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Audit about first consultations on head and neck oncological surgery in Brazil

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Abstract

Introduction: The establishment of high complexity centers in Oncology aims to guarantee faster access to a specialist. Objective: to evaluate the profile of the cases referenced to a head and neck oncology center. **Methods:** Retrospective cohort study, selecting first consultations for head and neck surgical oncology in a public service of a philanthropic institution, for 12 consecutive months. Clinical and demographical data were obtained, besides information about diagnosis, staging of malignant cases, treatment and outcomes. **Results:** From the308 cases included, 197 (63.9%) cases confirmed malignancy (62.0%) or had high suspicion for cancer (1.9%). The remaining 111 (36.0%) cases were confirmed benign diseases (53 - 17.2%) or cases with high suspicion of benignity (58 - 18.8%). Non-melanocytic skin cancer comprised most of the malignant cases (63.3%); non-cancerous thyroid pathologies were the majority of benign cases (45.9%). Most cases of skin and lip cancer presented with disease at early stages (86.8%), while most cases of cancer of the upper airway and digestive tract (UADT) and thyroid/salivary glands were in advanced stages (75.6 and 71.4%, respectively). There were not deaths related to the disease in the first year of follow-up, apart from the UADT cancer group. Among these, the 12-month survival was 45.9%. Advanced staging, history of alcoholism and irresectability/inoperability were associated with poorer prognosis. **Conclusion:** Compared to other global centers, the observed rate of first oncological consultations was high. Among the cases of UADT cancer, history of alcoholism and more advanced clinical and pathological presentation were associated with lower survival.

Keywords: Head and Neck Neoplasms, Medical Audit, Public Health, Prognosis.

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Introduction

It is desirable that most patients referred to a cancer specialty center do not confirm that they are carriers of malignant neoplasms. However, the possibility of the event and the anxiety behind the diagnostic possibility require quick access to the specialist[1]. In 2005, the Ministry of Health issued the number 741, which, considering the need to guarantee the population's access to cancer care, regulates the establishment of high complexity centers in Oncology within the Unified Health System (Sistema Único de Saúde - SUS)[2]. It is defined that the Oncology center should provide care to cancer patients regarding diagnosis, rehabilitation and treatment, if surgical, chemotherapeutic or radiotherapeutic. The specialty of Head and Neck Surgery should be part of its organizational structure.

The National Regulation Policy operationalized and implemented one of the prerogatives of the public manager, which is to organize the relation between supply and demand, in order to qualify the population's access to SUS health services[3]. The implementation of these measures occurred unevenly across the country. In our city, the regulation by the public manager within the regional Oncology center began in January 2014[4].

The launch of Portaria 741 regulated, among other actions, that Oncology centers became a reference for the care of patients with a diagnosis or a strong suspicion of malignancy, keeping articulation and integration with the local and regional health network. However, the criteria for the definition of high oncologic suspicion were not defined in all cases[2].

The National Committee for Technology Incorporation (Comissão Nacional de Incorporação de Tecnologias - CONITEC) in the SUS advises the Ministry of Health on the constitution or alteration of Clinical Protocols and Therapeutic Guidelines. According to the protocols of CONITEC, in line with the literature and recommendations of international specialty representations[5,6], the patient with a diagnosis of head and neck malignant neoplasia should preferably be attended in qualified hospitals such as CACON or UNACON, with radiotherapy and sufficient technological capacity to diagnose, treat and perform follow-up[7]. It is recommended to refer patients to these hospitals as soon as possible if they meet one of the following criteria: a) persistence for 3 or more weeks of: white or erythematous plaques or patches on the oral mucosa; ulcerations of the oral mucosa or oropharynx; dysphagia; hoarseness; cervical lymph node enlargement; unilateral serosanguineous nasal secretion; or edema of the oral mucosa; b) unexplained tooth mobility, not associated with periodontal disease; c) persisting pain or discomfort in the throat, particularly if unilateral or for more than 4 weeks; d) laryngeal stridor, a condition that requires immediate referral; e) facial paralysis, hypoesthesia or severe facial pain; f) orbital tumors; or g) otalgia without evidence of abnormalities on physical examination and otoscopy[7]. There is no specific recommendation from CONITEC for suspected cases of skin cancer or nodules of salivary glands. In the case of thyroid nodules, it is recommended that individuals with suspected or diagnosed thyroid nodule(s) should have access to the consultation with professionals who are experienced in thyroid diseases and basic propaedeutic, especially quality ultrasound and fine needle puncture guided by it. However, it does not restrict the evaluation to Oncology centers, nor does it define the cytological or ultrasonographic criteria that indicate treatment within the oncological scope[8].

We did not find in the national literature an estimative or survey of the rate of cases that end up confirming malignancy among the total referrals to the Oncology services. With the objective of evaluating the profile of the cases referred to the centers of high complexity in Head and Neck Oncology, we audited the first consultations in this specialty for a period of 12 consecutive months.

Methods

After the approval of the local Research Ethics Committee, we developed a retrospective cohort study, selecting all the first consultations performed between 01/01/2016 and 12/31/2016 by one of the doctors of the head and

neck oncology surgery service from SUS from a philanthropic Hospital of RS. This doctor absorbs about 2/3 of the total volume of attendance of the specialty in the Institution that is a reference in cancer care in a microregion of 33 municipalities, totaling about 750,000 inhabitants[4]. The headquarters of the Oncology center under study is located in the center of a region of typical German colonization, the largest tobacco producer in Brazil, a culture that employs a significant portion of the local population[9]. Information regarding age, gender, city and Regional Health Coordination (RHC) of reference, schooling, race, diagnosis, staging of cancer cases, treatment and outcome were collected. All data were collected by the principal investigator between April and June 2017. The clinical and pathological staging was performed at the time of the first visit and confirmed by the pathological findings in the cases operated, being described according to the 7th edition of the American Joint Committee on Cancer pTNM staging system[10]. The diagnosis was registered under the International Classification of Diseases (ICD)[11]. RHC were determined based on a survey on the website of the State Health Secretariat[12].

The selection of the sample cases and the analysis of the medical records were performed based on the computerized system of the Hospital, with data crossing through the regulatory center of the host municipality. During 2016, 342 new consultations were accounted, scheduled for the research professional. From the total, 33 (9.6%) abstentions occurred. According to information from the Regional Regulation Center, the waiting queue for consultation with the head and neck specialty at the Hospital under study was less than 30 days in all months of 2016.

All 308 new consultations were selected for the study. The reason for the consultation was analyzed, trying to correlate the final diagnosis with confirmation or high oncological suspicion, evaluating patterns or more frequent diagnostic groups, organized by topography.

The descriptive analysis was used to summarize the data. The Kolmogorov-Smirnov test was used to evaluate the normality of the continuous variables. Continuous variables were expressed as mean and standard deviation or median, minimum and maximum, as appropriate. Categorical variables were expressed in absolute and relative frequency. Continuous variables were evaluated using the ANOVA test, and the chi-square test was used to evaluate the categorical variables. Statistical analysis was performed in the software SPSS version 15.0 (SPSS Inc., Chicago, IL). All tests considered a significance level of 5%.

Results

Data about age, gender, origin, schooling and race are given in Table 1. From the 308 cases included, 191 (62.0%) cases confirmed malignant neoplasms and 6 (1.9%) had high suspicion, but they lost follow-up within the institution, without histological confirmation. The remaining 111 (36%) cases were confirmed benign diseases (53 - 17.2%) or cases with high suspicion of benignity (58 - 18.8%). The cases of malignancy and benignity were distributed according to their topography as shown in Tables 2 and 3, respectively. Among the cases of UADT cancer (mouth, larynx and pharynx), squamous cell

Table 1. Epidemiological data of patients attended at the first consultation at the head and neck surgical oncology ambulatory clinic.

		Mean(SD)	
Age		**62(14.01)**	
		N = 308	**% = 100**
Gender	Women	149	48.3
	Men	159	51.6
Origin	13rd RHC	253	82.1
	2nd RHC	55	17.8
Schooling	Illiterate	9	2.9
	1st ID	208	67.5
	1st FD	52	16.8
	2nd ID	10	3.2
	2nd FD	21	6.8
	3rd ID	2	0.6
	3rd FD	6	1.9
Race	Caucasian	303	98.3
	Black	4	1.2
	Brown	1	0.3

Caption: Subtitle: Variables were expressed in absolute (N) and relative (%) frequencies, mean (standard deviation), as appropriate; age was expressed in years; RHC = Regional Health Coordination; ID = incomplete degree; FD = full degree.

Table 2. Topographic distribution of confirmed cases of cancer.

		N = 197*	**% = 100**
Skin	non-melanoma	121	63.3
	Melanoma	9	4.7
Lip		14	7.3
Oral Cavity		12	6.2
Oropharynx		12	6.2
Cervical Mtx	Primary site ignored	5	2.6
	Primary site distant	3	1.5
Larynx		5	2.6
Hypopharynx		4	2.0
Thyroid		5	2.6
Lymphomas with cervical manifestation		3	1.5
Parotid		2	1.0
Jaw		1	0.5
TU of soft tissues		1	0.5

Caption: Variables were expressed in absolute (N) and relative (%) frequencies. *: the 191 confirmed cases were added to the 6 cases with high oncological suspicion; Mtx: metastasis; TU=tumor.

Table 3. Topographic distribution of confirmed or suspected cases of benignity.

	N = 111*	% = 100
Thyroid	51	45.9
Skin and annexes	27	24.3
Parotid and submandibular	12	10.8
UADT mucosa	10	9.0
Lymph nodes	3	2.7
Facial bones	2	1.8
Congenital cysts	1	0.9

Caption: Variables were expressed in absolute (N) and relative (%) frequencies. *: there are still 5 (4.5%) cases that were vague and nonspecific complaints, without any indicative sign or high suspicion of malignancy; UADT: Upper airway and digestive tract.

Table 4. Comparative analysis among the 3 groups of patients identified after evaluating patterns or more frequent diagnostic groups and organizing by topography: (A) patients with tumors or lesions of skin and lips; (B) patients with UADT tumors; (C) patients with nodules or pathologies of thyroid and salivary gland.

		A		B		C		Total		p value
		Mean(SD)		Mean(SD)		Mean(SD)		Mean(SD)		
Age		65(13.46)		62(10.95)		57(14.31)		63(13.73)		**<0.0001**
		N = 171	**%**	**N = 47**	**%**	**N = 70**	**%**	**N = 288**	**%**	
Malignant /		144	84.2	37	78.7	7	10.0	188	65.2	**<0.0001**
Benign		27	15.7	10	21.2	63	90.0	100	34.7	
Men /		100	58.4	37	78.7	10	14.2	147	51.0	**<0.0001**
Women		71	41.5	10	21.2	60	85.7	141	48.9	
Staging*	I-II	125	86.8	9	24.3	2	28.5	136	72.3	**<0.0001**
	III-IV	19	13.1	28	75.6	5	71.4	52	27.6	

Caption: variables were expressed in absolute (N) and relative (%) frequencies or Mean (Standard Deviation), as appropriate; age was expressed in years; p = significance level; *referring to confirmed cases of cancer.

carcinoma (SCC) was the predominant histopathological diagnosis (88.6%). Among the skin tumors, basal cell carcinoma (BCC - 65.2%) followed by SCC (19.8%) were the predominant ones.

Analyzing the reason for attending patients in the first consultation in the department, we identified 3 different epidemiological profiles of patients: (A) patients with tumors or lesions of skin and lips; (B) patients with UADT tumors; (C) patients with nodules or diseases of thyroid and salivary gland. Other 20 patients were not classified in any group, corresponding to a miscellanea of diagnosis and less frequent clinical situations. The three groups were compared to each other and their data are detailed in Table 4. These presented statistically significant differences relating to the proportion of men and women ($p<0.0001$), the mean age ($p<0.0001$), the proportion between malignant and benign cases ($p<0.0001$), and the clinical and pathological staging of the confirmed cancer cases ($p<0.0001$) – Table 4.

Of the total, 211 (68.5%) cases were submitted to surgical treatment and the rest to clinical management, whether or not oncological. Cases of basal cell carcinoma, except for those with multiple lesions or signs of invasion of deep structures, are not followed up in the service, being referred to the primary health care or to a dermatologist. Approximately half (49.0%) of the patients seen at the first visit remained in the service during the period under analysis.

There were no deaths related to the disease among the cases of skin, thyroid and salivary gland cancer in the study period. From the 37 patients with confirmed UADT cancer, 14 (37.8%) cases presented with an unresectable disease and another 2 (5.4%) were inoperable due to poor performance. Survival in 3, 6, 9 and 12 months post-diagnosis in this group was 70.2%, 62.1%, 54% and 45.9%, respectively, with 3 patients still alive after 1 year of follow-up, but in palliative treatment. The time of evolution of the symptoms until the consultation with specialist ranged from 1 to 18 months, with median of 6.08 months. Only 1 patient had time to develop symptoms ≤ 1 month. Smoking history was present in 33 (89.1%) cases, being associated with alcoholism in 25 (67.5%) cases. Within this group of 37 patients, factors associated with prognosis were analyzed in 12 months from the first consultation with the

Table 5. Factors associated with life expectancy in 12 months from the first consultation in the tertiary ambulatory clinic among cases of malignant neoplasia of upper airway and digestive tract.

		Alive at 12 months		Death at 12 months		Total		p value
		Mean(SD)		Mean(SD)		Mean(SD)		
Age		60(14.23)		60(9)		60(11.46)		0.8959
Time of evolution of symptoms		6.28(4.14)		5.91(4.50)		6.08(4.27)		0.8117
		N = 16	%	N = 21	%	N = 37	%	
Gender (M/F)		12/4	75/25	20/1	95.2/4.7	32/5	86.4/13.5	0.1941
Schooling	≤ 1st D	14	87.5	20	95.2	34	91.8	0.8053
	≥ 2nd D	2	12.5	1	4.7	3	8.1	
Color	Caucasian	16	100.0	19	90.4	35	94.5	NA
	Black	0	0.0	2	9.5	2	5.4	
Habits	smoking hx	12	75.0	21	100.0	33	89.1	NA
	alcoholism hx	6	37.5	19	90.4	25	67.6	**0.0022**
	active smoking	10	62.5	16	76.1	26	70.2	0.5895
	active alcoholism	2	12.5	13	61.9	15	40.5	**0.0071**
AP	SCC	14	87.5	21	100.0	35	94.5	NA
	Other	2	12.5	0	0.0	2	5.4	
Irresectability or inoperability		2	12.5	14	66.6	16	43.2	**0.0031**
Stage	I-II	7	43.7	2	9.5	9	24.3	**0.0437**
	III-IV	9	56.2	19	90.4	28	75.6	

Caption: variables were expressed in absolute (N) and relative (%) frequencies or Mean (Standard Deviation), as appropriate; age was expressed in years; time of evolution of symptoms expressed in months; p = significance level; 1st D: first degree; 2nd D: second degree; hx: history; AP: anatomopathological; SCC: Squamous cell carcinoma or epidermoid carcinoma; NA: not applicable (variable with result equal to zero or 100%).

specialist – Table 5. History of alcoholism and active alcoholism, irresectability or inoperability, and more advanced clinical and pathological stage were associated with a higher risk of death at the 1-year mark. We did not identify an association between time of onset of symptoms and mortality or more advanced staging (p = 0.8117). Similarly, dividing the group of patients according to the time of symptom evolution (> or ≤ 3 months), we also did not identify clinical and pathological staging differences in the initial presentation between the groups (p = 0.2204).

Discussion

Early access to cancer investigation and management improves unquestionably the overall outcome of treatment, although there are still doubts about the quantification of the delay that could impact the outcome in each type of cancer[13]. Despite the nuances among the different countries, all follow in a greater or lesser degree to the National Institute of Clinical Excellence (NICE) guidelines[6]. In England, the reality of a public structure similar to the one in Brazil, the expected waiting time for the first oncological care after the clinical suspicion is 2 weeks, and the waiting time from diagnosis to treatment of up to 30 days from the result of the biopsy, or 62 days from the referral of the general practitioner[1]. In Brazil, legislation on this topic is recent. In November 2012, Law number 12732, known as the "60-day law", was signed. It establishes the maximum legal period of 60 days, counted from the day in which the diagnosis is established in a pathological report, for the beginning of the cancer treatment[14]. CONITEC has developed specific recommendations for patient profiles that should be sent to Oncology centers, although it does not comprise all existing topographies and does not distinguish between cases that should be prioritized within a waiting line[7,8].

Our sample was represented by 3 groups of patients with different characteristics. The predominant group was of patients with skin lesions, mostly patients with lesions of indolent growth and good prognosis. Another large group was formed by patients with thyroid and salivary glands nodules, most of them patients with suspicion or confirmation of benignity. And the third group consists of patients with UADT tumors, mostly patients with advanced malignancies. The differences observed between the 3 groups are already well recognized in the literature[15], representing 3 different epidemiological and pathological profiles. The most advanced and of worst prognosis cases are among the individuals with UADT cancer. For different reasons that vary from personal negligence, vague symptomatology in the initial stages of disease to diagnostic failures by the front line professionals (general practitioners, dentists etc.), these patients usually present themselves late to the specialist physician, with a great impact on the disease survival[13,16,17]. Compatible with the literature, the cases with the worst outcomes in our sample were those with more advanced clinical and pathological staging. We also identified an association between history of alcoholism or active alcoholism at the first consultation with the specialist with a worse prognosis in the short term. On the other hand, we did not observe a prognostic association of the time of evolution of the symptoms, which could have occurred both by real similarity between the groups, thus suggesting a more rapid and aggressive evolution

of the disease in a part of the group, or undervalued perception among the patients which presented higher mortality, especially composed of smokers and chronic alcoholics. Other groups have already observed an association between heavy alcoholism and more advanced staging or worse prognosis among patients with head and neck carcinomas[18]. It is not uncommon to identify situations of suppression of symptoms and their severity with alcohol consumption, something that is consistent with our results.

The literature usually considers delay to the consultation with specialist a period superior to 30 days[18].

In our sample, all patients were attended for the specialist in a period of less than one month. However, only one patient was attended after one month of begining of symptoms. The rest was attended in a period superior to two months of symptoms, with a median's symptoms duration of 6.08 months, which hinder the use of this criterion for statistical analysis in our sample.

We did not identify in the national literature other studies that analyze the rate of confirmed cases of cancer among referrals to Oncology centers. Compared to other international centers, the rate of malignant cases among individuals referred to our institution is high (63.9% overall, considering cases highly suspect, and 78.7%, considering cases only in group B). British studies with patients with complaints related to UADT diseases showed variable rate between 8 and 15% of malignancy[19-22]. It is important to note that in Brazil and in the United Kingdom the referral criteria of the patient with suspicion of upper airway digestive tract cancer to the specialist are very similar and should be sent to the oncology centers of SUS those patients with suspected or confirmed malignant neoplasia. However, the discrepancies in the ratio between countries show that the selection method probably differs greatly from one country to another. It is possible that the secondary health care, a "bottleneck" in our country, is being used to access the center specialized in Oncology in many cases[23].

Considering that routing errors may be influencing the presentation stage of UADT tumors, it would be expected that, by increasing access to potentially malignant cases in the system, even without diagnostic tests, we could reduce the proportion of new advanced cases. However, despite the observed disparities between countries, the proportion of advanced cases of UADT malignancies in England follow the same trend as other developed and underdeveloped countries, suggesting that the facilities of access to the specialist have not been enough to change the prognostic expectations of these patients[20,23]. Likewise, it would be expected that patients with a later stage of the disease or with a higher mortality presented a higher time of evolution of the symptoms, different from that observed in our study. Other studies have already observed that disease staging resembles even in the comparison between patients from the public or private system, also suggesting that the facilities to access the health system do not necessarily have direct relation with later diagnosis[24].

Some authors consider that the solution lies in refining the criteria for referral to the specialist[22]. In the analysis of a large institutional series, it was identified that intermittent hoarseness and pharyngeal globe sensation, common

causes of referral to the head and neck cancer surgeon, were negatively associated with malignant neoplasia, indicating that, when isolated, referral is not necessary. On the other hand, dysphagia and odynophagia, signs that are not part of the NICE recommendations, have shown a significant association with head and neck neoplasms.

Other studies work with the hypothesis that one of the main reasons for the delay in the diagnosis and treatment of these patients is the negligence and possibly the ignorance of the patients in relation to their symptoms and the consequences of late detection of oncological pathologies[25-27]. Abusive alcohol and tobacco users and individuals with low schooling tend to increase the delay in the diagnosis of the disease[27]. In our sample, we evidenced a high rate of patients with a history of smoking and/or alcoholism, in addition to a low educational level. Although we did not find statistical significance between schooling and prognosis, we believe that factors directly related to the patient and their social structure must be related to the advanced staging of the disease and, consequently, with higher mortality rates, especially due to the influence of alcoholism observed in the analysis of cancer and UADT cases. Therefore, continued efforts in population education and primary prevention measures remain valid.

Conclusion

Compared to other global centers, the rate of first consultations with confirmation of cancer in our Oncology center is high, with variations according to the topographic site of the tumor. We did not identify an association between time of symptom evolution and clinical and pathological staging or short-term mortality. Higher mortality at 1 year was observed among patients with advanced disease and alcoholics.

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