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## START (SALIVARY DYSFUNCTIONS AFTER RADIOIODINE TREATMENT): PRELIMINARY RESULTS OF A SELF-CONTROLLED STUDY IN FRANCE

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### CONTEXT

Following radioiodine (<sup>131</sup>I) therapy of differentiated thyroid cancer, the salivary glands may become inflamed, leading to salivary dysfunctions. The incidence of these salivary dysfunctions after <sup>131</sup>I-therapy is poorly understood, and no clinical or genetic factors have been identified to date to define patients at risk.

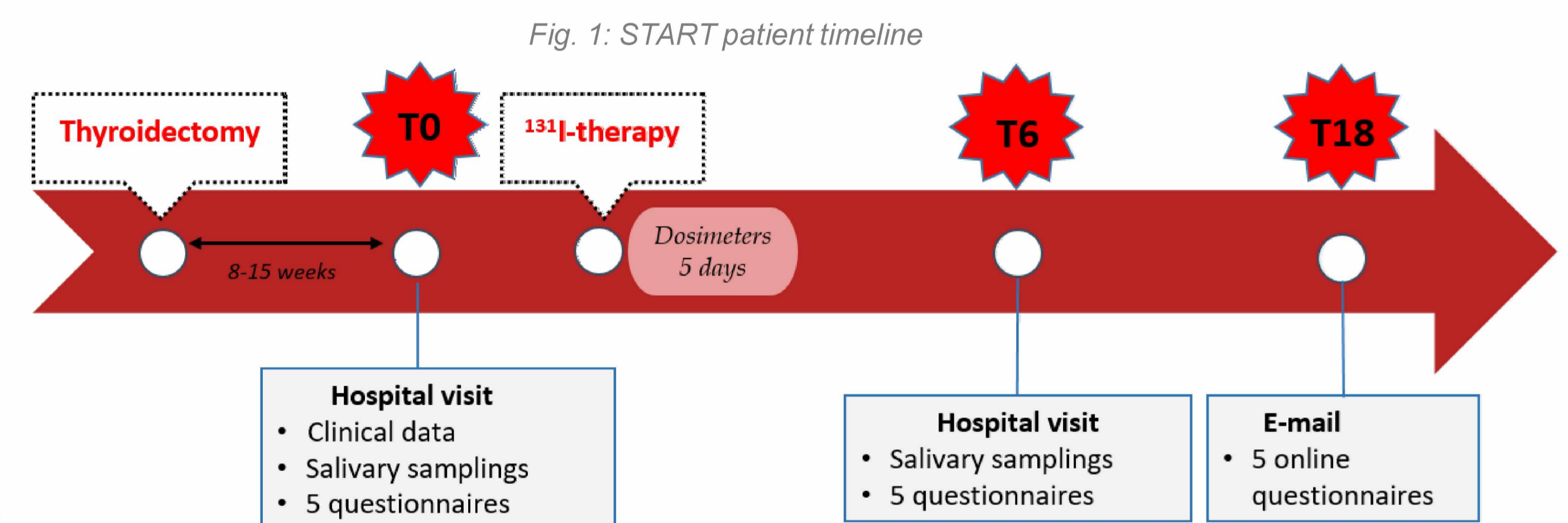
### OBJECTIVES

The aims of this study are

- 1) to estimate the incidence of salivary dysfunctions at 6 and 18 months after <sup>131</sup>I-therapy,
- 2) to characterize at-risk patients of salivary dysfunctions,
- 3) to characterize precisely the <sup>131</sup>I dose to the salivary gland

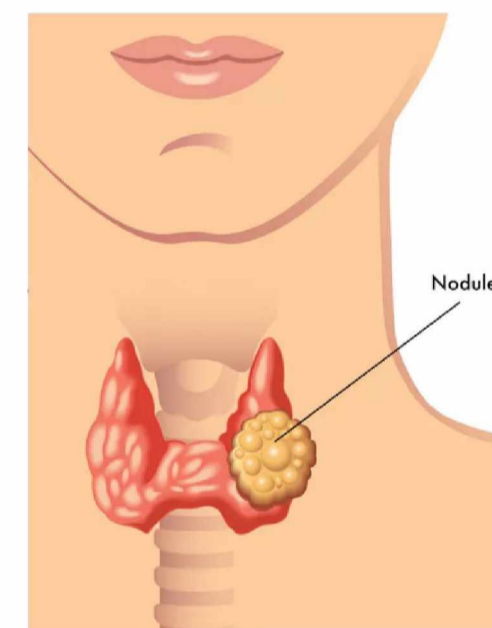
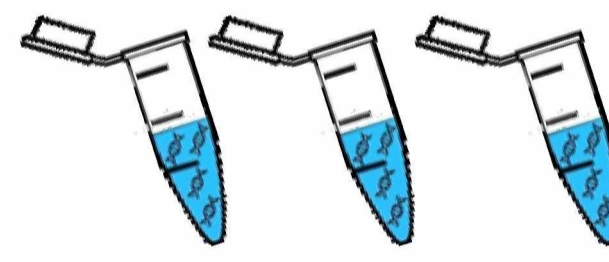
### MATERIAL and METHODS

- **Population** : 139 patients, candidates for a <sup>131</sup>I-therapy for differentiated thyroid cancer (Pitié-Salpêtrière hospital)
  - 2 groups : 45 patients treated by 1.1 GBq
  - 94 patients treated by 3.7 GBq
- **Inclusion** : the day of the therapy, immediately before radioiodine administration (T0)
- **Follow-ups**: at 6 (T6) and (T18) months after inclusion/therapy (Fig. 1)



- **Outcome: salivary dysfunctions**
  - ✓ Questionnaire (E. Moreddu, 2017)
 

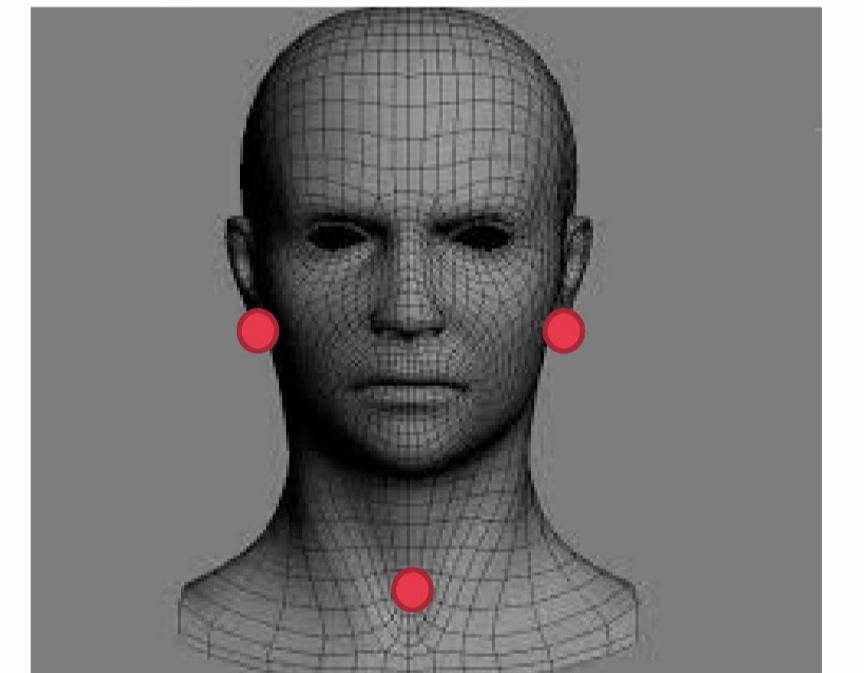
“Have you noticed a lack of saliva since the radioiodine therapy?”
  - ✓ Saliva samples
    - Samplings before and after the stimulation of salivary glands
    - Weight and volume measurements
- **Other factors of interest**
  - ✓ Quality of life (MOS SF-36)
  - ✓ Dry eyes (OSDI ©)
  - ✓ Nutrition (EVA of ingesta)
  - ✓ Anxiety and depression symptoms (HAD scale)



- **Dosimetry**:
  - ✓ 3 external thermoluminescent dosimeters (Fig. 2)
  - ✓ positioned at T0 (immediately before radioiodine administration), removed 5 days later (Fig. 1)
  - ✓ Dosimetric reconstruction → calculation of the dose precisely received by the salivary glands

- **Statistical analyses**:
  - ✓ Descriptive analyses
  - ✓ Paired comparisons tests

Fig. 2: Dosimeter locations



### RESULTS

The START study includes 71% of women and 29% of men, aged 47.1 (±14.1) years on average at baseline (Table 1).

Table 1: Baseline characteristics of the START population

Variables	N(%)
<b>Gender</b>	
women	99 (71.22)
men	40 (28.78)
<b>Age (years ±sd)</b>	47.07 (14.1)
<b>BMI</b>	27.06 (6.04)
<b>Histology</b>	
Follicular	20 (14.39)
Follicular & papillary	4 (2.88)
Papillary	115 (82.73)
<b>TNM tumor stage</b>	
Tx-T2	101 (73.19)
T3	33 (23.91)
T4	2 (1.45)
Nx-N0	77 (55.40)
N1	61 (43.88)
<b>TSH elevation protocol</b>	
L-thyroxin replacement stop	49 (35.25)
rTSH	90 (64.75)
<b>Family history of thyroid cancer</b>	
No	117 (84.17)
Yes	22 (15.83)
<b>Salivary disorders history</b>	
No	132 (94.96)
Yes	7 (5.04)
<b>Systemic disease comorbidity</b>	
Type 2 diabetes	5 (3.60)
Dyslipidemia	6 (4.32)
Diagnosed hypertension	28 (20.14)

There was **no change** in the number of patients with discomfort or swelling in parotids after <sup>131</sup>I-therapy, compared with before.

Although not statistically significant, the number of patients with dry mouth feelings was **higher** after <sup>131</sup>I-therapy.

Saliva volume and weight after the stimulation of salivary glands were **significantly decreased** after <sup>131</sup>I-therapy compared to before (Table 2).

Table 2: Pre and post <sup>131</sup>I-therapy comparisons for the factors of interest

Variables	Before <sup>131</sup> I-therapy	After <sup>131</sup> I-therapy	p <sup>c</sup>
<b>Discomfort or swelling in parotids<sup>a</sup></b>			
No	105 (84.7)	105 (84.7)	1.00
Yes	19 (15.3)	19 (15.3)	
<b>Dry mouth feeling<sup>a</sup></b>			
No	103 (83.1)	87 (70.2)	0.39
Yes	21 (16.9)	37 (29.8)	
<b>Saliva volume (mL)<sup>b</sup></b>			
Before saliva stimulation	3.85 (2.36)	3.65 (2.09)	0.21
After saliva stimulation	10.83 (4.47)	9.71 (3.99)	<0.001
<b>Saliva weight (mg)<sup>b</sup></b>			
Before saliva stimulation	3.95 (2.26)	3.90 (2.14)	0.75
After saliva stimulation	10.86 (4.46)	10.25 (4.10)	0.03

<sup>a</sup>N(%); <sup>b</sup>mean(sd); <sup>c</sup>Paired Comparison tests (McNemar test for qualitative variables, T-test for quantitative variables)

### DISCUSSION

This work presents **preliminary results** of the START study. The 18-month follow-up is still to be done for all the patients.

Preliminary results showed a **decrease in salivary gland activity after therapy**. However, salivary dysfunctions at 6-months post <sup>131</sup>I-therapy do not seem preponderant. Further analyses will allow to characterize patients at risk of salivary gland dysfunctions.

**Analyses will be completed** by data on saliva biochemical composition, and on genetic and epigenetic variants involved in salivary dysfunctions.

The impact of salivary dysfunctions following <sup>131</sup>I-therapy on **long-term quality of life and nutritional status** will also be assessed.