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Patterns of Relapse and Metastisation in Lip Squamous Cell Carcinoma - Experience of a Clinical Centre

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Abstract

Lip squamous cell carcinoma (SCC) represents between 10 and 20% of all oral cavity cancer. Surgical treatment is the gold standard approach. The objective of this study was to evaluate the impact of staging and intervention on relapse outcomes in patients with lip SCC at Instituto Português de Oncologia de Coimbra. In this study we employed Fisher's exact test to analyse associations between relapse patterns, staging and intervention. Additionally, Kaplan-Meier survival analysis and Cox regression were used to compare metastasis-free survival across staging, accounting for age of diagnosis. 55 patients were included in this study, with a follow-up of 12 months. We found that metastasis occurrence has a statistically significant association with initial staging. No such association was found with intervention type. Survival analysis confirmed that metastisation occurred earlier and more frequently in higher stages. Lip SCC prognosis is highly dependent of staging at diagnosis, with favourable outcomes at early stages and worse in advanced disease. Initial staging emerged as the primary predictor of metastasis risk. The high occurrence of metastasis in T-stage II lip SCC may indicate that these lesions should be approached as oral cavity cancer.

Highlights

- Lip SCC behaves more aggressively than cutaneous SCC.
- T-stage 2 tumours present a high metastisation rate.
- All patients with lip SCC should be submitted to a maxillofacial, neck and thorax CT scan for staging.
- Sentinel lymph node biopsy should be considered in dubious cases.

1. Introduction

Currently, cancer is one of the greatest challenges in global health, with an estimate of 20 million newly diagnosed cases and 9.7 million deaths worldwide in 2022, according to the Global Cancer Statistics [1]. Ranking 16th in global incidence, lip and oral cavity cancer accounted for 2% of all new cases [1]. In particular, squamous cell carcinoma (SCC) of the lip represents between 10 and 20% of all oral cavity cancers [2].

Regarding the etiology of lip SCC, it is established that ultraviolet radiation (UV) is the primary risk factor [3], disproportionally affecting outdoor workers and residents of areas with higher sun exposure. Use of tobacco, alcohol consumption as well as some socioeconomic factors also appear to influence the development of this carcinoma [3, 4].

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The vermilion lip is a unique structure as it is neither a part of the nonkeratinized mucosa of the oral cavity nor a part of the keratinized skin. The epithelium of the vermilion is densely vascular and it stands superficially to the orbicularis muscle, which is both vastly and superficially innervated [5, 6]. This web of blood vessels and nerves closely located near the epithelial surface represents a weaker barrier to lymphovascular and perineural invasion when compared to other cutaneous locations [6]. The lymphatic drainage of both the upper and lower lips is primarily to the submandibular group of lymph nodes and, to a lesser extent, the submental, intraparotid and internal jugular lymph nodes. Contralateral lymph node drainage is possible [7].

Lip SCC prognosis is highly dependent on the staging at diagnosis, with a generally favourable outcome at the early stages (stage I/II) but a much worse response to treatment at advanced disease (stage III/IV) [2, 3].

Surgical treatment is still considered the gold standard approach to lip SCC, similarly to the disease in the oral cavity [2, 3]. Several studies have shown that both surgery and radiotherapy (RT) provide similar survival and local control rates for early-stage SCC [2]. Still, surgical treatment has the advantage of including the histopathologic analysis of the primary tumour and cervical lymph nodes [2].

The aim of this study is to demonstrate the experience of the Stomatology Department of the Instituto Português de Oncologia de Coimbra Francisco Gentil (IPOC-FG) in the management of lip SCC and compare our findings with current literature.

2. Materials and Methods

2.1. Study Design

This is an observational retrospective study conducted through analysis of data from IPOC-FG patients. The observational essence of this study involved documentation and processing of findings without intervention in patient care.

2.2. Study Population and Selection Criteria

The study population was identified through a review of the medical records at IPOC-FG over a 5-year period (between 2020 and 2024). The eligible patients were those with a histopathologically confirmed lip squamous cell carcinoma on an incisional biopsy. The criteria for exclusion were incomplete surgical and histopathological data; follow-up under 12 months and patients positive for lymph node metastases at diagnosis.

2.3. Data Collection, Staging and Categorizing Interventions

The data gathered consisted in the sex, age at diagnosis, tumour location, initial T-staging, type of surgery, occurrence of local relapse and cervical lymph node metastases and time between surgery and relapse or metastisation.

Initial staging was accessed according to IPOC-FC own protocols which are based on the Journal of the National Comprehensive Cancer Network (JNCCN) and the American Joint Committee on Cancer (AJCC) Guidelines.

The surgical procedures were categorized into 3 groups. The first, vermilionectomy, was mainly performed on small, T-stage 1 tumours restricted to the lip vermilion and whose excision did not demand a reconstruction. The second (excision with flap) and third (excision with flap and vermilionectomy), were performed in tumours that required a wider resection or even a full amputation of the lip and it was not possible to achieve a direct closure of the surgical wound. Therefore, an advancement, rotation or another type of flap was used to reconstruct.

2.4. Data Analysis

Descriptive statistics were used to summarize relapse patterns across staging and intervention groups. The associations between these variables were assessed using Fisher's exact test. This non-parametric test was selected due to the presence of cells with expected frequencies below 5 in the contingency table. Effect size was quantified using Cramer's V.

Kaplan-Meier survival analysis with the log-rank test was used to compare metastasis-free survival across staging. Metastasis-free survival estimates at 12 months were presented. A Cox regression was then applied to estimate the hazard of metastases, adjusting for initial staging and age at diagnosis. Hazard ratios (HRs) and 95% confidence intervals were reported, and model significance was evaluated with the likelihood ratio test. Due to the low number of events and high censored rates, the results should be interpreted as exploratory.

All statistical analyses were performed using IBM SPSS Statistics software version 29.0.0.0, with a significance threshold set at $p<0.05$.

3. Results

After applying our exclusion criteria, a total of 55 patients were included in the study. These were patients diagnosed with lip SCC without lymph node involvement and submitted to surgery, with a follow-up of at least 12 months. Table 1 presents the clinical characteristics of the sample.

3.1. Demographics and Staging

A total of 55 cases of squamous cell carcinoma of the lip were identified between 2020 and 2024 after applying our exclusion criteria. The study population exhibited a strong male predominance (74.5%, n=41) with a male-to-female ratio of 3:1. The mean age at diagnosis was 76 years (SD=11.4). Involvement of the lower lip was predominant with 96.4% of the cases.

Over half (54.5%) of the cases represented T-stage 1 tumours, while T-stage 2 accounted for 40.0% and T-stage 3/4 only 5.5%.

Table 1. Clinical characteristics of the population sample (n=55).

Characteristics	N (%)
Gender	
Male	41 (74.5)
Female	14 (25.5)
Age at diagnosis (Mean ± SD)	76 ± 11.4
Diagnosis	
Lower Lip SCC	53 (96.4)
Upper Lip SCC	2 (3.6)
Staging	
T-Stage 1	30 (54.5)
T-Stage 2	22 (40.0)
T-Stage 3	1 (1.8)
T-Stage 4	2 (3.6)
Intervention	
Vermilionectomy	11 (20.0)
Excision + Flap	10 (18.2)
Excision + Flap + Vermilionectomy	34 (61.8)
Disease Recurrence	
Local relapse	3 (5.5)
Cervical lymph node metastases	9 (16.4)
Death	3 (5.5)

3.2. Surgical Treatment

Vermilionectomy was performed in a total of 11 cases (20.0%). Surgical excision of the tumour and reconstruction represented 10 cases (18.2%) while excision and reconstruction alongside vermilionectomy accounted for 34 cases (61.8%).

3.3. Disease Recurrence

After a 1-year follow-up there was a local relapse in 3 cases (5.5%). Cervical lymph node metastisation occurred in 9 patients (16.4%).

Mortality after the 1-year follow-up was 5.5%.

3.4. Association Between Staging, Intervention and Relapses

Local relapses were observed in only 3 patients and showed no statistically significant association with either initial staging (Fisher's exact test, p=1.00) or intervention type (p=0.54). The local relapse rate was 6.7% (2/30) in T-stage 1 patients, 4.5% (1/22) in T-stage 2 patients, and 0% (0/3) in T-stage 3/4 patients. Concerning the interventions performed on these patients, the local relapse rates were 0% (0/11) in the vermilionectomy group, 10.0% (1/10) in the excision with flap group, and 5.9% (2/34) in the combined excision with flap and vermilionectomy group.

Metastases occurred in 9 patients, showing a statistically significant association with initial staging (Fisher's Exact Test, p = 0.01). Metastases rates increased substantially with higher staging: 3.3% (1/30) in T-stage 1 patients, 31.8% (7/22) in T-stage 2 patients, and 33.3% (1/3) in T-stage 3/4 patients. The effect size (Cramer's V = 0.39) indicated a moderate association between staging and metastases development. No significant association was found between intervention type and metastases occurrence (p = 0.67). Metastases occurred in 9.1% (1/11) of patients in the vermilionectomy group, 10.0% (1/10) of patients in the excision with flap group, and 20.6% (7/34) of patients in the combined excision with flap and vermilionectomy group.

Table 2 and Table 3 present the complete cross-tabulation of local relapses and metastases, initial staging and intervention type.

Table 2. Distribution of local relapses and metastases by initial staging.

Relapse	T-stage 1 (N=30)	T-stage 2 (N=22)	T-stage 3/4 (N=3)	p-value
Local	2 (6.7%)	1 (4.5%)	0 (0.0%)	1.00
Metastases	1 (3.3%)	7 (31.8%)	1 (33.3%)	0.01*
Total	3 (10.0%)	8 (36.4%)	1 (33.3%)	

*Statistically significant at p < 0.05 (Fisher's Exact Test)

Table 3. Distribution of local relapses by intervention type.

Relapse	Vermilionector (N=11)	Excision with flap (N=10)	Excision with flap and vermilionectomy (N=34)	p-value
Local	0 (0.0%)	1 (10.0%)	2 (5.9%)	0.54
Metastases	1 (9.1%)	1 (10.0%)	7 (20.6%)	0.67
Total	1 (10.0%)	2 (20.0%)	9 (26.5%)	

3.5. Kaplan-Meier Survival Analysis

Given the significant association between initial staging and metastases occurrence identified in the previous analysis, we conducted a Kaplan-Meier survival analysis to further examine the temporal relationship between initial staging and metastases development. The event of interest was the occurrence of metastases and censoring reflected patients who did not develop metastases during the 12-month follow-up period.

Of the 55 patients included in this analysis, only 9 developed metastases, resulting in a high overall censoring rate of 83.3%. The 12-month metastasis-free survival rates varied by staging group. Patients with T-stage 1 showed the most favourable prognosis, with a 12-month metastasis-free survival rate of 96.6% (SE = 3.4%). In contrast, the T-stage 2 group exhibited a 12-month metastasis-free survival rate of 68.2% (SE = 9.9%), while the T-stage 3/4 group had a 12-month metastasis-free survival rate of 66.7% (SE = 27.2%). A log-rank test revealed a statistically significant difference in survival distributions across

staging groups ($\chi^2(2) = 7.57$, p = 0.02), indicating that initial staging was associated with time to metastisation. Figure 1 illustrates the Kaplan-Meier survival curves for each staging category, demonstrating the separation between the T-stage 1 curve and the more advanced staging groups, with metastatic events occurring earlier and more frequently in the higher-stages.

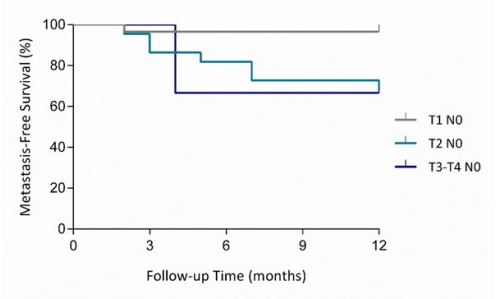

Figure 1. Kaplan-Meier curves for metastasis-free survival by initial staging category. The graph illustrates the probability of remaining metastasis-free over the 12-month follow-up period.

The timing of metastases development varied by staging group. The single metastatic event in the T-stage 1 group occurred early (2 months), while metastases in the T-stage 2 group appeared throughout the follow-up period (between 2-12 months), with the majority (5/7) occurring within the first 7 months. The single metastatic event in the T-stage 3/4 group occurred at 4 months.

3.6. Multivariable Cox Regression Analysis

A multivariable Cox proportional hazards regression was conducted to evaluate the effects of initial staging and age at diagnosis on the risk of metastases. The overall model was statistically significant ($\chi^2(3) = 8.44$, p=0.04).

Compared to T-stage 1, individuals with T-stage 2 had a significantly higher risk of metastases (HR=10.48, 95% CI: 1.29 – 85.36, p=0.03). Patients with T-stage 3/4 showed a similar elevated risk (HR=11.87, 95% CI: 0.74 – 191.41), though this did not reach statistical significance (p=0.08), possibly due to the small number of patients in this group (n=3). Age at diagnosis did not significantly influence metastases risk (HR=1.01, 95% CI: 0.95 – 1.07, p=0.83). The results of the multivariable Cox regression analysis are summarized in Table 4.

Table 4. Cox Proportional Hazards Regression Analysis for Factors Affecting Metastases Risk.

Factor	HR	95% CI	p-value
Initial Staging			
T-stage 1 (reference)	1.00		
T-stage 2	10.48	1.29 – 85.36	0.03*
T-stage 3/4	11.87	0.74 – 191.41	0.08
Age at diagnosis	1.01	0.95 – 1.07	0.83

*Asterisks indicate statistical significance at p<0.05.

4. Discussion

The male predominance (74.5%) is consistent with the general global trend, although our male-to-female ratio (3:1) differs from larger studies who report ratios of 2:1 [2], 2.4:1 [3] and 2.8:1 [8]. This regional difference may be justified by the presence of large seafaring communities in the centre of Portugal which mainly employ males [9].

The age distribution revealed a mean age at diagnosis of 76, far above the mean age reported in literature (65 [8], 65.51 [3] and 66.1 [10]). Several hypotheses may explain the disparity on these results. Greater healthcare awareness among the population may lead to the early detection and treatment of potential malignant lesions, such as actinic cheilitis or leucoplakia. Additionally, a shift from rural and outdoor jobs to office work may result in reduced exposure to UV radiation, the primary risk factor.

The anatomical distribution of our study showed a marked predominance of lower lip involvement, accounting for 96.4% of all cases. This pattern differs slightly from the rates reported in previous studies of 89.1% [3], 79.4% [8] and 77.8% [10]. No clear explanation has been found for such a difference in anatomical site distribution rates.

Initial tumour staging was the most significant factor associated with the risk of metastases. The multivariate Cox regression analysis indicated that patients with T-stage 2 tumours had a substantially higher risk of developing metastases (HR = 10.48) compared to T-stage 1 patients, after adjusting for age. This result corroborates findings from both Fisher's exact test and Kaplan-Meier survival analysis, which showed that advanced staging significantly increased the likelihood of metastatic events. Nonetheless, given the limited number of metastatic events, these findings should be interpreted as exploratory. Studies with more events would be necessary to obtain more precise estimates of hazard ratios.

Our high proportion of early-stage tumours (94.5% corresponding to stage 1 and stage 2) was higher than the findings in larger studies (83.3% [8] and 84% [11]). Again, these results may be justified by a greater healthcare awareness, leading patients to seek help earlier when they notice potentially malignant lip lesions. In addition, the Portuguese National Health Service and, in particularly, the Stomatology department at IPOC-FC are able to provide a quick response to any patient that is signalled with a malignant or potential malignant condition by their primary health care provider or dentist. On the other hand, for the majority of the period studied, the team managing these tumours discussed patients in a multidisciplinary meeting that managed lip SCC as a cutaneous cancer and therefore did not routinely request a CT scan for staging. We believe this could have led to the under-staging of some patients, as some lymph node

metastases undetected at clinical examination might have already been present prior to surgery, meaning that some stage 2 patients could actually have been a stage 3 prior to their surgical treatment. Currently, after a change in the surgical and multidisciplinary discussion team, lip SCC is managed according to the IPOC-FC oral cavity protocol. This means that a maxillofacial, neck and thorax CT scan is always requested for these patients, in order to complete the staging.

There also appears to be an increasing number of articles challenging the guidelines for staging of lip SCC and their implications. As mentioned before, being a transition structure between keratinised skin and dekeratinised mucosa, the lip presents its own challenges. In Kansara et al [12] systematic review it was found a 10% rate for occult nodal metastases in lip cancer, a rate not far from the threshold required for elective management of the neck. Ant et al [11] reported the high aggressiveness of lip SCC, mainly from the supposedly mild stage 2 disease, and suggests a 7.5mm depth of invasion cut-off for differentiating between stage 2 and 3 tumours.

With only 3 cases of local relapse, it was not possible to draw any significant conclusions as to the influence of the initial staging or intervention performed. Similarly, in relation to the metastisation rate, we also did not find any significant association with the type of surgery. These findings highlight the importance of initial staging as a prognostic indicator for metastatic progression, with more advanced stages associated with a substantially increased risk in lip SCC [3, 13, 14].

In our study, cervical lymph node metastases occurred in 16.4% of patients. It is comparable to results in literature which claim a regional metastases rates of up to 20% [15], although most reviews report lower rates, such as 2 to 5% [2] or 8% [14]. However, since our study only includes a 1-year follow up, it is expected that the metastisation rate increases if we repeat the study with a 5-year follow-up.

As Kansara et al [12] state, several authors recommend an elective neck dissection in high-risk patients but raises the issue of managing those with smaller tumours that present some high-risk features due to the morbidity of the procedure. With their findings, the authors recommend the use of a sentinel lymph node biopsy (SLNB) even in the earlier stage tumours that present themselves with high-risk factors [12]. Walton et al [14] created a prediction model for lymph node metastases in patients with lip SCC and suggest neck dissection or SLNB for patients that are "high risk" (3+ risk factors) and consideration for anyone with 2+ risk factors. Matos et al [16] considers SLNB for patients with lip and oral cavity SCC a feasible option as it shows similar rates of occult lymph node metastases detection and false-negative cases when compared to elective neck dissection. In their study, Loxha et al [15] found that lymphoscintigraphy was the test with the highest probability for detecting patients with true positive lymph node enlargements, and suggests applying this exam in all stage 1 and 2 patients with lip or oral cavity SCC in order to screen those who would benefit with a SLNB.

This shows a trend across the globe of surgeons dissatisfied with the current guidelines applied to lip SCC staging and the search for the most effective method to identify at-risk patients and prevent the metastisation of the disease.

5. Limitations and Future Directions

This single centred experience, although represents a large population sample, is limited to a single region of Portugal and the outcomes may be specific to this area. Besides that, IPOC-FG is not the only local major institution that treats SCC of the lip.

The small sample size, particularly for the T-stage 3/4 group (n=3), resulted in wide confidence intervals for hazard ratios, reducing the precision of these findings and highlighting the exploratory nature of this analysis. Additionally, the low incidence of local recurrences (n=3) limited our ability to explore predictors for this outcome. Contrarily to most literature we also have a short follow-up period of only one year which makes it difficult to compare our results.

The period bracket of this study captured a change in the surgical and multidisciplinary discussion team, meaning a change in the approach to these patients. This could have influenced both the initial staging of the tumours as well as surgical treatment outcomes.

Despite the limitations of the study, our findings provide understanding on the lip cancer patient patterns and outcomes in the Centre region of Portugal.

Ultimately these results point to the similarity in behaviour of lip and oral cavity SCC, yet, due to the low number of events and high censored rates, the results should be interpreted as exploratory. These findings should be integrated in a multi-centred or even nationwide study in order to achieve the most accurate possible results.

6. Conclusions

The high number of patients with metastases in this 1-year follow-up indicates that lip SCC behaves more aggressively than cutaneous SCC, similarly to the oral cavity disease.

We suggest that all patients with lip SCC should be submitted to a maxillofacial and neck CT scan and a SLNB to be performed in dubious cases.

It is our opinion that lip SCC should be managed by a Stomatology team experienced in managing patients with oral cancer.

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