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

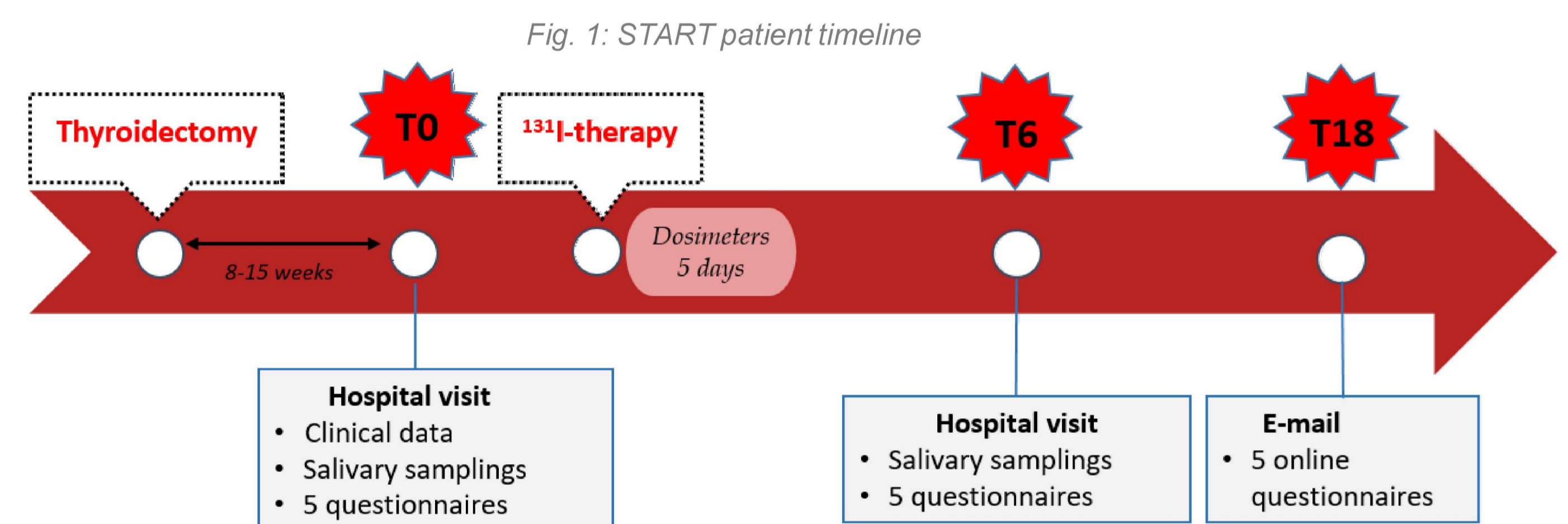
OBJECTIVES

The aims of this study are

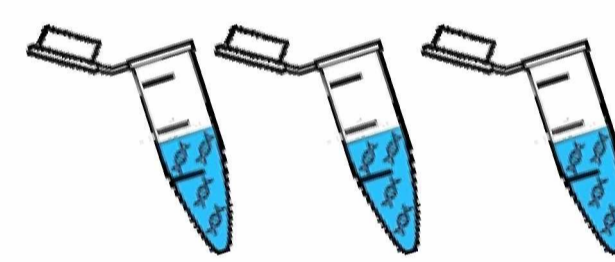
- 1) to estimate the incidence of salivary dysfunctions at 6 and 18 months after ¹³¹I-therapy,
- 2) to characterize at-risk patients of salivary dysfunctions,
- 3) to characterize precisely the ¹³¹I dose to the salivary gland

MATERIAL and METHODS

- **Population** : 139 patients, candidates for a ¹³¹I-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 18 (T18) months after inclusion/therapy (Fig. 1)

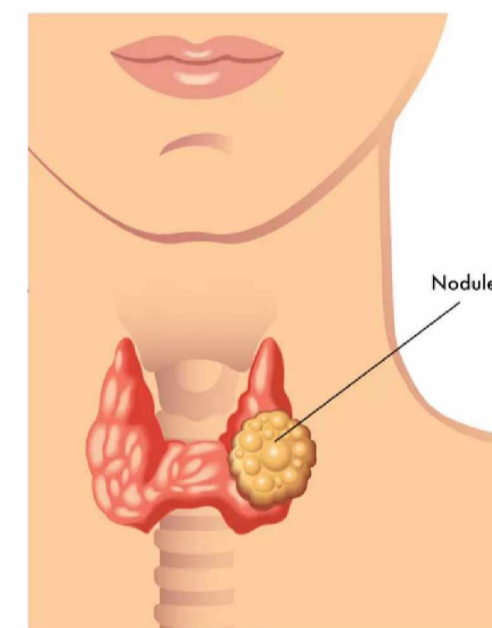


- **Outcome: salivary dysfunctions**
 - ✓ Questionnaire (E. Moreddu, 2017)
 - "Have you noticed a lack of saliva since the radioiodine therapy?"
 - ✓ Saliva samples
 - Samplings before and after the stimulation of salivary glands
 - Weight and volume measurements

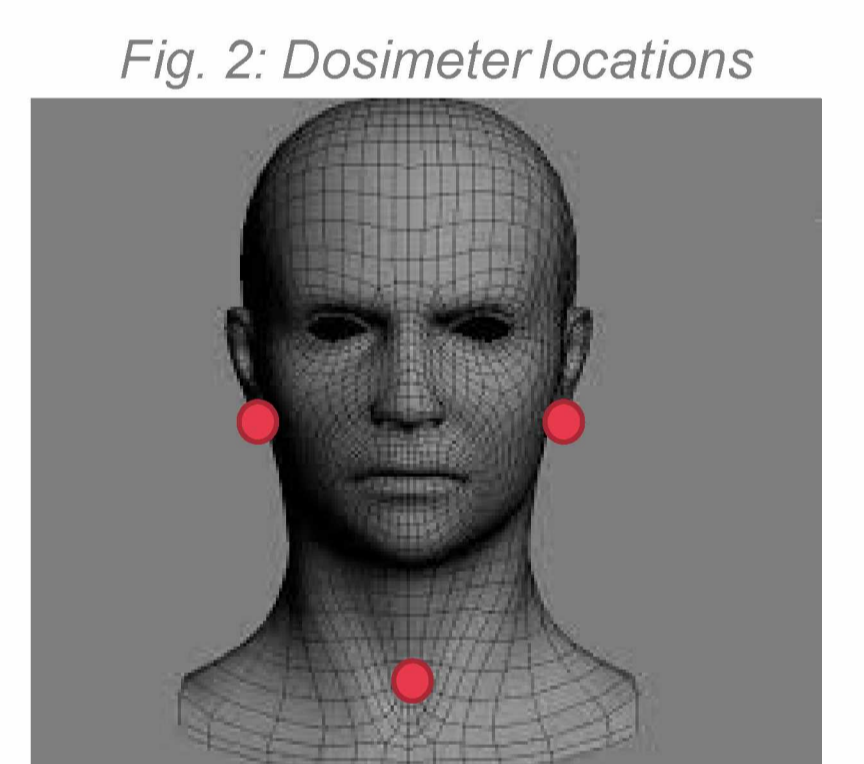


- **Dosimetry**:
 - ✓ 3 external thermoluminescent dosimeters (Fig. 2)
 - ✓ positioned at T0 (immediately before radioiodine administration), removed 5 days later (Fig. 1)
 - ✓ Dosimetric reconstruction → calculation of the dose precisely received by the salivary glands

- **Other factors of interest**
 - ✓ Quality of life (MOS SF-36)
 - ✓ Dry eyes (OSDI ©)
 - ✓ Nutrition (EVA of ingesta)
 - ✓ Anxiety and depression symptoms (HAD scale)



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



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(%)
Gender	
women	99 (71.22)
men	40 (28.78)
Age (years ±sd)	47.07 (14.1)
BMI	27.06 (6.04)
Histology	
Follicular	20 (14.39)
Follicular & papillary	4 (2.88)
Papillary	115 (82.73)
TNM tumor stage	
Tx-T2	101 (73.19)
T3	33 (23.91)
T4	2 (1.45)
Nx-N0	77 (55.40)
N1	61 (43.88)
TSH elevation protocol	
L-thyroxin replacement stop	49 (35.25)
rTSH	90 (64.75)
Family history of thyroid cancer	
No	117 (84.17)
Yes	22 (15.83)
Salivary disorders history	
No	132 (94.96)
Yes	7 (5.04)
Systemic disease comorbidity	
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 ¹³¹I-therapy, compared with before.

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

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

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

Variables	Before ¹³¹ I-therapy	After ¹³¹ I-therapy	p ^c
Discomfort or swelling in parotids^a			
No	105 (84.7)	105 (84.7)	1.00
Yes	19 (15.3)	19 (15.3)	
Dry mouth feeling^a			
No	103 (83.1)	87 (70.2)	0.39
Yes	21 (16.9)	37 (29.8)	
Saliva volume (mL)^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
Saliva weight (mg)^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

^aN(%); ^bmean(sd); ^cPaired 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 ¹³¹I-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 ¹³¹I-therapy on **long-term quality of life and nutritional status** will also be assessed.