Water Intake Volume and its Effect to the Radiation Level and Length of Hospital stay among Differentiated Thyroid Cancer (DTC) patients undergoing High Dose Radioactive Iodine (RAI) Therapy

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ABSTRACT

Introduction. Radioactive Iodine therapy is an established therapeutic application of well-differentiated thyroid cancer. However, the proven benefits of ionizing radiation of Iodine-131 also carry potential toxicities to other normal exposed tissues. Good water hydration during the course of RAI therapy is one of the radiation protection measures to minimize toxicities, directed to increase excretion of unbound iodine from the body. Apparently, a number of recognized medical societies had different recommendations on the amount of water intake during radioactive iodine therapy.

Objective. To determine if there is a significant difference in the decrease of exposure rate, total effective dose equivalent, and length of stay of differentiated thyroid cancer patients undergoing high dose RAI when comparing between different amounts of water intake per day (<3L/day vs ≥ 3 L/day).

Methods. This study employed a prospective cohort design. Patients with differentiated thyroid cancer (DTC) admitted for high-dose RAI therapy at Jose R. Reyes Memorial Medical Center were included in the study. Dose rate and water intake volume were measured and total effective dose equivalent was computed every 24-hrs until discharged. Student t test was used to compare two water intake levels on quantitative variables while fisher exact test for categorical data.

Results. A total of 47 participants were included in the study with 28 patients under ≥ 3L/day group and 19 patients under < 3L/day with a mean consumption of 4.9 L/day and 2.3 L/day, respectively. There was no significant difference on the mean exposure rate between those who consumed at least 3L (15.3 mR/hr) against those who consumed less than 3L (17.3 mR/hr) during the time of intake, after the 24 hours (p=.9935) and 48 hours (p=.7523). Likewise, **t**here is no significant difference on their mean total effective dose equivalent [in per day during intake (p=.9678), 24 hours (p=.4141) and 48 hours (p=.6706)]. The mean length of hospital stay is also the same for both groups with 1.7 days.

Conclusion. The study concludes that consuming different volume of water per day (> 3 L/day vs < 3L/ day) have the same rate of decreased in exposure rate, total effective dose equivalent (TEDE) as well as the same length of hospital

INTRODUCTION

Thyroid carcinoma is the most common malignancy of the endocrine system. Among these thyroid malignancies, Differentiated Thyroid Carcinoma (DTC) accounts for 95% of the cases. Differentiated thyroid cancers (DTC) originate from the thyroid follicular cells and are further classified into papillary and follicular type (1).

Papillary thyroid carcinoma is characterized histologically by large and pale nuclei which frequently contain clear, glassy, intranuclear inclusion bodies and comprises of about 80% of all malignant thyroid tumors. Follicular thyroid carcinoma on the other hand makes up about 10% of all malignant thyroid tumors and histologically presents with small follicles and poor colloid formation with capsular and/or vascular invasion (2).

The basic goals of therapy of DTC patients according from the American Thyroid Association (ATA) are to improve overall and disease-specific survival, reduce the risk of persistent/recurrent disease and associated morbidity, and permit accurate disease staging

and risk stratification in initial phase (Section. B2. Goals of initial therapy of DTC, 2015). Furthermore, some of the specific goals of therapy are to; (i) remove the primary tumor mainly by total or near total thyroidectomy and those that has extended beyond the thyroid capsule and the lymph node and (ii) Facilitate postoperative treatment with Radioactive Iodine (RAI) whenever appropriate (3).

The primary objective of post-operative RAI administration after total thyroidectomy in DTC patients depends on the post-operative risk stratification. This may include remnant ablation (*to facilitate detection of recurrent disease and initial staging by tests such as Tg measurements or whole-body RAI scans*), adjuvant therapy (*serves to improve disease-free survival by destroying presumed residual disease especially in patients at increased risk of disease recurrence*) and RAI therapy directed at known residual or metastatic disease (*treating persistent disease in higher risk patients*) (*Section B36. ATA, 2015*) (3).

ATA guidelines recommend the administration of low RAI activity of approximately of 30 mCi over higher administered activities (100 mci) for ATA low- to intermediate-risk thyroid CA with lower risk features. This however still remains point for discussion as some studies shows comparable outcomes with higher activity of 100 mCi versus 30 mCi. ATA further recommends higher administration of RAI activity for patients receiving less than a total or near-total thyroidectomy in which a larger remnant is suspected or in which adjuvant therapy is intended. RAI activities up to 150mCi are generally recommended (*in absence of known distant metastases*) for initial adjuvant therapy for suspected microscopic residual disease (3).

High dose RAI therapy exposes significant amount of radiation not only to the patients but also to family members, health care personnel and the general public. This makes Radiation Safety an integral part in the management of DTC patients undergoing RAI therapy. It is recommended that patients be admitted in shielded isolation rooms in hospitals as one of the radiation safety measures for preventing significant radiation exposures to other people. The ATA Taskforce on Radiation safety recommends admitting patients when the activity of Iodine-131 to be given is 33 mCi or more and allows release of patients when measured dose rate is < 7 mrem/hour at 1 meter (3). In Philippine setting, the Philippine Nuclear Research Institute (PNRI) recommends hospital admission when Iodine-131 administration activity is > 15mCi (555 MBq) and discharge when total effective dose equivalent (TEDE) to any other individual from the exposure not likely to exceed 3mSv. Traditional rate limit for discharged recommended by the PNRI is < 0.025 mSv/h (4).

Another measure in radiation safety during high dose RAI is to minimize the physiological and radioiodine uptake and retention by way of adequate hydration (EANM) (5). The ATA Taskforce on Radiation Safety (2011) also recommends sufficient fluid intake to enable frequent urination. Frequent urination by means of sufficient hydration is a sub component on the personal hygiene practices which aimed not only to reduce external exposure but also reduce ingestion of I-131 secretions and excretion of the patient (4).

While all recognized medical societies around the world acknowledge the need of a good hydration during RAI therapy, the specified quantity of water needed for hydration differs from society to society. The ATA Taskforce on Radiation Safety recommends consumption of about 3-4 liters per day for a sufficient hydration during RAI therapy (6). The Society of Nuclear Medicine (SNM) on the other hand recommends water intake of 2.5 – 3 liters to ensure a good hydration (7). The EANM however did not quantify the recommended water intake volume per day but specified that “liberal oral hydration” is required (5). Ziessman et, al. (2014) advocate to consume at least 2 quarts (1.88 liters) of fluid per day during high dose RAI therapy (8). The PNRI (2014) guidelines recommend the intake of plenty of water after the first 2 hours of RAI intake and for the next 2 days for a good hydration as one of the radiation safety measures but has not quantified the amount of water intake (4). All of these recommendations except from the PNRI, are meant for western population. Currently, there is no published guidelines on the recommendation on the water intake volume for Asian setting, specifically for Filipino population. This study aims to compare the effect of different amount of water intake per day (<3 li. and 3≥ li.) to the radiation levels of DTC patients undergoing RAI therapy at Jose R. Reyes Memorial Medical Center, Philippines.

In a study in Pakistan, the length of admission in isolation room ranges from 24-96 hours for high dose RAI therapy (9). Although there was no published study in the Philippines regarding the isolation period of RAI patients, there was almost the same duration of admission observed at Jose R. Reyes Memorial Medical Center, which is about 48-96 hours. If this study shows that there is an effect on the different amount of water intake per day on the radiation levels of DTC patients undergoing RAI

therapy, this study will further identify if the different amount of water intake could contribute to early discharge. As iso financial and psychological stress. Early discharge of patients from isolation room will translate to lower treatment cost.

OBJECTIVES

Research Question

Comparing between different amounts of water intake per day (< 3L/day versus ≥ 3L/day), is there a significant difference on the radiation level (*or Exposure rate*), total effective dose equivalent (TEDE), and length of stay of well-differentiated thyroid cancer (DTC) patients undergoing high dose RAI at Jose R. Reyes Memorial Medical Center?

Research Objectives

General objective: This study aims to determine if there is a significant difference in the decrease of radiation level (*or Exposure rate*), total effective dose equivalent (TEDE), and length of stay of DTC patients undergoing high dose RAI at Jose R. Reyes Memorial Medical Center when comparing between different amounts of water intake per day (< 3L/day versus ≥ 3L/day).

Specific objective: Specifically, this study aims

- To describe the socio-demographic and clinical profile of DTC patients undergoing high dose RAI at Jose R. Reyes Memorial Medical Center
- To estimate the following parameters:
- Average water intake in liters per day
- Average length of stay in days
- Average radiation level (*or Exposure rate*) during RAI intake, 24th hr, 48th hr, and at discharge.
- Average Total Effective Dose Equivalent (TEDE) during RAI intake, 24th hr, 48th hr, and at discharge.
- To determine if there is a significant difference on the radiation level (exposure rate), total effective dose equivalent (TEDE), and length of hospital stay between patients who consume at least 3 L of water per day and patients who consume less than 3 L of water per day.

Operational Definition

Radiation Level - Pertains to exposure rate or dose rate in which radiation emitted from the patient is measured in air with the unit of mR/hr.

Length of hospital stay- Measured by the number of days patients are "***allowed for discharge***" which is in accordance with the TEDE values set by the regulating body (Philippine Nuclear Research Institute). This is not synonymous to the "***actual date of discharge***" as some patients encountered administrative/processing problems (e.g. delay in health insurance processing, failure to settle billing and payment dues) despite being cleared and ***"allowed for discharge"*** by the attending physician and medical physicist.

DTC patients- Refers to patients with well-differentiated thyroid cancer with histopathological type of either papillary or follicular thyroid carcinoma.

METHODOLOGY

Study design

This study employed a prospective cohort study design. All eligible patients with differentiated thyroid cancer (DTC) who were admitted for high-dose RAI therapy at Jose R. Reyes Memorial Medical Center were included in the study. These patients were subjected to the same preparation and protocol for RAI therapy used in this institution (see appendix 1). The RAI therapy protocol is also recognized by other acknowledged medical society such as American Thyroid Association (ATA) and European Association of Nuclear Medicine (EANM).

The exposure variable was the amount of water intake in liters per day. Eligible patients were followed up

over time for their radiation level (Exposure rate) and total effective dose equivalent (TEDE) until discharged. The length of stay of patients was also recorded. Upon discharged, patients were classified into 2 groups (< 3L/day versus ≥ 3L/day) based from their water intake diary and were subsequently analyzed for significant difference.

Inclusion Criteria

Qualified patients based on the inclusion criteria were invited to join the study. Only patients who gave their consent were included in the study;

- Age: 18 - 70 yrs. old.
- Tumor Type: Papillary and Follicular Thyroid Carcinoma
- Surgical Intervention: Total or Near-Thyroidectomy.
- Normal Serum Creatinine Level
- TSH values: >30 mIU/L

Exclusion Criteria

- History of previous RAI treatment.
- With Co-morbidity (e.g. Congestive Heart Failure, Renal Failure).
- Unable to provide written consent

Data Gathering Procedures

Chart Review

The gathering of data was carried out using hospital records and documents along with the laboratory results (*e.g. surgical pathological report, creatinine, TSH*). The researcher utilized the existing charts and documents officially used by the hospital during patient's admission. The data were gathered from the following documents and forms:

- History and Physical Examination Form
- Doctor's Order Sheet
- Medication Sheet
- Vital signs record sheet
- Progress report
- Input and Output monitoring sheet
- Surgical Pathological report
- Laboratory results.

Protocol for Admission and Discharge

The current protocol implemented by the JRRMMC for high dose RAI of DTC patients was followed from admission until discharge.

A. Admission:

All patients who were admitted for Radioactive Iodine Therapy were interviewed by the nuclear medicine resident on-duty. The nuclear medicine resident-on-duty conducted the clinical evaluation (*Clinical history and Physical Examination*) and facilitated patient's admission.

The standard procedure for conducting health education regarding RAI as well as radiation protection measures was carried out by the resident-on-duty. Health education was also given to the patients, family members or any accompanying individual.

The nuclear medicine physician counselled the patients regarding importance of good hydration. Patients for admission were advised to take water as little as 2 liters per day and as high as 5 liters or more per day as long as tolerated. A *"fluid intake diary"* was provided to the patients to record their fluid intake per day during the entire hospital stay.

B. Measurement of Radiation Level (Exposure Rate) and Total Effective Dose Equivalent (TEDE)

Radiation level of DTC patients was quantified by means of "Radiation Exposure rate". The standard protocol currently used by JRRMMC for measuring dose rate for high dose RAI was employed. The nuclear medicine technician-on-duty measured the dose rate immediately after RAI intake and every 24 hrs thereafter. The dose rate was taken at 1-meter distance from anterior mid trunk using a survey meter (***SN243569, Model No. 14-C.)***. The total effective dose equivalent (TEDE) of each patient was computed from the dose rate reading . The nuclear medicine technician and medical physicist were blinded as to the patients' fluid volume intake per day.

C. Discharge

Patients were discharged from the hospital as soon as the computed total effective dose equivalent (TEDE) was less than 3mSv as per Philippine Nuclear Research Institute (PNRI) standard. The nuclear medicine resident-on-duty counselled the patients regarding their condition and radiation protection measures during travel and at home.

D. Follow-up

Patients were advised for follow-up whole body scan (WBS - post RAI) within 5-8 days after RAI Therapy. The standard guidelines used by the Nuclear Medicine Department of JRRMMC were employed in conducting whole body scan. Whole body and static anterior neck view were taken

using single and dual head gamma cameras (Mediso). Additional views were added if necessity requires.

Measurement of Water Intake Volume

Each patient was provided with a "fluid intake diary" to record the amount of fluid intake per day. The admitting physician instructed the patient how to record the volume fluid intake per day with the corresponding date and time. All type of fluids that were consumed by the patient were recorded which include water, soup, juice, coffee and milk. Patients were also provided with a measuring cup to quantify the volume of fluid intake. Other measuring quantities were also used in recording such as number of teaspoon and tablespoon of fluids consumed with corresponding volume. The "fluid intake diary" was collected upon discharged. (*Please refer to Appendix 5, sample of "Fluid Intake Diary".)*

Statistical Analyses

Descriptive statistics were used to describe the socio-demographic and clinical profile of DTC patients. Mean and standard deviations were used for quantitative variables, while frequencies and proportions were used for qualitative variables. Student t test was used to compare two water intake levels on quantitative variables while fisher exact test for categorical data. Level of significance is at 5%. Medcalc Statistical software was used to carry out statistical computations.

Minimizing Bias

Patients were given measuring cup during admissions to validly measure the amount of water intake during hospital stay. All patients were given the same instruction to consume as much water as they can. Daily rounds via telephone were done. Patients were reminded daily to religiously record water intake in the "fluid intake diary". Patients who failed to record their water intake even for 1 day were excluded in the analysis as late recording was not allowed. The results were blindly reviewed. Patient's data were de-identified and codes were assigned during analysis. Groupings of participants based on water intake volume ($\leq$ 3L/day vs > 3L/day) were only known after the data were subjected to statistical analysis.

RESULTS

Results no. 1. Socio-demographic and clinical profile of DTC patients undergoing high dose RAI at Jose R. Reyes Memorial Medical Center.

A total of 47 patients was included in the study where 59.6% of them have a water intake of at least 3L while remaining 40.4% has below 3L water intake. Table 1a shows that the average age of patients is around 45 years old (±13.7), where youngest is 21 years old while oldest is 70. Results show no significant difference on the mean age of those who consumed waters of at least 3L/day as compared to those who consumed below 3L/day. Likewise, no significant difference in terms of gender distribution, as mostly are female (83%).

Table 1b (below) shows that the overall mean BMI is 27.8 and most of the patients are overweight (42.6%). Results also show that BMI is just the same between those who intake at least 3L of water (27.5) as compared to less than 3L intake (28.1). Mean number of tumors also does not differ as the overall average is around 1.5. Likewise, largest tumor size positive for cancer also turns out be not significantly different, overall average size is around 2.9 cm. Furthermore, pathology and surgery type also turned out to be the same between those intakes water at least 3L against below 3L, as most of the patients have papillary thyroid cancer (95.7%) and underwent total thyroidectomy (83%). Lastly, results show no significant difference on the activity of RAI given to those who intake waters of at least 3L/day (mean = 110.7 ± 36.7 mCi) as compared to those who take below 3L/day (mean=111.0 ± 28.0 mCi).

Results no. 2. Outcome parameters (*water intake volume per day, Length of stay, radiation level or Exposure rate and Total Effective Dose Equivalent*) of DTC patients undergoing high dose RAI.

Table 2 shows that the overall mean average water intake is 3.9 Liters/day (95% CI 3.4 to 4.4) while overall length of hospital stay is 1.7 (95% CI 1.6 to 1.8) days. Moreover, average exposure rate during baseline is 16.1 (95% ci 13.6 to 18.6) while mean TEDE during intake is 15.8 (95% CI 14.5 to 17.1). In comparing the patients who take water at least 3L as compared to those who takes less than 3L, results show that they have the same length of hospital stay of around 1.7 days, same exposure rate during baseline 15.3 to 17.3, and same TEDE during baseline of 15.8 to 15.9.

Results no. 3. Comparison on the radiation level (exposure rate), total effective dose equivalent (TEDE), and length of hospital stay between patients who consumed water at least 3 L/day and less than 3 L/day.

Table 3 compares the mean exposure rate per day of DTC patients where results show no significant difference between patients who take at least 3L (15.3 (in mR/hr)) against those who take less than 3L (17.3 (in mR/hr)) during the time of intake. Likewise, no significant difference on the mean exposure rate after the 24 hours (p=.9935) and 48 hours (p=.7523). Table 4 compares the two groups where it also shows no significant difference on their mean total effective dose equivalent (in per day during intake (p=.9678), 24 hours (p = 0.4141) and 48 hours (p=.6706). Lastly, Table 5 also shows same mean length of stay, both resulting to 1.7 days for those who intakes at least 3L against those below 3L of water.

DISCUSSION

The radiation level of well-differentiated thyroid Cancer (DTC) patients undergoing RAI therapy in this study was quantified by exposure rate or dose rate. The total effective dose equivalent (TEDE) was computed from the dose rate to determine patients' clearance for discharge. In the Philippines, patients are cleared for discharge with a TEDE value of < 3 mSv. The length of stay was measured

Fig. 1. Flow Chart of the Study

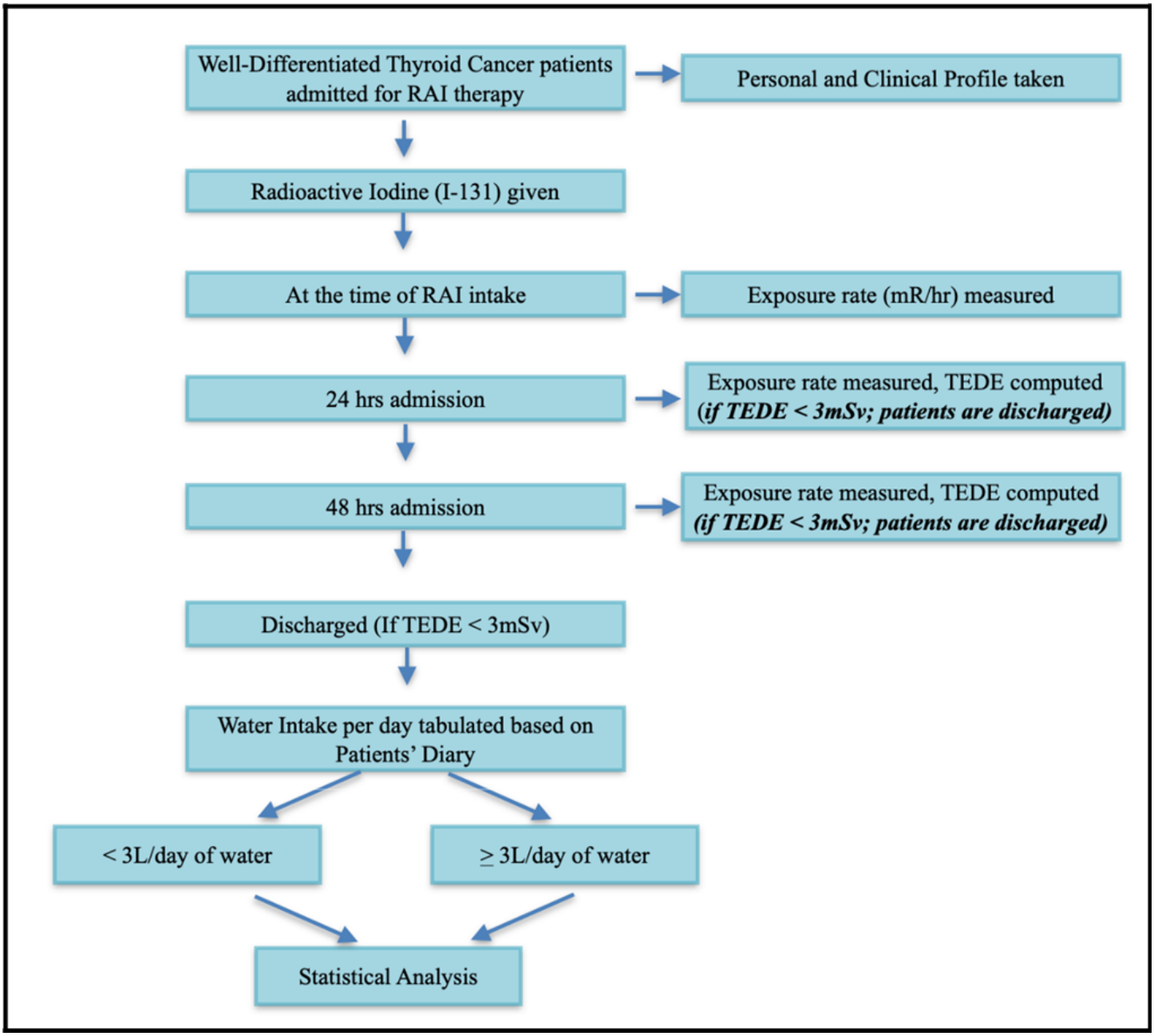

Table 1a. Demographic Profile of DTC Patients undergoing high dose RAI

Characteristics	≥3L/day water intake (n=28)	<3L/day water intake (n=19)	Overall (n=47)	p value
Age				
mean ± sd	47.8 ± 13.3	41.8 ± 13.8	45.4 ± 13.7	0.1431[ns]
Min - Max (range)	21 to 70	21 to 68	21 to 70	
Sex, n, %				
Male	7 (25.0)	1 (5.3)	8 (17.0)	0.1188 [ns]
Female	21 (75.0)	18 (94.7)	39 (83.0)	

**significant, ns not significant*
Student t test for age, Fisher Exact test for sex

Table 1b. Clinical profile of DTC patients undergoing high dose RAI

Characteristics	≥3L/day water intake (n=28)	<3L/day water intake (n=19)	Overall (n=47)	p value
Body Mass Index				
mean ± sd	27.5 ± 4.5	28.1 ± 4.2	27.8 ± 4.3	0.6842[n]
Min - Max (range)	20.5 to 37.2	22.4 to 37.3	20.5 to 37.3	
Normal	10 (35.7%)	4 (21.1%)	14 (29.8%)	
Overweight	10 (35.7%)	10 (52.6%)	20 (42.6%)	0.6021[ns]
Obese I	5 (17.9%)	4 (21.1%)	9 (19.1%)	
Obese II	3 (10.7%)	1 (5.3%)	4 (8.5)	
Number of Tumors Positive for Cancer				
mean ± sd	1.5 ± 0.6	1.6 ± 1.0	1.5 ± 0.8	0.6523[ns]
Min - Max (range)	1 to 3	1 to 4	1.0 to 4.0	
Largest Tumor Size Positive for Cancer				
mean ± sd	2.9 ± 1.9	2.8 ± 1.9	2.9 ± 1.9	0.7932[ns]
Min - Max (range)	0.2 to 8	0.2 to 8	0.2 to 8.0	
Pathology, n, %				
Follicular	1 (3.6)	1 (5.3)	2 (4.3)	1.0000[ns]
Papillary	27 (96.4)	18 (94.7)	45 (95.7)	
Surgery, n, %				
Completion Thyroidectomy	1 (7.1)	4 (21.1)	6 (12.8)	
Total thyroidectomy	25 (89.3)	14 (73.7)	39 (83.0)	0.1437[ns]
Near-Total	1 (3.6)	1 (5.3)	2 (4.3)	
RAI Activity				
Prescribe (mCi)	100.0 ± 33.3	100.0 ± 23.6	100.0 ± 29.5	1.0000[ns]
Actual RAI Dose (mCi)	110.7 ± 36.7	111.0 ± 28.0	110.8 ± 33.1	0.9690[ns]

**significant, ns not significant*
Student t test for age, Fisher Exact test for sex

Table 2. Estimate of outcome parameters (*water intake volume per day, Length of stay, radiation level or Exposure rate and Total Effective Dose Equivalent*) of DTC patients undergoing high dose RAI

	Overall (n=47)	95% CI	≥3L/day water intake (n=28)	<3L/day water intake (n=19)	p value
Water intake (L/day)					
Mean ± SD	3.9 ± 1.9	3.4 to 4.4	4.9 ± 1.8	2.3 ± 0.4	0.0001*
Min - Max (range)	1.5 to 9.9		3.1 to 9.9	1.5 to 2.9	
Length of Hospital Stay					
Mean ± SD	1.7 ± 0.5	1.6 to 1.8	1.7 ± 0.5	1.7 ± 0.5	0.9684 ns
Min - Max (range)	1.0 to 2.0		1.0 to 2.0	1.0 to 2.0	
Exposure Rate Baseline					
Mean ± SD	16.1 ± 8.9	13.6 to 18.6	15.3 ± 8.0	17.3 ± 10.3	0.4460 ns
Min - Max (range)	5.0 to 50.0		5.0 to 40.0	5.5 to 50.0	
TEDE Baseline					
Mean ± SD	15.8 ± 4.7	14.5 to 17.1	15.8 ± 5.2	15.9 ± 4.0	0.9678 ns
Min - Max (range)	7.7 to 25.0		7.7 to 24.3	7.8 to 25.0	

**significant, ns not significant*
Student t test

Table 3. Mean Exposure rate (in mR/hr) per day of DTC patients undergoing high dose RAI at Jose R. Reyes Memorial Medical Center of the two groups who consumed ≥ 3li/day and <3li/day.

	≥3L/day water intake (n=28)	<3L/day water intake (n=19)	p value
Time of intake	15.3 ± 8.0	17.3 ± 10.3	0.4460 ns
24 Hours	3.6 ± 1.3	3.6 ± 1.3	0.9935 ns
48 Hours	1.2 ± 0.7	1.3 ± 0.5	0.7523 ns

**significant, ns not significant*
Student t test

Table 4. Mean Total Effective Dose Equivalent (in mSv) per day of DTC patients undergoing high dose RAI at Jose R. Reyes Memorial Medical Center of the two groups who consumed > 3li/day and <3li/day.

	≥3L/day water intake (n=28)	<3L/day water intake (n=19)	p value
Time of intake	15.8 ± 5.2	15.9 ± 4.0	0.9678 ns
24 Hours	4.3 ± 2.5	3.8 ± 1.8	0.4141 ns
48 Hours	1.4 ± 0.6	1.5 ± 0.8	0.6706 ns

**significant, ns not significant*
Student t test

Table 5. Mean length of stay (in days) of DTC patients undergoing high dose RAI at Jose R. Reyes Memorial Medical Center of the two groups who consumed > 3li/day and <3li/day.

	≥3L/day water intake (n=28)	<3L/day water intake (n=19)	p value
Length of Stay	1.7 ± 0.5	1.7 ± 0.5	0.9684^{ns}

**significant, ns not significant*
Student t test

by the number of days that patients were hospitalized until they were "allowed for discharge" and not the "actual date of discharge". The latter was affected by several administrative factors / concerns (e.g. delay in health insurance processing, failure to settle billing and payment dues). The study also took into consideration the different demographic and clinical profiles of the patients which included age, sex, body mass index (BMI), number of tumors positive for cancer, largest tumor positive for cancer, histopathology of tumor, surgical procedure undertaken and activity of Iodine-131 taken. Taking into account these demographic and clinical profiles, the results of this study showed that different volumes of water intake per day (<3 li/day vs > 3 li/day) do not have significant difference on the patients' decrease in radiation level and the length of hospital stay.

The dose rate emitted from the patient was measured using a survey meter. A survey meter is generally an accepted tool for the said purpose which indirectly measures the whole-body retention of Iodine -131 (12). In an ideal setting according to Hoe et.al (2018), whole body retention of Iodine-131 is best evaluated by serial blood test, analysis of I-131 in urine and IC survey meter. Serial blood test and analysis of I - 131 in urine were not performed in this study due to the limited nuclear medicine facility of Jose R. Reyes Memorial Medical Center. The dose rate measurement provided an estimate amount of radiation and possible toxicity that the DTC patient undergoing RAI therapy received.

The established therapeutic applications and benefits of Radioactive Iodine therapy for well-differentiated thyroid cancer do not come without significant risk for adverse effects or toxicities. The ionizing radiation emitted by Iodine-131 may potentially harm other normal exposed tissues and organ systems. Most common organ systems affected by the adverse effects of radiation includes salivary glands and nasolacrimal ducts as well as the gastrointestinal, pulmonary, genital, hematopoietic system and many more (13, 14). According to Matoviü (2013), the challenge lies in the achieving the maximal benefits of radioiodine therapy while minimizing its adverse effect or toxicities. This compromised could be achieved in two ways; first, is to achieve the best therapeutic efficiency of radioiodine by increasing Iodine - 131 uptake in target tissue with the lowest possible dose. Second, to reduce the adverse effects of Radioactive Iodine therapy by accelerating elimination of unbound Iodine-131 to thyroid/tumor tissue (14).

Radioactive Iodine uptake mechanism does not differ from the uptake of nutritional iodine in the normal thyroid gland (15). After oral ingestion of Iodine, 90% is rapidly absorbed within 60 minutes in the proximal small intestine after being reduced to iodide. Its predominant route for excretion is via the urinary tract with about 35% to 75% in the first 24 hours while fecal route is very minimal (11, 16).

One of the popularly known methods that may increase unbound iodine excretion from the body is good hydration. Several clinical practice guidelines advised good hydration during the course of Radioiodine therapy as part of radiation protection measures. The **American Thyroid Association** (ATA) Taskforce on Radioiodine Safety recommends sufficient fluid intake of about 3-4 liters per day to facilitate frequent urination while the **Society of Nuclear Medicine** (SNM) advocate a daily fluid intake of 2,500-3,000 ml in the average-sized adult for good hydration along with instructions for frequent urination to reduced radiation exposure to the bladder, salivary glands and adjacent internal organs (6, 7). These recommended amount of fluid intakes during RAI therapy is for western population and it also parallel with adequate intake (AI) volumes of water per day set by the National Academy of Medicine, USA (2004) for general western population which is about 3,700 ml for adult male and 2700 ml for adult female (17).

While many relevant literatures suggest that extensive hydration accelerate urinary excretion

of Iodine - 131 there are also data that states the otherwise (14). One study concluded that water diuresis does not induced iodine diuresis as 95% of the filtered iodine is reabsorbed by the tubule along proximity to water absorption spots, this study however was conducted on dogs (18). However, for patients undergoing radioiodine therapy, extensive hydration is still recommended as it promotes dilution of radioiodine in urine and thereby decreases in urinary radioiodine retention in the bladder. This further reduce the absorbed dose to the urinary tract, especially the bladder and the surrounding tissues (7).

To date, there is no recommended daily water intake for Asian population specifically for Filipinos undergoing radioiodine therapy. It is important to identify the recommended fluid intake for the Filipino population undergoing RAI therapy as insufficient fluid intake or excessive hydration may possibly lead to further harm. Insufficient fluid intake as stated above, leads to delayed excretion of Iodine-131 from the body and further exposes normal organs and tissues to higher radiation. On the contrary, excessive fluid intake may lead to electrolyte imbalance (hyponatremia) and may exacerbate fluid retention on hypothyroid elderly patients in rare cases (12).

In the Philippines, the Food and Nutrition Research Institute (2015) recommends daily water intake for adults ages 19 y.o. - >70 y.o. of about 1540 ml - 1930 ml for female and 1960 ml - 2530 ml for male (19). In this study, the range of water intake for those who consumed < 3 liters per day is from 1.5 to 2.9 Liters / day with the average of 2.3 Liters / day. This further revealed that advising Filipino RAI patient on water intake volume per day within the range set the FNRI for the general population will achieve the same rate of decrease in exposure rate, TEDE per day as well as same "allowable time of discharge" compared with those who consumed $\geq$ 3L/day as set by the ATA guidelines. While it is not a contraindication to consume about 3 - 4 L/day during RAI therapy in most cases, this may not also be necessary for Filipino patients as this will still achieve the same rate of decrease in patients' radiation level and same duration of hospital admission even if they consume less than < 3L/day.

There are limited studies regarding fluid intake on DTC patients undergoing RAI therapy. One study conducted by Haghighatafshar et.al (2018) in Iran, revealed that increasing the amount of fluid above the physiologic rate [> 60ml/hr (mean - 83ml/hr) or > 1440 ml/day (mean - 1992 ml/day)] did not result in the reduction of measured dose rate which is widely used as a criterion for safe discharge (20). Another study in Malaysia found out that the minimum amount of fluids needed to achieve the fastest time to reach permissible level for release in DTC patients undergoing high-dose RAI therapy is 2,148 ml/day regardless of protocol used (12). Both of the studies also agreed that dehydration or insufficient fluid intake should be avoided as it leads to delayed clearance of I-131. The above literatures, are comparable with the findings of this study that patients who consumed higher fluid volume per day ($\geq$ 3 li/day) had no significant difference than those who consumed < 3 liters of water per day with a mean value of 2.3 Liters/day (range 1.5-2.9 Liters) in terms of reduction in radiation level and length of hospital stay.

CONCLUSIONS AND RECOMMENDATIONS

The study concludes that consuming different volume of water per day (> 3 L/day vs < 3L/day) have the same rate of decreased in radiation level and total effective dose equivalent (TEDE) as well as the same length of hospital stay among well-differentiated thyroid cancer patients undergoing high dose radioactive iodine therapy. Increasing consumption of water equal or above 3L/day

APPENDIX

Appendix 1. Protocol for High Dose Radioactive Iodine Therapy

A. **Patient Preparation**

- Withhold hormone medications until TSH >30 μU/Ml.
  - (*This is usually 3 weeks after thyroidectomy or 4-5 weeks after discontinuing levothyroxine. Triiodothyronine can be substituted until 2 weeks before treatment*).
- Low-iodine diet for 2 weeks (*significant iodine is found in iodized salt, seafood, seaweed, multivitamins)*
- Pregnancy and Breastfeeding:
  - Pregnancy test will be done 72 hours or less before RAI Therapy for potential pregnant women.
  - Discontinue breastfeeding 6 weeks prior to RAI therapy. Breastfeeding may resume in the future after birth of another child.
  - Pregnancy should be avoided for 6 months to 1 year.

B. **Administration of Radioiodine**

- Advised fasting for 2 hrs. prior and 1 hour after administration.
  (Refrain from large meals 4 hours before RAI administration)
- Secure informed consent (*with signature*) with written directive which include the ff;
  - Purpose of treatment
  - Additional treatments may be needed Side effects
  - Early effects (salivary tenderness [30%], gastritis [30%], transient metallic taste, neck pain due to thyroiditis [10%-20%], transiently decreased white cell count [rare], transient hypospermia [rare] mucositis, and transient nausea or vomiting [rare])
  - Late side effects (xerostomia [10%-20%], dental caries, reduced taste, dry eyes [rare], temporary, <1% possibility of radiation-induced neoplasms, pulmonary fibrosis [with multiple high administered activities with iodine-avid pulmonary metastases], permanent bone marrow depression [rare])

C. **Determination of Radioactive Iodine Activity prior administration**

- Check the attending physician's order as to the RAI activity dose and route of administration.
- Verify the radiation activity of RAI capsule using the Dose Calibrator (***Capintec; CRC-15R***)

D. Monitoring of Radiation Exposure Rate

- Dose rate will be measured immediately after giving of RAI capsule using survey meter (***SN243569, Model No. 14-C.)***
- The dose rate will be taken at 1-meter distance from anterior mid trunk, room and outside the patient's door.
- Monitoring of dose rate will be taken every 24 hrs until the discharge.

E. **Release of Patient**

- Patient will be discharged from the hospital once the computed Total Effective Dose Equivalent (TEDE) of the patient was <3 mSv as per Phil. Nuclear Research Institute (PNRI) regulations.
- Patients will be strongly advised to go home directly without stopping at any public places.
- Hotel stay after discharged is strongly discouraged but not prohibited.
- Radiation safety instructions sheet will be given to the patients upon discharge as well as the documentation of radionuclide activity administered.

F. **Follow-Up**

- Whole body imaging will be performed about 5-8 days after treatment using dual head gamma camera (Mediso, AnyScan SPECT)
    - Whole Body Scan with Static anterior neck view will be taken upon follow-up.

APPENDIX 2.1: CONSENT FOR INCLUSION IN THE STUDY

Project Title: Water Intake Volume and its effect to the Radiation Level and Length of Hospital stay among Differentiated Thyroid Cancer (DTC) patients undergoing High Dose Radioactive Iodine (RAI) Therapy.

Principal Investigator: Elgie JF. Gregorio MD.

Co-investigator: Marcelino A. Tanquilut MD. Wenceslao S Llauderes MD. FPSNM, Emelito O. Valdez-Tan MD. DPSNM

Sponsor: None

PARTICIPANT INFORMATION SHEET

You are being invited to participate in the study to assess the relationship of radiation level (dose rate) and water intake volume among patients undergoing high dose Radioactive Iodine (RAI) Therapy admitted at Jose R. Reyes Memorial Medical Center.

WHAT IS THE OBJECTIVE OF THIS STUDY?

The objective of this study is to determine the significant difference in the radiation exposure rates among patients undergoing high dose RAI therapy with different volume of water intake per day at Jose R. Reyes Memorial Medical Center.

WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?

If you volunteer to participate in this study, we will acquire all your personal information and hospital records in relation to your disease (Thyroid Cancer) and Treatment during your entire admission. **As part of the RAI therapy guidelines, your radiation levels will be taken using a monitoring device during your stay at the hospital, this will also be recorded as one of the valuable data of the research.**

You will not have to do anything for this study other than giving consent to document all your personal data and hospital records during the entire course of your admission.

HOW MANY PARTICIPANTS WILL BE IN THIS STUDY?

In this study we expect to have about 100 participants for observation. All patients admitted for 2 years (late 2017- late 2019) at Jose R. Reyes Memorial Medical Center for High dose RAI will considered potential participants.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

It is possible that some participants may feel uncomfortable sharing their information during the interview (Clinical History Taking) but that is in relation to admitting protocol for RAI therapy. There will be no direct health risk or physical danger for your inclusion in this study as this will only be an observational study. We will only document all the pertinent information during your entire hospital stay.

WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?

There will be no direct benefits to the participants who will be included in this study. The results of this study will be helpful to the field of nuclear medicine specifically future patients undergoing RAI therapy. This will be a great contribution in formulating future protocol for high dose RAI therapy in the Philippines.

IF I DO NOT WANT TO TAKE PART IN THE STUDY, CAN I HAVE OTHER OPTIONS?

Yes. You are free to withdraw anytime from this study without any consequences. You may choose to withdraw anytime during the course of the study (*from admission until discharge).*

Once you choose not to be included in this study, we will not obtain any information from you for the inclusion in this study but the standard protocol for admission of RAI therapy will still be followed until discharge and follow-up.

WHAT INFORMATION WILL BE KEPT PRIVATE?

Your personal information will be de-identified. All your personal information such as name, residential address and contact number will be remove during analysis and will be coded. The data will be gathered from this study will not be shared to anyone outside the research team or as required by the law. There will be no single person's identity will be reported. Data will be examined in volumes. Data will be kept by the researcher and will be destroyed 10 years after publication of the study.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

There will be no payment for your participation in this study. The researchers however will be forever grateful for your participation and sharing your health data as this will be of great contribution to body of knowledge in nuclear medicine.

WILL THERE BE ANY COSTS?

There will be no additional costs to you for your participation in this study.

APPENDIX 2.2: PAHINTULOT NG PASYENTENG LALAHOK SA PAG-AARAL.

Project Title: Water Intake Volume and its effect to the Radiation Level and Length of Hospital stay among Differentiated Thyroid Cancer (DTC) patients undergoing High Dose Radioactive Iodine (RAI) Therapy.

Principal Investigator: Elgie JF. Gregorio MD.

Co-investigator: Marcelino A. Tanquilut MD. Wenceslao S Llauderes MD. FPSNM, Emelito O. Valdez-Tan MD. DPSNM

Sponsor: None

IMPORMASYON PARA SA MGA KALAHOK SA PAG-AARAL

Ikaw ay inaanyayahan na sumali sa pag-aaral upang malaman ang kaugnayan ng "radiation level (Dose Rate)" at dami ng tubig na iniinom ng mga pasyente na may kanser sa thyroid na sumasailalim sa pangagamot gamit ang "Radioactive Iodine" (RAI).

ANO ANG LAYUNIN NG PAG-AARAL NA ITO?

Ang layunin ng pag-aaral na ito ay para malaman kung may pagkakaiba ang "radiation level"
ng mga pasyenteng may kanser sa thyroid sumasailalaim sa "RAI therapy" at magkakaibang dami ng tubig na iniinom kada araw sa Jose R. Reyes Memorial Medical Center (JRRMMC).

ANO ANG KONTRIBUSYON NG MGA KALAHOK SA PAG-AARAL?

Ang mga kalahok na boluntaryong sumali para sa pag-aaral na ito ay pagkukuhanan ng mga personal na impormasyon at rekord sa ospital na may kinalaman lamang sa paggamot ng sakit na kanser sa thyroid ng pasyente habang nasa loob ng JRRMMC. **Bilang bahagi ng patnubay para sa "RAI therapy", ang antas ng radiasyon mula sa ininom na Iodine-131 ay susukatin gamit ang "survey meter" sa buong paglagi sa ospital. Ito din ay itatala bilang isang mahalagang datos ng pagsasaliksik.**

ILANG PARTISIPANTE ANG INAASAHANG SASALI SA PAG-AARAL NA ITO?

Sa pag-aaral na ito, 100 na pasyente inaasahang sasali. Lahat ng pasyenteng may kanser sa thyroid at gagamutin sa JRRMMC gamit ang RAI therapy mula bandang huli ng 2017 hanggang 2019 (2 taon) ay mga potensyal na maisasali sa pag-aaral na ito.

ANO ANG MGA POSIBLENG PANGANIB KUNG SASALI AKO?

Walang direktang panganib sa iyo kung ikaw ay sasali sa pag-aaral na ito dahil ito ay limitado lamang sa pag-oobserba sa iyo at iyong sakit habang ikaw ay ginagamot sa loob ng JRRMMC.

Posible lamang na ikaw ay hindi maging komportable sa paghahayag ng iyong medikal na impormasyon, pero lahat ng impormasyon na ibabahagi mo ay naayon lamang sa protokol sa pagtanggap ng pasyente sa JRRMMC para sa "RAI therapy" na matagal nang ginagamit na pamamaraan ng ospital na ito.

ANO ANG BENEPEPSIYONG MAKUKUHA KO SA PAGSALI O BENEPISYO NG KOMUNIDAD?

Walang direktang benepisyo sa mga pasyente na sasali sa pag-aaral na ito ngunit ang makukuhang kaalaman sa pag-aaral na ito ay magiging malaking kontribusyon sa larangan ng "Nuclear Medicine" lalo na sa mga susunod na pasyenteng gagamutin ng RAI therapy.

MAARI BA AKONG HINDI SUMALI SA PAG-AARAL NA ITO?

Opo. Ang sinumang pasyente ay may karapatan na tumangging sumali sa pag-aaral na ito. Kung ikaw ay sumali at nag-iba ang iyong isip, maari mong bawiin ang iyong pahintulot anumang oras. Walang magiging negatibong konsekwensya sa sino mang pasyente na hindi sasali sa pag-aaral na ito. Hindi isasali ang mga personal at rekord mo sa ospital sa pag-aaral kung wala o binawi mo ang iyong pahintulot.

Isasailalim pa rin sa tamang patnubay sa pangagamot ng kanser sa thyroid ang bawat pasyente kahit na siya ay hindi sumang-ayon na sumali sa pag-aaral.

ANONG IMPORMASYON ANG MAGIGING PRIBADO?

Lahat ng personal na impormasyon ng pasyente na kasali ay hindi papangalanan. Ang mga personal na impormasyon gaya ng pangalan, tirahan, numero sa telepono ay tatangalin at papalitan ng koda. Ang mga personal na impormasyon na makukuha sa pag-aaral na ito ay hindi kailanman maaring ibahagi sa ibang tao o ahensya. Ang pag-aanalisa sa mga impormasyon ay gagawing pangkalahatan at hindi pang-indibidual.

MAY BAYAD BA AKONG MATATANGGAP SA PAGSALI SA PAG-AARAL?

Walang bayad sa mga pasyente na magbabahagi ng kanilang impromasyon sa ospital para sa pag-aaral. Ang tagapagsaliksik ay habang-panahon na tatanawing utang-na-loob sa mga pasyente ang kanilang pagsali at kanilang kontribusyon sa larangan ng "Nuclear Medicine"

MAGBABAYAD BA AKO KUNG AKO AY SASALI SA PAG-AARAL NA ITO?

Hindi. Ang pagsali sa pag-aaral na ito ay walang bayad.

does not give additional radiation protection benefits nor additional harm to well-differentiated thyroid cancer patients undergoing radioactive iodine therapy.

It is recommended that similar study be conducted in a large population. The limited implementation duration of the study limits the gathering of sample population to only 47 participants. It is also recommended that more studies should be conducted to assess if international medical guidelines are also suited for Asian population specifically Philippine setting. The recommendations include not just studies related to radiation protection but also to the management of thyroid cancer.

Appendices

Appendix 4. Data Collection Form

DATA COLLECTION FORM
(*This information is confidential, for research team-use only*)
Page 1 of 2

Code Identification Number: _____

Name: _____ Age: _____ Gender: _____
Birth Date: _____ Religion: _____ Marital Status: _____
Address: _____

Date of Admission: _____ Date of Discharged: _____
Length of Hospital Stay: (no. of days admitted):_____

Weight: _____ Height: _____ Body Mass Index (BMI):_____

Diagnosis:

Surgical History:
Type of Surgery: ( ) Total Thyroidectomy ( ) Near total Thyroidectomy
( ) Others:_____
Date of Surgery: _____

Surgical Pathological Report:
Tumor Type: ( ) Papillary ( ) Follicular; Histological Variant:_____
Largest tumor Size: _____ No. of Tumor positive for Carcinoma:_____

Presence of Metastasis:
( ) No ( ) Yes, specify : _____
( ) Lymphnode, ( ) Capsular invasion, ( ) Lymphovascular invasion

Past Medical History:
( ) Congestive Heart Failure or ( ) Heart Problems, Specify_____
( ) Renal Failure
( ) Previous Radioactive Iodine Therapy (RAI)
( ) Others, specify:_____

Medications (other than thyroid disease medications):
_____, _____, _____,

Laboratory Values:
TSH _____ (Date Conducted) _____
Serum Creatinine _____ (Date Conducted) _____

Radioactive Iodine activity and intake:
Radioactive Iodine-131 activity : _____mCi
Time of RAI intake : _____
Radiation level after intake (at 1 meter): _____ mR/hr
TEDE : _____

DATA COLLECTION FORM
(*This information is confidential, for research team-use only*)
Page 2 of 2

Water Intake Volume and Radiation Level (Dose rate)

Day no.	Date	Time taken	Water Intake Volume (ml)	Radiation Levels (Dose Rate at 1 meter: mR/hr)	Total Effective Dose Equivalent (TEDE)
Day 1 (24hrs admission)					
Day 2 (48hrs admission)					
Day 3 (72hrs admission)					
Day 4 (96hrs admission)					
Day 5 (120 hrs admission)					

Appendix 5.1. Fluid Intake Diary

FLUID INTAKE DIARY

Direction: Please write the volume of fluid intake per day with the corresponding time in milliliter (ml) with the use of a measuring cup. Fluids will include water, soup, juice, coffee and milk (*pls refer on the box below*). The equivalent volume of fluid intake by the number of teaspoon and tablespoon consumed can also be used in recording.

Time of the Day	DAY 1 Date:_____ Volume of Fluid (ml)	DAY 2 Date:_____ Volume of Fluid (ml)	DAY 3 Date:_____ Volume of Fluid (ml)	DAY 4 Date:_____ Volume of Fluid (ml)	DAY 5 Date:_____ Volume of Fluid (ml)
12mn-1am					
1am-2am					
2am-3am					
3am-4am					
4am-5am					
5am-6am					
6am-7am					
7am-8am					
8am-9am					
9am-10am					
10am-11am					
11am-12nn					
12nn-1pm					
1pm-2pm					
2pm-3pm					
3pm-4pm					
4pm-5pm					
5pm-6pm					
6pm-7pm					
7pm-8pm					
8pm-9pm					
9pm-10pm					
10pm-11pm					
11pm-12mn					

Example Fluids:
- Water
- Soup
- Juice
- Coffee
- Milk

Equivalents:
1 teaspoon - 5ml
1 tablespoon – 15ml

Appendix 5.2. Fluid Intake Diary (Filipino version)

FLUID INTAKE DIARY
(Filipino version)

Direksyon: Isulat ang dami ng ininom na tubig kada-araw kasama ang kaukulang oras nito gamit ang panukat na baso. Ang mga sumusunod na likido tulad ng tubig, sopas, juice, kape at gatas ay maaaring isaalang-alang. (mangyaring sumanguni sa kahon sa ibaba). Ang katumbas na dami ng ininom na tubig sa pamamagitan ng bilang ng kutsarita o kustara ay maaring gamitin sa pagtala.

Oras	Unang Araw Petsa:_____ Dami ng likido nainom (ml)	Pangalawag Araw Petsa:_____ Dami ng likido nainom (ml)	Pangatlong araw Petsa:_____ Dami ng likido nainom (ml)	Pang-apat na araw Petsa:_____ Dami ng likido nainom (ml)	Panglimang araw Petsa:_____ Dami ng likido nainom (ml)
12mn-1am					
1am-2am					
2am-3am					
3am-4am					
4am-5am					
5am-6am					
6am-7am					
7am-8am					
8am-9am					
9am-10am					
10am-11am					
11am-12nn					
12nn-1pm					
1pm-2pm					
2pm-3pm					
3pm-4pm					
4pm-5pm					
5pm-6pm					
6pm-7pm					
7pm-8pm					
8pm-9pm					
9pm-10pm					
10pm-11pm					
11pm-12mn					

Halimbawa ng Likido:
- Tubig
- Sopas
- Juice
- Kape
- Gatas

Mga katumbas:
1 kutsarita - 5ml
1 kutsara – 15ml

CONSENT TO PARTICIPATE

To indicate consent to the following options, please initial in the box:

(place initials here)

☐ **I consent to be part of the study and have my personal health record in relation to my high dose RAI treatment be obtained by the researcher.**

☐ **I did not consent to be part of the study. All my personal health record will be limited only for the use of my health care providers but not for research purposes.**

You can withdraw from the study at any time.

- I understand that whether I do or decide not to participate in any part of the research will not affect the care that I receive for my RAI treatment.
- I understand that my participation is purely voluntary.
- I am not obliged to provide any information or to answer any questions that I do not wish to answer.
- I am aware that my personal identification will be kept private and secure.
- My personal information will only be used for purposes which I have agreed.
- I am aware that I can withdraw my information anytime or discontinue to participate in the study by calling the Principal Investigator Dr. Elgie Gregorio at 711-9491 local 236, Nuclear Medicine Department, Jose R. Reyes Memorial Medical Center.

All my queries regarding my inclusion in this study and the information I need to make this informed consent were clarified and answered.

By affixing my name and signature on the space provided below affirmed my inclusion in this study.

Name and signature	**Name of Person Obtaining Consent**
Date	**Date**

- **If you have any questions about the study** now or later, please contact **Dr. Elgie Gregorio, at tel no,** 711-9491 local 236,
- **If you have any questions regarding your rights** as a study participant, you may contact **Dr. Crismelita Banez, Chairman, JRRMMC Institution Review Board at 732-1071 loc. 296.**

PAGSANG-AYON SA PAGSALI

Markahan ng tsek ang kahon ng iyong tugon hinggil sa pagbibigay pahintulot sa pagsali sa pag-aaral:

☐ **Ako ay nagbibigay ng pahintulot na suriin ang aking personal at rekord sa ospital na may kinalaman sa aking "RAI therapy".**

☐ **Ako ay hindi nagbibigay ng pahintulot na suriin ang aking personal at rekord sa ospital na may kinalaman sa aking "RAI therapy". Ang personal na rekord ko ay magagamit lamang ng aking doctor at nars para lamang sa aking pagpapagamot at hindi puwede isali sa pag-aaral**

Ikaw ay puwede umatras sa pagsali sa pag-aaral na ito anumang oras na iyong naisin.

- Naiintindihan ko na kung magpapasya ako na sasali o hindi sa pag-aaral na ito ay hindi maapektuhan ang aking pagpapagamot sa aking sakit na kanser sa thyroid.
- Naiintindihan ko na ang aking pagsali ay boluntaryo at hindi sapilitan.
- Hindi ako obligado na magbigay ng impormasyon o sumagot sa mga tanong na hindi ko nais sagutin.
- Naiintindihan ko na ang aking personal na imporsyon ay mananatiling pribado at hindi maaring galawin ng sinuman.
- Ang personal na impormasyon at rekord sa ospital ay gagamitin lamang ayon sa napagkasunduan at hindi para sa ibang layunin.
- Maari akong huminto sa pagsali sa pag-aaral na ito anumang oras ko naisin sa pamamagitan ng pagtawag sa Prinsipal na imbestigador na si Dr. Elgie Gregorio sa numero ng telepono 711-9491 local 236, Nuclear Medicine Department, Jose R. Reyes Memorial Medical Center.

Lahat ng katanungan ko at pagdesisyon ko sa pagsali sa pag-aaral na ito ay nasagot at nilinaw.
Sa paglagda ko ng aking pangalan ay nagpapatunay sa pagsali ko sa pag-aaral na ito.

Pangalan at lagda	**Pangalan ng Kumukuha ng pahinulot**
Petsa	**Petsa**

- Kung ikaw ay may katanungan tungkol sa pag-aaral na ito, maari kang tumawag anumang oras kay **Dr. Elgie Gregorio** sa teleponong numero 711-9491 local 236.
- Kung ikaw ay may katanungan ukol sa iyong karapatan sa pagsali sa pag-aaral na ito ay maari kang tumawag kay **Dr. Crismelita M. Banez, Chairman, JRRMMC Institutional Review Board sa teleponong numero 732-1071 loc. 296**

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