

## Original article

# Radioactive Body Burden Measurements in $^{131}\text{I}$ Iodine Therapy for Differentiated Thyroid Cancer: Effect of Recombinant Thyroid Stimulating Hormone in Whole Body $^{131}\text{I}$ Iodine Clearance

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## Abstract

Protocols in the management of differentiated thyroid cancer, recommend adequate thyroid stimulating hormone (TSH) stimulation for radioactive  $^{131}\text{I}$  administrations, both for imaging and subsequent ablations. Commonly followed method is to achieve this by endogenous TSH stimulation by withdrawal of thyroxine. Numerous studies worldwide have reported comparable results with recombinant human thyroid stimulating hormone (rhTSH) intervention as conventional thyroxine hormone withdrawal. Radiation safety applications call for the need to understand radioactive  $^{131}\text{I}$  (RA $^{131}\text{I}$ ) clearance pattern to estimate whole body doses when this new methodology is used in our institution. A study of radiation body burden estimation was undertaken in two groups of patients treated with RA $^{131}\text{I}$ ; (a) one group of patients having thyroxine medication suspended for 5 weeks prior to therapy and (b) in the other group retaining thyroxine support with two rhTSH injections prior to therapy with RA $^{131}\text{I}$ . Sequential exposure rates at 1 m in the air were measured in these patients using a digital auto-ranging beta gamma survey instrument calibrated for measurement of exposure rates. The mean measured exposure rates at 1 m in  $\mu\text{Sv/h}$  immediately after administration and at 24 h intervals until 3 days are used for calculating of effective  $\frac{1}{2}$  time of clearance of administered activity in both groups of patients, 81 patients in conventionally treated group (stop thyroxine) and 22 patients with rhTSH administration. The  $^{131}\text{I}$  activities ranged from 2.6 to 7.9 GBq. The mean administered  $^{131}\text{I}$  activities were  $4.24 \pm 0.95$  GBq ( $n = 81$ ) in "stop hormone" group and  $5.11 \pm 1.40$  GBq ( $n = 22$ ) in rhTSH group. The fall of radioactive body burden showed two clearance patterns within observed 72 h. Calculated  $T_{\frac{1}{2}\text{eff}}$  values were 16.45 h (stop hormone group) 12.35 h (rhTSH group) for elapsed period of 48 h. Beyond 48 h post administration, clearance of RA $^{131}\text{I}$  takes place with  $T_{\frac{1}{2}\text{eff}} > 20$  h in both groups. Neck and stomach exposure rate measurements showed reduced uptakes in the neck for rhTSH patients compared with "stop thyroxine" group and results are comparable with other studies. Whole body clearance is faster for patients with rhTSH injection, resulting in less whole body absorbed doses, and dose to blood. These patients clear circulatory radioactivity faster, enabling them to be discharged sooner, thus reduce costs of the hospitalization. Reduction in background whole body count rate may improve the residual thyroid images in whole body scan. rhTSH provides TSH stimulation without withdrawal of thyroid hormone and hence can help patients to take up therapy without hormone deficient problems in the withdrawn period prior to RA $^{131}\text{I}$  therapy. This also will help in reducing the restriction time periods for patients to mix up with the general population and children.

**Keywords:** Body burden, cancer thyroid, effective half-life, iodine-131, recombinant thyroid stimulating hormone

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## Introduction

Radioactive iodine (RA $^{131}\text{I}$ ) treatment for thyroid cancer is the selective irradiation of thyroid tissue by systemic administration of I-131 and the magnitude of cell functional damage is proportional to the radiation absorbed dose. Only well-differentiated

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thyroid cancer (papillary, follicular, and mixed papillary-follicular cancers) cells concentrate radioiodine to a significant degree whereas anaplastic thyroid cancers do not concentrate radioiodine. In recent years, there has been an increasing trend to avoid pretherapy scan altogether because a pretreatment diagnostic dose <sup>131</sup>I-induced stunning of thyrocytes. However, if the extent of the thyroid remnant cannot be accurately ascertained from neck ultrasonography, <sup>131</sup>I scans are performed with low-dose of 40–100 MBq (1–3 mCi). Successful remnant ablation is defined as an absence of visible radioiodine uptake on a subsequent diagnostic radioiodine scan, and there are many protocols followed internationally.<sup>[1-6]</sup> Long-term surveillance in followup period carried out with whole-body iodine scans and stimulated thyroglobulin. For low risk patients, activity 1.10–3.7 GBq (30–100 mCi) is necessary for successful treatment. Higher doses 3.7–7.5 GBq (100–200 mCi) are considered appropriate, if residual disease is suspected or with aggressive tumor histology and or with distant metastases.

Radioactive iodine uptake by residual thyroid tissue or thyroid metastases for pretreatment imaging and treatment are preferred when the thyroid stimulating hormone (TSH) level in serum is > 30 µIU/dL. After near-total thyroidectomy, a waiting period of 6 weeks is recommended for the patient is being taken up for therapy. If the patient is on thyroxine, it should be discontinued for 4–6 weeks prior to therapy to allow for adequate rise in the TSH level. The protocol followed in our hospital is reported earlier<sup>[7]</sup> in which we follow endogenous TSH stimulation by withdrawal of thyroxine.

Recently, a few reports mention application of “recombinant human TSH (rhTSH)” to provide TSH stimulation without withdrawal of thyroxine and hence help overcome the associated morbidity. The use of rhTSH is based on its ability to stimulate the uptake of radioiodine into thyroid remnants and metastases of thyroid cancer, as well as its ability to stimulate normal or neoplastic thyroid cells to produce thyroglobulin.<sup>[8-12]</sup> Two consecutive daily injections of rhTSH (commercial name Thyrogen<sup>TM</sup>) are given for adequate stimulation of TSH. It is claimed that treatment of thyroid cancer

with RAI<sup>131</sup> after rhTSH stimulation is associated with longer retention of the I-131 in the thyroid remnant<sup>[3,4]</sup> simultaneously reduce exposure to the rest of the body and therefore to the general public whom come into contact with RAI<sup>131</sup> treated patients. During 2009, RAI<sup>131</sup> treatments with rhTSH stimulation were started in a few patients. To study the radioactive clearance pattern in these patients, the exposure rate fall off in these patients was studied, and compared with thyroid hormone withdrawn group of patients.

## Materials and Methods

### Patients

The patients who received RA<sup>131</sup>I were referred from endocrinology department of the Royal Hospital based on accepted protocol.<sup>[7]</sup> These patients were properly counseled by the nuclear medicine consultants about the procedure, preparations needed prior to therapy and possible associated risks. They were accepted for their treatments after obtaining informed consent. The patients treated during the period 2010–2012 were included in the study. There are two groups of patients (a) who received RA<sup>131</sup>I after they are advised to stop thyroxine for 5 weeks (b) who continue to be on hormone therapy, received rhTSH injection (Thyrogen<sup>TM</sup>) 24 and 48 h prior to administration of RA<sup>131</sup>I, as per endocrinology protocols. Table 1 indicates the details of the number of patients treated during the study period. Their distribution is shown in Figure 1.

### Administration of radioactive iodine

The RA<sup>131</sup>I is in the form of capsules supplied by GE Healthcare, Amersham, UK. The administrations were carried out on Mondays, and the activities were ordered to suppliers with reduced activities on reference dates (Thursdays). The radioactive strengths (activity) of the capsules were assayed in Mark V, CalRad Isotope Calibrator (Model 34–164, Nuclear Associates, USA) immediately after arrival of the consignment. The containers are labeled with suitable identifications, and activity certificates are prepared in the department. The work flow relating to RA<sup>131</sup>I administrations followed in the department had been described previously.<sup>[7]</sup> The details of the amount of RA<sup>131</sup>I activity administered are shown in Table 2.

**Table 1: Ca.thyroid thyroid-details of number of patients for 3 years**

Year	Total no. of RA <sup>131</sup> I treatments	Activity administered					
		2.0-4.0 GBq		4.0-6.0 GBq		6.0-8.0 GBq	
		Stop hormone	rhTSH group	Stop hormone	rhTSH group	Stop hormone	rhTSH group
2010	32	16	1	8	5	1	1
2011	38	15	2	14	4	-	3
2012	33	14	4	12	1	1	1
Total	103	45	7	34	10	2	5

RAI: Radioactive iodine; rhTSH: Recombinant thyroid stimulating hormone

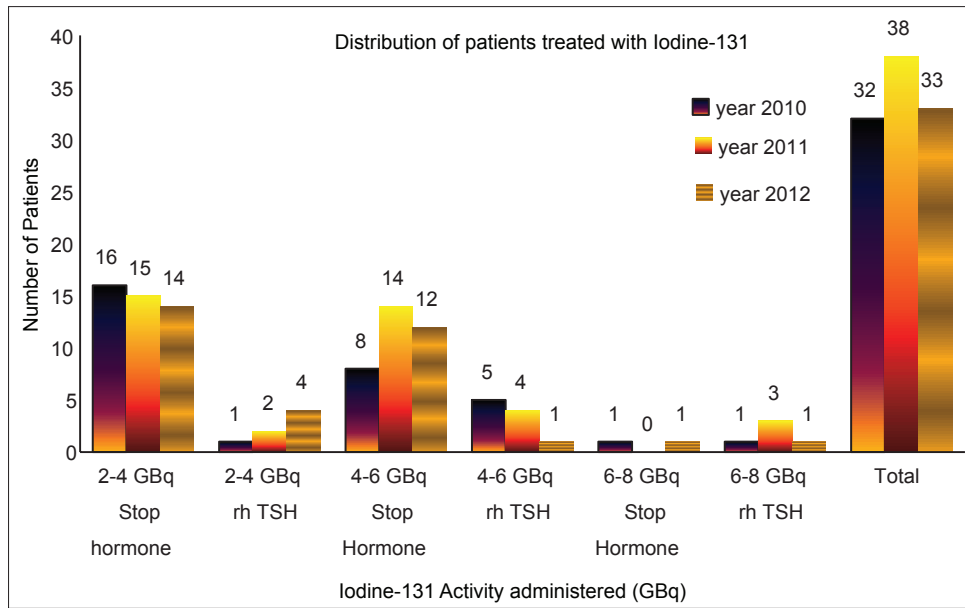


Figure 1: Distribution of patients and activity administered

Table 2: Details of administered RA<sup>131</sup>I in two groups of patients

Category of patients' treatments	Number of patients	Administered RA <sup>131</sup> I activity GBq
Stop thyroxine	81	4.24 ± 0.95 (1σ) (range 2.92-7.87)
rhTSH	22	5.11 ± 1.39 (1σ) (range 3.52-7.90)

RAI: Radioactive iodine; rhTSH: Recombinant thyroid stimulating hormone

### Measurement of exposure rates

Radiation monitoring is carried out using a wide range beta gamma survey meter, auto-ranging with digital reading facility made up of built-in ionization chamber (Inovision, USA). This is hand held type with a measuring range 0.1 μSv/h to 100 Sv/h. The exposure rates are measured at 5 cm distance at the stomach and neck levels, and at 1 m and 2 m distances with the patient sitting on the hospital bed. These measurements are recorded on the 1<sup>st</sup> and subsequent days till discharging the patient. Patients are allowed to go home when their exposure rates fall below 10 μSv/h (1.0 mR/h) at 1 m distance. This may correspond to retention of residual body burden of about 170 MBq (4.6 mCi).

### Determination of effective half lives

#### Effective half-life for the whole body

The mean exposure rate (1 m) at the time of administration obtained from all the individual patients, is taken as X<sub>0</sub>, and the measured mean exposure rates at t = 24 h, t = 48 h, t = 72 h are designated as X<sub>24</sub>, X<sub>48</sub>, X<sub>72</sub> respectively. Whole body effective half-lives of clearance (T<sub>1/2eff</sub>) data are calculated comparing X<sub>0</sub>/X<sub>24</sub>, X<sub>0</sub>/X<sub>48</sub>, X<sub>0</sub>/X<sub>72</sub> ratios using Equation 2.

which is derived from the exponential relation (1)

$$X_t = X_0 \exp^{-0.693 \times t} \tag{1}$$

$$T_{1/2eff} = \frac{0.693 \times t}{\ln[X_0/X_t]} \tag{2}$$

With a semi-log plot between mean exposure rates at 1 m and time elapsed, the T<sub>1/2eff</sub> is estimated from graphical method also.

#### Effective half-life from neck, and abdomen exposure rates

Neck and stomach exposure rates at the time of administration are not considered for reference, because the capsule is in transit stage in the body. Therefore, X<sub>24neck</sub>, X<sub>48neck</sub>, X<sub>72neck</sub> and X<sub>24stomach</sub>, X<sub>48stomach</sub>, X<sub>72stomach</sub> were used to estimate effective half-lives representing thyroid remnant and GIT activities, with the similar relation given in Equation 2.

## Results

### Radioactive body burden

The measured exposure rates at 1 m distance are compared for both groups of patients and shown in Table 3. The mean activity encountered in 22 patients of rhTSH group [Table 2] is 5.11 GBq compared to "stop hormone group" 4.24 GBq. The normalized value at t = 0 for 1 GBq for both groups are agreeable within 3% (20.09 uSv/h/GBq for rhTSH group and 20.69 uSv/h/GBq for "stop hormone group" respectively) [Table 3]. The standard deviation is shown separately because of the large range of exposure rates. The plot of time-dependant

exposure rates is shown in Figure 2. From the figure it could be observed that the mean exposure rate falls to 10  $\mu\text{Sv/h}$  radiation levels (which is the accepted limit for discharging the patient) at 39 h for rhTSH patient group and 49 h for “stop hormone” group of patients.

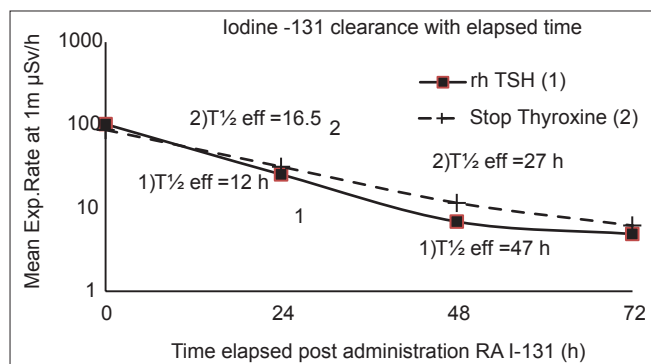
It can be observed from Tables 4 and 5 that in rhTSH group of patients the mean neck and stomach exposure rates are always less than the “stop hormone” group of patients, at all stages 24, 48 and 72 h elapsed periods of time. As could be inferred from Tables 4 and 5, the standard deviations are large because of the interpatient variations encountered, more in terms of their body weight and differences in clearance patterns. Moreover, the exposure-rate meter does not have collimation and

therefore represent global average from body scatter also.

### Effective half-lives (whole body) for recombinant human thyroid-stimulating hormone patients compared with “stop hormone” patients

Effective half-life of clearance of radioactive body burden for “rhTSH administered” patients are less than that of “stop hormone” patients [Table 6]. Until first 48 h  $T_{1/2\text{eff}}$  remain same in both group of patients in the three intervals 0–24 h, 0–48 h and 24–48 h, but differs when the interval 0–72 h is taken [4<sup>th</sup> row, Table 6]. The fall of radioactive body burden showed two clearance patterns within observed 72 h. Calculated  $T_{1/2\text{eff}}$  values were 16.45 h (stop thyroxine group) 12.35 h (rhTSH group) respectively, for elapsed period of 48 h. Beyond 48 h, clearance of RA<sup>131</sup>I takes place with  $T_{1/2\text{eff}} > 20$  h in both groups. The calculated values are compared with  $T_{1/2\text{eff}}$  estimates from the semi-log plot and presented in Figure 2.

Effective half-lives calculated from sequential exposure rates measured at neck and stomach levels of the patients  $T_{1/2\text{eff, neck}}, T_{1/2\text{eff, stomach}}$  are compared for rhTSH and “stop thyroxine” patients and shown in Table 7. It is observed that the effective half-lives determined from neck and stomach measurements also indicate that respective effective half-lives are less in the case of rhTSH patients.



**Figure 2:** Radioactive body burden changes with time elapsed postadministration of <sup>131</sup>I radioactive iodine in two groups of patients

**Table 3: Mean exposure rates at 1 m post administration RA<sup>131</sup>I at various elapsed durations**

Parameter	At time of administration <i>t</i> =0 (patients)		Time elapsed 24 h <i>t</i> =24 (patients)		Time elapsed 48 h <i>t</i> =48 (patients)		Time elapsed 72 h <i>t</i> =72 (patients)	
	rhTSH	Stop hormone	rhTSH	Stop hormone	rhTSH	Stop hormone	rhTSH	Stop hormone
Mean exposure rate ( $\mu\text{SV/h}$ )	102.6	87.68	25.46	31.60	6.92	11.65	4.90	6.19
Standard deviation ( $1\sigma$ )	55.6	55.60	15.76	25.40	3.71	13.00	4.00	5.63
Exposure rate/GBq	20.09	20.69						

RA<sup>131</sup>I: Radioactive iodine; rhTSH: Recombinant thyroid stimulating hormone

**Table 4: Mean exposure rates at neck level post administration RA<sup>131</sup>I at various elapsed durations**

Parameter	Time elapsed 24 h <i>t</i> =24 (patients)		Time elapsed 48 h <i>t</i> =48 (patients)		Time elapsed 72 h <i>t</i> =72 (patients)	
	rhTSH	Stop hormone	rhTSH	Stop hormone	rhTSH	Stop hormone
Mean exposure rate ( $\mu\text{SV/h}$ )	440	758	123	323	66.5	220
Standard deviation ( $1\sigma$ )	226	652	80	367	52.0	290

RA<sup>131</sup>I: Radioactive iodine; rhTSH: Recombinant thyroid stimulating hormone

**Table 5: Mean exposure rates at stomach level post administration RA<sup>131</sup>I at various elapsed durations**

Parameter	Time elapsed 24 h <i>t</i> =24 (patients)		Time elapsed 48 h <i>t</i> =48 (patients)		Time elapsed 72 h <i>t</i> =72 (patients)	
	rhTSH	Stop hormone	rhTSH	Stop hormone	rhTSH	Stop hormone
Mean exposure rate ( $\mu\text{SV/h}$ )	395	524	107	194	60.0	125
Standard deviation ( $1\sigma$ )	170	410	68.6	226	33.6	132

RA<sup>131</sup>I: Radioactive iodine; rhTSH: Recombinant thyroid stimulating hormone



**Table 6: Body radioactive burden clearance pattern in two patient groups**

Calculated $T_{1/2\text{eff}}$ (h) values from combination of exposure rates at different intervals of time				$T_{1/2\text{eff}}$ (h) estimates from semi-log plot [Figure.1]	
Compared intervals	rhTSH group (h)	Stop hormone group (h)	rhTSH group (h)	Stop hormone group (h)	
0 and 24 h	11.93 n=20	16.30 n=78	12.0	16.5	
0 and 48 h	12.34	16.48			
24 and 48 h	12.77	16.66			
0 and 72 h	16.40 n=8	18.82 n=30	47.0	27.0	
24 and 72 h	20.40	20.19			
48 and 72 h	48.18	26.31			

rhTSH: Recombinant thyroid stimulating hormone

**Table 7: Body burden clearance pattern (neck, stomach measurements) in two patient groups**

Calculated $T_{1/2\text{eff}}$ neck (h) and $T_{1/2\text{eff}}$ stomach values from combination of exposure rates at different intervals of time				
Compared intervals	$T_{1/2\text{eff}}$ neck		$T_{1/2\text{eff}}$ stomach	
	rhTSH group	Stop hormone group	rhTSH group	Stop hormone group
24 and 48 h	13.01 (n=20)	19.46 (n=75)	12.73 (n=20)	16.69 (n=20)
24 and 72 h	17.61 (n=6)	26.89 (n=28)	17.65 (n=6)	23.15 (n=6)
48 and 72 h	27.23 (n=6)	43.48 (n=28)	28.78 (n=6)	37.78 (n=6)

rhTSH: Recombinant thyroid stimulating hormone

## Discussion

In this study, the body burden measurements using radiation monitoring revealed different clearance pattern in patients treated with stopping thyroxine versus those with rhTSH administration; the calculated  $T_{1/2\text{eff}}$  values were 16.45 h (stop hormone group) 12.35 h (rhTSH group) for elapsed period of 48 h. This can be seen in Figure 2. Beyond 48 h clearance of RA131 takes place with  $T_{1/2\text{eff}} > 20$  h in both groups. In a publication by American Thyroid Association (ATA),<sup>[3]</sup> they studied blood and urine samples of the treated patients for several days; and also studied radioactivity given off by the I-131 for several days in thyroid remnant tissue in the neck. They reported<sup>[3]</sup> the total-body half-life of I-131, 17.1 h in the thyroid hormone withdrawal group compared with 14.8 h in the rhTSH group. Our results 16.45 h compares with their reported value of 17.1 h. Thus, the overall clearance of I-131 from the body was faster in the rhTSH group than in the thyroid hormone withdrawal group. In the same report,<sup>[3]</sup> they mentioned the half-life of I-131 in the thyroid remnant tissue was significantly longer after rhTSH (43.5 h) than with thyroxine withdrawal (28.7 h). Our reported values [Table 5, last row]  $T_{1/2\text{eff}} = 48.18$  h ( $n = 8$ ) for rhTSH group and 26.3 h ( $n = 30$ ) compares well with previously reported<sup>[3]</sup> values. Though we cannot comment on thyroid remnant activity in residual thyroid using external exposure rate values at 1 m, because after 48 h

in our eight patients (48–72 h studied group), we feel that mostly the exposure rate would have contributed from the neck area only, and therefore the 72 h  $T_{1/2\text{eff}}$  value may be more applicable to thyroid remnant rather than the whole body.

In a previous study,<sup>[7]</sup> we reported “stop thyroxine” group in another group of patients (year 2006–2009) longer  $T_{1/2\text{eff}}$  value viz. 22.0 h, which compares well with 20.1 h/26.3 h in this present work, confirming the same trend. The 1<sup>st</sup> day mean exposure rate in the earlier study<sup>[7]</sup> was  $83.69 \pm 33.5 \mu\text{Sv/h}$  ( $n = 69$  in the range of 34–184  $\mu\text{Sv/h}$ ) compares well with the present study for “stop thyroxine” group of patients viz.  $87.70 \pm 55.60 \mu\text{Sv/h}$ . The mean activity in the previous study<sup>[7]</sup> was  $4.19 \pm 0.95$  is slightly lower than the present report mean activity in “stop thyroxine” group is  $4.24 \pm 0.95 \text{ GBq}$ .

It should be appreciated that the ATA study<sup>[3]</sup> is based on blood and urine samples counting, whereas in our study the body burden estimates are based on 1 m exposure rate by a beta-gamma survey meter. We also obtained averaging on the large number of patients, and obtained  $T_{1/2\text{eff}}$  estimates from calculation from pairs of exposure rates at fixed intervals. There may be following uncertainties in our present study in a global value of  $T_{1/2\text{eff}}$  viz. (a) variable activities of individual patients (b) slight variations in distance of 1 m (c) not accounting for patient’s thickness and differences in individual clearance patterns (d) interobserver measurement variations (e) most of patients in rhTSH group are discharged in 48 h, and therefore less number of patients ( $n = 8$ ) for this group to study late clearance pattern 48–72 h. External exposure rate monitoring method is one of a well-accepted methods explained in previous reports,<sup>[7,13]</sup> therefore our results in this study is acceptable. Results of  $T_{1/2\text{eff}}$  determined from contact exposure rates at neck and abdomen [Tables 4 and 5] clearly show that retention of radioactivity is less in rhTSH group of patients. Less thyroid uptake in rhTSH group compared to thyroxine withdrawn patients has been reported earlier,<sup>[4,14]</sup> and our measurements agree with their results. Longer retention in remnant thyroid was reported in an earlier communication,<sup>[3]</sup> but our results in Table 7 for both neck and whole body show less  $T_{1/2\text{eff}}$  for rhTSH group of patients shorter than for “stop thyroxine” patients. This may be due to the contribution to the “neck measurements” from the remnant radioactivity present in the whole body.

Earlier studies<sup>[8–12,14]</sup> with rhTSH stimulation mentioned good acceptance by patients and reported that not only do patients feel dramatically better after rhTSH therapy than after thyroid hormone withdrawal, and they are treated just as effectively, while reducing the exposure to family members and/or others living with the patient. In

countries in which patients are admitted to the hospital for treatment, they should be able to be discharged sooner, thus lowering costs of the hospitalization. From health physics point of view, faster whole body clearance of RA<sup>131</sup>I will have implications in reducing whole body doses, and also help in better whole body images because of less background radioactive count rate.

## Conclusion

This study has brought out radioactive clearance pattern in the treated patients with rhTSH administrations. With the above background, if rhTSH cost factor and patient selection is acceptable, there is efficacy in adding this with RA<sup>131</sup>I in reducing patient whole body doses which is apparent from our results.

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