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

Clémence Baudin<sup>1</sup>, Charlotte Lussey-Iepoutre<sup>2,3</sup>, Alice Bressand<sup>4</sup>, Camille Buffet<sup>5</sup>, Fabrice Menegaux<sup>5,6</sup>, Marine Soret<sup>2,7</sup>, David Broggio<sup>8</sup>, Céline Bassinet<sup>9</sup>, Christelle Huet<sup>9</sup>, Catherine Ory<sup>10</sup>, Gemma Armengol<sup>11</sup>, Laurence Leenhardt<sup>5</sup>, Marie-Odile Bernier<sup>1</sup>

### 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

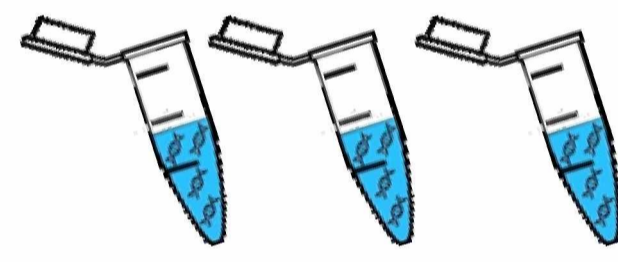
- **Population** : 139 patients, candidates for a <sup>131</sup>I-therapy for differentiated thyroid cancer (Pitié-Salpêtrière hospital)
  - 2 groups : 45 patients treated by 1.1 GBq
  - 94 patients treated by 3.7 GBq

- **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

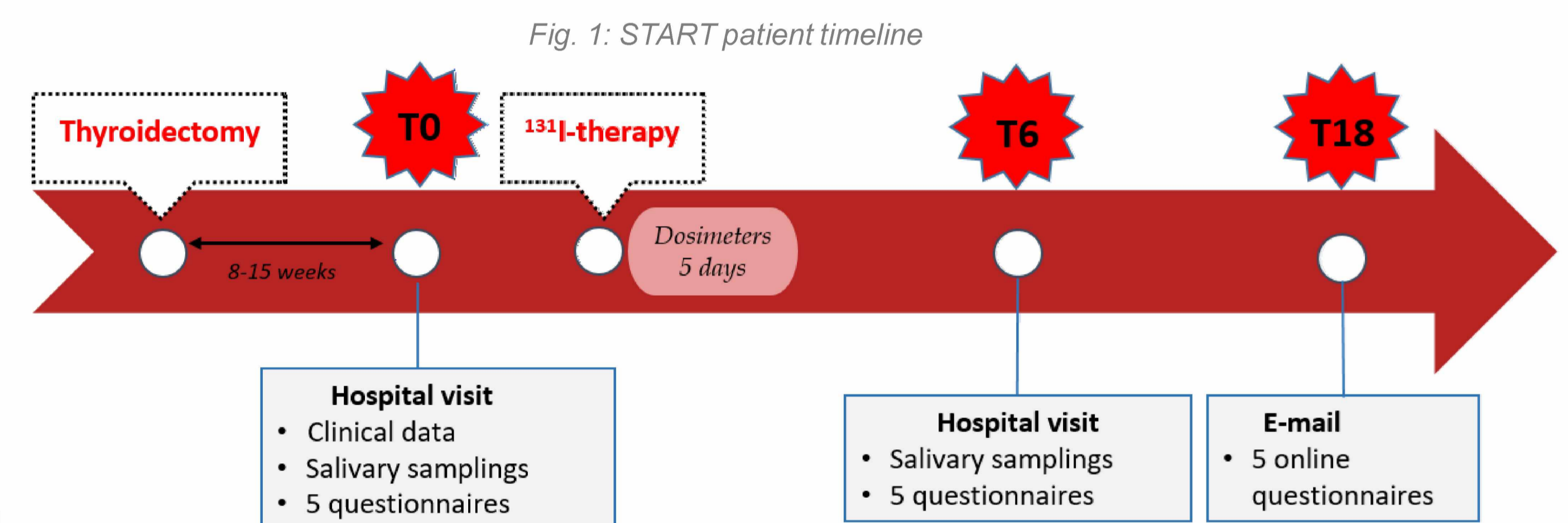
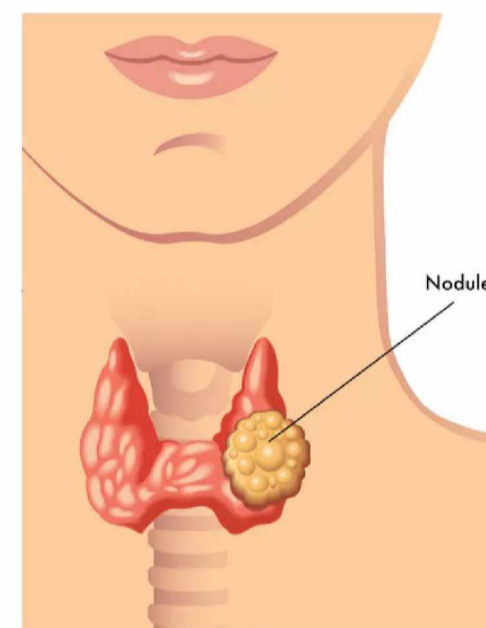
- ✓ Questionnaire (E. Moreddu, 2017)
 

“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)



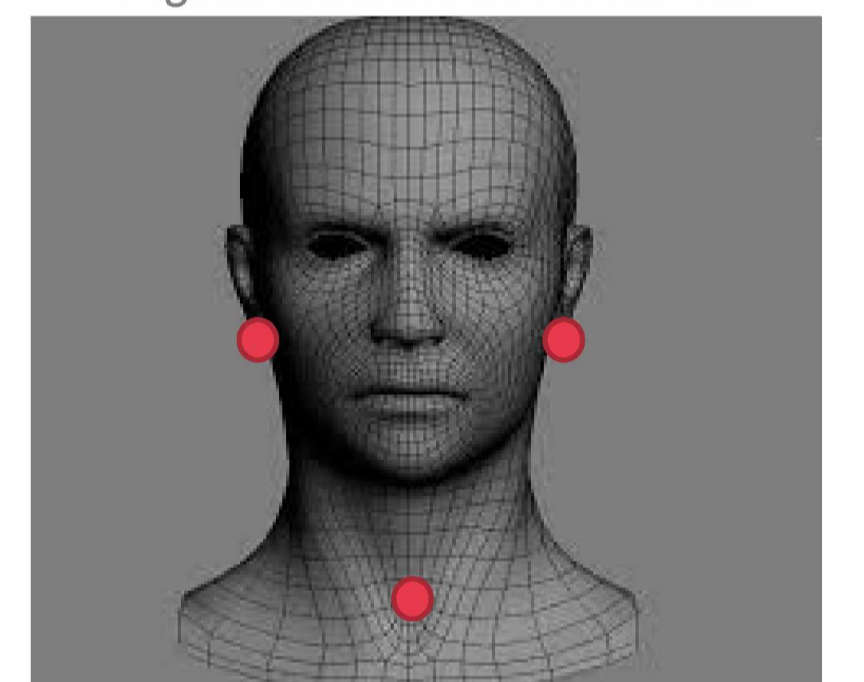
#### • Dosimetry:

- ✓ 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.