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Original Research Article

A STUDY ON SENTINEL LYMPH NODE BIOPSY IN ORAL CAVITY SQUAMOUS CELL CARCINOMA -AN INTERIM ANALYSIS

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ABSTRACT

Background: Management of the clinically node-negative (cN0) neck in early oral cavity squamous cell carcinoma remains challenging. Elective neck dissection, though oncologically effective, leads to overtreatment and increased morbidity in a significant proportion of patients. Sentinel lymph node biopsy (SLNB) has emerged as a minimally invasive technique that allows accurate staging of the neck while potentially avoiding unnecessary neck dissection. The aim is to evaluate the feasibility and diagnostic yield of sentinel lymph node biopsy in early oral cavity squamous cell carcinoma. **Materials and Methods:** This prospective observational study included patients with T1–T2 oral cavity squamous cell carcinoma and clinically/radiologically node-negative necks. SLNB was performed using a dual-tracer technique with indocyanine green (ICG) and methylene blue, as per institutional protocol. Sentinel lymph nodes were identified intraoperatively using near-infrared fluorescence and visual dye uptake and were subjected to histopathological examination. Clinicopathological variables including depth of invasion (DOI), perineural invasion (PNI), lymphovascular space invasion (LVSI), and worst pattern of invasion (WPOI) were analyzed. An interim analysis of the first 10 patients is presented. **Result:** Sentinel lymph nodes were successfully identified in all patients, yielding a detection rate of 100%. Occult nodal metastasis was detected in 20% of clinically node-negative patients. The mean number of sentinel lymph nodes identified per patient was 2.7. Higher DOI and adverse pathological features such as LVSI and higher WPOI demonstrated a directional association with SLN positivity, though statistical significance was not achieved in this interim cohort. At a median follow-up of 4–8 months, no regional recurrences were observed. **Conclusion:** The interim results demonstrate that sentinel lymph node biopsy is a feasible and reliable staging modality for the cN0 neck in early oral cavity squamous cell carcinoma. SLNB accurately identifies occult nodal metastasis and has the potential to reduce unnecessary elective neck dissections. Completion of planned recruitment and longer follow-up are required to confirm oncologic outcomes.

INTRODUCTION

Oral cavity squamous cell carcinoma (OCSCC) represents one of the most common malignancies encountered in head and neck oncology, particularly in the Indian subcontinent, where the prevalence of tobacco chewing, smoking, and betel nut consumption is high. Cervical lymph node involvement is the single most important prognostic factor influencing survival in these patients.[1-15]

Even in early-stage oral cavity cancer (T1–T2), occult cervical lymph node metastasis has been reported in approximately 20–30% of patients.[9,16] This presents a significant challenge in the management of the clinically node-negative (cN0) neck. Traditionally, elective neck dissection (END) has been recommended for early oral cavity cancers to address the risk of occult metastasis. Although END improves regional control, it leads to overtreatment in nearly 70–80% of patients who do not harbor nodal disease and exposes them to unnecessary morbidity such as shoulder dysfunction, sensory deficits, cosmetic deformity, and prolonged hospital stay.[11,12]

Sentinel lymph node biopsy (SLNB) has emerged as a minimally invasive alternative for staging the cN0 neck. The principle of SLNB is based on the concept that lymphatic drainage from a primary tumor follows an orderly and predictable pattern, and that the first draining lymph node(s), termed the sentinel

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lymph node(s), reflect the metastatic status of the entire nodal basin. If the sentinel node is free of metastasis, the probability of involvement of the remaining nodes is extremely low.[1,2]

SLNB is well established in breast cancer and malignant melanoma and has gained increasing acceptance in head and neck oncology over the last two decades. Several prospective studies and meta-analyses have demonstrated high sentinel node detection rates, acceptable false-negative rates, and excellent negative predictive values for SLNB in early oral cavity cancer.[3-6] However, data from Indian centers are limited. Therefore, this study was undertaken to evaluate the feasibility and early outcomes of SLNB in early OCSCC using a dual-tracer technique with indocyanine green (ICG) and methylene blue.[13-21]

Enhanced Detection Accuracy with Dual Tracer (ICG & Methylene Blue) — ICG fluorescence imaging allows precise, real-time visualization of lymphatic drainage pathways, even in deeper tissue planes. Methylene blue provides visual confirmation through direct staining, aiding in intraoperative SLN identification. The combination of these dyes is expected to improve sensitivity and specificity in SLN detection compared to single-agent techniques.[7,8]

Reduction in False Negatives & Improved Staging — A significant limitation of SLNB is the risk of false-negative results, which can lead to understaging and inadequate treatment. Using a dual-dye technique may improve SLN identification rates, increasing diagnostic accuracy and leading to better treatment decisions.[5,6]

Safety & Feasibility — Both ICG and methylene blue are widely used in clinical practice with well-established safety profiles. The combination of these tracers is expected to be a feasible and effective strategy for SLN mapping in oral cancer without significant adverse effects.[7,8]

Potential Impact on Clinical Practice — This study aims to refine the standard approach to SLNB in oral cancer, providing evidence for a more effective and less invasive technique. If proven successful, the combined use of ICG and methylene blue could be integrated into routine clinical protocols, leading to better patient outcomes and improved surgical decision-making.[3,4,21]

Aim: To evaluate the role of sentinel lymph node biopsy in staging the clinically node-negative neck in early oral cavity squamous cell carcinoma.

Objectives:

- To determine the sentinel lymph node detection rate, accuracy, and safety using a dual-tracer technique.
- To estimate the incidence of occult cervical nodal metastasis in clinically node-negative patients.
- To correlate sentinel lymph node positivity with pathological risk factors such as depth of invasion (DOI), perineural invasion (PNI), lymphovascular space invasion (LVSI), and worst pattern of invasion (WPOI).
- To assess early postoperative outcomes and short-term regional control.

MATERIALS AND METHODS

Study design and setting: This study was designed as a prospective observational clinical study conducted in the Department of Surgical Oncology at a tertiary care teaching hospital. The study was carried out over a period of one year. Institutional Ethical Committee approval was obtained prior to the commencement of the study, and written informed consent was taken from all patients.

Patient selection

Inclusion criteria

- Age ≥ 18 years
- Histologically proven squamous cell carcinoma of the oral cavity
- Early-stage primary tumor (T1 or T2)
- Clinically and radiologically node-negative neck (cN0)
- Fit for surgical management and willing to give informed consent

Exclusion Criteria

- Recurrent oral cavity cancer
- Previous neck surgery or radiotherapy
- Known hypersensitivity to indocyanine green or methylene blue

Methods of study

- Preoperative Preparation: Primary tumor was evaluated clinically and radiologically with contrast-enhanced computed tomography/ magnetic resonance imaging from the base of the skull to the neck whenever required and staged according to American Joint Committee on Cancer 8th Edition. Negative nodal status was confirmed clinically which included ultrasound neck. Standard anesthesia evaluation and preoperative workup were done.
- **Tracer Injection (ICG & Methylene Blue):** Indocyanine Green (ICG): 0.5–1.0 mg/ml injected peritumorally in four quadrants around the primary tumor site. This allows lymphatic uptake and near-infrared fluorescence imagingMethylene Blue: 1–2 ml (1%) injected in the same peritumoral regions to aid visual identification of SLNs intraoperatively. Time Interval: 10–15 minutes allowed for tracer migration before SLNB.
- **Intraoperative Sentinel Lymph Node (SLN) Detection:** A near-infrared fluorescence camera (using laparoscopic infrared camera) for ICG is used to track fluorescent lymphatic drainage pathways. Methylene blue-stained nodes are identified visually. SLNs are carefully dissected and excised
- **SLN Histopathological Examination:** The excised SLNs are sent for frozen section and final histopathology. Hematoxylin & Eosin (H&E) staining followed by immunohistochemistry

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(IHC) for cytokeratin if required. SLN positivity is correlated with final histopathological findings

- **Neck Dissection Decision:** Neck dissection will be continued with a minimum of selective neck dissection (SND) (extended supraomohyoid neck dissection [ESOHND] for tongue primary and supra omohyoid neck dissection [SOHND] for rest of subsites) if frozen is negative or modified radical neck dissection (MRND) if frozen is positive.

RESULTS

A total of 10 consecutive patients with early oral cavity squamous cell carcinoma fulfilling the study eligibility criteria were included in this interim analysis. All patients underwent sentinel lymph node biopsy using the dual-tracer technique as per the study protocol. No patient was excluded after enrollment, and SLNB was successfully attempted in all cases.

Baseline demographic and clinicopathological characteristics: The mean age of the cohort was 57.0 years (range 46–70). There was a female predominance (70%). Buccal mucosa constituted the most frequent primary tumor site (60%), followed by tongue (30%) and lip (10%). Majority of tumors were staged as T2 (70%). The mean depth of invasion was 6.0 mm (range 0.3–10 mm). Perineural invasion and lymphovascular space invasion were present in 10% of cases each. High-risk worst pattern of invasion (WPOI 4–5) was observed in 40% of tumors.

Table 1: Baseline characteristics (n = 10)

Variable	Value
Age (years)	Mean 57.0 (Range 46–70)
Gender	• Male 3 (30%), • Female 7 (70%)
Primary site	• Buccal mucosa 6 (60%), • Tongue 3 (30%), • Lip 1 (10%)
T stage	• T1 3 (30%), • T2 7 (70%)
Tumor grade	• Well 7 (70%), • Moderate 3 (30%)
Mean DOI (mm)	6.0
PNI present	1 (10%)
LVSI present	1 (10%)
High WPOI (4–5)	4 (40%)

Sentinel lymph node biopsy performance: Sentinel lymph nodes were successfully identified in all patients, yielding a detection rate of 100%. The mean number of sentinel lymph nodes identified per patient was 2.7. Occult nodal metastasis was detected in 2 patients, resulting in an SLN positivity rate of 20%, despite all patients being clinically node-negative.

Table 2: Sentinel lymph node outcomes

Parameter	Result
SLN detection rate	10/10 (100%)
SLN positivity rate	2/10 (20%)
SLN negativity rate	8/10 (80%)
Mean number of SLNs	2.7

Clinicopathological factors associated with SLN positivity: SLN-positive patients tended to be older and demonstrated a higher prevalence of adverse pathological features such as LVSI and high WPOI. Both SLN-positive patients had high-risk WPOI (4–5). These trends were clinically meaningful but did not reach statistical significance due to small sample size.

Table 3: Clinicopathological variables by SLN status

Variable	SLN− (n=8)	SLN+ (n=2)
Median age (years)	55	64.5
T2 stage	5 (62.5%)	2 (100%)
Mean DOI (mm)	6.1	5.8
PNI present	1 (12.5%)	0
LVSI present	0	1 (50%)
High WPOI (4–5)	2 (25%)	2 (100%)

Postoperative outcomes:

All patients tolerated the procedure well without major perioperative complications. Completion neck dissection was performed in both SLN-positive patients. At a median follow-up of 4–8 months, no regional recurrences were observed. All patients were alive and disease-free at last follow-up.

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DISCUSSION

Sentinel lymph node biopsy (SLNB) offers a minimally invasive alternative that enables accurate pathological staging of the neck while avoiding unnecessary surgery.[1,2]

Detection rate – comparison with literature: In this study, the sentinel lymph node detection rate was 100%, which is comparable with high detection rates reported in major international studies. Civantos et al. reported detection rates exceeding 95%, while the European SENT trial documented a detection rate of approximately 99.5%.[3,4] Meta-analyses have consistently shown pooled detection rates between 95% and 99%.[5,6]

Table 4: Comparison with previous studies

Study	No. of patients	Detection rate (%)	Occult metastasis (%)
Civantos et al.	106	~95	~26
SENT Trial (Europe)	>400	~99.5	~23
Meta-analysis (Liu et al.)	3566	96.3	20–30
Present study	10	100	20

Occult metastasis rate and oncologic significance: Occult nodal metastasis was detected in 20% of clinically node-negative patients in this study. This is consistent with the reported incidence of occult metastasis in early OCSCC, which ranges from 20% to 30%.[9,10] This finding reinforces the limitation of clinical and radiological staging alone and highlights the oncologic importance of SLNB.

Morbidity-sparing potential of SLNB: In the present study, 80% of patients avoided elective neck dissection, confirming the morbidity-sparing advantage of SLNB. END is associated with shoulder dysfunction, sensory deficits, cosmetic deformity, and reduced quality of life. By selectively treating only SLN-positive patients, SLNB allows individualized neck management without compromising oncologic safety.[11-13]

Pathological predictors of SLN positivity: SLN-positive patients demonstrated a higher prevalence of adverse pathological features, particularly high-risk worst pattern of invasion (WPOI 4–5) and lymphovascular space invasion (LVSI). Although statistical significance was not achieved due to small sample size, these trends are biologically plausible and consistent with existing literature.[15-17]

Depth of invasion: Depth of invasion (DOI) did not show a significant difference between SLN-positive and SLN-negative patients in this interim cohort. This is likely due to limited statistical power, as larger studies have demonstrated a strong association between DOI and nodal metastasis.[18-20]

Short-term oncologic outcomes: At a median follow-up of 4–8 months, no regional recurrences were observed in either SLN-positive or SLN-negative patients. These short-term outcomes are reassuring and comparable to previously published series.

Indian relevance: The present study provides valuable data from an Indian tertiary care center and demonstrates that SLNB is feasible, safe, and reproducible in the Indian setting.

Limitations: This is an interim analysis with a small sample size and limited follow-up; therefore, long-term oncologic outcomes must be interpreted cautiously.

CONCLUSION

This interim study demonstrates that SLNB is a feasible and reliable staging modality for the clinically node-negative neck in early oral cavity squamous cell carcinoma. The detection rate and occult metastasis rate are comparable with major international studies, and most patients were spared elective neck dissection without compromising short-term regional control.

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