Original Article

Do Current Radiation Safety Guidelines allow the Safe Release of a Thyroid Cancer Patient after High-dose Radioiodine Therapy? An Indian Perspective

Abstract

Aim: Radionuclide therapy may produce a significant radiation exposure risk to the patient's caregivers. The study aims to assess the radiation exposure rate to caregivers after the patient's discharge from the isolation ward. **Materials and Methods:** Patients of the well-Differentiated thyroid cancer (DTC) were given high-dose radioiodine therapy as an inpatient. Their radiation exposure was measured daily, and they were discharged once the exposure rate falls as per standard guidelines. Detail counseling of the patient and caregiver about radiation safety was done before admission and at the time of discharge. Caregivers were given thermoluminescence dosimeter (TLD) to wear as a locket for 7 days. Radiation exposure received by the caregiver was measure after that. **Results:** A total of 22 patients (8 male and 14 female) of DTC were recruited in the study. The mean age was 39.0 ± 14.5 years. Patients were treated with 3.79 ± 1.07 (102.4 ± 28.9 mCi) (1.85–5.55 (50–150 mCi) GBq of radioiodine. They were discharged from the isolation ward at a radiation level of 0.028 ± 0.015 mSv/h (3.193 ± 1.71 mR). The mean effective dose received by the caregiver was 14.60 ± 3.43 mSv (1460 ± 343 mR) (9.73–24.25 (973–2765 mR) mSv. **Conclusion:** Our study denotes that the caregivers of DTC patients receive a significant radiation dose. It was well above the caregiver's annual dose-limit constraints regarding the rationales well as international guidelines of 5 mSv/yr. These could be related to the long travel in public transport and housing conditions. There is a need for patient-specific discharge criteria rather than following standard guidelines to minimize radiation exposure to caregivers.

Keywords: *DTC, iodine-131, radionuclide therapy, thermo luminescence dosimeter, thyroid cancer*

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Introduction

Thyroid cancer is the most common endocrine malignancy, accounting for approximately 1% of all new cancer cases. Differentiated thyroid carcinoma (DTC) is the most common pathological type of thyroid cancer and accounts for more than 80% of all cases.[1] The current treatment of DTC is surgical resection. It is followed by high-dose radioiodine (I-131) therapy and thyroid-stimulating hormone (TSH) suppression therapy. The need for I-131 therapy and level of suppression depends on the stage and risk considerations.[2] The postoperative I-131 treatment may considerably decrease the recurrence rate and improve the survival of DTC patients' subgroups.[2]

The treatment with I-131 is done either as an inpatient or outpatient procedure depending on the dose administered and country-specific guidelines. For inpatient treatment, each patient receiving I-131 treatment for DTC requires approximately 1–3 days of hospital stay as the standard practice. The decay of I-131 releases β and γ radiations. High-energy γ-rays are responsible for emitting radiation into the surrounding environment. The potential hazards are from both external irradiation and contamination. Patient-release criteria are set to ensure that no individual shall receive exposures above the regulatory dose limit.[3]

Based on current regulations and understanding of radiation, recommendations have been made to guide physicians and patients in safe practices. Patients may be released when the total effective dose equivalent of I-131 is unlikely to exceed 5 mSv/h (500 mrem/h). If any person is expected to receive a radiation dose of more than 1 mSv/h (100 mrem/h), appropriate

How to cite this article: Kheruka SC, Shankar N, Ora M, Gambhir S. Do current radiation safety guidelines allow the safe release of a thyroid cancer patient after high-dose radioiodine therapy? An Indian perspective. Indian J Nucl Med 2021;36:148-52.

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Received: 12-10-2020
Revised: 17-12-2020
Accepted: 19-12-2020
Published: 21-06-2021

Access this article online

Website: www.ijnm.in

DOI: 10.4103/ijnm.ijnm_210_20

Quick Response Code:

written and verbal precaution advice are required.[4] Similarly, the International Commission on Radiological Protection (ICRP) recommends releasing a patient as long as the radiation exposure to any other individual will likely not exceed 5 mSv/year (500 mrem/h). However, the radiation dose to a child, a pregnant woman, or an individual not involved in the patient's care should not exceed 1 mSv (100 mrem) per annum.[5] According to the NRC regulation, patients may not be released if, despite precautionary measures, exposure will exceed 0.05 mSv/h (50 mR/h).[6] As per the present Indian regulatory requirement, patients receiving <1.1 GBq (30 mCi) do not require hospitalization and can be treated on an outpatient basis. It also follows a similar recommendation and suggests that dose to any family member other than caregivers should not exceed 1 mSv/year (100 mrem/year).[7]

However, the restricted number of beds, nursing staff, and substantial patient numbers, especially in developing countries, have been vital health-care issues. Several studies have shown that the traditional practice of inpatient treatment for 2–3 days should not be obligatory for many cases. An outpatient treatment results in a minimal dose to the family members if the patient's families could comply with statutory dose limits and restrictions.[8-11] It could be more cost effective and has better patient acceptance.[12]

Studies have shown that after 1 day of hospitalization, most patients receiving up to 7.4 GBq (200 mCi) of I-131 have exposure rates below 0.07 mSv/h (7.98 mR/h). Over 75–80% of the dosage is excreted through urination.[13] Thus, any possibility of shorter inpatient treatment is always welcome. The outpatient treatment and discharge decision should be based on dose rate, administered activity, distance and time estimation, and occupancy factor. These factors need to be considered before the radionuclide therapy.[4] There is a significant difference in dose received by family members depending on these factors.[14] Both treating physicians and patients must be informed if radiation safety, an integral part of therapy with I-131, is attained. Although several guidelines have been proposed for outpatient treatment, they have not been well recognized by physicians and are rarely implemented for patients.

In our hospital set-up, we frequently encounter patients with low socioeconomic backgrounds. These patients travel in public transport and live in small houses. Many of them use common or community washrooms. We evaluated the radiation dose received by the caregivers of high-dose radioiodine therapy patients after discharge. We aim to evaluate if the current guidelines allow a safe release of patients after radionuclide therapy.

Materials and Methods

Patients

This prospective study enrolled a total of 22 radioiodine radionuclide therapies from May 2019 to October 2019. Written informed consent was obtained from each enrolled patient and their attendant.

The inclusion criteria:

1. Patients had undergone total thyroidectomy or subtotal resection
2. Postoperative pathological examination confirmed DTC
3. The surgical wound was well healed.

The exclusion criteria:

1. Patients with mobility difficulties such that the radiation dose rate could not be measured were excluded (we excluded patients with limited mobility as it was expected to bias the study for more exposure to the caregiver)
2. Patients or caregivers who did not give consent for the study.

Radionuclide therapy

l-Thyroxin administration was stopped at least 3 weeks before radioiodine administration. All patients were administered radioiodine when the TSH levels were >30 μIU/ml. Patients were administered 3–5 mCi of I-131 after fasting for more than 4 h and then remain fasted for 2 h after radioiodine administration. An I-131 whole-body scan (I-131-WBS) was then performed at 48 h. Radionuclide therapy dose was determined based on the postoperative pathology, residual thyroid status, and I-131-WBS. Other factors such as age, serum thyroglobulin level, a and metastatic sites (lymph nodes, lung, or bone) were also considered. The activity of the I-131 administered (sodium iodide I-131 oral solution, radiochemical purity ≥95%) was determined by two or more nuclear medicine physicians. The patient remained hospitalized after I131 administration, and the dose rate was measured every day at the distances of 1 m. Patients were instructed to maintain adequate hydration. The dose rate measurements were performed with a calibrated TBM-15D Digital Radiation Frisker/Survey meter. It has a Detector T-1190 with a 2" diameter (5 cm) and a "pancake GM" tube. It has plateau of 150 V <10%/100 V, window diameter of 1 ¾" (4.5 cm), area 16 cm^2, and window thickness of 1.5 mg/cm^2. The range of the survey meter was 0.01 to 200 mR/h (0.0000877–1.754 mR/h).

Discharge of the patient

Patients were discharged once the radiation dose decreased below 50 μSv/h (5 mR/h). On discharge, all the patients and caregivers were given detailed written safety instructions to minimize the exposure of persons coming in close contact Precautions for 7 days after therapy to reduce exposure to others.

- Flush the toilet twice after use; keep the lid down during flushing
- Males should sit down during urination to prevent contamination of the toilet
- After brushing teeth, rinse the sink with plenty of water

- Sleep alone
- Avoid kissing and close physical contact with others
- Avoid contact with pregnant and lactating females as well as infants and children up to 12 years of age
- Do not share utensils with the patient and wash them separately
- Do not share towels, bed linen, and undergarments
- Wash clothes separately, especially if they are stained with saliva, urine, or other body secretions
- Wipe the telephone's mouthpiece after use using a damp wipe and dump it in a plastic bag.

Long-term precautions

- Female patients should avoid pregnancy for 6–12 months after receiving I-131 therapy
- Male patients should not father a child for 2 months.

Breastfeeding

- Breastfeeding should be discontinued 6 weeks before radioactive iodine (RAI) therapy
- Breastfeeding should not be restarted after RAI therapy
- Breastfeeding is allowed if the woman conceives after 6–12 months of therapy.

Clear written instructions were given to the caregiver to minimize contact with patients. The caregiver's whole-body radiation dose was determined using thermoluminescent dosimeter (TLD) worn by the caregiver as a locket.

Radiation dose measurement

After 7 days following the patient's discharge, TLDs were collected from the caregiver. The effective dose estimations were carried out with TLD. It contains hot pressed chips from lithium fluoride (LiF: Mg, Ti) 3.2 mm × 3.2 mm × 0.15 mm, encapsulated between two sheets of plastic, and make the locket to give the patients. It has a 10 μGy–1 Gy (linear) detection threshold, 1 Gy–20 Gy (supralinear), with a detection threshold ≤10 μGy based on 2.26 standard deviations for ten sequential readings of an unexposed dosimeter. Harshaw TLD™ Model 3500 TLD reader was used. It has an emission spectrum of 3500–6000 Å (4000 maximum) and photon energy response of 1.25 keV/^{60}Co. Sensitivity is 1.0 at ^{60}Co relative to LiF, and measurement ranges are 10 pGy–10Gy. The TLD reader and cards were calibrated regularly. The combined accuracy of the dosimetry system was ±15 (±2 sigma) %. The control TLD was kept separately to measure the background. The background readings were subtracted from the readings of estimated effective doses to relatives TLDs.

Results

A total of 22 patients (8 male and 14 female) were recruited in the study. All patients were referred to the department after adequate surgery for radioiodine therapy. All the patients recruited in the present study had Karnosfky's performance score >60, i.e., they did not need any assistance in their daily activities. The mean age was 39.0 ± 14.5 years. Hitopathologies were papillary and follicular carcinoma of the thyroid in 18 and 4 patients, respectively. Out of 22 patients, eight patients show systemic metastases to bone or lung. Patients were treated with 3.79 ± 1.07 (1.85-5.55) GBq of radioiodine. The patient remains admitted in the ward for 1–5 days depending on the radiation burden. The radiation level at the time of discharge was <50 μSv/h in all patients. They were discharged from the isolation ward at a radiation level of 28 ± 15 μSv/h.

Out of 22, 13 caregivers were women. All caregiver returned the TLD batch after 1 week. The mean age of caregivers was 47.0 ± 11.1 years. The mean dose received by the caregiver was 14.60 ± 3.43 (9.73–24.25) mSv.

Discussions

Radioiodine therapy remains an indispensable adjuvant therapy for DTC. It is used as remnant ablation in high-risk patients, for lymph nodes and distance metastases. The primary emissions of I-131 decay are beta particles with a maximal energy of 606 keV (89% abundance), and 364 keV gamma-rays (81% abundance). Gamma rays escape from the patient's body and lead to undesirable exposure to other caretakers and health-care workers. Benefits to patients treated with radioiodine-131 must be balanced against radiation exposure to family members or relatives.

The eligibility criteria for outpatient treatment are living in a suitable environment, self-care abilities, and the possibility of being treated as an outpatient for radioiodine therapy. Several elements, including patient environment, financial costs, waste disposal, and psychological effects, contribute to the patient release in outpatient treatment.[15] Outpatient treatment or shorten hospitalization may reduce the load of public hospitals. However, many patients could not be considered for outpatient therapy if evaluated with a detailed history before dose administration. The common reasons are the unavailability of separate toilets and mode of transport.[16]

If properly implemented, the mean, external, effective doses to caregivers after patient quarantine for 3–4 days in the hospital were found to be 0.12 ± 0.10 mSv.[17] Other authors make similar observations in different settings.[18] In a study by Willegaignon *et al*., ninety monitored individuals received a mean dose of 0.27 (±0.28) mSv, and the maximum dose registered was 1.6 mSv. Outpatient therapy is considered as a high potential for reducing costs in health care and improving patient acceptance.[12] Outpatient-based remnant thyroid ablation with I-131 (1,110 MBq) performed in patients with DTC could be a safe alternative if applied under experts' appropriate supervision and guidance.[9,10] Despite poor compliance with safety guidelines, a short-stay protocol respects current legislation and applies to most

patients treated with 3.7 GBq.[19] Higher body weight and distant metastases may predict higher radiation exposure from patients after RAI therapy.[20]

However, there are issues of radiation safety of caregivers after outpatient treatment or release. In a large study, including 1549 patients, a patient-based survey was done. This survey suggests several concerns about radiation safety such as the decision process regarding inpatient versus outpatient treatment, instructions about radiation safety, transportation, and lodging after radioiodine therapy.[21] Greenlee *et al*. surveyed safety recommendations given to patients who receive I-131. A total of 311 endocrinologists, surgeons, nuclear medicine radiologists, and allied health professionals completed questionnaires. The author suggested a diversity of responses and a need for a uniform recommendation for patient safety instructions during and after I-131 treatment.[13] The decision of outpatient treatment or discharge should not only be based on the regulatory guideline. Safe I-131 outpatient treatment was achieved in a previous study by selective screening and providing instructions for patients and their caregivers. However, many patients (18 out of 62) could not be given outpatient treatment as they did not have separate bathrooms.[16] It is imperative to note that long travel in a public vehicle after discharge may lead to significant radiation to cotravelers. Measured dose rate profiles showed that, on average, one-third of the caregiver dose was received during the journey home from the hospital.[22]

In our study, we found a very high radiation dose received by the caregivers. Radiation dose to caregivers ranging from 9.7 mGy to 24.2 mGy (9.7 mSv to 24.2 mSv) reported in our study is not agreeable with many publications. In a study by the Pant *et al*., the family member's mean dose was <1 mSv. However, few caregivers received higher doses.[14] The caregivers do every day supporting and caring activities in the 1st week of the oral administration of radioiodine. It also includes traveling together in the shared vehicle, eating, and sleeping in the next or the same room, providing food and medications. Many factors can be attributed to highly discordant observations than the previously published data. The most critical factor in this regard is the socioeconomic constraints in developing countries. The lack of a different means of transportation and the long duration of the journey in close contact (from the remote areas to the tertiary care) may be the primary reasons behind it. Further, the lack of separate (or presence of single) rooms, toilets, and bathing/washing areas may have added to the cumulative doses. The prevalence of low literacy levels, especially in the rural setup, is also a substantial factor for the noncompliance of the instructions at the time of discharge.

Thus, patients can be considered potential sources of a high dose of exposure that may have radiation hazards for close contact with them.[23] Quarantine regulations for I-131-treated patients vary between countries and regions within countries. Both treating physicians and patients must be informed if radiation safety, an integral part of therapy with I-131, is attained.[4] In developing or poor socioeconomic countries like ours, individual detailed patient counseling should be done to minimize radiation exposure to the caregiver and caregivers. There are a few critical limitations of the study. First, the sample size is small. Proper usage and storage of the TLD batch could not be supervised. Large, prospective studies from the other institutes are needed to accumulate radiation exposure knowledge and understanding. There is an urgent need to relook at the dose limit for outpatient therapy policy as it may also lead to significant radiation to a caregiver.

Conclusion

Caregivers of DTC patients receive a significant radiation dose after the patients' discharge from the isolation ward. It was found well above the caregiver's annual dose-limit constraints regarding the local and ICRP guidelines of 5 mSv/year. This raises the possibility of inadequate counseling of radiation safety or the patient's inability to follow it. This also indicates a possibility of patient-specific discharge criteria rather than following standard guidelines.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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