Patterns and quality of care for head and neck cancer in Belgium : a population-based study

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ABSTRACT

Objectives: We evaluated the quality of care for patients with squamous cell carcinoma (SCC) of the oral cavity, oropharynx, hypopharynx or larynx in Belgium.

Methods: Data of the Belgian Cancer Registry were coupled with health insurance data and hospital discharge data. Quality of care and the association with hospital volume were evaluated based on six quality indicators.

Results: Half of the patients were treated with primary radiotherapy, with or without systemic therapy (49.7%) and 38.1% with surgery, with or without (neo)adjuvant therapy. Single-modality treatment was provided to 78.1% of early-disease patients. Of the patients with cN0 disease, 56.4% underwent neck dissection. Post-operative radiotherapy was completed timely in 48.5% of patients. Concomitant chemotherapy was administered to 58.2% of patients < 70 years with locally-advanced disease. Imaging of the neck after radiotherapy was performed appropriately in 32.7% of patients. Variability between centers was considerable. No clear relationship between hospital volume and results of the individual QIs was observed.

Conclusions: Results show that for the measured QIs, targets are not met and variability between centers is considerable. Through individual feedback, centers are motivated to improve the quality of care for head and neck cancer patients in Belgium.

Keywords: Head and neck cancer; Squamous cell carcinoma; Quality indicators; Quality of care; Variability in care; Patterns of care; Population-based study

INTRODUCTION

Cancers of the head and neck (HNC) region are a heterogeneous group of tumor entities, which are anatomically close to each other, but dissimilar in terms of etiology, histology, treatment and prognosis.[1] Typically, HNC develop in a population with important tobacco and alcohol consumption but other risk factors such as human papilloma virus infection also play a role.[2] Different histological types may be encountered, the most frequent being squamous cell carcinoma (SCC). HNC are rare and one of the most complex tumor entities to treat, as many structures critical for normal speech, swallowing and breathing function may be invaded and impaired by the tumor. As a consequence, treatment should be performed in a narrow time window following well defined guidelines by experienced multidisciplinary specialized teams.

In 2014-2015, the first Belgian evidence-based guidelines were published to advise on diagnosis, treatment and follow-up of HNC patients so that chances for cure and survival can be optimized, quality of life can be preserved as much as possible and side effects of treatment can be kept to a minimum.[3, 4] However, guidelines may not always be followed in clinical practice compromising the quality of care, as shown in several countries.[5-8]

To promote the uptake of the national evidence-based guidelines and to identify priority areas for improvement, we evaluated the patterns and quality of care in patients with a squamous cell carcinoma of the head and neck region (HNSCC) diagnosed in Belgium between 2009 and 2014, thus before the publication of the KCE guidelines. We also provided individual feedback reports to all Belgian hospitals providing care to HNC patients.

METHODS

Data sources

Three databases were linked: (1) the Belgian Cancer Registry (BCR) database, a population-based registry of all cancer cases in Belgium;[9, 10] (2) the database of the Intermutualistic Agency (IMA) which is a national registry of health insurance data in which all Belgian Sickness funds are represented, providing details on diagnostic and therapeutic procedures and pharmaceuticals reimbursed by the compulsory Belgian health care insurance and (3) the hospital discharge database, including data regarding diagnoses and interventions for each hospital stay.

The linkage was based on the patients' unique social security number and has been approved by the Belgian Privacy commission.[11] The data sets were coded before analysis.

TNM classification available in the BCR database depended on the incidence year of the tumor: for the incidence year 2009 the sixth edition of the TNM was used, while for incidence years 2010-2014 the seventh edition of the TNM was used.[12, 13]

Selection of patients

All patients diagnosed in 2009-2014 with a SCC of the oral cavity, oropharynx, hypopharynx and larynx were selected from the BCR database (the layer 2 RARECARE definition of HNSCC was used, http://www.rarecarenet.eu/). Patients with no link to the IMA database and patients who died or were lost to follow-up at the incidence date of their tumor were excluded. Patients with multiple invasive tumors were not included in the analyses because IMA data have no direct link between the registered medical procedures or pharmaceuticals and the indication for which they

are applied. That way, a link between the performed procedures and the HNC could be assumed.

Quality indicators (QI)

Relevant QIs were identified from peer-reviewed papers, reports published by international healthcare agencies and Belgian evidence-based guidelines on the management of SCC of the oral cavity, oropharynx, hypopharynx and larynx.[3, 4] The QIs were then scored by a multidisciplinary panel for their relevance and importance, followed by a final selection during two consensus meetings where criteria other than relevance (e.g. measurability, actionability) were also taken into account. As a result, some quality indicators that were relevant to measure quality of care could not be included because of measurability limitations. Finally, six treatment related QIs were selected. When applicable, a target was defined by expert consensus before the analysis.

Hospital allocation

For each patient, a treatment scheme was defined based on the IMA – AIM data. First we started with defining surgery with curative intent for the patients, based on an algorithm constructed with the clinical experts, taking into account minor and major surgical procedures, lymphadenectomy, and reconstructive surgery. If surgery with curative intent was found for a patient, pre-operative and adjuvant treatments were defined. When no surgery with curative intent could be identified, radiotherapy and systemic therapy were defined. Based on these treatment modalities, treatment schemes were defined and grouped into six categories: surgery with curative intent, (systemic therapy/) radiotherapy with curative intent, (systemic therapy/) radiotherapy

with curative intent followed by surgery, systemic therapy only, palliative treatment, no treatment.

In Belgium, patients are free to seek care in the hospital of their choice. Parts of the diagnostic work-up or treatment can occur in a different hospital than the one where the initial diagnosis is made. To benchmark the treatment-related QIs between hospitals, each patient was assigned to the hospital where the main treatment took place. Surgery with curative intent, primary radiotherapy and systemic therapy were taken into account in a hierarchical manner if treatment took place in more than one center: center of surgery if applicable, center of radiotherapy if applicable followed by the center of systemic therapy and center of biopsy if no treatment was identified in the data. For example, if a patients had surgery and adjuvant radiotherapy in a different hospital, the patient was assigned to the center of surgery.

Funnel plots

The variability between institutions was graphically represented using funnel plots, whereby each institution's QI result was plotted against the institutional volume, with prediction limits of 95% and 99% around the overall national result. These prediction limits allow the comparison of the variability of the observed estimates with the expected variability around the overall national result due to sample size. In these plots, institutions within the prediction limits were assumed to be subject to 'common-cause' variability, whereas those that are 'out- of- control' can exhibit 'special cause' variability and may deserve further scrutiny.[14] Centers which reported stage information to the BCR for less than 50% of their assigned patients, were represented differently (i.e. by an open triangle) in the funnel plots, because underreporting of TNM stage information may bias the results.

Association between hospital volume and quality of care

The association between receiving an advised therapy and hospital volume was assessed with logistic regression. A model with patient and tumor baseline characteristics was constructed first. Baseline patient case-mix variables taken into account were: sex, age group at diagnosis, WHO performance status, combined stage, anatomic site, Charlson Comorbidity Index (CCI) and number of inpatient bed days during the year before diagnosis. Second order interactions between the main terms were evaluated in a backwards elimination model building procedure. The goodness-of-fit was evaluated with the Hosmer-Lemeshow test, the χ^2 test of the Pearson and deviance residuals and visual inspection of the model residuals.

In a second step, center size was added as a continuous variable to the regression model. Linear or piecewise linear associations on the log-odds scale were evaluated, but no categorization was applied. For the piecewise linear models a set of knot positions within the observed volume range were considered, the model giving the best fit was retained. Patients from the same hospital, their treatment, care or outcomes can be considered as correlated. In order to account for the clustering of patients into hospitals, hospital was added as a random term to the final logistic model.

RESULTS

In Belgium, 12,756 SCC of the oral cavity, the oropharynx, hypopharynx or larynx were diagnosed in the period 2009-2014. Two hundred twenty-four tumors (1.8%) were excluded from the study because health insurance data were not available or because the incidence date equaled the date of death or date of loss of follow-up. Patients with multiple tumors in the cancer registry (3,287 tumors; 25.8%) were not

included in the analyses to ensure the link between the HNSCC and the therapeutic procedures performed. The final study population consisted of 9,245 patients diagnosed with one HNSCC.

Mean age at diagnosis was 62.3 years and 75.9% of the patients were male. The majority of patients (79.3%) had WHO performance status 0 or 1.

Two thirds of the patients with known stage were diagnosed with an advanced stage of the tumor (clinical stage III-IV, 66.7%). The proportion of advanced stage cancers at diagnosis ranged between 46.5% in in laryngeal cancer and 89.9% in hypopharyngeal cancer.

Treatment patterns

Half of the population was treated with primary radiotherapy (RT), with or without systemic therapy (49.7%) and another large group with surgery with curative intent, with or without (neo)adjuvant therapy (38.1%) (Table S1). Clear differences can be seen between the anatomic sites: while the majority of oral cavity SCC patients (73.4%) received surgery with curative intent and only 15.2% primary RT, the opposite is true for patients with a hypopharyngeal SCC who were predominantly treated with primary RT (69.9%). Seven percent of the overall population received no oncological treatment or a short course radiotherapy assumed to be delivered in the context of palliative treatment.

Of the surgical patients, 59.7% had surgery to both the primary tumor and the regional lymph nodes, while 31.1% underwent surgery restricted to the primary tumor.

Quality indicators

The results of the six quality indicators are shown in Table 1.

For early-stage disease, single-modality treatment is recommended to reduce side effects and to maximize organ function.[1] The target for single-modality treatment (QI 1: 80-85%) was almost reached (78.1%). Table S2 shows an overview of treatment schedules received by patients with clinical stage I and II who received surgery and/or radiotherapy (without systemic treatment), by age group, clinical stage and anatomic site.

Surgically treated patients with clinical N0M0/x disease should have an elective dissection of the lymph nodes in the neck.[3, 4] Only 56.4% of the surgically treated patients with clinical N0 disease underwent an elective neck dissection (QI 2). Of the patients without lymphadenectomy, 173 (12.8% of all N0M0/x patients) received adjuvant radiotherapy, possibly also on the neck region. For 30.8% of patients who were staged as cN0M0/x and who had surgery with curative intent, no treatment of the lymph nodes in the neck region could be detected in the database. The proportion of surgically treated patients who had a lymphadenectomy was higher in the more advanced clinical stages and increased over the years (Table 2).

Post-operative radiotherapy (PORT) was completed within 13 weeks after surgery in less than half of the patients (QI 3). Detailed results regarding timelines of post-operative radiotherapy are summarized in Table 3.

In patients with advanced disease treated with primary radiotherapy, the use of concomitant chemotherapy (QI 4), and imaging after completion of therapy (QI 5) show substandard results. Of the patients with locally advanced HNC younger than 70 years old who were treated with radiotherapy, only 58% received concomitant chemotherapy. Patients with node positive HNSCC who were treated with

radiotherapy had a diagnostic evaluation of the neck after therapy at the appropriate time point in 32.7% of the cases only.

A total laryngectomy, as recommended in national guidelines, was not performed in 37% of non-metastatic T4a laryngeal cancer patients (QI 6), but it must be noted that this last QI was difficult to evaluate due to insufficiently detailed reporting of clinical stage in many cases.

Variability between centers for five quality indicators are shown in Figure 1. Most indicators demonstrate more variability between centers than what can be expected based on random variability, with few centers whose results are above the upper 99% prediction limits.

Association between hospital volume and QI results

Patients were treated in 99 different hospitals. The median treatment center volume was 25 patients (included in the study) over six years' time, or on average four patients a year. A quarter of the centers treated not more than ten patients over the six-year period. No clear association between hospital volume and results of the QIs was seen (Table 4). Only for QI 2, a limited volume-effect was seen. In hospitals that performed surgery in 20 or less patients with cN0M0/x HNC over the six-year period, volume was positively associated with the probability of having a lymphadenectomy of the neck (OR per additional surgery performed = 1.13, 95%CI = 1.08-1.18; $p < 0.0001$). For hospitals that treated more than 20 patients over six years, no further volume-effect was seen (OR = 0.99, 95%CI = [0.98-1.00]; $p = 0.1889$).

DISCUSSION

This population-based study in patients with a SCC of the oral cavity, oropharynx, hypopharynx or larynx diagnosed in Belgium in 2009-2014 confirms that radiotherapy and surgery are the cornerstones of treatment for HNSCC.

For several QIs, similar results have been reported in other countries. For example, in Ireland during the period 1997-2007, 60% of early stage oral cavity cancers were treated with surgery alone, while 19.5% were treated with radiotherapy or concomitant chemoradiotherapy.[15] In England and Wales, 41% of the patients with a T1-T2 N0 tongue tumor underwent a neck dissection in 2013-2014.[5] In the United States, the rate of neck dissection was 63.9% in the patients with clinical N0 oral cancers.[16] The differences in the frequency of lymphadenectomy between anatomic sites in our study population may be explained by different distributions of clinical stage.

Time between surgery and start of PORT as well as overall treatment time between surgery and end of PORT are important prognostic factors.[17] There may be reasons for delaying the start of PORT such as postoperative complications, however different fractionation strategies (e.g. slightly accelerated treatment) may in part compensate for this.[18] Therefore, we opted to measure time from surgery to end of PORT as a QI. Studies in other countries focused on a timely start. In a large American cohort, 55.7% of patients failed to start PORT within the recommended six weeks of surgery, and this percentage increased over time (52.9% of patients in 2006 vs. 58.7% of patients in 2014).[19] In an audit from the UK, the median interval between surgery and start of adjuvant radiotherapy was fifty days (seven weeks) for all anatomic sites with a large variability between cancer networks, from a median of 39 days (5.5 weeks) to a median of 76 days (11 weeks).[5] In Italy, the interval between discharge from surgery and start of PORT was less or equal to 60 days in 69.9% of patients.[19]

Although many studies have shown the important role of expertise in treating HNC, in Belgium no centralization of care for HNC exists.[6, 20, 21] Treatment for HNC patients is very dispersed in Belgium. Although Belgium is a small country, patients were treated in 99 different hospitals. In our study, a quarter of hospitals treats less than on average two patients yearly (the actual volume will be higher given the exclusion criteria applied). However, no clear association between hospital volume and the results of the QIs has been seen, apart from one QI that showed a positive association between volume and lymphadenectomy restricted to hospitals that treated less than 20 patients over the 6-year period. Better adherence to the measured QIs thus seems not an explaining factor for the better survival for patients of higher volume hospitals seen in this population.[21, 22] Other process factors or the volume factor itself, in other words more experience, are probably more important.

The results of our study call for more attention to quality of care and treatment according to guidelines in all treating hospitals. Suboptimal quality of care should not hamper optimal outcomes for HNC patients. However, several other reasons for the substandard results obtained for the different QIs can be hypothesized. Firstly, national updated guidelines were published in 2014-2015, while included patients were diagnosed (and treated) between 2009 and 2014. This can partially explain that some practices do not fit with clinical recommendations. The results should thus be regarded as a baseline for further follow-up of the quality of care in the future. This baseline assessment identifies where improvement of the quality of care should receive particular attention. Secondly, access to certain interventions may be limited. For example, PET-scan and MRI are not available in all Belgian hospitals and waiting lists exist. Thirdly, patients may have contraindications to certain interventions that are not captured in the available data. That may explain for example why a significant

proportion of patients treated with primary radiotherapy did not receive concomitant platinum-based chemotherapy. Lastly, interventions that are not reimbursed because they are delivered within the framework of a clinical trial are not registered in the used databases and may incorrectly be registered as poor quality of care.

Weaknesses of our study include missing data and the lack of specificity of the available administrative data. Although the BCR has an excellent coverage of cancer diagnoses in Belgium, some of the data, such as TNM-stage and performance status, are lacking for a significant number of patients.[9, 21] Missing data can cause bias and hamper the accurate evaluation of care in hospitals who registered necessary data for only a small proportion of their patients. Health insurance claims data give information about which procedures were performed but not about the indication for which a procedure was performed. Therefore, patients with multiple cancer diagnoses were excluded, to ensure that recorded procedures were performed for the HNSCC and not for another indication. However, uncertainties about the diagnostic or therapeutic nature or palliative versus curative intent remained. In addition, the health insurance claims data did not always allow to make a clear distinction between surgical interventions with a diagnostic or therapeutic aim, which may have introduced some bias in certain QIs. Also, the use of administrative databases did not allow us to further explore other definitions of volume and analyze the association between e.g. surgeon volume or radiation oncologist volume and the QIs. Lastly, while a multidisciplinary approach is essential in this patient group, it was impossible to reveal whether each HNC case benefitted from a multidisciplinary approach throughout the whole care process: as the administrative databases tend to somewhat underestimate the real frequency of MDTs (due to among others the reimbursement rules) it was opted not to include these in the analyses.

Nevertheless, by using administrative data, we were able to perform a population-based study including all patients diagnosed with a single HNC between 2009 to 2014 without the need for extra data collection efforts and resources. Another strength of our study is the individual feedback sent at the end of the study to all Belgian hospitals involved in the care for HNC. Each hospital received its own results for the QIs with anonymized benchmarking against the other hospitals. Hospitals were encouraged to review their individual results and take action where needed. Other countries have shown that continued nation-wide efforts to improve the quality of care can be successful. Both the Netherlands and Denmark, have seen improved survival for HNC patients after the implementation of national comprehensive quality improvement initiatives.[23-25]

In conclusion, this study illustrates that for the measured QIs, targets are not met and variability between centers is considerable. Through individual feedback to the centers and benchmarking, centers are encouraged to standardize and improve the quality of care for HNC patients. Follow-up evaluations of the QIs with updated individual feedback to the hospitals could further advance improvement of the quality of care in the future.

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Table 1: Results treatment-related quality indicators

Number	Quality Indicator	n/N	QI Result (%)	Target (%)
1	Proportion of patients with early stage (cI or cII) HNSCC who received treatment with curative intent (with or without systemic treatment), who were treated with a single-modality approach	1845/2362	78.1%	80-85%
	Oral cavity	540/773	69.9%	
	Oropharynx	253/388	65.2%	
	Hypopharynx	56/94	59.6%	
	Larynx	996/1107	90.0%	
2	Proportion of surgically treated patients with HNSCC and cN0M0/x with any T stage (except T1 glottic cancer), who underwent elective neck dissection	760/1347	56.4%	≥ 90%
	Oral cavity	500/869	57.5%	
	Oropharynx	91/210	43.3%	
	Hypopharynx	21/29	72.4%	
	Larynx	148/239	61.9%	
3	Proportion of patients with HNSCC who were treated with postoperative radiotherapy in whom the radiotherapy was completed within thirteen weeks after surgery	792/1632	48.5%	≥ 90%
	Oral cavity	388/860	45.1%	
	Oropharynx	221/377	58.6%	
	Hypopharynx	55/116	47.4%	
	Larynx	128/279	45.9%	
4	Proportion of medically fit patients (WHO PS 0-1) with locally-advanced (cIII-cIV)) non-metastatic HNSCC treated with primary RT, who received concomitant platinum-based chemotherapy §	1241/2350 < 70 years: 1125/1934	52.8% < 70 years: 58.2%	NA† < 70 years†: 75-80%
	Oral cavity	101/236	42.8%	
	Oropharynx	630/1156	54.5%	
	Hypopharynx	306/556	55.0%	
	Larynx	204/402	50.7%	
5	Proportion of patients with node-positive HNSCC treated with primary (chemo)radiotherapy, in whom a diagnostic evaluation of the neck with PET/CT or DW-MRI was performed not earlier than three months after completion of primary therapy	709/2171	32.7%	≥ 80%
	Oral cavity	52/193	26.9%	
	Oropharynx	374/1116	33.5%	
	Hypopharynx	183/492	37.2%	
	Larynx	100/370	27.0%	
6	Proportion of patients with non-metastatic T4a laryngeal cancer who underwent total laryngectomy‡	73/116	62.9%	≥ 80%

cI, cII: clinical stage I, clinical stage II; HNSCC: Head and Neck squamous cell carcinoma, WHO PS: World Health Organization Performance Status; PET/CT: Positron emission tomography /Computed tomography; DW-MRI: Diffusion-weighted magnetic resonance imaging

† *For patients older than 69 years old, no target was specified.*

‡ *Only 116 patients were identified with non-metastatic T4a laryngeal cancer, 212 patients with T4 laryngeal cancer were excluded since available TNM staging information was not specific enough.*

§ *Concomitant chemotherapy was defined as chemotherapy that started from seven days before the start of radiotherapy to any time during the RT series.*

Table 2: Proportion of surgically treated TxN0M0/x patients who had elective lymphadenectomy of the neck

Characteristics	Denominator	Numerator	Proportion (%)
Overall	1,347	760	56.4
Clinical stage			
I	500	194	38.8
II	430	274	63.7
III	100	75	75.0
IVA/IVB	242	184	76.0
X (missing)	75	33	44.0
Incidence year			
2009	207	114	55.1
2010	207	112	54.1
2011	220	129	58.6
2012	240	129	53.8
2013	218	122	56.0
2014	255	154	60.4

Table 3: Timelines of post-operative radiotherapy

	n/N	Proportion (%)
Time interval between date of surgery until start date RT		
Started within 6 weeks	556/1,632	34.1
Started within 7 weeks	864/1,632	52.9
Time interval between date of surgery until end date RT		
Completed within 13 weeks	792/1,632	48.5
Completed within 14 weeks	1,028/1,632	63.0
Completed within 15 weeks	1,170/1,632	71.7

Table 4: Association between hospital volume and QI results

Quality indicator	**OR (95% CI)‡**	**p-value**
1 Proportion of patients with early stage (cI or cII) HNSCC who received treatment with curative intent (with or without systemic treatment), who were treated with a single-modality approach	1.002 (0.999-1.005)	0.1292
2 Proportion of surgically treated patients with HNSCC and cN0M0/x with any T stage (except T1 glottic cancer), who underwent elective neck dissection ≤ 20 patients treated during 6-year period > 20 patients treated during 6-year period	 1.13 (1.08-1.18) 0.99 (0.98-1.00)	 <.0001 0.1889
3 Proportion of patients with HNSCC who were treated with postoperative radiotherapy in whom the radiotherapy was completed within thirteen weeks after surgery	0.997 (0.998-1.006)	0.4993
4 Proportion of medically fit patients (WHO PS 0-1) with locally-advanced (cIII-cIV)) non-metastatic HNSCC treated with primary RT, who received concomitant platinum-based chemotherapy	1.000 (0.996-1.005)	0.9397
5 Proportion of patients with node-positive HNSCC treated with primary (chemo)radiotherapy, in whom a diagnostic evaluation of the neck with PET/CT or DW-MRI was performed not earlier than three months after completion of primary therapy	1.005 (0.997-1.014)	0.2237
6 Proportion of patients with non-metastatic T4a laryngeal cancer who underwent total laryngectomy†	NA†	NA†

† *Not analysed given the low number of patients*

‡ A*djusted for sex, age group at diagnosis, WHO performance status, stage, anatomic site, Charlson Comorbidity Index and number of inpatient bed days during the year before diagnosis*

Captions to figures

Figure 1: Funnel plots showing centre variability between centres for five QIs