

Treatment Patterns in Head and Neck Squamous Cell Cancer in France: ARTISTE Study of Cancerology Patient Charts

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Background

- Head and neck cancer tumours predominantly comprise squamous cell carcinomas (HNSCC), and include malignancies from different head and neck locations.
- In 2015, the predicted incidence of HNSCC in France was approximately 14,700 patients; this has steadily decreased in both men and women over the past 2 decades.^{1,2}
- The number of deaths due to HNSCC has also decreased from approximately 5000 in 1995 to 3790 in 2015 due to lower exposure to risk factors, improvements in treatment, and increased HPV-related cancers, which have relatively better prognoses.³
- Standard treatment guidelines for advanced stage III and IV HNSCC include surgery, adjuvant radiotherapy, adjuvant chemotherapy for patients with high-risk features, and chemoradiation without surgery for patients with poor prognosis.³
- It is expected that new immuno-oncology (IO) therapies to treat HNSCC will modify treatment patterns for treating recurrent or metastatic HNSCC.^{4,7}
- Thus, it is critical to examine current treatment patterns in HNSCC to understand current standards of care and inform the role of these newly available therapies.

Objective

- To describe treatment patterns according to relevant patient demographic and clinical factors among recurrent or metastatic (R/M) HNSCC patients in France using 2015 data.

Methods

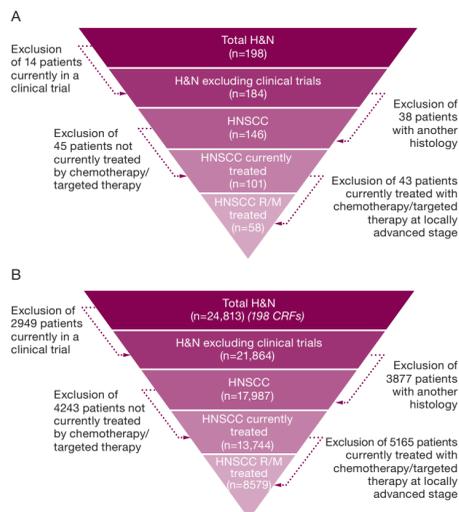
Data

- Cancerology is a descriptive, noninterventional study conducted by Kantar Health. It is a cross-sectional, real-world dataset that is representative of all main onco-hematological malignancies treated in France.
- Patient data for Cancerology were collected directly from physicians who care for patients with 1 or more tumours treated in public and private practices in France.
- Data were collected between April and June 2015 from the Cancerology database, and included patient characteristics, clinical profiles, current and previous antitumour treatment, and toxicities.
- Data for the present analyses were extracted from case report forms (CRFs) collected by physicians regarding their patients with R/M HNSCC, then extrapolated to represent R/M HNSCC patients treated in France.⁸
- Data extrapolation was performed using a two-step model:
 - Each patient was weighted according to the caseload of the practitioner, estimated from the reported prevalence across 2 weeks.
 - Next, data collected were re-weighted to assign a more population-representative value to each case, according to the type of practice.
- These extrapolation methods were used to reduce bias and improve the generalisability of the sample.

Sample

- Data representative of 8579 patients from 58 CRFs that met the criteria outlined below were included in final analyses (Figure 1).

Figure 1. R/M HNSCC sample – unweighted data (A) and extrapolated data (B)



- Inclusion criteria:
 - Being treated for cancers whose primary tumour corresponds to the following sites: Oropharynx (ICD-10 C10.0), Amygdala (ICD-10 C09.0), Tongue (ICD-10 C02.0 and C01.0), Larynx (ICD-10 C32.0), Piriform sinus (ICD-10 C12.0), Mouth (ICD-10 C04.0 and C06.0), Hypopharynx (ICD-10 C13.0), Rhinopharynx (ICD-10 C11.0), and Others (ICD-10 C00.0, C03.0, C05.0, C07.0, C08.0, C14.0, C30.0, C31.0, C33.0, D00.0).
 - Currently receiving a chemotherapy or targeted therapy for a recurrent/metastatic condition.
 - Treated between April and June 2015 by a physician in France participating in data collection.
- Exclusion criteria:
 - Currently involved in a clinical trial.
 - Head and neck with histology other than squamous.
 - Localised or locally advanced stage amenable to curative therapy.⁹
 - Not treated by chemotherapy or targeted therapy.

Measures

Patient characteristics

- Patient demographics included age, sex, and body weight.
- Patient clinical characteristics included performance status as measured by Eastern Cooperative Oncology Group (ECOG) score.¹⁰

Treatment patterns and characteristics

- Treatment pattern measures included type of treatment, frequency of the line of treatment, agents prescribed in the chemotherapy/targeted therapy and combined chemotherapies, and tumour response to treatment.

Safety of treatment

- Safety of treatment was assessed by capturing the level of toxicity for toxicities associated with each possible treatment regimen.
 - Toxicity scores:
 - 0 = absence of any sign of toxicity
 - 1 = minor toxicity or toxicity responding well to the symptomatic treatment and/or not leading to any change in the treatment
 - 2 = toxicity responding badly to the symptomatic treatment and/or implying a change in the treatment or delayed toxicity arriving after the end of treatment
 - 3 = major toxicity requiring the stop of the treatment
 - 4 = inappreciable toxicity

Statistical Analyses

Descriptive statistics

- Descriptive statistics are reported as counts and percentages for categorical variables and means and standard deviations (SD) for continuous variables.
- Double counts of patients in varying units of the same provider were removed from analyses, and all data are reported from the extrapolated methods outlined.

Results

Sample Characteristics

- The majority of patients were male (79.4%), had a mean age of 61.0 years (SD=9.8), and had mean weight of 68.4 kg (SD=14.8) (Table 1).
- The most common cancer type was oropharynx (25.9%).

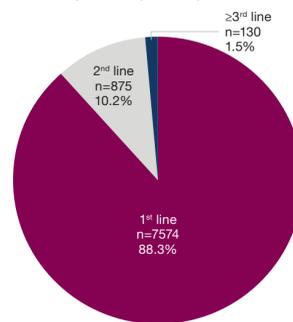
Table 1. Sample characteristics at the time of data collection

	R/M HNSCC (N=8579)
Male, n (%)	6809 (79.4)
Age, years, mean (SD)	61.0 (9.8)
Body weight, kg, mean (SD)	68.4 (14.8)
ECOG score, n (%)	
0	3202 (37.3)
1	3750 (43.7)
2	1626 (19.0)
Cancer type, n (%)	
Oropharynx	2220 (25.9)
Tongue	1438 (16.8)
Amygdala	1291 (15.1)
Piriform sinus	1088 (12.7)
Larynx	696 (8.1)
Mouth	663 (7.7)
Rhinopharynx	320 (3.7)
Hypopharynx	134 (1.6)
Others	729 (8.5)

Treatment Patterns

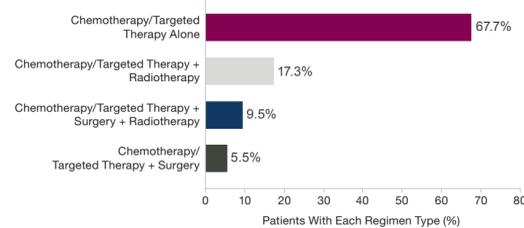
- The majority of patients (88.3%) were receiving first-line treatment (Figure 2).

Figure 2. Line of treatment for patients (N=8579)



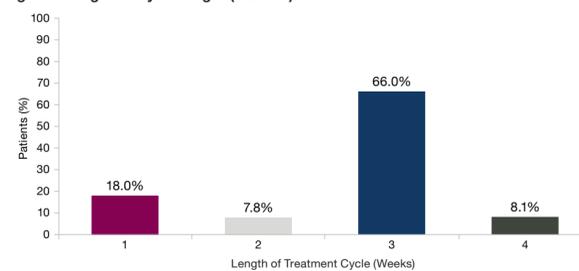
- The majority of patients had ECOG scores of 0 or 1 (81.0%) (Table 1).
- The majority of patients (67.7%) were prescribed chemotherapy or targeted therapy alone without any other concomitant treatment (eg, surgery or radiotherapy) (Figure 3).

Figure 3. Current cancer treatment type (N=8579)



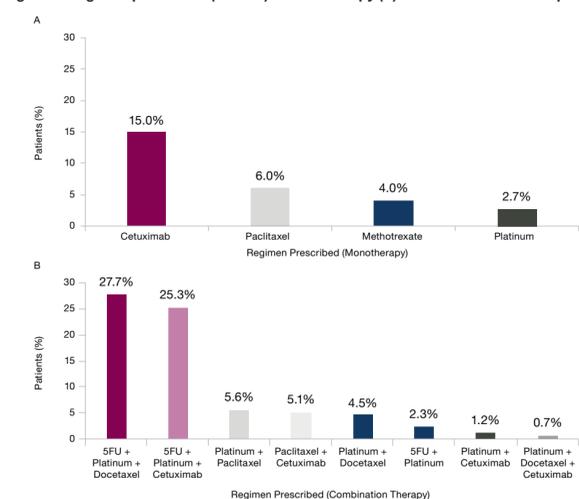
- The majority of patients (66.0%) received a regimen with a cycle length of 3 weeks (Figure 4).

Figure 4. Regimen cycle length (N=8579)



- Overall, combination therapies (72.4%) were preferred to monotherapies (27.7%) (Figure 5).
 - The most common monotherapy treatment regimen was cetuximab (15.0%) (Figure 5A).
 - The most common combination treatment regimen was 5-Fluorouracil (5FU) + platinum + docetaxel (27.7%) (Figure 5B).

Figure 5. Regimen prescribed (n=8579) – monotherapy (A) and combination therapies (B)



Safety of the Treatment

- Across all lines of therapy, toxicities occurred in 79.5% of patients, with the most common AEs reported being mucositis (45.1%), nausea/vomiting (41.8%), and skin rash (40.0%) among those patients reporting AEs (Table 2).

Table 2. Safety measures reported for all lines combined among patients treated with chemotherapy

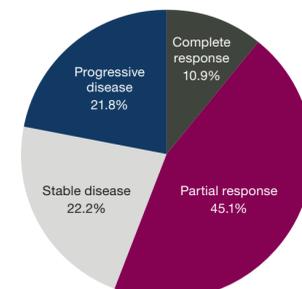
Toxicities reported, n (%)	Patients who reported toxicities* (n/N = 6819/8579)
Mucositis	3078 (45.1)
Nausea/Vomiting	2852 (41.8)
Skin rash	2727 (40.0)
Leukopaenia	1770 (26.0)
Diarrhoea	1682 (24.7)
Alopecia	1491 (21.9)
Thrombocytopenia	1257 (18.4)
Anaemia	1097 (16.1)
Xerostomy	1093 (16.0)
Myalgia	450 (6.6)
Constipation	341 (5.0)
Peripheral neuropathy	294 (4.3)
Asthenia	177 (2.6)
Renal/urinary	134 (2.0)
Hypokalaemia	130 (1.9)
Hand-foot syndrome	79 (1.4)
Infection/sepsis	65 (1.0)
Embolism/thrombosis	65 (1.0)
Circulatory disorder	65 (1.0)

*Toxicities were reported by 6819 R/M HNSCC patients. Each patient can experience multiple toxicities; hence, percentages do not sum to 100%.

Tumour Response to Treatment

- Among patients for whom tumour response was reported (n=5182), 10.9% had a complete response, 45.1% had a partial response, 22.2% had stable disease, and 21.8% had progressive disease (Figure 6).

Figure 6. Tumour response among those whose response was specified (n=5182)



Conclusions

- The majority of advanced-stage HNSCC patients were treated with chemotherapy/targeted therapy as a single treatment without surgery or radiotherapy.
 - Combination therapy regimens were used more often than monotherapy.
- Treatment patterns observed in the present study aligned predominantly with general treatment patterns, which exist in current treatment protocols.^{11,12}
- The toxicities observed in the present study also aligned with those anticipated according to drug labels and clinical practice guidelines.^{11,13}
- The current 2010 ESMO treatment guidelines for HNSCC are limited for all lines, especially the second and third lines of treatment.
- It is expected that the approval of IO therapies for HNSCC will result in an evolution in treatment regimens and standard of care to fill the unmet need of limited treatment options.
- There are some limitations to this study:
 - All data in this study come from a self-reported physician survey; therefore, the responses may be subject to recall bias.
 - The case mix of the physicians may be over-represented by patient groups who see their treatment provider more often than others.

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