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Prospective randomized study of selective neck dissection versus observation for N0 neck of stage I-II oral tongue carcinoma in Hong Kong

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Abstract:

Background: It is well documented to have high risk of nodal recurrence of observed neck of early oral tongue carcinoma. Elective selective neck dissection is commonly practiced in the routine management of N0 neck. The aim of the present study is to conduct a prospective randomized study to address the unresolved controversies of nodal control and survival benefits of elective selective neck dissection compared with observation in the treatment of stage I-II oral tongue carcinoma.

Method: This is a multicentre prospective randomized study of elective selective I,II,III neck dissection versus observation for N0 neck of stage I-II oral tongue carcinoma. There were 35 patients in the observation arm and 36 patients in the elective neck dissection arm. The main outcome assessment parameters are nodal related mortality rate and disease free survival rate.

Results: The nodal recurrence rate, successful nodal salvage rate, nodal failure related mortality rate and actuarial 5-year disease free survival rate of the two groups of patients were 31%, 100%, 0%, 87% respectively for observation arm and were 6%, 100%, 0% and 89% respectively for neck dissection arm. There were no significant differences in nodal failure related mortality and tumor free survival rates.

Conclusions: Elective selective neck dissection has no significant benefits of both nodal failure related mortality and survival compared with observation in the management of N0 neck of early oral tongue carcinoma. Routine elective neck dissection of N0 neck is not advisable. Both options of elective neck dissection and observation should be clearly discussed with the patient, and the final selection of treatment should be judged individually by the patient.

INTRODUCTION

Oral tongue carcinoma is well documented for its propensity of subclinical nodal metastasis in the early stage. Although screening of clinically N0 neck by ultrasound, CT, MRI or PET can help to detect some of these non-palpable nodal metastases, the recurrence rate of observed neck of radiologic N0 neck can still be found in over 30% patients[1-4]. In view of the high incidence of nodal recurrence of observed neck, elective neck dissection has been advocated as routine management protocol of N0 neck of oral tongue carcinoma by many surgeons[5]. Although elective neck dissection has been well documented to be able to reduce nodal recurrence rate in retrospective studies, there is no prospective randomized study to prove its benefits of reduction of nodal failure related mortality and improvement of tumor free survival compared with observation.

There was one prospective randomized study in the literature to compare elective ipsilateral radical neck dissection versus observation in the treatment of stage I-II oral tongue carcinoma in India.[6]. In this study, the nodal recurrence rate and nodal failure rate were 58% and 40% respectively for observation arm, and were 30% and 23% respectively for elective radical neck dissection arm. There was exceptionally high nodal recurrence rate of 30% after radical neck dissection of N0 neck and also exceptionally low salvage rate of 30% of nodal recurrence of observed neck in this study. The remarkable reduction of nodal failure rate from 40% to 23% however did not improve the overall 5-year survival due to high local and distant metastasis in the neck dissection arm[6]. Another prospective randomized study of T1-3N0M0 of mixed oral tongue and floor of mouth carcinomas was conducted in France comparing observation and elective ipsilateral radical neck dissection[7]. There were also no significant differences in nodal failure rate and survival in this study. Radical neck dissection of N0 neck was performed in both prospective randomized studies.

Radical or modified radical neck dissection are considered to be over-treatment for N0 neck because of their associated risk of mortality and morbidity on shoulder function. A prospective randomized study conducted in Brazil comparing selective level I,II,III (supraomohyoid) neck dissection and modified radical neck dissection sparing the

accessory nerve for treatment of oral cavity carcinomas of T2-4 N0 M0 showed no significant difference in nodal control and surival[8]. Selective neck dissection is a more acceptable option for elective treatment of the N0 neck with lower shoulder functional morbidity.

Although elective selective neck dissection of N0 neck of early oral tongue carcinoma is the preferred treatment by many surgeons nowadays, it is still unresolved on the controversies of nodal control and long term survival benefit of elective selective neck dissection compared with observation. There is no prospective randomized study comparing selective I,II,III neck dissection and observation for stage I-II oral tongue carcinoma in the literature. The aim of the present study is to conduct a prospective randomized study to address the unresolved questions of nodal control and survival benefits of elective selective neck dissection compared with observation in the treatment of stage I-II oral tongue carcinoma.

Method and patients:

This is a multicentre prospective randomized study conducted in Queen Mary Hospital, Kwong Wah Hospital and United Christian Hospital in Hong Kong. Suitable patients were also referred to these three hospitals from co-authors of three other regional hospitals including Queen Elizabeth Hospital, Routonjee Hospital and Yan Chai Hospital for this study. The study has been approved by the research ethnic committee of The University of Hong Kong (reference number EC 807-96). The research protocol has been posted to the website of clinical trial public information centre of The University of Hong Kong for free public access of information on this study in 2005 (http://www.hkclinicaltrials.com, clinical trial registration number HKCTR-17, registration name: prospective randomized study of selective I,II,III neck dissection for stage I and II squamous cell carcinoma of oral tongue). All patients had written informed consent for the randomization of treatment of N0 neck. All patients recruited had AJCC staging of cT1-2N0M0 squamous cell carcinoma of oral tongue. All patients had pre-operative ultrasonic scanning of neck, and if necessary also had ultrasonic guided aspiration of the neck node to rule out non-palpable nodal metastasis. All patients had no

prior surgery, chemotherapy or radiotherapy treatment of the oral tongue carcinoma. Oral cavity carcinoma of other subsites and tongue base carcinoma were not included in this study. The patients were stratified into T1 and T2 for randomization with sealed envelop in order to ensure comparable T1 and T2 patients in both arms. The sample size and randomization design were based on the published data of our previous retrospective study of 63 patients demonstrating reduction of node related mortality from 23% of observation to 3% of selective neck dissection[4]. With type I error of 0.05 and power of 0.70, the minimum sample size required is 69. A sample size of 72 patients was planned to see if our previous retrospective study results could be reproducible or verified in a prospective randomized study. The patients were recruited in the period between 1996 and 2004.

All patients had transoral glossectomy with 1.5 cm resection margin according to the recommendation in our previous study[9]. Those patients who had been randomized to elective neck dissection also had ipsilateral selective level I,II,III neck dissection (SND). All pathologic specimens were serially sectioned in 3 mm interval in Queen Mary Hospital using our previous reported method[1]. The histologic slides were examined by the co-author pathologists KY Lam, WF Yuen or J Trental-Smith. Of those patients with pN+ neck, post-operative radiotherapy to the neck was advised to the patients. All patients were followed up regularly with interval of 1 month in first year, 2 months in second year, 3 months in third year, 4 months in 4th and 5th year. This policy of follow-up interval has been routine practice for all head and neck cancer patients in our hospitals and is not solely designed for this study as illustrated in our previous publication on the survival benefit of surgical salvage of early locoregional recurrences[10]. Of those patients who had nodal recurrence, radical or modified radical neck dissection would be performed. Radiotherapy to the neck after salvage radical neck dissection would be advised for all pN2-3 nodal recurrence or in presence of extra-capsular spread. Adjuvant post-operative radiotherapy was not advised to the patient for pN1 neck without extracapsular spread. The main outcome assessment parameters in this study are node related mortality and disease free survival. The data was evaluated by the first author using SPSS software.

Results

There were 72 patients recruited into the study. One clinically T2 patient who was randomized to the observation arm was found to have pathologic T3 and therefore was excluded from the data analysis in this study. The demographic data of the 71 patients were shown in Table 1. There were no significant differences in sex, age, T stage and tumor grade of the two groups. Of those 36 patients with SND, the specimens were evaluated by 3 mm serial sectioning. There were 22% (8/36) pathologic positive subclinical nodal metastases including 2 specimens having multiple metastatic nodes. None of the subclinical metastatic node had extracapsular spread. Of these 8 pN+ patients, 7(88%) patients accepted the advice to proceed to post-operative adjuvant radiotherapy treatment of the nodal metastasis.

The sites of recurrence of the two groups of patients are shown in Table 2. Of the 36 patients with SND, nodal recurrence occurred in 4%(1/28) pN0 patients and 13%(1/8) pN+ patients. There were 37% (13/35) patients of observed arm who developed nodal metastasis, of which 31% (11/35) patients had nodal recurrence alone without associated local or distant recurrence. The group on observation had significantly higher nodal recurrence alone of 31% compared with the 6% of elective selective neck dissection group (Chi-square test, p=0.006). The difference was much higher if all nodal metastases were included, 37% versus 6%.

Of the 11 patients with nodal recurrence alone on observation, the median size of nodal recurrence was 1.5cm (range 1.0 - 5.0 cm). All patients had surgical salvage. The pathologic nodal stagings of nodal recurrences of observed necks were 5 pN1, 1 pN2a and 5 pN2b. There were 45% (5/11) specimens with extracapsular spread. Based on the pathologic findings of pN2 or extracapsular spread, 7 (64%) patients accepted the advice to proceed to post-operative adjuvant radiotherapy treatment of the neck. The other 4 (32%) patients with pN1 without extracapsular spread did not have post-operative radiotherapy.

There were 2 patients with nodal recurrence after elective SND. The first patient had contralateral neck recurrence of 3.5 cm at the time of detection. He had pN0 neck on the ipsilateral elective neck dissection specimen. Pathologic examination of specimen showed multiple nodal metastasis with extracapsular spread (pN2b) on the contralateral neck recurrence. This patient died of lung metastasis subsequently after successful surgical salvage and radiotherapy treatment of contralateral neck recurrences. The second patient had pN1 on the elective SND specimen. He also received post-operative radiotherapy to the neck. He had ipsilateral level I neck recurrence of 2 cm with extracapsular spread to involve the skin. The patient had salvage neck dissection and DP flap reconstruction of neck skin. He developed ipsilateral nodal recurrence again and had further resection. He again developed ipsilateral nodal recurrence with infiltration to larynx, and eventually underwent laryngectomy. He again developed contralateral neck nodal recurrence and was salvaged by radical neck dissection and chemoradiotherapy. This patient remained alive free of tumor 8 years after the last surgical salvage.

The treatment results of recurrences are shown in Table 3. Of the 20 patients with local and/or nodal recurrences, 19 (95%) had surgical salvage. Radiotherapy or chemoradiotherapy with cisplatin were also given after surgical salvage in 74%(14/19) patients. All nodal recurrences were successfully salvaged in both groups and there was no patient who died of nodal recurrence alone. There was one patient in each group who died of lung metastasis after successful salvage of neck recurrence, overall 15% (2/13) died of distant metastasis despite successful treatment of neck recurrence.

Of those patients who were still alive at last follow-up, all were free of tumor. The minimum follow-up duration of patients who were alive free of tumor was 34 months (mean 86 months, longest 122 months). The actuarial 5-year survival rates were 87% for observation and 89% for elective neck dissection as shown in figure 1 (Log Rank test, $p = 0.89$).

Discussion

Comparing with our previous retrospective study, the nodal recurrence rate was lower (31% versus 47%) in this study due to the routine neck assessment with ultrasound and ultrasound guided fine needle aspiration cytology for all patients nowdays[4]. It again shows that ultrasonic examination is a useful but not adequate diagnostic tool for subclinical nodal metastasis, and the 31% nodal recurrence rate of observed neck remained high after ultrasonic assessment. The quantity of cancer cells in nodal micrometastasis is so scanty that it may be missed by microscopic examination on histologic sections. By using 3mm serial sectioning method, we could identify subclinical nodal metastasis in 36% patients who were assessed by clinical palpation alone without ultrasonic assessment[1]. Compared with the 47% nodal recurrence of observe neck in that period to time, we missed about 11% nodal metastasis histologically. By using the same 3mm serial sectioning method, we could identify 22% nodal metastasis in ultrasonic N0 neck. By comparing to the 37% nodal metastasis of ultrasonic N0 neck of this study, we also missed about 15% micrometastasis histologically. The data in the present study again confirmed that most nodal micrometastases could not be detected with available diagnostic technology, and subclinical nodal metastasis missed by radiologic evaluation continued to be a clinical management problem of early oral tongue carcinoma.

The nodal recurrence rate of pN0 neck after SND was very low, only 1 (4%) patient developed contralateral nodal recurrence in this study. The result is consistent with our previous report in which no patient developed ipsilateral nodal recurrence and 1 pN0 patient developed contralateral neck recurrence[4]. In considering the probable 10-15% histologically missed micrometastasis present in those pN0 neck, selective neck dissection alone is an adequate treatment for nodal micrometastasis missed histologically with minimal risk of ipsilateral neck recurrence without further adjuvant radiotherapy.

Although radical or modified radical neck dissection alone is an adequate treatment for subclinical pN+ neck, it is still controversial whether selective neck dissection alone is an adequate treatment of pN+ subclinical nodal micrometastasis particularly for patients without extracapsular spread. The question of benefit of adjuvant radiotherapy after selective neck dissection of N0 neck with subclinical pN+ neck without extracapsular

spread cannot be easily answered because the number of patients would not be enough to answer this question in any single institute. In our previous retrospective study, selective neck dissection however is not an adequate treatment for histologically pN+ neck, the ipsilateral neck recurrence rate of subclinical pN+ neck was 50%[4]. Based on our own experience, we therefore advised patients with pN+ neck to proceed to radiotherapy for possible better nodal control nowadays. One (13%) patient developed ipsilateral nodal recurrence after combined elective SND and post-operative adjuvant radiotherapy treatment of subclinical pN+ neck in this study.

The nodal recurrence rate was 0% after salvage neck dissection of nodal recurrence of observed neck. Despite the higher nodal recurrence rate of 31% of observed neck and higher nodal staging of the nodal recurrences, the results of the present prospective randomized study show that there were no significant differences on both node related mortality and disease free survival comparing selective neck dissection and observation. The benefits of elective neck dissection on nodal control and survival being published in our previous retrospective study could not be verified in this prospective randomized study.

Although there are many published papers on nodal recurrence of cN0 neck of early oral tongue carcinoma, there are only a few studies with available published details on salvage results of nodal recurrence comparing elective neck dissection and observation as shown in Table 4. The most remarkable change in this randomized study is the improvement of nodal salvage rate of nodal recurrence from 50% in our previous retrospective study to 100% in the present prospective randomized study[4]. In our previous retrospective study, patients were not closely followed up after glossectomy, many patients were found to have advanced nodal recurrence at diagnosis and had poor salvage results. None of the patients in this prospective study died of nodal recurrence irrespective to observation or elective neck dissection. There was one patient in each group who died of distant metastasis after successful salvage of nodal recurrence.

The retrospective study published by Klingerman *et al* on a mixed group of patients with both oral tongue and floor of mouth carcinomas showed low salvage rate of only 27% for nodal recurrence of observed neck and their result demonstrated survival benefit of elective neck dissection[11]. The study of Vandenbrouck *et al* showed high salvage rate of 84% and therefore their results showed no survival benefit of elective neck dissection[7]. The prospective study of Fakih *et al* showed low (30%) salvage rate of nodal recurrence of observed neck. The low salvage rate was expected to demonstrate benefit of elective neck dissection in their study[6]. However, their study also had exceptionally high (23%) nodal failure rate even after radical neck dissection of cN0 neck. It is more commonly to have less than 5% nodal failure rate after radical neck dissection of cN0 neck. Despite of the low salvage rate of observed neck, their study did not demonstrate any survival benefit of elective radical neck dissection.

The benefits on nodal control and survival of elective neck dissection depend critically on the salvage rate of observed neck. Elective neck dissection will have benefits of both nodal control and survival only on condition that the salvage rate of nodal recurrence of observed neck is low. On the other hand, elective neck dissection has no benefits of nodal control and survival if the salvage rate of nodal recurrence is high. We have previously shown that elective neck dissection had benefits of both nodal control and survival because the salvage rate of nodal recurrence of observed neck was only 50%[4]. The same conclusion could be found in the study of Klingerman *et al* in which their salvage rate was only 27%[11]. The present study however demonstrates that the nodal salvage rate could be increased significantly if the patients have been advised clearly of the risk of nodal recurrence and the necessary follow-up protocol before the treatment. Although the nodal recurrence of observed neck was in a higher stage with higher risk of extracapsular spread compared with the subclinical nodal metastasis of SND patients, the salvage rate could be as high as 100% as shown in this study in different hospitals in Hong Kong. Successful salvage could be achieved with radical or modified radical neck dissection alone without radiotherapy in 32% patients with early pN1 nodal recurrence without extracapsular spread. Combined neck dissection and radiotherapy were however necessary for nodal recurrence of pN2 or pN1 with extracapsular spread. The patients can

be reassured of the high salvage rate if they can follow our recommended follow-up protocol. There are also studies which show high salvage rate of nodal recurrence of observed neck of oral cavity carcinomas including 85% by Vandenbrouck *et al* in France[7] and 79% by Nieuwenhuis *et al* in Netherlands[12].

We have previously demonstrated the benefits of early detection of locoregional recurrences of head and neck cancers[10]. The chance of successful surgical salvage is higher if the recurrences are detected in early stage. Close follow-up is essential for early detection of locoregional recurrences. There is misconception that patients with elective neck dissection do not need close follow-up monitoring because the necks have been treated prophylactically. In fact, 17% patients who had elective neck dissection treatment would still develop either local recurrence or nodal recurrence. The nodal recurrence rate of pN+ patients was 13% after combined SND and radiotherapy treatment of the neck. The nodal recurrence rates after elective neck dissection could be as high as 30% as shown in literature review in table 4. Close follow-up is therefore essential for patients who had elective neck dissection for early detection of recurrence. Patients should be advised clearly of the importance of close follow-up monitoring with the same protocol of those on observation. The same principle of close follow-up is also applicable to all our head and neck cancer patients. Of the 19 patients who had locoregional recurrence in this study, 95% underwent surgical salvage. The high surgical salvage rates in this study again demonstrate that close follow-up and early detection of salvageable local and nodal recurrences has major contribution in achieving nearly the same high survival rates nearly 90% for patients in both observation and elective neck dissection arm.

Although elective selective neck dissection is commonly performed worldwide due to the high nodal recurrence rate of oral tongue carcinoma, there are well documented risks of shoulder morbidities including neck pain, keloid, reduced shoulder mobility and power despite preservation of functional structures of selective neck dissection[13]. We have noted a patient recently in our hospital who died of complication of post-operative bleeding in the neck after selective neck dissection of N0 neck of early stage I oral tongue carcinoma. It is more unfortunate that the N0 neck is pathologically N0. The outcome is hardly

accepted by the relatives and the surgeon in retrospect. The risks of additional mortality and morbidity of prophylactic selective neck dissection should always be clearly informed to the patient undergoing glossectomy of early tongue carcinoma.

The disadvantage of prophylactic elective neck dissection is that about 70% truly N0 neck patients will undergo unnecessary neck dissection and have to bear the additional cost of treatment, additional risk of operative mortality and morbidity. The advantage of observation is that only about 30% patients who have truly subclinical nodal metastasis require treatment. Since there were no differences in both nodal control and survival, routine recommendation to the patient for elective neck dissection of N0 neck of patients who can be closely followed up is not recommended. Of those patients who can be followed up closely according to our protocol, both observation and elective neck dissection are safe options, and observation is the preferred treatment of choice without unnecessary risks of neck dissection of the majority of patients who are truly node negative. Of those patients who are unable to be followed up closely after operation, elective selective neck dissection is a safer and recommended option.

In conclusion, elective selective neck dissection has no significant benefits of both nodal control and survival compared with observation in the management of N0 neck of early oral tongue carcinoma. Routine recommendation to the patient for elective neck dissection of N0 neck is not advisable. Both options of elective neck dissection and observation should be clearly explained to the patient, and the selection of treatment should be judged individually by the patient. Close follow-up is essential for detection of early surgically salvageable local or nodal recurrences irrespective to the choice of observation or prophylactic neck dissection treatment of the N0 neck.

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Legend:

Figure 1: Actuarial survival curves of selective neck dissection (upper curve) versus observation (lower curve).

Table 1. Demographic data

		observation **35 patients**	**SND** **36 patients**	**statistics**
sex	male	22	21	chi-square test
	female	13	15	p = 0.702
age		mean = 58 years (29-81 years)	mean = 56 years (30-77 years)	t-test p = 0.517
T stage	T1	21	22	chi-square test
	T2	14	14	p = 0.925
tumor grade	well	19	14	chi-square test
	moderate	12	18	p = 0.405
	poor	4	4	

Table 2. Sites of recurrences

treatment group	**local**	**local + node**	**node**	**distant**	**node + distant**
observe (35 patients)	2 (6%)	1 (3%)	11 (31%) *10 ipsilateral neck* *1 contralateral neck*	1 (3%)	1 (3%)
SND (36 patients)	4 (11%)	0	2 (6%) *1 ipsilateral neck within SND field* *1 contralateral neck*	0	0

Table 3. Treatments and results of recurrences

site of recurrence	observe group			elective neck dissection group		
	patient	treatment	success salvage	patient	treatment	success salvage
local	2	1 op + RT 1 op	100% (2/2)	4	1 op 1 op + RT 1 op + CTRT 1 CTRT	25% (1/4)
local + node	1	1 op + RT	0% (0/1)	0		
node	11	4 op 5 op + RT 2 op + CTRT	100% (11/11) *1 died of distant metastasis	2	1 op + RT 1 multiple op + CTRT	100% (2/2) *1 died of distant metastasis
node + distant	1	0	0% (0/1)	0		
distant	1	1 RT	0% (0/1)	0		

op = operation, RT= radiotherapy, CTRT=concurrent chemoradiotherapy

Table 4. Literature review of elective neck dissection versus observation of oral tongue carcinoma

author	tumor stage & subsites	observation			elective neck dissection			survival benefit
		node recur	success salvage	node failure	node recur	success salvage	node failure	
Fakih *et al*. 1989[6]	T1-2 tongue	58% (23/40)	30% (7/23)	40% (16/40)	30% (9/30)	22% (2/9)	23% (7/30)	no
Vandenbrouck *et al*. 1980[7]	T1-3 tongue & FOM	53% (19/36)	84% (16/19)	8% (3/36)	9% (3 /32)	0% (0/3)	9% (3/32)	no
Kligerman *et al*. 1994[11]	T1-2 tongue & FOM	33% (11/33)	27% (3/11)	24% (8/33)	12% (4/34)	25% (1/4)	9% (3/34)	yes
Yuen *et al*. 1997[4]	T1-2 tongue	47% (14/30)	50% (7/14)	23% (7/30)	9% (3/33)	67% (2/3)	3% (1/33)	yes
present study	T1-2 tongue	31% (11/35)	100% (11/11)	0% (0/35)	6% (2/36)	100% (0/2)	0% (0/36)	no

FOM = floor of mouth