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**Title: Sentinel lymph node biopsy versus selective neck dissection in patients with early oral squamous cell carcinoma: a cost analysis**

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ABSTRACT:

**Objective:** Sentinel lymph node biopsy (SLNB) has been proved to be as efficient as selective neck dissection (SND) for the treatment of occult metastases in T1-T2cN0 oral squamous cell carcinoma (OSCC). The aim of our study was to assess and compare the cost of these two surgical procedures.

**Patients and methods:** This retrospective cost analysis includes consecutive patients treated between 2012 and 2017 in two French hospitals either by SLNB or SND. Hospital cost (hospital stay for initial surgery and re-hospitalizations over a period of 60 days after the initial surgery), the length of hospital stay for the initial surgery and the perioperative management were described and compared between the two techniques. The propensity score regression adjustment method was used to address selection bias.

**Results:** Ninety-four patients underwent SLNB procedure and seventy-seven patients underwent SND. The length of hospital stay for initial surgery was lower in SLNB group: 5.8 days (SD: 3.8) versus 9.2 days (SD: 5) in the SND group. Hospital costs were lower in SLNB group: €7 489 (standard deviation: €3 691) versus €8 886 (standard deviation: €4 381) but this difference was not significant after propensity score regression adjustment. The rate of complication, the delay of full oral feeding and postoperative drainage were lower in SLNB group.

**Conclusion:** SLNB in T1-T2cN0 OSCC is less invasive than SND with fewer complications, a shorter length of hospital stay and favorable perioperative management. This study shows that this technique could be also less expensive than SND.

## INTRODUCTION

Oral squamous cell carcinoma (OSCC) is among the most frequent cancers worldwide (1). Half of the patients are diagnosed at an early stage (T1 or T2, cN0) while 20 to 30% have occult lymph node metastases, a significant prognostic factor (2, 3).

The guidelines (4, 5) for the detection of occult lymph node metastases are to systematically perform a CT scan in addition to a complete clinical examination. However, these procedures are insufficiently sensitive and 20% of the cN0 cases have lymph node metastases (6).

Selective neck dissection (SND) of areas I to IV is currently recommended for OSCC. This procedure, even in small tumors, improves overall survival, disease free survival and reduces local recurrence rate comparing to watchful waiting (7, 8). However, this procedure is invasive with postoperative complications such as lymphorrhea, infections, chronic pain and shoulder dysfunction induced by the dissection of the spinal nerve (9, 10).

Sentinel lymph node biopsy (SLNB) has been used for the management of OSCC in early stage for years. Several clinical studies showed that SLNB is as effective as SND in terms of overall survival and disease-free survival in the long term (11, 12, 13). Recently, a French multicentric phase III trial proved the equivalence of oncologic outcomes between SLNB and SND for T1-T2cN0 OSCC with better functional outcomes in the SLNB group, defining SLNB as the new standard of care (14). The SLNB procedure in oral cancer is already recommended in national practice guidelines in the UK (5), in Denmark and in the US (4). However, this technique is still not widely used in France. In other European countries, SLNB was shown to be less expensive than SND (15, 16, 17, 18). Such economic data were not available in the French context.

Our objective was to perform a cost analysis comparing SLNB versus SND in patients with T1-T2 cN0 SCC of the oral cavity.

## **PATIENTS AND METHODS**

This was a retrospective study in patients with T1-T2cN0 OSCC staged after clinical examination and imaging (CT-scan +/- MRI). Patients underwent SLNB or SND (I-III or I-IV) between January 2012 and December 2017 in two hospitals (Tours University Hospital (TUH) and Gustave Roussy Cancer Campus (GR)).

This study was performed once approval was received from the local Research Ethics Committee, in accordance with the World Medical Association – Declaration of Helsinki – ethical principles for medical research. Each patient provides a written informed consent for care and the use of their data for studies.

As consensual guidelines for the management of T1-T2cN0 OSCC have not been established in France, we compared the results of two different departments recognized for their expertise in the field of head and neck cancer treatment, but with different therapeutic algorithm for T1-T2cN0: one performing both techniques (GR) and the other, only SND (TUH).

### **Sentinel lymph node biopsy protocol**

The SLNB procedure (19) consist of four injections of <sup>99m</sup>Tc-rhenium few hours before surgery around the tumor. The detection of SLNB is by dynamic lymphoscintigraphy or SPECT-CT. In case of failure of sentinel node detection, a selective neck dissection was performed. If the sentinel node was detected, the surgeon uses a gamma probe identify it during the surgery and send one to three sentinel nodes for frozen section primary analysis. If the radioactive signal did not permit the identification of one sentinel node, the entire area containing the sentinel lymph node was removed. In case of floor of mouth tumor with extension near the Wharton canal, a sub-mandibular gland resection was systematically performed. If the frozen section had shown tumor cells, a modified radical neck dissection (MRND) was carried out. A second analysis with hematoxylin and eosin staining was performed. If tumor cells were found, a MRND was carried out within a month.

### **Patients**

All patients who underwent either SLNB or SND between January 2012 and December 2017 were identified through administrative databases or medical registries available in both

centers. We reviewed the medical records of all these eligible patients and selected T1/T2 N0 patients. Patients with a multifocal tumor, history of neck dissection, radiotherapy of the neck or free-flap reconstruction were excluded.

We distinguished five groups of patients according to the type of surgical procedures performed. One group of patients had SND only and four groups of patients had SLNB. Node-negative patients (pN0) who underwent SLNB were divided into two subgroups: SLNB alone for patients with one to three nodes analyzed and expanded SLNB when the excision of submaxillary gland was necessary. Node-positive patients (pN+) who underwent SLNB were also divided into two subgroups: patients with SLNB followed by MRND during the same procedure (based on the results of frozen section), and patients with SLNB followed by MRND in a second hospital stay due to a false negative frozen section analysis.

### **Data collection**

For each patient, we collected age, sex, TNM stage, surgical procedures, location of the primary tumor, number of days of continuous care hospitalization, duration of drainage, delay until a full oral feeding and perioperative complications (hemorrhage, infection...).

### **Cost analysis**

Costs were assessed from the perspective of healthcare providers. The cost calculation included the cost of the hospital stay for the initial surgery, the cost of the second hospital stay for delayed MRND and the cost of any subsequent hospital stay for postoperative complication over a period of 60 days after the initial surgery.

Cost data and diagnostic-related group (DRG) for each hospital stay were extracted from the hospital cost accounting system in each center. Costs accounting systems of both hospitals were comparable and included in the National Cost Study (20) (NCS). The NCS monitors the costs of administration and costs of stay, by annually collecting data from a sample of private and public hospitals in France. Several items related to the hospitalization took into account for the cost analysis are listed in Supplementary.

The primary endpoint was the difference in mean per-patient cost between the SLNB and SND techniques. In a subgroup analysis, we also estimated the mean per-patient cost in each of the five groups described above (SLNB only, expanded SLNB, SLNB plus immediate MRND,

SLNB plus delayed MRND, SND). We performed a sensitivity analysis of the mean per-patient cost varying the proportion of node-positive patients in the SLNB group.

### **Statistical analysis**

Continuous variables were described using the mean, median, with standard deviation or 95% confidence intervals. Between-group comparisons were performed using the student t-test. Qualitative variables were described using frequency and percentage and the chi square or the fisher exact tests were used for between-group comparisons.

To handle a potential selection bias due to the absence of randomization of the patients between the two techniques (SNLB and SND respectively), we used the regression-adjustment propensity score method. First, we implemented a multivariate logistic regression to estimate the probability (the propensity score) for each patient to underwent SNLB. Age, gender, tumor location, tumor grade, alcohol and smoking habits and diabetes status were included as cofounders in the model. Secondly, we used the propensity scores together with the cofounders in a separate multi covariate adjustment model in which the per-patient cost was the outcome of interest. All statistical analyses were performed using SAS version 9.4.

## RESULTS

In total, 171 patients with T1-T2cN0 OSCC were included in the cost analysis, 94 in the SLNB group and 77 in the SND group. In the SND group, 28 patients were treated in GR and 49 patients in TUH. Patient characteristics are shown in Table 1. The two groups were comparable for age, tobacco, alcohol, diabetes and other comorbidities (such as chronic inflammatory, cardiovascular or pulmonary diseases) and anatomical location of the primary and nodal status (pN). There was a statistically significant difference between the two groups for gender, size (pT), pN status, and tumor location. However, in the SND group, there was no difference in the pT1-pT2 distribution between the two centers ( $p \approx 1$ ).

The mean length of stay was significantly shorter in the SLNB group (5,8 days versus 9,2 days,  $p < 0,001$ ) (Table 2). Regarding postoperative management, the duration of drainage and the delay of full oral feeding were also significantly shorter in the SLNB group ( $p < 0,001$ ). The rate of post-operative complications was higher in the SND group (18.2% versus 8.5%,  $p = 0.06$ ).

Per-patient cost was lower in SLNB group (mean: €7 489, standard deviation: €3 691) with a difference of €1 400 compared to SND group (mean: €8 886, standard deviation: €4 381) ( $p = 0,0253$ ) (Table 2). The SLNB group was heterogeneous in terms of cost and length of stay due the pN status and the necessity to perform or not a MRND (Table 3). As expected, the cost and length of stay were higher in the two groups with immediate or delayed MRND. If the proportion of pN+ patients in the SLNB group was 20%, as usually reported in the literature, instead of 12.8%, mean per-patient cost would reach €7 789, remaining lower than SND group (Figure 1). In the sensitivity analysis, the mean per-patient cost in the SLNB group remained inferior, up to 45% of pN+ patients.

The mean cost per patient after the propensity score regression adjustment was estimated at €9 564 [95% CI: €7 646: €11 483] in the SLNB group and at €10 562 [95%CI: €8 985: €12 138] in the SND group. With a difference of €997 (standard error= €856), the mean cost per patient was not significantly different between the two groups ( $p = 0.246$ ). Variables that had a significant impact on the cost per patient were the pN status, the tumor location and the presence of surgical complications (Table 4). In average, the cost per patient increased by €2 962 ( $p = 0.006$ ) in pN+ patients. The cost per patient was increased by €2 741 ( $p = 0.012$ ) in



tumors located on the floor of mouth (reference: other parts of oral cavity). In the presence of a postoperative complication, the mean cost per patient was increased by €3 666 ( $p < 0.0001$ ). Flap reconstruction increased the cost per patient by €1 433 compared to primary closure or secondary healing ( $p = 0.068$ ). The side of lymph node dissection, whether unilateral or bilateral as well as the age and risk factors such as smoking, alcohol consumption and type 2 diabetes had no impact on the cost per patient.

## DISCUSSION

To our knowledge, this is the first cost analysis in the French context comparing the cost of two surgical procedures for node exploration of T1-T2 cNO squamous cell carcinomas of the oral cavity. In our study, SLNB procedure was less expensive than SND but after adjustment by the propensity score, this difference was not significant. The length of stay was significantly shorter in the SLNB group. Drainage duration and delay of full oral feeding were significantly lower in the SLNB group. The rate of complications was higher in the SND group. Previous economic evaluations have found that SLNB was a cost-effective option in comparison to other techniques. In Japan, Kosuda et al (21) performed an economic evaluation comparing SLNB and SND in 11 consecutive patients. SLNB procedure would save \$ 1 218 per node-negative patient compared to SND. In this study, 36% of occult nodal metastases were found. Resources taken into account in the calculation of costs were labour per hour, lymphoscintigraphy, SLNB, gamma probe or neck dissection but neither the duration of hospitalization nor the presence of complications were included. In the Netherlands, Govers (16) carried out a modeling study in a theoretical patient population. Input data were issued from a meta-analysis (2). Several strategies were compared: watchful waiting, SND or SLNB. The cost calculation was based on the duration of surgery, consumables, the hourly rate for medical staff and a length of hospital stay of 11.8 days in all strategies. The cost of SLNB was slightly higher than SND. However, in this study, the cost of hospitalization was assumed to be identical in all strategies. In our study, results show that hospital length of stay is the main cost driver with a substantial reduction in the SLNB group. Van der Linden (15), in the Netherlands, has compared several strategies: SLNB, SND, ultrasound-guided biopsy and ultrasound-guided biopsy combined with SLNB. All cost data had been collected alongside the SNUS trial (22). SLNB procedure was less expensive with a difference of €795 on average. A European multicenter study (18) has compared cost data in a cohort of 481 patients from three countries. Patients reconstructed by free flaps were not excluded, constituting a potential bias given that this complex procedure may increase significantly the total cost of management of these patients. Patients with SLNB have positive lymph nodes in 25%. A Relative Cost Ratio (RCR) for a theoretical cohort of 100 patients was

calculated to compare the cost of SLNB and SND in different centers. SLNB technique was a less costly option in each center with a relative cost ratio (RCR) between 0.35 and 0.60 (cost reduction). However, the cost reduction was dependent on the percentage of sentinel lymph node positivity because of the necessity of a second hospitalization and surgery. In case of 100% sentinel lymph node positivity, the RCR was 1.36 (cost increase). The length of stay, the duration of surgical procedure, materials, pathology and the use of the gamma camera were all taken into account and they were different among the SLNB and SND groups. However, the absolute costs were not provided and the cost of complications and the prolongation of length of stay were not taken into account in this study. Finally, a Spanish study (17) estimated the cost of SLNB and SND in a series of 73 patients. The length of stay was different between groups (7.2 days for SLNB group and 11 days for SND group) and was the main cost driver. SLNB was less expensive than SND in pN0 patients but more expensive in pN+ patients. Overall, our results are consistent with these previous findings.

Our study has some limitations. First, the distribution of the two techniques in two different centers may lead to a potential selection bias. To establish the comparability of these centers, we assessed, in the subgroup of patients with SND, the mean length of stay and the rate of postoperative complications requiring a new surgical procedure. Indeed, the surgical resection of a T1-T2 OSCC with SND constitutes a standardized procedure in head and neck oncology. Thus, no statistically significant difference was found between the two centers ( $p=0.06$  and  $p=0.175$ , respectively). Moreover, the retrospective analysis and the absence of randomization expose to another potential selection bias. The two groups were not comparable for tumor size and nodal status. We attempt to address these differences using regression-adjustment propensity score method. Finally, although the number of patients included was significant, only two centers participated in the study. Because medical practices are variable and production costs may vary from one hospital to another, our cost estimates should be completed by further studies.

## **CONCLUSION**

This is the first cost study in France assessing the cost of SLNB and SND in early oral squamous cell carcinomas. Our study shows that the cost of management could be decreased for patients undergoing sentinel lymph node biopsy versus selective neck dissection. In our study, the SLNB technique seems to reduce the length of hospital stay, the duration of drainage and the delay before resuming feeding as well as the rate of postoperative complication.

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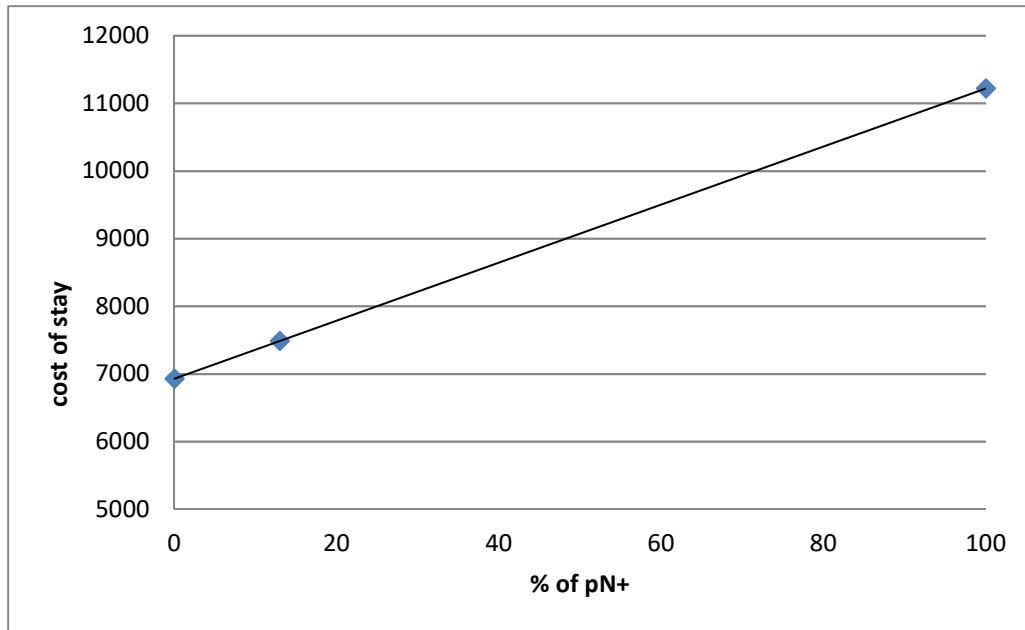


Figure 1. Cost of stay in case of SLNB procedure with variation of pN+ proportion.



**Table 1 : Patient and tumour characteristics**

	<b>Sentinel lymph node</b>	<b>Selective lymph node</b>	
	<b>biopsy</b>	<b>dissection</b>	
	<b>N (%)</b>	<b>N (%)</b>	<b>p-value</b>
<b>N</b>	94	77	
<b>Gender, Male</b>	57 (60.6)	60 (77.9)	0.0156
<b>Age, Mean (median, SD)</b>	60.5 (60, 13.2)	60.4 (59,12.4)	0.9573
<b>Size (pT)</b>			0.0012
T1	60 (63.8)	30 (39.0)	
T2	34 (36.2)	47 (61.0)	
<b>Nodal status (pN)</b>			0.0443
Node-negative	82 (87.2)	58 (75.3)	
Node-positive	12 (12.8)	19 (24.7)	
<b>Tumour location</b>			0.0402
Mobile tongue	55 (58.5)	44 (57.1)	
Floor of mouth	23 (24.5)	20 (26.0)	
Intermaxillary commissure	1 (1.1)	6 (7.8)	
Gingival	4 (4.3)	1 (1.3)	
Cheek	2 (2.1)	4 (5.2)	
Upper Lip	2 (2.1)	0	
Lower Lip	2 (2.1)	2 (2.6)	
Tonsil	4 (4.2)	0	
Velum	1 (1.1)	0	

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<b>Side</b>			
Unilateral	74 (78.7)	58 (75.3)	
Bilateral	20 (21.3)	19 (24.7)	
<b>Flap</b>			
Local flap	17 (18.1)	11 (14.3)	0.5790
Regional flap	1 (1.1)	2 (2.6)	0.4473
<b>Smoking habit</b>		Missing 1(1.3)	0.6715
Never smoke	31 (33.0)	22 (28.6)	
Past smoker	22 (23.4)	19 (24.7)	
Current smoker	41 (43.6)	35 (45.5)	
<b>Alcohol consumption</b>		Missing 1(1.3)	0.5261
No alcohol	57 (60.6)	41 (53.2)	
Stop alcohol	8 (8.5)	6 (7.8)	
Current drinking	29 (30.9)	29 (37.7)	
<b>Type 2 diabetes</b>	8 (8.5)	5 (6.5)	0.5161
<b>Other comorbidities</b>	44 (46.8)	37 (48.1)	0.8713

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**Table 2 : Cost per patient, length of hospital stay and postoperative management**

	<b>Sentinel lymph node biopsy N =94</b>	<b>Selective lymph node dissection N =77</b>	<b>P-value</b>
<b>Cost per patient, mean (median, SD)</b>	<b>7 489</b> (6 631, SD=3 691)	<b>8 886</b> (8 516, SD=4 381)	<b>0.0253</b>
<b>Length of hospital stay (days), mean</b>	5.8 (SD=3.8)	9.2 (SD=5)	<b>&lt;.0001</b>
<b>Length of hospital stay in intensive care unit (days), mean</b>	0.4 (SD=0.5)	0.3 (SD=0.6)	0.3975
<b>Length of postoperative drainage (days), mean</b>	2.1	3.3	<b>&lt;.0001</b>
<b>Time to full oral feeding (days), mean</b>	1.7 (SD=1.5)	3.9 (SD 2.9)	<b>&lt;.0001</b>

SD: standard deviation

**Table 3: Cost per patient, length of hospital stay and postoperative management in the SLNB group**

	SLNB alone N=45	Expanded SLNB N=37	SLNB + immediate MRND N=5	SLNB + delayed MRND N=7
<b>Cost per patient,</b> mean (median, SD)	6 328 (6 067, 2 405)	7 688 (7 032, 2 932)	11 193 (6 262, 10 178)	11 246 (12 121, 3 134)
<b>Length of hospital stay (days), mean</b>	4.38 (SD=4)	6.38 (SD=5)	9.80 (SD=5)	9.43 (SD=10)
<b>Length of postoperative drainage (days), mean</b>	1.6 (SD=0.9)	2.2 (SD=1.17)	3 (SD=0.82)	4.4 (SD=0.89)
<b>Time to full oral feeding (days), mean</b>	1.3 (SD=1)	1.9 (SD=1.7)	3 (SD=2.1)	1.7 (SD=1.3)

SD: standard deviation; SLNB: sentinel lymph node biopsy; RND: radical neck dissection

**Table 4: Adjusted multivariate analysis of cost difference**

	Cost difference estimate	Standard error	p-value
<b>Surgery type</b>			
SLNB (Ref: SND)	-997	856	0.2462
<b>Gender</b>			
Male (Ref : Female)	2 708	1 400	0.0551
<b>Nodal status (pN)</b>			
Node-positive (Ref : N0)	2 962	1 062	0.0060
<b>Size (pT)</b>			
T <sub>≥2</sub> (Ref : T1)	2 199	1 663	0.1883
<b>Smoking status</b>			
Current smoker	-58	768	0.9397
Stop smoking	-45	881	0.9590
Non smoker (Ref)	0	-	-
<b>Alcohol</b>			
Current drinking	399	748	0.5949
Stop drinking	-8	1 235	0.9949
No drinking (Ref)	0	-	-
<b>Type 2 diabetes</b>			
Yes (Ref : No)	-449	1 047	0.6687
<b>Recontruction by flap</b>			

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Yes (Ref : Suture or Wound Healing)	1433	780	0.0684
<b>Tumour location</b>			
Floor of mouth	2 741	1 075	0.0119
Tongue	422	921	0.6475
Other (Ref)	0	-	-
<b>Side</b>			
Bilateral (Ref : Unilateral)	88	689	0.8983
<b>Complications</b>			
Yes (Ref : No)	3 666	813	<.0001

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*A propensity score regression adjustment analysis was used. Lecture note: In this study, men have an average cost of €2708 higher than female.*