

## **T1-T2 “NO” oropharyngeal cancers treated with surgery alone. GETTEC\* study**

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### **Introduction**

Early-stage cancers of the oropharynx are treated with radiotherapy alone by many medical teams<sup>[1,2,3,4]</sup>. Most studies comparing radiotherapy and surgery do so on series of T1 to T4 patients and come to the conclusion that radiotherapy is better owing to the complications linked with surgical treatments<sup>[5,6]</sup>. A preliminary study seemed to show that surgery alone in the treatment of T1-T2 NO lesions brought at least comparable carcinological results, while at the same time avoiding radiotherapy after-effects and keeping this therapeutic weapon for subsequent carcinological occurrences which often occur in these patients<sup>[7]</sup>. We present a multivariate retrospective study conducted within the framework of GETTEC with a larger number of patients. The aim of this study is to show that this surgical treatment alone gives identical carcinological results, if not better than the classic radiotherapy treatment in terms of locoregional control and survival.

### **Patients and methods**

Fifty three patients have been included in this study, all coming from the following centers: Centres anticancereux Francois Baclesse of Caen, Antoine Lacassagne of Nice, Institut Gustave Roussy, Hôpital de la Croix-Rousse and a private surgery from Dijon. They were operated on during the years1995-2000. Among them were 45 men and 8 women. The average age is 55 years old with extremes of 32 and 80 years old. All these lesions were squamous cell carcinomas.

The various localizations figure in table I. One patient presented a double localization : tonsillar fossa and uvula; two patients had a soft palate or tonsillar lesion associated with an extra oropharyngeal localization. Given this double localization, this table comprises 54 lesions in 53 patients

**Table I:** the various localizations

Tonsillar fossa	24	45,29%
Furrow amygdalo-glosse	14	26,42%
Soft palate	9	16,98%
Uvula	7	11,31%

The lesion was exophytic in 21 patients, infiltrative in 14 of them. In 18 cases this datum was not specified.

As regards TNM, 32 patients were classified T1 (60.38%), 21 T2 (39.62%). None of them presented any palpable nodes in the initial assessment.

Surgical treatment consisted in a resection by transoral approach in 43 patients (81.13%). Ten patients (18.87%) benefited from a pharyngectomy with (7) or without (3) mandibular resection

A quality control of the excision through intra operative examination was performed in 22 patients (41.51%). Two teams systematically carry out this technique at least for T2 lesions. The three other centers do not use it.

Closure was done by simple suture or by letting the tonsillar fossa heal in 44 patients (83.02%) and necessitated a reconstruction with myocutaneous flap in 9 others (16.98%).

The neck dissection consisted in a lateral and suprahyoid neck dissection (zones I thought V) in 35 patients (66.04%), one of which was bilateral, and in a lateral neck dissection (zones II thought V) in 5 patients. Thirteen patients (24.53%) did not have any neck dissection owing to medical history or bad general condition necessitating a short anesthetic procedure, or when dealing with certain T1 tonsillar lesions. In total 40 patients (75,47%) benefited from a neck dissection. These 40 neck dissections were functional ones. The average number of ganglions removed was 16 in the lateral neck dissections and 25 in the lateral and suprahyoid neck dissection.

The anatomo-pathological result showed a complete tumoral resection in the 53 patients and out of the 41 neck dissections done, 37 were free of nodal metastasis and 4 presented a single invaded node without extracapsular spread. Therefore we had 4 N0 positives cases in our series. The decision not to carry out any post-operative radiotherapy was made after reading the anatomo-pathological result and on these two criteria : complete resection, and absence of any nodal invasion or a single nodal metastasis without extracapsular spread. As regards statistics, survivals were calculated according to the actuarial method. Classical prognostic factors, macoscopic aspect of the lesion, initial localization, tumoral stage, were studied by univariate analysis using the Logrank test. Concerning the initial localization, we regrouped these different localizations in three groups: tonsillar fossa, furrow amygdalo-glosse and soft palate-uvula. Uvula lesions were regrouped with soft palate ones on account of the small number of patients in these two localizations. The data were analyzed using Access® and Statview® software.

## Results

The one-year overall survival rate of our series is 100%, the three-year rate is 94.6% and the five-year rate is 73%. There is no significant difference according to the tumoral stage

(p = 0.69). In the same way the initial localization is not a prognostic factor (p = 0.64). In the 35 cases in which the macroscopic aspect of the lesion was specified (21 exophytic and 14 infiltrative) this element is not a prognostic factor either (p = 0.65).

There is no significant difference according the management done in the different centers (p = 0.19).

Six patients died, three of an intercurrent disease and three due to the evolution of a second localization. No patient died of a local evolution.

The 5-year rate of specific survival is 100%.

The average survival without recurrence is 27 months.

The one-year rate of locoregional control is 96.22%, the 3-year rate is 92.45% and the 5-year rate is 88.68%.

The carcinological occurrences observed were two persistent diseases , five local recurrences, one nodal recurrence and eleven second primary cancers. There where no nodal recurrence in this series.

The persistent diseases (recurrence before the end of the first year) concern two patients. The first one was a 79-year-old man carrying a T2 N0 lesion of the tonsillar fossa. He benefited from a resection of his lesion by transoral approach without a neck dissection because his general condition only permitted a short anesthetic. The persistent disease was observed during the fourth month. It was treated with another surgical procedure by transoral approach and radiotherapy with succes. This patient presented a 3-year second localization.

The second patient was a 73-year-old man carrying a T1 N0 of the tonsillar fossa which was treated with transoral surgery and lateral and suprahyoid neck dissection. The persistent diseases was diagnosed at 6 months and treated with radiotherapy. This patient has been alive and free of disease for three years.

local recurrences (recurrence after the end of the first year) figure in table II. They occurred in 5 patients within a period of 12 to 37 months with an average of 24 months.

**Table II:** local recurrences

<b>TNM</b>	<b>localization</b>	<b>date of diagnostic</b>	<b>date of recurrence</b>	<b>treatment</b>	<b>follow up after recurrence</b>	<b>condition</b>
T2N0	soft palate	05/97	07/00	surg	2 years	lung evolution
T2N0	soft palate	09/99	09/01	surg	1 year	free of disease
T2N0	uvula	01/99	01/01	surg	1.5 year	free of disease
T1N0	tonsillar fossa	02/98	09/99	surg -RT	3 years	free of disease
T1N0	AGF	04/96	05/98	surg	4 years	free of disease

AGF: amygdalo-glosse furrow

surg: surgery alone

surg RT: surgery and postoperative radiotherapy

### Synthesis of locoregional failures

In the series we have seven local regional failures, two extensions of the primary tumour and five local recurrences, that is to say 13.20%. Out of these seven patients, two have an extension of a second localization and five have been free of disease within a one-to-four-year follow up period since their relapse. For four of these patients radiotherapy is still available for another possible carcinological occurrence.

### Second primary cancers

Eleven patients have presented second primary cancers, that is to say 20.75%. This appeared within an average period of 27 months, with extremes of 8 and 55 months. These second localizations were six oropharynx, two oral cavities, one hypopharynx and the two patients already mentioned : tongue - esophagus and lung.

The treatment of these second primary cancers has been with surgery alone seven times, twice with radio-surgical associations and twice with radiotherapy alone. Three patients have died, two are alive with an extension of another localization and six are alive and free of disease. For these six patients free of disease, the average follow-up period since their relapse is 19 months, one patient has been free of disease for over a year, and two of them for over three years. Four of these patients who are alive and free of disease could still, should the need arise, benefit from radiotherapy since they have never had radiation treatment.

## **Discussion**

### The population studied

The population our series study is quite comparable to the usual epidemiological data in carcinology as far as the average age and men-women distribution are concerned. As regards localization, this series is homogeneous as all the lesions concern the tonsillar fossa, the soft palate, furrow amygdalo-glosse or the uvula. The macroscopic aspect of the lesion is missing in eighteen observations, but we have seen that in the other thirty-five, this aspect had no influence on survival. This macroscopic aspect is classically a predictive factor of response to radiotherapy but is not a prognostic factor in these patients treated with surgery alone for these small lesions. Finally let us repeat that this is a selected population since the decision of surgical treatment alone is made after surgery in the light of the anatomo-pathological report.

### Survival and local control

In the literature, the study of survival according to tumoral stages and the treatments used is not always easy to assess. The series published generally comprise all tumoral stages and finally few studies bear on these early-stage lesions particularly without any nodal metastasis <sup>[1,2,7]</sup>. Similarly in the series of oropharyngeal cancers treated with radiotherapy alone, the anatomo-pathological study of nodes is of course missing. However 52 to 64% of T1-T2 patients are N0 <sup>[1,2]</sup>.

This being said, we observe that the 3-year survival rate of oropharynx T1-T2 patients treated with radiotherapy alone is 90% and the 5-year rate varies from 43 to 83% for T1 patients. The 3-year rate for T2 patients moves to 71-80% and their 5-year rate to 39-68% (table III). The 3-year survival rate in our series for T1 and T2 together is 94.6% and the

5-year rate 73%. These survival figures are comparable to those in the literature studying surgical treatment alone of early-stage oropharyngeal cancers<sup>[9]</sup>.

**Table III : survival of T1-T2 lesions in the literature**

Authors	Patients	3-year survival		5-year survival	
		T1	T2	T1	T2
Lusinchi <sup>[2]</sup>	193		73%	64%	56%
Bataini <sup>[10]</sup>	465	90%	80%		
Johansen <sup>[3]</sup>	213			57%	51%
Perez <sup>[11]</sup>	296			76%	54%
Lee <sup>[4]</sup>	243			44%	57%
Regueiro <sup>[12]</sup>	254			43%	39%
Cuisnier <sup>[1]</sup>	95	89%	71%	83%	68%
GETTEC	53	94,6%		73%	

We do not note any significant difference between the various T stages as we have few deaths and therefore T1 and T2 groups with few occurrences. We note four deaths among the T1 and two among the T2.

In the same way, specific survival and local control rate are noticeably better in our series than in these various series<sup>[1,11]</sup>. This improvement in survival due to surgery alone can be explained in two ways. On the one hand because we note no nodal recurrence in our series. On the other hand, the fact of operating on these early-stage lesions makes it possible to treat them with equal chances of success, whether they are classically estimated to be responsive to radiotherapy or not, depending on their macroscopic aspect and their localization on the anterior or posterior pillar for instance.

#### Local recurrences

Our rate of persistent diseases and local recurrences is 7 patients out of 53, that is 13,21% while it is 24% for the T1 and 38.5% among the T2 in Cuisnier's series out of 95 early-stage oropharyngeal lesions, all of which at stage N it must be said<sup>[1]</sup>.

#### Nodal recurrences

In our series we have no nodal recurrence. Nodal recurrences are certainly more frequent among patients treated with radiotherapy alone. This rate of nodal recurrence after radiotherapy alone is in the region of 10% all N put together and can be estimated to be 5 to 6% among the N0 since O. Cuisnier reports 10.5% of recurrences among 95 patients, 64% of whom are N0<sup>[1]</sup>. It is worth noting that the latter has not observed any contralateral nodal recurrence in these early-stage lesions, which raises the question of radiotherapy use on contralateral nodal areas. On this subject, O.Sullivan reports only 3.5% of contralateral nodal recurrence out of 228 cases of tonsillar fossa lesions treated with radiation on ipsilateral nodes only<sup>[13]</sup>.

Our low rate of nodal recurrences can be explained on the one hand because we are dealing with N0 patients most of whom free of invasion and on the other hand because neck dissection is systematic with us and failure to perform a neck dissection is the

exception to the rule, motivated either by medical history or by a bad general condition. For us a neck dissection is indeed just as much a diagnostic procedure as a therapeutic one : diagnostic because it is only thanks to this procedure that the patient's nodal status can be known, therapeutic because it protects the patient from a nodal recurrence more surely than with radiotherapy. This neck dissection must be a lateral and suprahyoid neck dissection, that is to say it must remove the nodal areas usually treated with radiation.

#### Quality of salvage treatments

The improvement of survival observed on these early-stage lesions thanks to surgery alone has most certainly to do with the quality of the treatment carried out in case of a recurrence or a second localization. Should this happen, it will be possible to perform surgery in non irradiated areas and therefore the **functional** and surgical outcomes will be much more simple. Indeed the complications due to oro and hypopharyngeal salvage surgery are well-known with for example a post-operative mortality rate of 6 to 8% and a high rate of severe complications<sup>[14,15]</sup>. According to J.Rodriguez, 60% of the deaths after salvage surgery is due to complications and or to locoregional failures<sup>[15]</sup>. In our series, we treated 18 patients with salvage surgery : 2 persistent diseases, 5 local recurrences and 11 second localizations. Fifteen patients were operated on, among whom were 11 surgery alone and 4 radiotherapy-surgery associations; the other 3 patients benefited from radiotherapy alone. It is true that the complications due to these treatments have not been notified but anyway we have not had any post-operative death among our 15 patients who were operated on. These 15 operations were performed in non irradiated areas and we may therefore rightly estimate that the rate of post-operative complications among these patients is inferior to what can be observed in salvage surgery after radiotherapy<sup>[14,15]</sup>.

#### Diagnosis of early-stage recurrences

The fact that we did not use radiation on our patients during the first treatment must have facilitated the follow-up and early-stage diagnosis of recurrences or second localizations. Indeed out of 18 cases of salvage surgery, 11 patients, that is close to two thirds of them, were able to benefit from surgery alone, which implies a small lesion since the post-operative radiotherapy which was fully available was not used.

A bad prognosis of salvage surgery after radiotherapy has mainly to do with the fact that the lesion has often extended and is often not accessible to a curative treatment the moment the diagnosis is made. Thus J.W.Meyza observes that out of 62 patients in oropharyngeal recurrence after radiotherapy, only 33 can be operated on<sup>[16]</sup>. In the same way, L.V.Johansen notes that out of 173 patients in oropharyngeal recurrence after radiotherapy, only 52, that is fewer than a third, were able to be operated on, 24 of whom successfully and 22 were able to be irradiated again, 4 of whom successfully<sup>[17]</sup>. In our series, our 18 patients in recurrence or with a second localization were able to benefit from a curative treatment as if this carcinological occurrence were the beginning of their cancer disease.

#### Salvage surgery prognosis

Besides this late diagnosis and this high rate of complications, post-radiotherapy salvage surgery has extremely disappointing results in terms of survival. The phrase "salvage surgery" often used by Anglo-Saxon authors aptly conveys the somewhat desperate

nature of this attempt<sup>[14]</sup>. In the literature, the 3-year rate of survival of these patients varies from 22 to 38% and the 5-year rate from 16 to 24%<sup>[14,15,18]</sup>. Our series surely lacks the follow-up it would need for recurrences or second localizations in order to provide a rigorous calculation of survivals since these occurrences happened. Nevertheless out of our 18 patients treated with salvage surgery, 12 are alive and free of extensions, six of whom after over three years since their relapse. Among these 12 patients, 8 did not have radiation treatment for their relapse and will therefore be able to benefit, if need be, from surgery again in non-irradiated areas associated with post-operative radiotherapy, should the need arise.

### Morbidity

Radiotherapy side-effects are well-known and related complications sometimes tragic, particularly osteoradionecrosis<sup>[19,20]</sup>. They significantly alter quality of life, particularly in reducing the salivary flow, and as we have seen, they delay any recurrence diagnosis. On the mucous plane, the oropharynx, namely the anterior pillar and the furrow amygdalo-glosse are particularly exposed<sup>[19]</sup>. Admittedly modern techniques of radiotherapy make it possible to reduce the rate of complications and after-effects but they still exist<sup>[21,22]</sup>. None of our 53 patients has benefited from radiation and has therefore been exposed to these complications and after-effects. Besides, the majority of these patients, that is 43 (81.13%) have been operated on by transoral approach. Most of the lesions under three centimeters are indeed accessible by this approach. This is particularly true for soft palate and tonsillar lesions, less true for lesions of the furrow amygdalo-glosse. For these T1 and T2 under 3 centimeters, this technique gives the same carcinological results as classic surgery with mandibulotomy. It makes it possible to appreciably shorten the length of hospitalization, of tracheotomy and of feeding tube<sup>[23]</sup>. For these patients operated on by transoral approach, it would certainly have been interesting to record these notions of hospitalization length as well as possible complications so as to work out the cost of their treatment and compare it with the cost of a radiation treatment. Comparison of indirect costs, namely sick leave and travelling expenses for the daily radiation sessions would most likely have been in favour of surgical treatment.

### Critical analysis of the series

Recruitment for this series comes from 5 different teams and is therefore not homogeneous. As we have seen, there are differences in the ways of dealing with the primary treatment. Thus the macroscopic aspect of the lesion is missing in 18 cases coming from two centers, but we have seen that in the 35 cases documented on this point, this macroscopic aspect is not a prognostic factor.

Quality control of the resection margins is carried out by two teams only and it would certainly have been interesting to find out for these 5 centers how many T1-T2 N0 oropharyngeal patients treated over the same period had needed post-operative radiotherapy, that is to say find out the ratio of this selected population treated with surgery alone in relation to the total of early-stage cancers.

Surgical procedures also vary since the proportions of surgery with pharyngectomy with or without mandibular resection and with reconstruction by myocutaneous flaps noticeably vary according to the centers. In our series however, there is no “center effect” on survival.

As we have seen, this study has not recorded the morbidity of the surgery performed, whether on initial lesions or during salvage surgery. In the same way, the economic aspect has not been studied. However for the 43 (81.13%) patients operated on an N0 neck by transoral approach with or without a functional neck dissection, the rate of complications is bound to be very low and hospitalization short. These patients' quality of life is certainly better than with a radiation treatment.

## **Conclusion**

Surgery alone on T1-T2 N0 oropharyngeal lesions gives better carcinological results than radiotherapy in terms of locoregional control and survival and should in our opinion become the standard treatment. It makes it possible to spare patients the complications and late sequelae of radiotherapy and to propose to them a simpler and quicker primary treatment. This is particularly true for the soft palate and tonsillar lesions under 3 centimeters which can nearly always be safely approached by the transoral approach. It makes it possible to keep this therapeutic weapon for subsequent carcinological occurrences which moreover are diagnosed earlier. It also makes it possible during these recurrences to operate on patients in non-irradiated areas with lower morbidity and mortality and a better effectiveness since it will be possible to irradiate after surgery if need be. This most certainly explains the improvement in survival observed.

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