Epidemiologic Findings of Locally Advanced Squamous Cell Carcinoma of the Head and Neck (LA SCCHN) in a German Liquid Biopsy Database: A Feasibility Analysis

RWD35

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Background and Rationale

- Head and neck cancer (HNC) is the 7th most common cancer worldwide [1].
- Squamous cell carcinoma, a prevalent form of HNC affecting areas like the oral cavity, oropharynx and larynx, at initial diagnosis often presents at locally advanced stages [2-4].
- HNC is conventionally diagnosed through tissue biopsy. New, non-invasive techniques such as liquid biopsies can offer monitoring of the cancer through the detection of tumor DNA in body fluids.
- This analysis aimed to show epidemiological characteristics of locally advanced squamous cell carcinoma of the head and neck (LA SCCHN) patients in a German liquid biopsy database and to evaluate the potential of the database for future usage in Real-World Evidence (RWE) research.

Methods

Data source

- The Indivumed Services Liquid Biopsy Biobank is a cell-free plasma biobank containing longitudinal whole blood samples from over 3,000 cancer patients/year with all types of tumors.
- >45 oncology centers from Germany contribute basic clinical information, current diseases, tumor classification, biomarker, therapy and treatment information as well as response and clinical outcome information.
- Patient samples are included in the database with start of a new drug therapy. An initial/baseline blood draw is taken before therapy start (T0, Figure 1). During treatment, up to five additional plasma samples are collected at 4-12 weeks intervals.
- Circulating tumor DNA (ctDNA) can then be isolated from the cell-free plasma to monitor tumor characteristics.
- Patient clinical data is collected at the start of therapy, during therapy at each blood sampling and, finally, at the end of therapy including clinical outcomes.
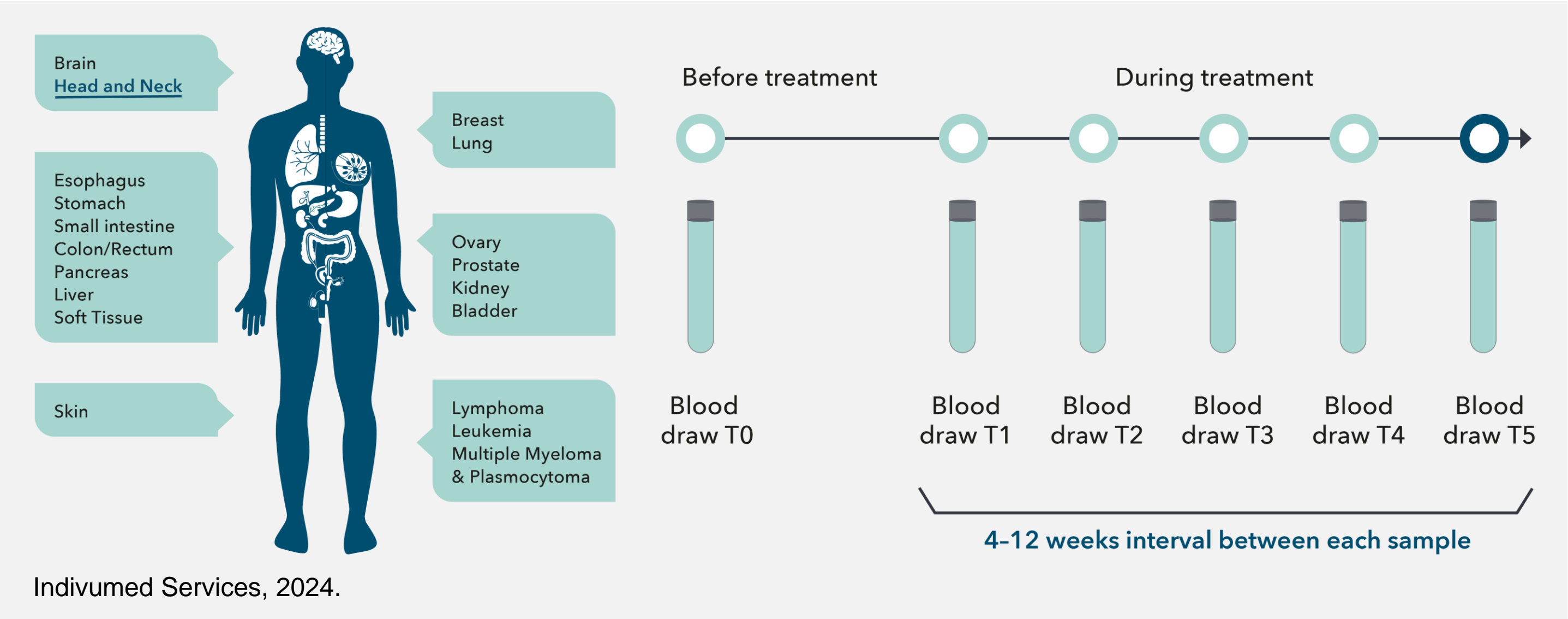- Informed patient consent is obtained prior to inclusion to sample and data collection.

Indivumed Services, 2024.

Figure 1: Longitudinal plasma sample collection in the Indivumed Services Liquid Biopsy Biobank

Analysis design

- We descriptively analyzed a cohort of LA SCCHN patients identified within the Indivumed Services Liquid Biopsy Biobank in terms of epidemiologic parameters, covering the period from Jan 2016 to Mar 2022 (observational period).
- LA SCCHN patients were selected based on the criteria described in Figure 2.
- The included population comprised LA SCCHN (T3/4 or N1-3) patients with oral cavity, oropharynx, hypopharynx or larynx carcinomas who were ≥18 years old at diagnosis.
- Each patient was assigned an index date based on the earliest observed LA SCCHN diagnosis and the observation period lasted until the end of the observational period, death or disenrollment in Indivumed Services Liquid Biopsy Biobank, whichever occurred first.
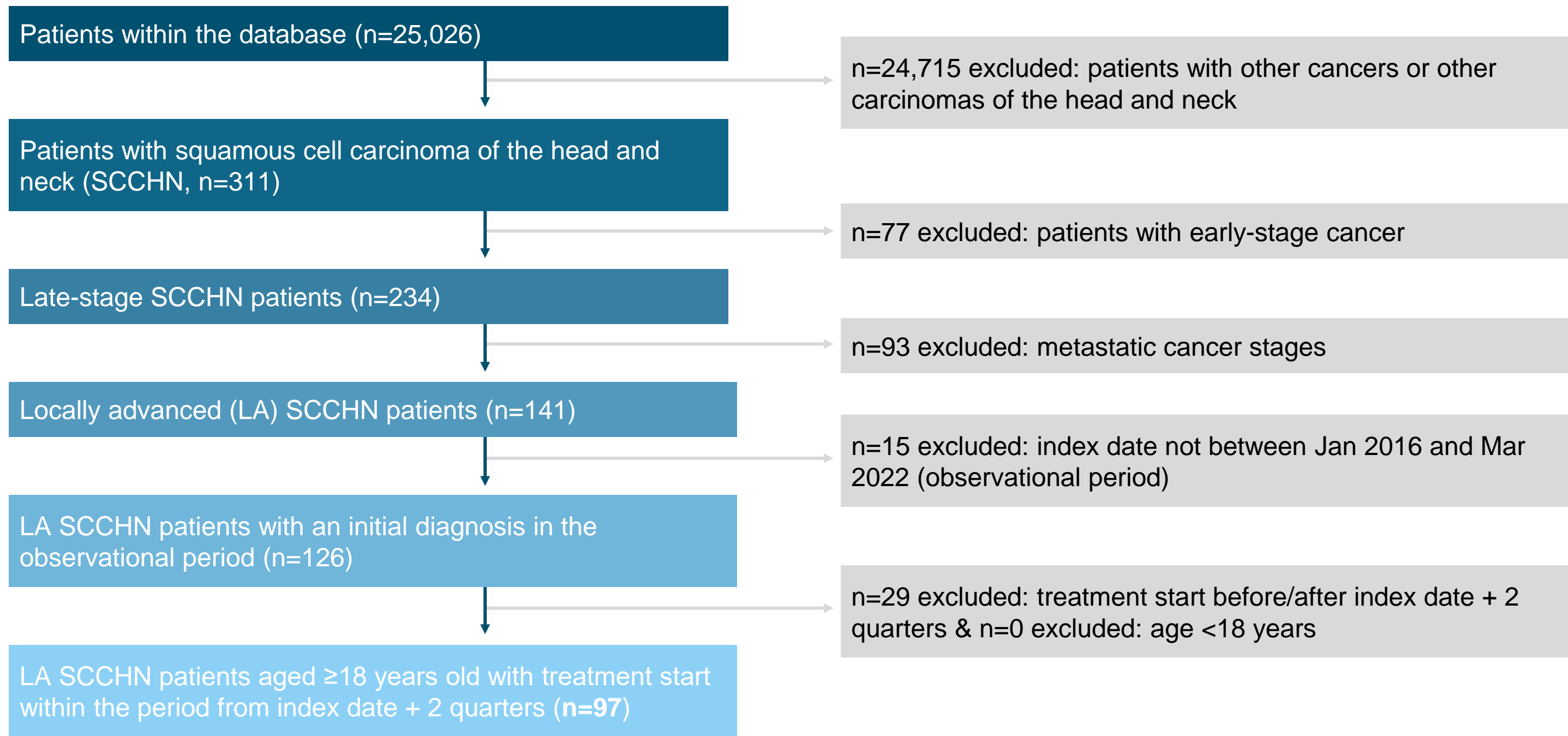

Figure 2: Flow diagram of patient selection

Limitations

- Lack of prior or concomitant therapy information, such as radiotherapy and surgery, are a limitation for interpretation of treatment patterns in a locally advanced SCCHN setting.
- The database does not contain information on HPV status, leading to an incomplete or less accurate classification of oropharyngeal cancer patients.
- Representativeness for the overall LA SCCHN patient population in Germany is limited by the size of the database and the limited number of patients with liquid biopsies.
- Depending on cancer entity, specific parameters, such as mutation testing may not be consistently collected in the database.

Results

- Table 1 shows baseline characteristics of the 97 eligible LA SCCHN patients with a 72.2% male representation and an average age of 60.9 years (sd: 9.0).
- The most frequent tumor locations were oral cavity (41.2%) and oropharynx (29.9%), followed by hypopharynx (18.6%) and larynx (10.3%).
- Most common systemic LA treatments were cisplatin (58.8%), followed by the combination of 5-FU + cisplatin + docetaxel (25.8%), and cetuximab (7.2%), see Table 2.
- Information regarding TNM staging and tumor morphology is displayed in Figure 3. Mutation testing was infrequent, reflecting current treatment protocols.

Table 1: Baseline characteristics

|	Total (N=97)
Age [years], mean (sd)	60.9 (9.0)
Gender male, n (%)	70 (72.2)
Cancer site, n (%)	
Oral cavity	40 (41.2)
Oropharynx	29 (29.9)
Hypopharynx	18 (18.6)
Larynx	10 (10.3)
Treatment intention*, n (%)	
Curative	34 (35.1)
Adjuvant	29 (29.9)
Neoadjuvant	22 (22.7)
Palliative	8 (8.2)
Induction/Unknown	4 (4.2)
Height [cm], mean (sd)	173.5 (8.7)
Minimum weight [kg], mean (sd)	74.4 (17.1)
Maximum weight [kg], mean (sd)	77.0 (17.5)
Minimum BMI, mean (sd)	24.5 (4.9)
Maximum BMI, mean (sd)	25.4 (5.0)

BMI: body mass index; sd: standard deviation.
*Based on patient record (as indicated by treating oncologist).

Table 2: Baseline characteristics

	Total (N=97)
Agents involved, n (%)	
Cisplatin	57 (58.8)
5-FU + Cisplatin + Docetaxel	25 (25.8)
Cetuximab	7 (7.2)
Carboplatin	2 (2.1)
Other*	6 (6.0)

5-FU: fluorouracil.
*Includes: 5-FU + Carboplatin, 5-FU + Cisplatin, Carboplatin + Cisplatin, Carboplatin + Docetaxel, Carboplatin + Paclitaxel, Carboplatin + Paclitaxel + Pembrolizumab

Figure 3: TNM staging and tumor morphology
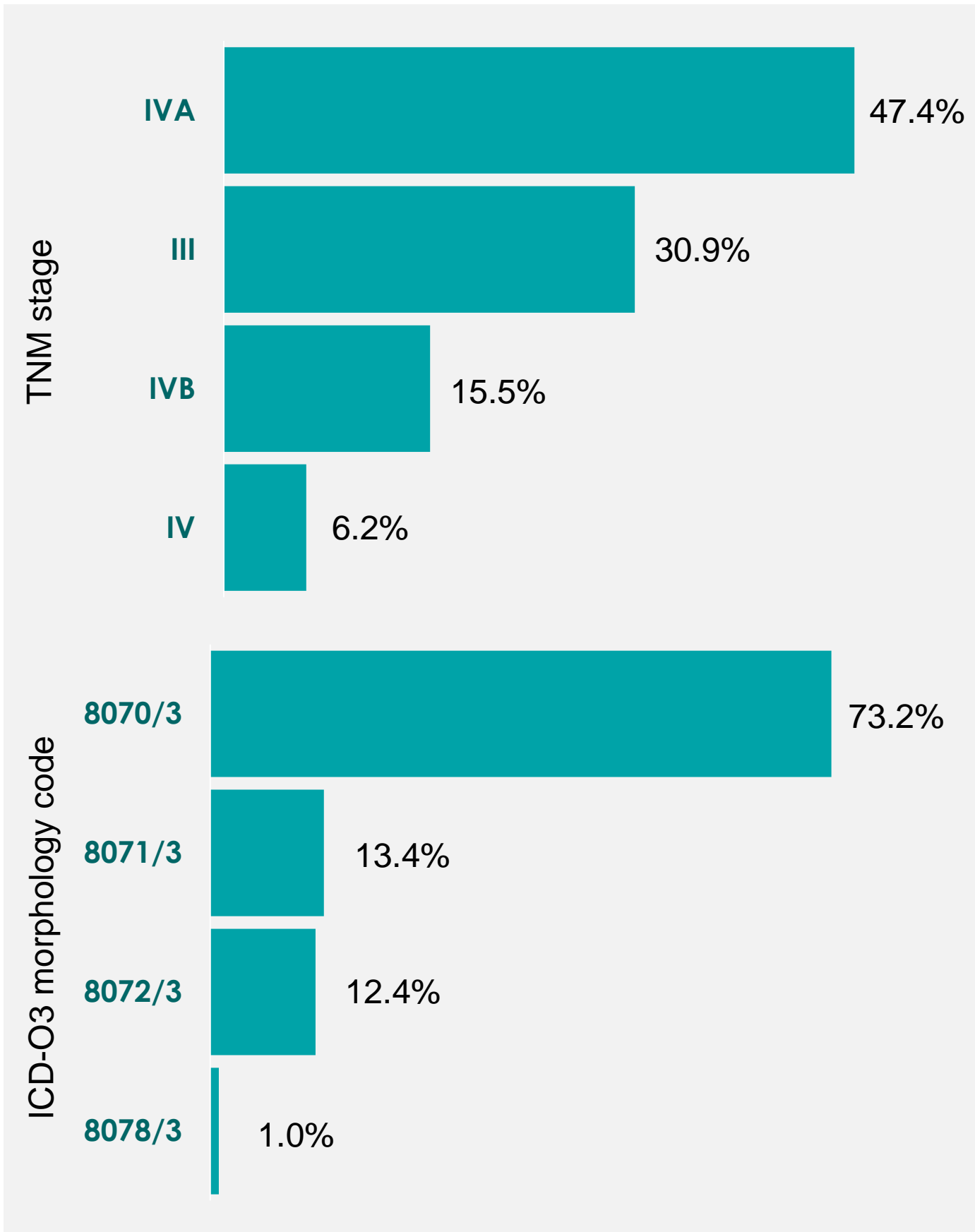
ICD-O3: International Classification of Diseases for Oncology, 3rd Edition; TNM: tumor node metastasis classification of malignant tumors.

8070/3: Squamous cell carcinoma (SCC), not otherwise specified (NOS); 8071/3: SSC, keratinizing, NOS; 8072/3: SSC, large cell, nonkeratinizing, NOS; 8078/3: squamous cell carcinoma with horn formation.

Conclusions and Outlook

- This feasibility analysis provided a comprehensive depiction of epidemiological features of LA SCCHN patients, including patient demographics, clinical characteristics, tumor characterization, and systemic treatment modalities.
- Liquid biopsy databases can present a valuable complement in Real-World Data analysis.
- Further research should therefore leverage this dataset to expand the scientific understanding, ultimately aiding in personalized treatment strategies.

Additional Opportunities for Future Research

While the presented feasibility analysis focused on a few key initial aspects, the database offers valuable benefits for future real-world oncological research:

- Detailed tumor characterization (staging, morphology, biomarkers)
- Available information on therapy intention and persistence over time (including treatment stop reasons)
- Monitoring patients' progression (e.g. clinical improvements/deterioration, Karnofsky performance score)
- Tracking success of therapy (e.g. RECIST status)
- Potential re-testing of selected parameters

References

[1] Hermanns I et al. Cancers (Basel). 2021. [2] Vigneswaran N et al. Oral Maxillofac Surg Clin North Am. 2014;26(2), pp. 123–141; [3] Ang KK, et al. Oncologist; [4] Pai SI et al. Annual review of pathology.2009;4, pp. 49–70.