itching. The physician assessment of adverse events in cancer therapy will be essentially performed during the clinical visit once at the registration point.

Other data

In this study, additional surveys related to the lifestyle of participants will also be performed, and the following information will be collected:

1. Other surveys: general information (such as education, income, marital status and occupation), lifestyle habits (such as alcohol consumption, smoking, exercise, health status, stress, depression and sleeping hour), medical history, intake of health supplementation, female history (age at menarche, menopause status), and physical measurements (such as height, weight and blood pressure).
2. Dietary habits: meal frequency, skipping meals, regularity of mealtimes, snack frequency and type, frequency of eating out, removal of fat from meat, meal portion, mealtimes, consumption of food variety, preferred flavours, preference of hot food.

Genomic data

Sample preparation

For SNP analysis, oral epithelial cell samples were collected using the Buccal collection kit (ACN21.01, AccuGene) based on the manufacturer's instructions. The whole process of DNA extraction will be performed by LabGenomics (LabGenomics, Seongnam, Republic of Korea). The quality of the extracted double-stranded DNA was confirmed using the Quant-iT PicoGreen ds DNA Reagent Kit (Invitrogen, California, USA).

Microarray analysis

To perform the microarray analysis, a genome background analysis was conducted using the Axiom Korean Biobank Array 1.1, which comprises 827 000 SNP marker chipset data (table 2). All equipment and resources required for the Axiom 2.0 Assay with automated target preparation will be in the Axiom 2.0 Assay Automated Workflow User Guide (Affymetrix, Santa Clara, California, USA, P/N 702963). The genomic DNA will be amplified, fragmented, purified and denatured according to the established processes. The hybridisation will proceed in accordance with the protocol outlined in the User's Manual for the GeneTitan Multichannel Instrument (Affymetrix, P/N 08-0306), using the Axiom Peanut Genotyping Array. After ligation, the arrays will undergo staining and be subjected to imaging using the GeneTitan Multichannel Instrument. The image will be subsequently processed using the user manual of the Affymetrix GeneChip Command Console Software (Affymetrix, P/N 702569). LabGenomics will conduct the whole microarray analysis procedure.

Analysis of SNP

SNP analysis was performed using the rMVP package (V.1.1.1) in R V.4.2.1. In brief, all samples were initially filtered using a minor allele frequency threshold of 0.05 and a missing rate threshold of 0.05. Subsequently, for the control samples of each anticancer drug adverse event, an additional filtering step was conducted using a Hardy-Weinberg equilibrium threshold of 0.001. The generalised linear model method was then employed to select SNPs with a $p<0.00001$. Finally, the annotation of the selected SNPs was carried out using the Korea Biobank Array annotation database (V.1.1).

Table 2 The Korea Biobank Array: design and identification of coding variants

Category	Number of SNPs*	Contents (%)
Tag SNP for genome-wide coverage	600 294	72.02
Functional loci (nonsynonymous SNPs and Indels)	208 039	24.96
Expression Quantitative Trait Loci	16 690	2.00
Human leucocyte antigen	6659	0.80
Fingerprint	255	0.03
NHGRI GWAS catalogue	7811	0.94
Killer cell immunoglobulin-like receptor	1544	0.19
Pharmacogenetics/ absorption, distribution, metabolism and excretion	1881	0.23
Common mitochondrial DNA variants	178	0.02
Y chromosome markers	806	0.10
Total	833 535	100

*Some SNPs overlap among the categories.
NHGRI GWAS, National Human Genome Research Institute Genome-Wide Association Study Catalog; SNPs, single-nucleotide polymorphisms.

Management, storage and disposal plan for the collection of human-derived materials and genetic information

For patients who provided consent to this study, swab samples will be taken from oral epithelial cells to collect genetic information. Samples will be collected using a dedicated oral epithelial cell collection kit provided to the patient, who will obtain the sample themselves and submit it to the research nurse. Patient registration information will be encrypted and stored separately. Samples will be sent to an analysis facility under the management of the principal investigator (PI) for SNP analysis. The study participants may discontinue sample collection or withdraw consent at any time during the sample acquisition process if they do not wish to proceed. If a participant no longer wishes for their sample to be used in this study, they must inform their attending physician. The attending physician will ensure that the sample is disposed of. Samples that have already undergone testing cannot be withdrawn and will be included in the analysis or publication. Additional testing will not be conducted by default. However, if there is an insufficient sample

quantity for DNA extraction, additional testing may be conducted with the patient's consent. The remaining samples used for research will be retained until the point of consent withdrawal by the research participant. If a patient withdraws consent for the storage and use of their sample at any time, the sample will be discarded.

Outcomes

Primary outcome

The primary outcome is the identification of dietary factors associated with the alleviation of cancer-related adverse events.

Secondary outcomes

The secondary outcome is the association between an individual's genotype and cancer-related adverse events. In addition, the association between nutritional status and survival in cancer patients, as well as the association of dietary patterns with cancer recurrence, will be evaluated.

Data management and quality assurance

All research data will be securely stored and managed in compliance with applicable data protection laws. The technical appendix, statistical code and dataset will be stored in a local server with restricted access. Patient information will be kept confidential and handled according to the Trust policies. To prevent the disclosure of the personal information of the participants, all aggregated data will be coded to ensure that individual identification is not possible. Patient identifiable data and information will be separated from non-identifiable data and stored separately. Each patient will be assigned a unique study ID number, which will be used in all study documentation. Access to the data during the study will be restricted to the PI and research personnel authorised by the PI. The study will be conducted in compliance with a protocol approved by the Institutional Review Board. Data safety monitoring will be conducted annually to once a year to ensure accuracy and completeness.

Statistical analysis and consideration

1. Descriptive statistics: Analysis of general and disease-related characteristics, symptoms, and dietary factor survey data.
2. T-test, χ^2 test: Analysis of general and disease-related characteristics, symptoms and dietary factor survey data.
3. Logistic regression analysis, Cox proportional hazards analysis: Analysis of the association between adverse events during cancer treatment and dietary factors.
4. Generalised linear model: Analysis of SNPs to identify genetic variants associated with adverse events during cancer treatment.
5. A $p<0.05$ will be considered to indicate statistically significant differences, and all statistical analyses will be performed using the Statistical Package for the Social Sciences software V.26.0 (IBM) and the SAS software V.9.4 (SAS Institute).
6. Missing data management plan: Excluding patients with missing data may introduce bias. Thus, analyses of all patients regardless of missing data will be conducted.
7. Subgroup analyses: Subgroup analyses will be performed for cancer types with a higher nutritional impact to investigate the association between cancer treatment-related adverse events and dietary factors in addition to overall cohort analyses.

DISCUSSION

To the best of our knowledge, this is the first cohort study that simultaneously examines the adverse events, dietary habits and genotypes of patients with cancer. Cancer is the second most common cause of mortality globally, accounting for 10 million fatalities in 2020. To overcome this challenge, several anticancer therapeutic strategies are currently applied, and efforts are currently exerted to develop novel drugs. However, the efficacy of anticancer therapy has long been hindered by its collateral damage to normal tissues.

Conventional chemotherapy and radiotherapy cannot differentiate normal from cancerous cells, and their efficacy is dependent on their cell-destructing effects.[28 29] In recent years, immune checkpoint inhibitors, which are widely used, are associated with well-defined toxicity profiles that include immune-mediated adverse events affecting various organs.[30] The inevitable damage to healthy cells during anticancer treatments can lead to adverse events. Thus, it can be a major determinant of treatment strategies and the QoL of patients. Several factors contribute to the development of anticancer treatment-related adverse events. These include treatment duration, treatment type and dosage,[31] interactions with other medications,[32] the overall health and pre-existing conditions of the patients,[33] individual genetic factors,[34] and dietary and lifestyle habits.[35 36] Overall, these various factors collectively contributed to the development of adverse events during anticancer therapy.

Cohort studies focusing on patients with cancer primarily evaluate prognosis and survival, assess treatment response and adverse events, and investigate associated lifestyle factors, aiming to improve cancer management strategies. To date, research on cancer and nutrition has predominantly focused on prevention,[37] with limited studies addressing treatment and healthcare. In this regard, studies exploring the association between nutrition and cancer treatment are highly valuable. Di Fiore *et al* evaluated the association between nutritional status during treatment and increased therapy-related toxicity, recurrence or mortality in 101 patients with oesophageal cancer.[38] Zahn *et al* conducted a prospective, single-arm, observational study involving 40 patients with head and neck cancer undergoing radiation therapy to evaluate the effect of nutrition on oral mucositis.[39] de Vries *et al* performed an observational study comparing chemotherapy-related symptoms and

dietary characteristics among 117 patients with breast cancer undergoing chemotherapy using FFQ and 24-hour recalls.[40] IJpma *et al* examined the impact of cisplatin-based chemotherapy on changes in gustatory and olfactory functions, food preferences, dietary intake and body composition in 12 patients with testicular cancer.[41] Although conducted on a limited population, these cohort studies have several strengths. In particular, they have clearly established temporal causality, are applicable in real-world settings, have long-term follow-up and diverse outcome measurement, and have controlled confounding variables.

Our study has the following strengths: First, as a cohort study that does not differentiate specific types of cancer, it has the advantage of including patients with various cancer types. This will allow for a broader generalisation of the study findings, which is beneficial for evaluating treatment strategies and attenuating adverse events in different patients with cancer in actual clinical settings. Second, a large-scale cohort study can facilitate the collection of diverse data points and long-term tracking, which can efficiently evaluate long-term outcomes and treatment effects, enable control over various confounding variables and facilitate a more precise understanding of outcomes within specific population subgroups via diverse subgroup analyses. Third, by analysing both dietary and genomic data, we can identify how specific genetic markers interact with dietary factors, which can potentially influence cancer progression, treatment response, overall prognosis and adverse events. This will provide opportunities for the provision of personalised treatment approaches that consider both genetic predispositions and dietary influences. Fourth, the simultaneous collection of dietary and genomic data enhances the predictive power of studies. Researchers can identify genetic markers associated with dietary patterns to help predict treatment outcomes and the risk of adverse events, thereby improving the accuracy of prognosis prediction. Fifth, as a prospective study, it will evaluate the effect of dietary factors and genomic characteristics on the risk of recurrence or long-term survival via tracking. This will play an essential role in predicting long-term health outcomes in patients with cancer and in developing individualised strategies for recurrence prevention. Our study undoubtedly has strengths. However, it also has some limitations: First, due to the nature of the study, the sample size of specific groups with cancer may be small, thereby limiting generalisability. Second, our study will attempt to collect specific dietary data using the FFQ and use PRO-CTCAE for assessing adverse events. Nevertheless, there may be limitations in terms of the tools or methods used to accurately collect such data. Third, assessments of dietary habits and adverse events often vary subjectively among patients or researchers, potentially lacking objectivity. Fourth, it will be challenging to completely control individual factors or treatment characteristics among patients, which can impact the interpretation of results. Fifth, most importantly, changes in dietary habits during cancer treatment can affect the consistency of long-term tracking data.

Despite these limitations, the results derived from the cohort study proposed here will be crucial for developing effective strategies that can alleviate adverse events in patients with cancer, thereby enhancing treatment efficacy and improving QoL based on dietary factors. Further, the analysis of genomic data will be valuable in testing whether these strategies can be tailored to individual patients, thereby enabling personalised nutrition/treatment approaches. Our study will contribute to the advancement of methods for collecting and evaluating information such as dietary habits, adverse events and genomic characteristics in patients undergoing treatment. In the long term, we believe that our study will enhance the QoL of patients by providing appropriate dietary guidance during cancer treatment.

Ethics and dissemination

This study will be conducted based on a protocol approved by the IRB of Severance Hospital, Yonsei University Health System, Seoul, Korea (4-2021-1110). Any changes, violations or other events occurring in the study will be reported to the IRB. Access to the data derived from the study will be restricted to the PI and authorised researchers. Findings obtained from the study may be published in peer-reviewed journals or presented at relevant academic conferences to contribute to cancer treatment and prevention.

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