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Research Article

Evaluating the Necessity of Level IIb Dissection in Oral Squamous Cell Carcinoma: A Retrospective Cohort Study in an Iraqi Population

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Abstract

Aims: This study aimed to evaluate the necessity of level IIb dissection in patients within an Iraqi cohort.

Materials and Methods: The histopathological and clinical data of 50 patients with oral squamous cell carcinoma (29 males and 21 females), treated between June 2018 and June 2020, were analyzed. Histopathological studies were conducted on 857 lymph nodes, including 143 from level IIb, after immunohistochemical staining with cytokeratin 5/6. Statistical tests assessed predictors of level IIb involvement.

Results: Level IIb involvement was observed in only 2 cases (4%) with concurrent level IIa metastasis. No isolated level IIb involvement was detected. Primary tumor location (p =0.03) was a significant predictor of level IIb involvement. Other variables, such as age (p-value = 0.2675), sex (p-value = 0.503), grade (p-value = 0.1), DOI (p-value = 0.617), size (p-value = 0.319), and neck status (p-value =0.099), showed no significant association with level IIb involvement.

Conclusion: Routine dissection of level IIb is unnecessary in clinically negative oral squamous cell carcinoma cases and should be reserved for clinically positive or advanced diseases. Further studies incorporating advanced diagnostics are needed to refine clinical guidelines.

Keywords: Level IIb, Lymph node metastasis, Oral Cancer, Shoulder Dysfunction

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INTRODUCTION

Oral squamous cell carcinoma (OSCC) is among the most prevalent head and neck cancers. (1) representing a significant global health challenge, with nearly 390,000 new cases annually, including over 300 new cases every year in Iraq (2). Tumor characteristics, treatment modalities, and host defense influence the prognosis of OSCC; however, regional lymph node metastasis reduces the survival rate by half and is considered the most significant survival factor (3).

Along with surgical management of primary cancer, neck dissection is done in therapeutic and elective settings to increase the survival rate and improve regional control of the disease (3).

Memorial Sloan Kettering Cancer Center initially proposed a description of neck levels, which Suen and Goepfert later subdivided into sublevels at MD Anderson Center (4,5).

Originally, neck dissection was based on the fact that OSCC has a predictable lymphatic pathway for metastasis, with levels I, II, and III carrying the highest risk, underscoring the necessity of selective neck dissection (6).

In 1880, Kocher introduced an approach for removing nodal metastasis. Later, in 1906, George Crile refined it with a series of 132 neck dissections and described the classical radical neck dissection (7,8).

Shoulder dysfunction is one of the most frequent problems in patients undergoing neck dissection, whether selective or comprehensive. This is mainly due to the nerve retraction to extirpate nodes in this area, as the spinal accessory nerve crosses level II and divides it into level IIa anterior to the nerve and level IIb lying postero-medially to the nerve (9). Different opinions about the added value of dissecting level IIb in selective neck dissection have been raised because of the added morbidity, time, and therapeutic benefits (10,11). Studies have shown improved quality of life, better shoulder function, and comparable locoregional control when level IIb was spared (12,13).

Due to the frequent incidence of shoulder dysfunction among Iraqi patients after neck dissection, the present study aimed to evaluate the necessity of routinely including level IIb in neck dissection for OSCC patients by studying their histopathological samples after immunohistopathologic staining with cytokeratine5/6. To the best of the author's knowledge, this is the first study to be carried out on an Iraqi population.

MATERIALS AND METHODS

Ethical approval

This study was conducted in accordance with the principles outlined in the Declaration of Helsinki for research ethics. Ethical approval to use human material and data was granted by the Research Ethics Committee of the Duhok General Health Directorate, with license number (**05022025-2-3**), on the fifth of February, 2025; the patients' consent to participate was waived by the committee.

This is a retrospective cohort study. Clinical data and histopathological samples were collected from case sheets and biopsies of 50 patients diagnosed with OSCC, including 29 male and 21 female patients between 25 and 80 years old. All patients underwent surgery at Ghazi Al-Hariri Teaching Hospital for Surgical Specialties, Baghdad/Iraq between June 2018 and June 2020. Patients with a history of preoperative chemotherapy or radiotherapy and incomplete clinical or histopathological samples were excluded from the study.

The data collected comprised clinical examination and imaging (head and neck computed tomography (CT), chest radiograph, abdominal ultrasound) performed on all patients. Sex, age, and tumor information were gathered from the patient records. Clinical and Pathological staging was implemented according to the 7th edition of the American Joint Committee on Cancer (AJCC) tumor lymph node metastasis (TNM) staging system (14), as shown in Tables 1 and 2.

Table (1). TNM staging system according to AJCC.[14]

T Category	**T Criteria**
TX	Primary tumor cannot be assessed
Tis	Carcinoma *in situ*
T1	Tumor ≤ 2 cm with a depth of invasion (DOI)* ≤ 5 mm
T2	Tumor ≤ 2 cm with DOI* > 5 mm *or* tumor > 2 cm and ≤ 4 cm with DOI* ≤ 10 mm
T3	Tumor > 2 cm and ≤ 4 cm with DOI* > 10 mm *or* tumor > 4 cm with DOI* ≤ 10 mm
T4	Moderately advanced or very advanced local disease
T4a	Moderately advanced local disease Tumor > 4 cm with DOI* > 10 mm *or* tumor invades adjacent structures only (e.g., through cortical bone of the mandible or maxilla or involves the maxillary sinus or skin of the face) Note: Superficial erosion of bone/tooth socket (alone) by a gingival primary is not sufficient to classify a tumor as T4.
T4b	Very advanced local disease Tumor invades masticator space, pterygoid plates, or skull base and/or encases the internal carotid artery
cN Category	**cN Criteria**
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single ipsilateral lymph node, 3 cm or smaller in greatest dimension ENE[1](−)
N2	Metastasis in a single ipsilateral node larger than 3 cm but not larger than 6 cm in greatest dimension and ENE (−[2]); *or* metastases in multiple ipsilateral lymph nodes, none larger than 6 cm in greatest dimension and ENE (−); *or* in bilateral or contralateral lymph nodes, none larger than 6 cm in greatest dimension, and ENE (−)
N2a	Metastasis in a single ipsilateral node larger than 3 cm but not larger than 6 cm in greatest dimension, and ENE (−)
N2b	Metastases in multiple ipsilateral nodes, none larger than 6 cm in greatest dimension, and ENE (−)
N2c	Metastases in bilateral or contralateral lymph nodes, none larger than 6 cm in greatest dimension, and ENE (−)
N3	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE (−); *or* metastasis in any node(s) and clinically overt ENE (+[3])
N3a	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE (−)
N3b	Metastasis in any node(s) and clinically overt ENE (+)
M Category	**M Criteria**
cM0	No distant metastasis
cM1	Distant metastasis
pM1	Distant metastasis, microscopically confirmed

[1] ENE = Extra-nodal extension;
[2] (−) = negative
[3] (+) = positive

Table (2). AJCC Prognostic Stage Groups[14]

Stage	When T is…	And N is…	And M is…
0	Tis	N0	M0
I	T1	N0	M0
II	T2	N0	M0
III	T3	N0	M0
III	T1, T2, T3	N1	M0
IVA	T4a	N0, N1	M0
IVA	T1, T2, T3, T4a	N2	M0
IVB	Any T	N3	M0
IVB	T4b	Any N	M0
IVC	Any T	Any N	M1

Surgical Management and Sample Collection

Samples were collected from patients with OSCC treated surgically by excision of the primary lesion; the procedure involved excision of the primary lesion with a 1- 1.5 cm margin for curative intent. Reconstruction was attained by primary closure, skin grafting, and local or regional flaps. Neck dissection was performed based on clinical criteria and National Comprehensive Cancer Network (NCCN) guidelines, whether selective or comprehensive (15).

Histopathological samples were collected from archival tissue blocks retained at the Department of Pathology in Ghazi Al-Hariri Teaching Hospital for Surgical Specialties. The samples processed and diagnosed between June 2018 and June 2020 were enrolled in the study. The inclusion criteria included formalin-fixed, paraffin-embedded (FFPE) tissue blocks with a histopathologically confirmed diagnosis of OSCC and neck dissection, good preservation, and paired hematoxylin and eosin (H&E)-stained slides available. The samples with poor preservation, incomplete clinical data, or inadequate volume of tissue for additional analysis were excluded.

Sample identification numbers were accessed from the laboratory information management system (LIMS). Demographic and clinical data, including age of patient, sex, clinical diagnosis, site of biopsy, and date of procedure, were accessed from laboratory records and anonymized to preserve confidentiality.

Histopathological Analysis

The collected pathological specimens were processed using hematoxylin and eosin (H&E) staining for tumor grading and staging.

An immunohistochemical study using cytokeratin (CK5/CK6) staining was conducted on paraffin-embedded tissue sections. Antigen retrieval and staining procedures followed standard protocols, and two independent consultant pathologists validated the results. Tumor staining intensity was categorized using the Dako Omnis scoring system (Agilent Technologies, Santa Clara, CA, USA, distinguishing between positive and negative cases according to manufacturer instructions.

The depth of invasion (DOI) was measured as the perpendicular distance from the adjacent normal tissue's basement membrane to the tumor invasion's deepest point. The World Health Organization (WHO) grading system was used to categorize tumors into well-differentiated, moderately differentiated, and poorly differentiated grades (16).

Statistical Analysis

Data were analyzed using SPSS version 25 and R version 4.5.1. Data completeness and normality were assessed using visual inspection and the Shapiro–Wilk test. Continuous variables were reported as mean ± SD for normally distributed data and median (IQR) for skewed data. Associations between categorical variables were assessed using the chi-square or Fisher's exact test, while independent t-tests and Mann–Whitney U tests were used for continuous variables as appropriate. Statistical significance was set at $P < 0.05$, with 95% confidence intervals calculated where appropriate.

RESULTS

Fifty patients, comprising 21 females (42%) and 29 males (58%), aged between 25 and 84, were included in this study. The mean age was 59.3 years ± 12.98, as shown in Figure 1. The tongue was the most frequently involved site, with 19 cases (38%), followed by buccal mucosa, with 17 cases (34%), as illustrated in Figure 2. Buccal

mucosa was the most commonly affected site in males (41.38%), while the tongue was the most affected in females (38.1%) (Figure 3). The depth of invasion ranged from 2 to 14 mm, with a median of 6 mm (IQR5-8). DOI was stratified into 3 categories, and in most cases (78%), DOI exceeded 5 mm, as shown in Table 3.

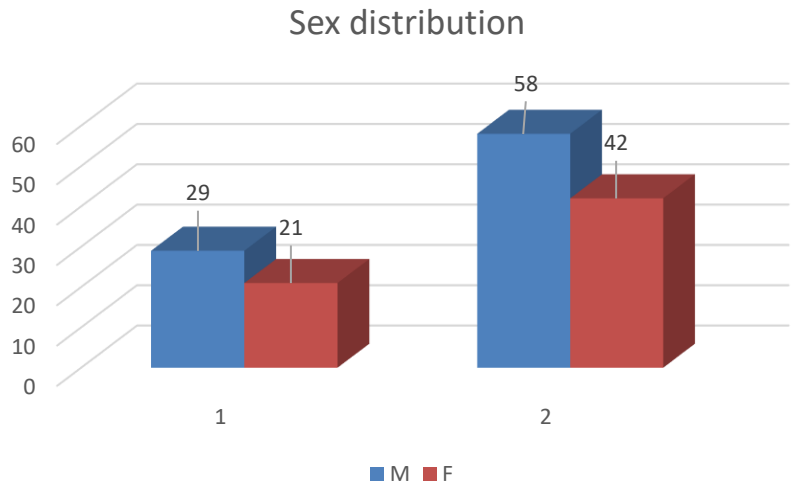

Figure (1). Sex distribution of patients by number and percentage

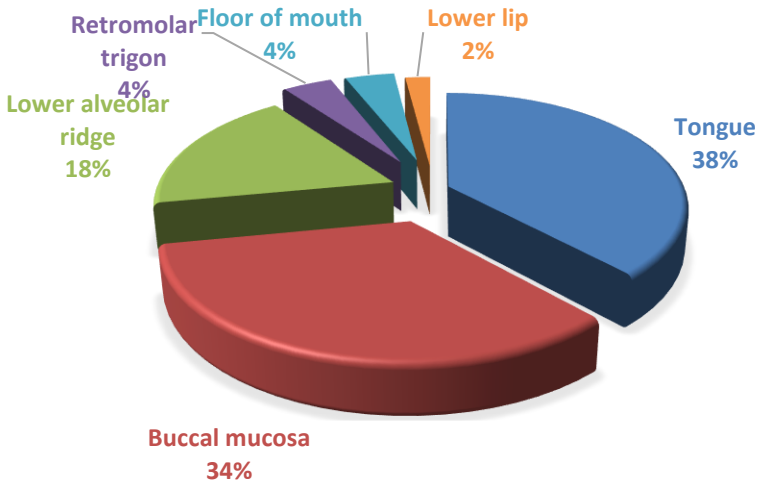

Figure (2). Percentage Subsite distribution of cancer cases

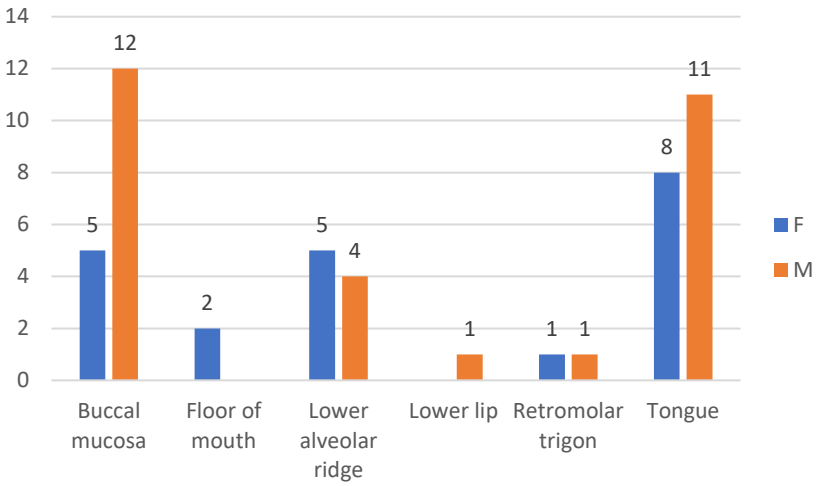

Figure (3). Percentage of Subsite distribution according to sex

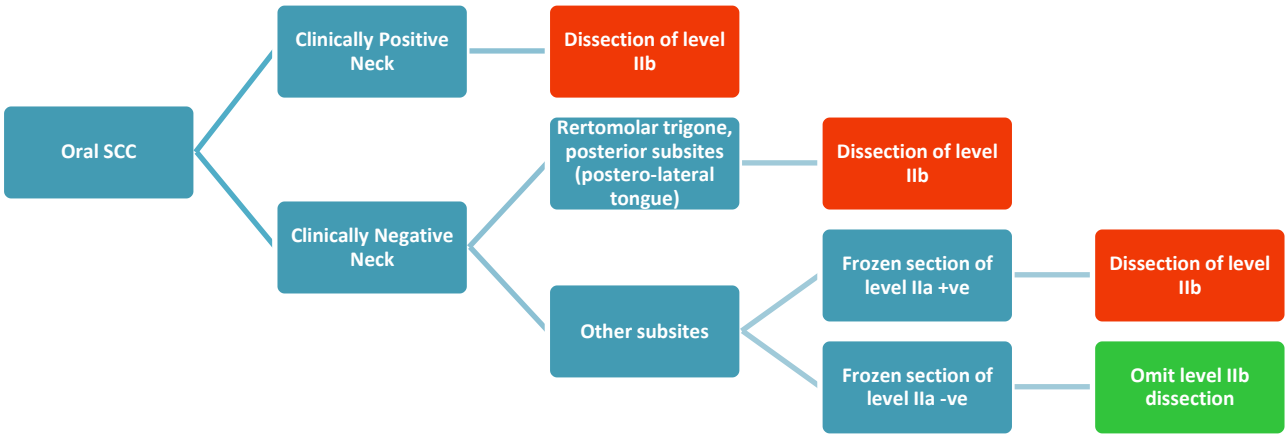

Figure (4). Proposed decision-making algorithm for level IIb dissection in oral squamous cell carcinoma

Table (3). Distribution of patient data

Category	Count	Percentage
Grade		
Well Differentiated	22	44
Moderately Differentiated	16	32
Poorly Differentiated	12	24
Stage		
IVA	21	42
III	13	26
II	10	20
I	3	6
IVB	3	6
Depth of invasion		
5–9.99 mm	33	66
0–4.99 mm	11	22
≥10 mm	6	12

Twenty-two cases (44%) were well differentiated at presentation, 16 (32%) were moderately differentiated, and 12 were poorly differentiated. Concerning the tumor stage, 21 cases (42%) were stage IVA (Table 3).

In this study, 29 patients (58%) had clinically negative lymph nodes (cN0) at the time of presentation, while 21 (42%) had clinically positive lymph nodes (cN+).

Out of 50 patients included in the study, 20 (40%) underwent unilateral supra-omohyoid neck dissection (SOHND), 26 (52%) had extended SOHND, 2 (4%) had unilateral Comprehensive Neck Dissection (CND), and 2 underwent bilateral SOHND. Eight hundred fifty-seven lymph nodes were examined, with an average of 17.14 nodes per neck dissection. Of these, 143 lymph nodes were extirpated from level IIB, with an average of 2.86 (143/50 patients).

Eight of 29 patients (27.6%) who were cN0 at presentation had occult metastasis, with an average of 2 nodes per patient, all in level IIa; however, none of the cN0 patients had level IIb involvement pathologically. The total number of patients with pathologically positive nodes (pN+) included in the study was 29 patients (58%). The rate of extracapsular lymphatic extension was 8%, with 4 cases involved (Table 4).

Out of 50 patients included in the study, level IIb involvement was observed in only 2 cases (4%). Notably, both cases exhibited concomitant level IIa involvement, and no isolated level IIb involvement was detected. In all patients with clinically node-negative (cN0) disease, no metastasis to level IIb was seen, while the clinically node-positive (cN+) group demonstrated a 9.5%; 2 of 21 cN+ patients had level IIb involvement (Table 4).

Table (4). Characteristics of lymph nodes studied

Category	Count	Percentage
Clinically Positive LN		
Positive	21	42
Negative	29	58
Pathologically Positive LN		
Positive	29	58
Negative	21	42
Extracapsular extension		
Positive	4	8
Negative	46	92
Level IIb involvement		
Positive	2	4
Negative	48	96

A significant association was found between tumor site and level IIb lymph node (LN) involvement (p-value < 0.05, Chi-square test). On the other hand, there was no significance for other variables like age (p-value > 0.05, T-test), sex (p-value > 0.05, Fisher's test), grade (p-value > 0.05 Chi-square), DOI (p-value> 0.05, Mann–Whitney U), and size (p-value > 0.05, Mann–Whitney U) as predictor for level IIb involvement (Tables 5 and 6).

Table (5). Significance of variables with normal distribution as a predictor for level IIb involvement

Variable	p-value	Test Used
Age	0.2675	T-test
Subsite	0.03	Chi-square
Grade	0.1	Chi-square

Table (6). Significance of variables with skewed distribution as a predictor for level IIb involvement

Variable	IIB Negative (n=48)	IIB Positive (n=2	p-value	Test Used
Tumor size (cm)	4.2 [3.5–5.0]	3.5 [3.2–3.8]	0.319	Mann–Whitney U
Depth (mm)	6.0 [5.0–8.0]	7.0 [6.5–7.5]	0.617	Mann–Whitney U
Clinically +ve[§] LN	0.0 [0.0–1.0]	1.0 [1.0–1.0]	0.099	Mann–Whitney U
Pathologically +ve LN	1.0 [0.0–3.0]	9.5 [8.2–10.8]	**0.022**	Mann–Whitney U
Sex	F[†]: 21 (43.8%); M[‡]: 27 (56.2%)	F: 0 (0.0%); M: 2 (100.0%)	0.503	Fisher's Exact
ECE[*] (positive)	4 (8%)	1 (50%)	0.192	Fisher's Exact

[§]+ve: positive**;** [†]F: female; [‡]M: male; [*]ECE: extracapsular extensi

DISCUSSION

In OSCC, lymphatic metastasis is the single most important prognostic factor, reducing the survival rate by 50% (17). It typically follows a predictable pathway mainly to levels I, II, and III, and sometimes to levels VI and V (18).

Since the early 20th century, neck dissection, as a therapeutic concept, underwent a major revolutionary development to increase the survival rate and decrease the

associated comorbidities (19). However, despite all efforts to circumvent complications, they still do occur, and the argumentative issue of the extent of neck dissection is still an area of debate and research (13).

One of the frequent complications of neck dissection, especially in elective procedures, is shoulder dysfunction ranging from 10-100% in comprehensive neck dissection (CND) and 9-25% in SND, imposing a direct relation between the extent of surgery and post-operative outcome (20,21). The cause of dysfunction can be attributed to direct injury to the spinal accessory nerve or excessive traction to facilitate access to the area for good clearance (9,21).

In their 11-year retrospective study of 389 cN0 OSCC patients, Duvernay, J. et al. (22) found no evidence of metastasis in level IIb. These findings agree with the results of this study, in which level II was not involved in all cN0 patients; however, only 2 of 21 cN+ patients (9.5%) had level IIb involvement. These data challenge the therapeutic benefits of dissecting level IIb when compared to the quality of life associated with the increased prevalence of patients with shoulder dysfunction

Immunohistochemical staining has been found to be advantageous for detecting micrometastases in lymph nodes. (22–24) Therefore, immunohistochemical staining using cytokeratin 5/6 was implemented in all study samples to enhance the detection sensitivity.

Subsites of the primary

Two cases out of 50 (retromolar trigon, buccal mucosa) showed metastatic deposits in level IIb, and there was a significant relation between subsite and level IIb involvement (p-values = 0.03); anatomical proximity could be a possible cause for such results. Other studies revealed that subsites could be a significant predictor; however, the tongue and gingivo-buccal sulcus were the most significant subsites with a metastatic propensity to level IIb involvement (25–27). These disparities in results can be attributed to differences in sample size and methodology.

Lymph nodes

There was an association between the clinical status of lymph nodes cN+ and level IIb lymphatic involvement; however, this relation did not reach statistical significance (p-value = 0.09). No evidence of skip lymphatic metastases was observed in the studied samples. In the only cases where region IIb was involved, concomitant level IIa involvement was present, making the clinical involvement level IIa a strong indication for dissection of the entire level II. The findings were consistent with results from previous studies, where a strong association was found between level IIa positivity and level IIb metastasis (9,25,26,28–33).

Depth of invasion

Although the depth of invasion(DOI) is considered an independent predictor for early lymphatic metastasis (34–36), this study's results showed no significant impact of DOI as a predictor for region IIb involvement, especially in cN0 cases. These results align with data from previous studies that did not show a direct relation between DOI and level IIb involvement or the possibility of skip metastasis to this region (31,33,37–39).

On the other hand, clinicopathological variables like sex, grade, and size were not significant predictors of involvement of level IIb. The limited sample size might have affected the significance of the results, though data from this research align with data from other studies with larger sample sizes (9,40).

Clinical implications

According to our findings, a pragmatic decision-making strategy for level IIb neck dissection in oral SCC is suggested, considering the primary tumor subsite and clinical neck status (Figure 4). For patients with a clinically positive neck (cN+), standard inclusion of level IIb dissection seems appropriate. For cN0 clinically negative necks, a more judicious strategy can be applied: level IIb dissection can be advocated for retromolar trigone or other posterior location tumors, such as posterolateral tongue. For the rest of tumor locations, intraoperative frozen section analysis of level IIa nodes can guide the decision; in case of no metastasis, level IIb dissection avoidance could be

safe. This technique strives to reduce accessory nerve manipulation morbidity without compromising oncologic outcomes in adequately selected patients.

CONCLUSIONS

Within the limitations of this study:

The routine dissection of level IIb is not recommended, particularly on an elective basis for clinically negative lymph nodes (cN0). However, for therapeutic neck dissection, where clinical node involvement is evident, dissection of level IIb is highly recommended. Advanced-stage disease, tumor subsite, and certain pathological features may increase the likelihood of this level of involvement. Future research, comprising more extensive multicenter studies employing advanced molecular diagnostics, imaging modalities, and other biomarkers to refine the results and strengthen the decision, is recommended.

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Authors' Contribution

Shazo S contributed to conceptualization, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, validation, visualization, writing–original draft, writing–review and editing.

Ethical statement:

Ethical approval to use human material and data was granted by the Research Ethics Committee of the Duhok General Health Directorate, with license number (**05022025-2-3**), on the fifth of February, 2025; the patients' consent to participate was waived by the committee.

Conflict of interest

The author declares that there are no conflicts of interest regarding the publication of this manuscript.

Availability of data and materials: All data generated or analyzed during this study are included in this published article.

Declaration of Generative AI and AI-assisted technologies

While preparing this work, the author used ChatGPT 4.0 and Grammarly (Grammarly Inc.) web service to improve the manuscript's readability and correct grammatical issues. After using this tool, the author reviewed and edited the content as needed and takes full responsibility for the content of the published article.

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تقييم ضرورة استئصال المستوى الثاني ب في سرطان الخلايا الحرشفية الفموية: دراسة أترابية استرجاعية في السكان العراقيين

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الملخص

الأهداف: هدفت هذه الدراسة إلى تقييم ضرورة استئصال العقد اللمفاوية من المستوى الثاني (ب) لدى المرضى ضمن مجموعة عراقية. **المواد وطرائق العمل:** تم تحليل البيانات النسيجية والسريرية لخمسين مريضًا مصابًا بسرطان الخلايا الحرشفية الفموية (29 ذكرًا و21 أنثى)، والذين عولجوا بين يونيو 2018 ويونيو 2020. أُجريت دراسات نسيجية على 857 عقدة لمفاوية، منها 143 عقدة من المستوى الثاني (ب)، بعد التلوين المناعي النسيجي باستخدام السيتوكيراتين 6/5. قيّمت الاختبارات الإحصائية مؤشرات التنبؤ بانتشار الورم إلى المستوى الثاني (ب). **النتائج:** لوحظ انتشار الورم إلى المستوى الثاني (ب) في حالتين فقط (4%) مع وجود نقائل متزامنة إلى المستوى الثاني (أ). لم يُرصد أي انتشار منفرد للورم إلى المستوى الثاني (ب). كان موقع الورم الأولي (قيمة $p = 0.03$) مؤشرًا هامًا للتنبؤ بانتشار الورم إلى المستوى الثاني (ب). لم تُظهر متغيرات أخرى، مثل العمر (قيمة $p = 0.2675$)، والجنس (قيمة $p = 0.503$)، ودرجة الورم (قيمة $p = 0.1$)، وعمق الغزو (قيمة $p = 0.617$)، والحجم (قيمة $p = 0.319$)، وحالة العنق (قيمة $p = 0.099$)، أي ارتباط ذي دلالة إحصائية مع إصابة العقد اللمفاوية من المستوى IIb. **الاستنتاجات:** لا داعي للاستئصال الروتيني للعقد اللمفاوية من المستوى IIb في حالات سرطان الخلايا الحرشفية الفموية ذات الأعراض السريرية السلبية، وينبغي حصره في الحالات ذات الأعراض السريرية الإيجابية أو المتقدمة. هناك حاجة إلى مزيد من الدراسات التي تتضمن تقنيات تشخيص متقدمة لتحسين الإرشادات السريرية.

الكلمات المفتاحية: المستوى IIb، نقائل العقد اللمفاوية، سرطان الفم، خلل وظائف الكتفالكلمات المفتاحية: الدقة، نموذج الأسنان، راتنج صديق للبيئة، راتنج نباتي، طباعة ثلاثية الأبعاد، خصائص ميكانيكية.