

Management of challenging radioiodine treatment protocols: a case series and review of the
literature

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Abstract

Purpose: Radioactive iodine therapy with ^{131}I is standard of care for treatment in many patients with differentiated thyroid cancer. Typically, ^{131}I is administered as a pill, and much of its radioactivity gets excreted via the urine. This can present challenges in patients who are unable to swallow pills, absorb iodine via the gastrointestinal tract, or eliminate radioiodine via the urine (i.e. dialysis patients and patients with renal failure). In this case series, we present three cases in which the standard ^{131}I treatment protocol for thyroid cancer could not be executed due to these challenges, and discuss the strategies to overcome these challenges.

Results: Case 1 was a 4-year-old boy with Noonan syndrome, dysphagia, and metastatic papillary thyroid cancer. He was unable to swallow the standard ^{131}I pill due to the dysphagia. After a multi-disciplinary discussion between healthcare staff, a joint decision was made to proceed with liquid ^{131}I therapy. The system, which was used to orally administer 75 mCi (2775 MBq) of Na^{131}I in a liquid form, involved a vial provided to allow for mixing in grape juice. Case 2 was a 45 year-old male patient with significant scleroderma, severe gastric motility disorder, and papillary thyroid carcinoma. His severe gastric motility and malabsorption disorder precluded oral treatment due to risks of vomiting. Per discussions and collaborations with the patient's gastroenterologist, the decision was made to proceed with intravenous ^{131}I therapy, which was successfully performed after approval from the Radiological Health Branch of California. Case 3 was a 59 year-old male patient on hemodialysis with diabetes, hypertension, and follicular thyroid cancer. The challenge, in addition to waste disposal and dosimetry, was ensuring radiation protection for everyone present, given the risks of occupational exposures from radioactive iodine contaminating the dialysis machine. The radiation safety team monitored all healthcare workers and equipment involved, as per a joint decision by healthcare providers.

Additionally, the planned dose was reduced from 50 mCi (1850 MBq) to 30 mCi (1110 MBq).

None of the cases reported further disease progression since ^{131}I treatment.

Conclusion: These cases highlight unique challenges that can be encountered during radioactive iodine administration and approaches that can overcome these challenges. We conclude that provider collaboration and treatment customization are critical to overcome patient-specific challenges.

Keywords: Radioactive iodine, ^{131}I , thyroid cancer, patient care

Introduction

Radioactive iodine is considered one of the key treatment modalities for hyperthyroidism and differentiated thyroid cancer. The use of radioactive iodine isotopes for treatment of hyperthyroidism and metastatic thyroid cancer was first documented in 1946 (1). ^{131}I is used to treat Graves' disease (therapeutic dose: 10-15 mCi; 370-555 MBq), toxic multinodular goiter (therapeutic dose: 15-30 mCi; 555-1110 MBq), and thyroid cancer (therapeutic dose: 30+ mCi; 1110+ MBq) (2-4).

With a half-life of 8.02 days, ^{131}I emits gamma-rays and beta-particles, the latter causes localized therapeutic thyroid tissue destruction (5). The gamma-rays emitted by ^{131}I pass through body tissue and can therefore be valuable for diagnostic imaging (5). Together, these properties make administration of ^{131}I a useful adjunct therapeutic strategy for hyperthyroid disorders and thyroid cancer. With a marked increase in thyroid cancer incidence over the past several decades, the use of RAI as supplementary treatment is likely to remain important (6). In general, ^{131}I is administered as a pill, and much of the administered activity is excreted in the urine. While this is generally not an issue for most patients, there are exceptions, such as when patients are unable to take pills or absorb the administered dose, or in patients undergoing dialysis, where the normal urinary elimination is not possible. In this case series, we present three cases in which the standard treatment protocol could not be executed due to these challenges, and aim to inform providers of some available options should they encounter a similar case.

Case 1

Case 1 was a boy with a past medical history of Noonan syndrome with dysphagia diagnosed at birth. At four years of age, the patient came to our institution with an enlarged right thyroid lobe and was diagnosed with multiple thyroid nodules on a neck ultrasound. The ultrasound demonstrated a diffusely abnormal thyroid gland with microcalcifications, and bilateral enlarged cervical lymph nodes were abnormal with suspicious microcalcifications. These findings were highly suspicious for thyroid malignancy, and a fine-needle aspiration of the right thyroid nodule revealed papillary thyroid cancer. The following week, a CT of the neck and chest with contrast was performed, finding a lobulated heterogeneous mass in the right thyroid gland and multiple suspicious lymph nodes (Figure 1). The following month, a thyroidectomy was performed with radical neck dissection removing the suspicious nodes. A pathology report of the thyroid described a 4.2 cm primary papillary thyroid cancer with positive margins. In addition, angioinvasion and perineural invasion was present. 14 positive lymph nodes were identified at right neck levels II, III, IV, and VB, and left levels IIb and III. A pathologic stage classification, based on AJCC 8th edition, was determined to be at least pT3aN1b(cMx).

Given the patient's intermediate risk thyroid cancer, a recommendation was made for treatment with ¹³¹I. However, this case presented challenges due to the patient's young age and difficulty swallowing. Due to the patient's dysphagia, it was not feasible to administer the standard ¹³¹I pill orally. A joint decision was made to proceed with liquid ¹³¹I therapy as a result of a multi-disciplinary effort. As the patient had extensive bilateral neck involvement on pathology, a pre-therapy scan was recommended to assess for macroscopic residual disease burden.

Since ^{131}I is volatile, liquid administration required special preparations. Specifically, to avoid staff exposure to ^{131}I , a pharmacist provided a 5-10 mL oral solution of ^{131}I mixed with grape juice in a French square glass vial with a screw cap. The patient drank through a straw with a spinal needle that was attached to poke the Teflon septum within the cap. These preparations were designed to minimize evaporation of liquid ^{131}I . An anterior and posterior whole-body scan with SPECT/CT imaging of the neck was taken 24 hours after oral administration of 1.5 mCi (55.5 MBq) Na^{131}I (^{123}I was not available as a liquid for the diagnostic scan). Focal uptake was noted in the thyroid bed region in the neck, consistent with remnant thyroid tissue. There were no visible suspicious cervical or distant foci of radioiodine uptake to suggest metastasis.

The following day, the patient was admitted (as per the patient's legal guardian's request due to situations in the home) to our hospital for high dose RAI therapy. For the therapeutic dose of 75 mCi (2775 MBq) of Na^{131}I in a liquid form, the dose was again mixed with grape juice and ingested via a similar method as in the pre-therapy scan.

The patient was discharged two days after being admitted, and returned the following week for the post-therapy anterior and posterior whole-body scan supplemented by SPECT imaging of the neck (Figure 2). A year after therapy, the patient received a follow-up neck ultrasound to evaluate the surgical bed. Post-surgical changes related to total thyroidectomy were observed, while no new suspicious soft tissue nodules or lymph nodes were found. There were a few bilateral non-specific soft tissue nodules, but they have been unchanged from his last ultrasound the previous year, and were felt to represent postsurgical and post-treatment changes. The most recent lab results using an ultra-sensitive thyroglobulin assay showed an expected very

low level of thyroglobulin (0.6 ug/L; normal range is 1.4 – 29.2 ug/L) and undetectable thyroglobulin antibodies of <2.00 IU/ml.

Case 2

Case 2 is a 45-year-old man with a medical history of scleroderma with severe gastric motility disorder. An ultrasound followed by fine-needle aspiration a year prior to treatment led to a diagnosis of papillary thyroid carcinoma. Imaging showed bilateral solid thyroid nodules with microcalcifications. Later that year, the patient underwent thyroidectomy with radical neck dissection. Features typical of papillary thyroid carcinoma, including papillary architecture, nuclear crowding, nuclear clearing, and nuclear groove and intranuclear pseudoinclusion were observed in sections of both the right and left thyroid lobes. In both lobes, there were two foci and the cancer was confined to the thyroid with negative margins.

The patient was then referred to our service for RAI. A major challenge identified in this patient's treatment was his medical history of scleroderma resulting in gastric motility and malabsorption disorders precluding oral intake and requiring total parenteral nutrition (TPN). Due to these challenges, the risks of treatment with oral ^{131}I in this patient included significant difficulties in absorbing the pill and a very high risk of reflux and vomiting. As a result, and per discussions with the patient's treatment team, the decision was made to proceed with ^{131}I therapy via intravenous administration.

However, in contrast with case 1, this required special dispensation from the state for intravenous administration due to the different route (IV vs. PO). Therefore, a one-time request was placed to the Radiological Health Branch of California for dispensation to administer IV

^{131}I , which was granted in April of 2018. This request was an amendment to the license for a one-time IV usage. In addition, a vendor had to be located to provide a sterile form for IV. The patient was pretreated with two daily intramuscular injections of 0.9 mg of thyrogen. Following state board approval, the 50 mCi (1850 MBq) Na^{131}I used was administered through an intravenous catheter (IV). No immediate adverse events were observed.

Post-therapy whole-body SPECT/CT imaging of the neck was taken the following week did not find any distant metastatic disease (Figure 3). This year, a neck ultrasound found that the patient was status post thyroidectomy without new or suspicious findings. The most recent thyroglobulin lab-work taken (four months ago) revealed thyroglobulin levels of 0.1 ug/L (nearly undetectable, reference range for intact thyroid: 2.8-40.9 ug/L and thyroglobulin antibodies of 1 IU/mL (within the normal range of ≤ 1 IU/mL).

Case 3

Case 3 is a 59-year-old man with diabetes mellitus, hypertension, and end stage renal disease on hemodialysis. One challenge with hemodialysis in the context of radioactive iodine treatment is ensuring radiation protection for everyone present, as there is a risk of the radioactive iodine contaminating the dialysis machine and increasing occupational exposures. In addition to the contamination control and occupational exposure issues, there are concerns with waste disposal, dosimetry, and patient release issues. Finally, since the elimination of the ^{131}I is largely through the dialysate, the administered dose may need to be modified from typical protocol.

The patient was referred from outside of our medical center for treatment with radioactive iodine after surgery for an 8 cm, pT3aNx, follicular thyroid cancer with capsular vascular invasion. The patient underwent a whole-body scan with ^{123}I . Anterior and posterior images of the neck and entire body were taken 24 hours after oral administration of 2.59 mCi (95.83 MBq) Na^{123}I . No distant uptake was found to suggest metastasis, and the focal uptake noted within the thyroid bed was consistent with residual thyroid tissue after recent thyroidectomy.

The two major problems in patients with end stage renal disease on dialysis are requirement of dose reduction due to negligible renal clearance of radioiodine and the radiation protection during dialysis. The patient's hemodialysis requirement presented challenges (including radioiodine accumulation and radiation exposure) for radiation protection of the providers who would be caring for the patient during dialysis. Our workflow for managing this case is illustrated on figure 4. Specifically, multidisciplinary meetings were held involving radiation safety, nuclear medicine, endocrinology, and nephrology. The decision was made that the radiation safety team would monitor all the personnel and equipment involved, check for contamination of dialysis machines and dialysis ports, and hold the kits for decay as needed, including the first 3-4 dialysis sessions after the ^{131}I dose. Training materials for dialysis lab personnel are included as a supplemental file. Additionally, all dialysis unit staff received training from radiation safety personnel.

The following month, the patient received 29.8 mCi (1102.6 MBq) of Na^{131}I as a pill for the treatment of follicular thyroid cancer. The dose selection was lowered (following a discussion among healthcare staff and consultation of the relevant literature) from an anticipated

dose of 50 mCi (1850 MBq) due to the use of dialysis, to reduce radiation dose to the marrow secondary to the lowered clearance. The patient was admitted to our hospital for this procedure.

The patient was prepared for therapy by thyroid hormone withdrawal. The patient's outpatient dialysis record showed a normal session the day before the therapy without any adverse events. Following collaboration between the nuclear medicine and radiation safety teams, primary nephrologist, and outpatient nephrologist, the patient received dialysis the day after the radioactive iodine therapy, with intermittent hemodialysis (IHD) for 3.5 hours planned for 3 consecutive days following RAI. The patient tolerated the IHD well. Radiation safety checked the dialysis machines and ports for contamination, and due to the effluent volume of 800 ml/minute, no contamination was detected. There were no complications nor radiation risks after careful planning.

The post-therapy ^{131}I scan supplemented by SPECT/CT imaging of the neck found no evidence of distant metastatic disease (Figure 5). Most recently, a year and two weeks after the radioactive iodine therapy, the patient underwent anterior and posterior imaging of the neck and entire body without SPECT 24 hours after oral administration of 2.24 mCi (82.88 MBq) Na^{123}I . No abnormal radioiodine uptake was observed to suggest recurrent or metastatic disease.

Discussion

Case 1 described a patient unable to take pills due to developmental anomalies and young age. At present, ^{131}I pills are the standard medicinal preparation for RAI treatment of hyperthyroidism and thyroid cancer. Bekier et al. concluded that administration of capsular ^{131}I is

a safe formulation for treatment of thyroid disease, demonstrating that gastric radiation dose from ^{131}I pills was only high locally and was below the level that would cause tissue necrosis (7). However, unique patient challenges, such as dysphagia, may limit or restrict safe administration of oral ^{131}I in pill form. The patient in case 1 and his family cited an inability to swallow pills, and was consequently administered liquid oral ^{131}I . No adverse events took place, and dose was administered safely without exposure to technologist staff.

Previous studies concerning ^{131}I therapy also describe administration difficulties and alternative treatment protocols similar to those discussed here (Table 1). Aside from difficulty swallowing pills, Aamri et al. reported pill-related instances of patient-caused radiation hazard, pill adherence to the container, and technologist mishandling of the substance (8). Additionally, Halpem et al. proposed the formation of iodine-gelatin complexes in the GI tract as a possible mechanism for lower thyroidal uptake of capsular ^{131}I relative to the liquid form (9). One proposed solution involved endoscopically depositing the solid ^{131}I pill into the stomach—effectively minimizing risk of spillage, exposure, and incorrect administration (10). However, endoscopy is invasive and carries risks for the patient.

Rini et al. commented on the more-than-intended irradiative impact of encapsulated ^{131}I —particularly when used as a diagnostic tracer—compared to liquid-form ^{131}I (11). Using a pill-form ^{131}I tracer, this group observed a mean diagnostic ^{131}I uptake 14% lower than the corresponding therapeutic ^{131}I uptake (44% versus 58%), reflecting the increased uptake when a pill is delivered with a therapeutic dose than a diagnostic dose. They concluded that in hyperthyroid patients treated with ^{131}I liquid therapy compared to encapsulated ^{131}I , uptake of diagnostic doses of ^{131}I liquid better predicts uptake of therapeutic doses of ^{131}I liquid (11). It is therefore recommended that health teams familiarize themselves with liquid and intravenous

(IV) ^{131}I administrative safety and technique. Overall, while administration of ^{131}I in a pill form is used as the first option, it is important to remember that liquid administration remains a safe, and effective alternative, provided appropriate radiation safety precautions are followed (3,12).

Unlike Case 1, Case 2 did not have dysphagia, and could swallow, but he had significant gastrointestinal dysmotility which often manifested as episodes of pseudoobstruction with gastroparesis. Therefore, the patient was largely dependent on total parental nutrition. Thus, the decision to use IV treatment was due to severe gastric motility and malabsorption precluding oral or gastrostomy tube treatment, and was made after months of ongoing discussion. Advantages of IV treatment relative to oral ^{131}I therapy include enhanced diagnostic accuracy, rapidity, and the ability to treat patients with impaired gastro-intestinal absorption (13). The risks associated with IV treatment include the liquid iodine's volatility which makes it more dangerous to handle and increases the risk of major spills and exposure to technologists. Meticulous care was undertaken and no spill or other adverse event took place.

Patients are more prone to experience nausea as ^{131}I dosage increases (14,15). Additionally, patients demonstrating multiple disease processes including gastroesophageal reflux disease, gastroparesis, gastric outlet obstruction, and other similar conditions are at increased risk of vomiting (15). Overall, this case demonstrates that intravenous administration of ^{131}I is a safe and effective alternative in cases where great difficulty with oral administration and gastrointestinal absorption is anticipated.

Case 3 evidences an instance of end stage renal disease complicating radioactive iodine treatment for follicular thyroid cancer. In patients with normal renal function, the ^{131}I would be excreted through the urinary system; thus, impaired renal function complicates iodine clearance and theoretically potentiates blood radioactivity risks. Although the dialysis machine would

likely compensate to some extent for this decreased clearance, hemodialysis patients are still impacted by decreased clearance of ^{131}I (16). In addition, there are risks of dialysis staff and machinery contamination (16). In fact, the main challenge with this patient was the radioactive dialysate waste, and managing staff exposure and training. Contingency plans are necessary for addressing fluid spills during dialysis (17). Mercurt et al. supplied an illustrated schematic and protocol for safe hemodialysis of patient in need of ablative ^{131}I RAI therapy, much of which mirrors the methods described here (18). Additionally, under dosimetry guidance, high-dose IV treatment of differentiated thyroid cancer patients is safe and may also reduce radiation dose (19). To limit risks of bone marrow toxicity and further renal insult, therapy doses should not exceed the prescribed amount in any patient, including those on dialysis, as Magné et al. have recommended. In their dialysis patient case report, a radioiodine dosage no more than 125% of the currently prescribed concentration (20). Table 2 describes other successful oral ^{131}I administration cases for patients with end-stage renal disease on hemodialysis.

Prior studies have suggested that dialysis patients have increased systemic retention of ^{131}I , and therefore have suggested reductions in the administered ^{131}I dose, although no uniform consensus exists. Citing rapid iodine clearance, Betcher et al. concluded that dialysis reduces effective radiation dose and necessitates larger ^{131}I treatment doses to achieve equivalent outcomes of patients with normal renal function (21). Jimenez et al. administered the same doses of ^{131}I to hemodialysis patients that patients with normal renal function receive. In their small cohort (n=3), this therapeutic protocol provided ^{131}I dosages and avoided patient radiation overexposure (22). Alevizaki et al. utilized a 40-50% activity reduction of ^{131}I , finding that none of their patients experienced short-term side effects or presented with detectable thyroglobulin levels on their first post therapy evaluation (n=5, inclusion criteria = end stage renal disease)

(23). Vermandel et al. concluded that an approximately 30% reduction from nominal ^{131}I dosage struck the best balance between hematologic toxicity and treatment efficacy (n=6, inclusion criteria = ESRD patients undergoing hemodialysis) (24). Following their lead, we chose to reduce the dosage despite some of the literature recommending no change or even increased doses; our case involved a 40% reduction from our typical 50 mCi (1850 MBq) to 30 mCi (1110 MBq) to minimize radiation exposure to marrow secondary to reduced clearance of ^{131}I .

Conclusion

In summary, ^{131}I is a common treatment for hyperthyroidism and thyroid cancer, and most patients may be treated using standardized protocols as defined by The Society of Nuclear Medicine and Molecular Imaging (12). We have presented three cases which presented technical difficulties for nuclear medicine and radiation safety staff. All three cases included patients that received alternatives protocols due to their specific clinical status/challenges (dysphagia in Case 1; severe gastric dysmotility in Case 2; End stage renal disease on hemodialysis in Case 3), and all cases reported no further disease progression since ^{131}I treatment. These shared cases should be of particular use to nuclear medicine technologists and physicians presented with clinically similar challenging cases. Through this case series of patient-specific applications of ^{131}I RAI therapy, we hope to inform providers of alternatives to standard RAI treatment protocols, and the importance of provider collaboration and treatment customization to overcome patient-specific challenges.

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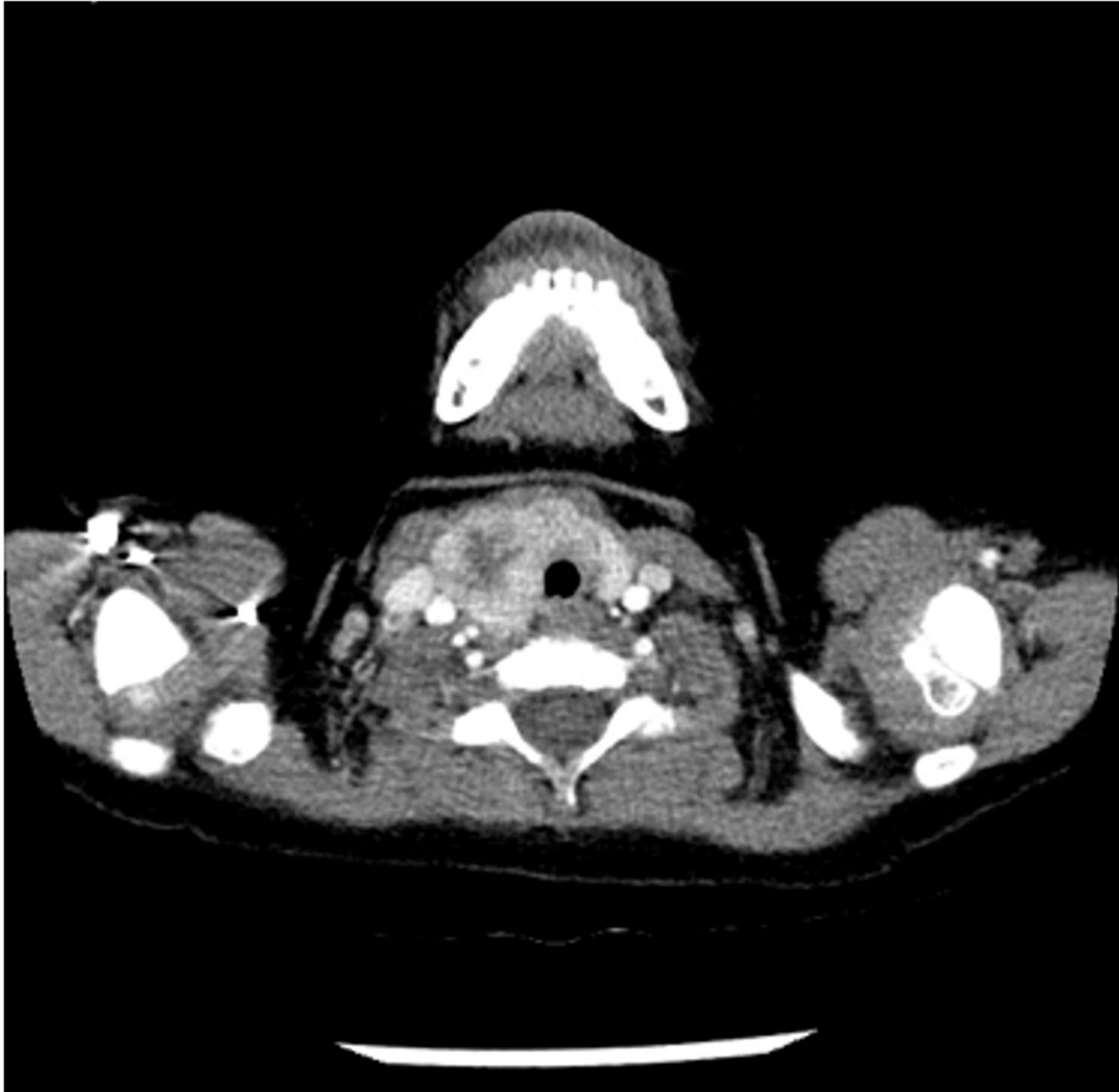


Figure 1. Case 1, CT Scan. Axial CT demonstrates a lobulated and heterogeneous 3.4 x 2.9 x 3.3 cm right thyroid mass extending into the right superior paratracheal space. Abnormal right cervical and bilateral paratracheal lymph nodes and a nonspecific 2 mm left lower lobe pulmonary nodule were also seen. Findings were suggestive of thyroid cancer with cervical nodal metastases.

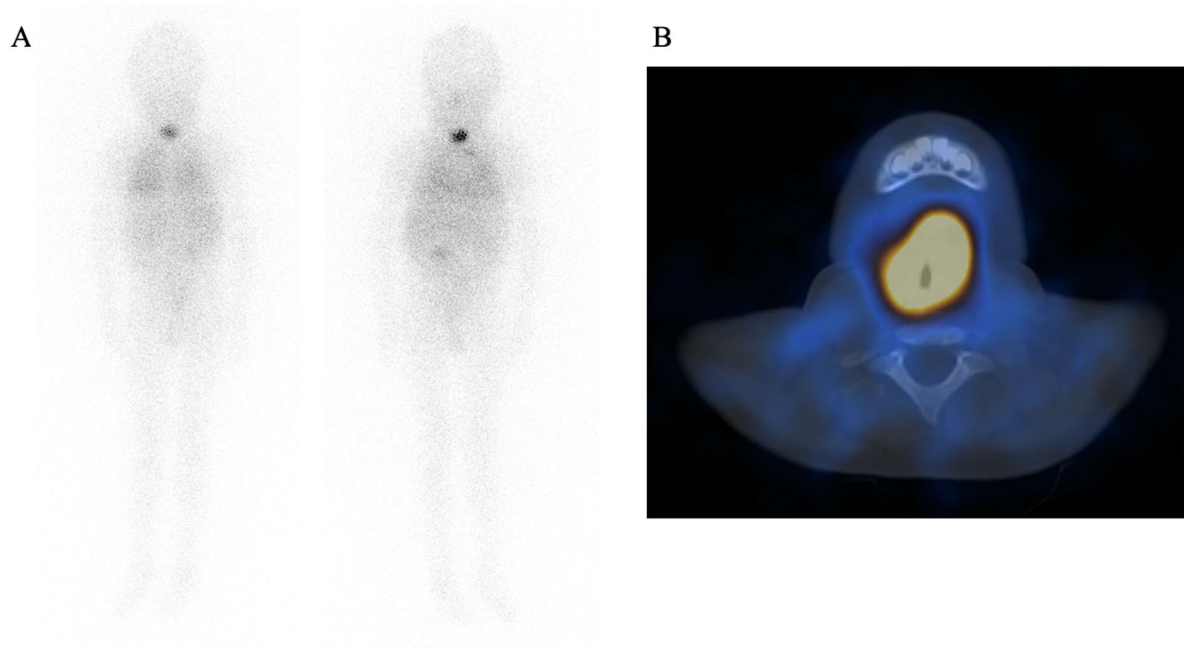


Figure 2. Case 1, Post-therapy Scan of patient 1. Left (A): Whole body scan obtained after administration of 75 mCi ^{131}I (2775 MBq). Right (B): SPECT imaging of the neck. These images are consistent with residual thyroid tissue, as focal tracer uptake was noted within the thyroid resection bed.

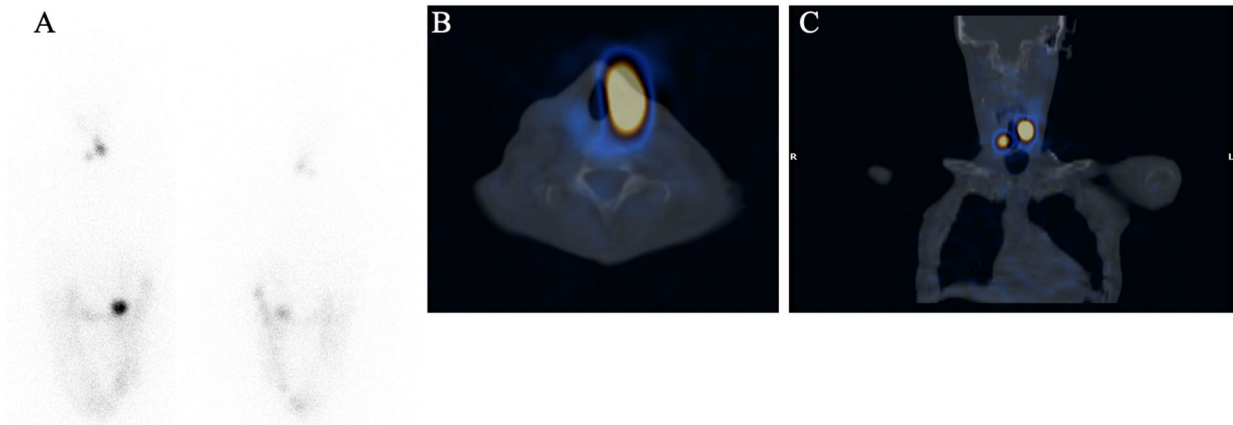


Figure 3. Post-RAI therapy scan of case 2 with intravenous administration of ^{131}I . (A): Whole-body scan obtained after administration of 50 mCi ^{131}I (1850 MBq). (B) and (C): SPECT/CT imaging of the neck, showing focal tracer uptake in the thyroid bed was observed, consistent with residual thyroid tissue. No distant metastases were observed.



Figure 4. Workflow for management of ESRD patients on dialysis referred for RAI.

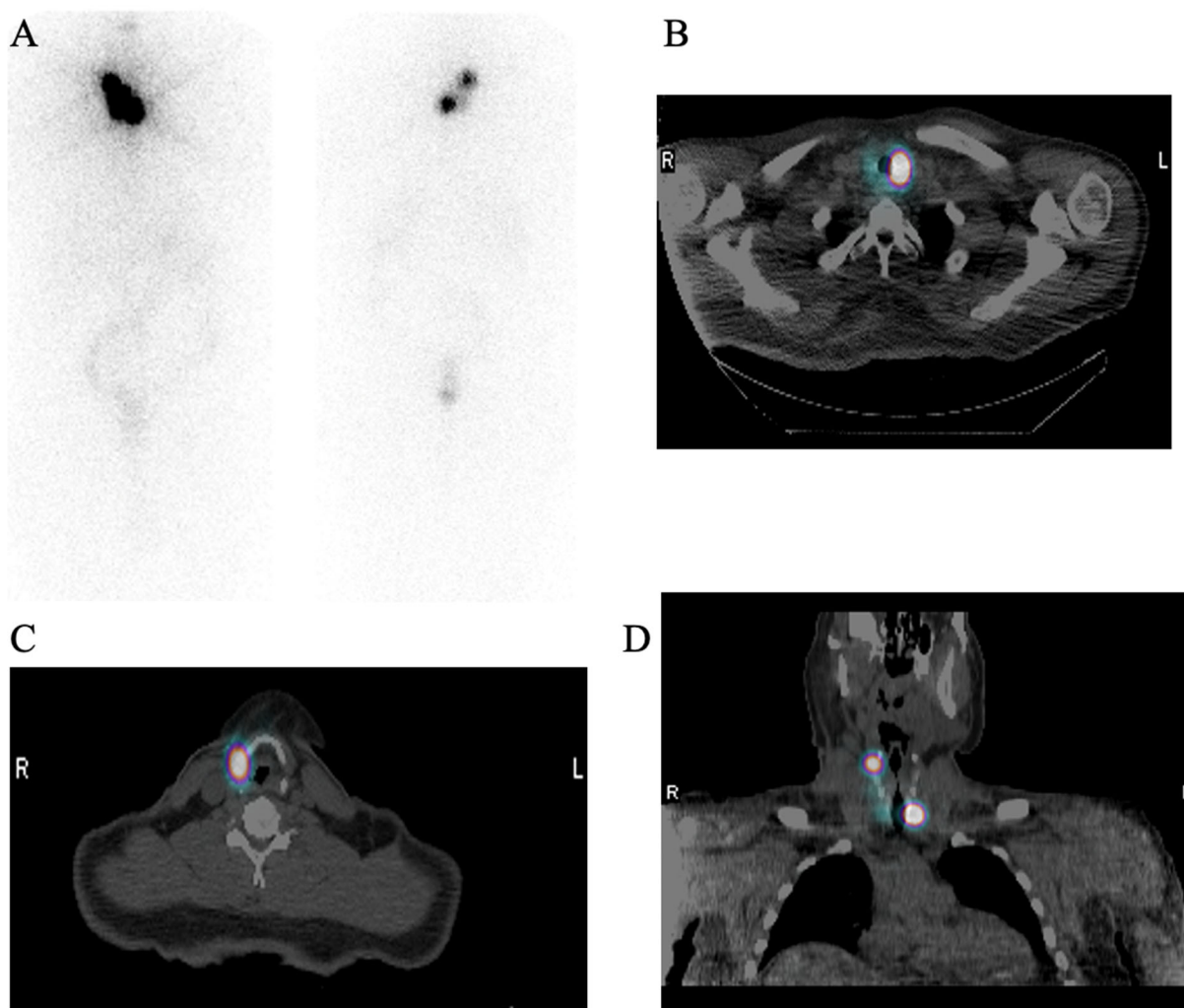


Figure 5. Case 3, Post-therapy Scan of Dialysis Patient. Left (A): Whole-body post ^{131}I scan. B-D: SPECT/CT imaging of the neck and upper chest. These images show no evidence of distant metastatic disease. However, they did find three discrete regions of tracer activity within the neck, consistent with radioiodine avid tissue, likely residual thyroid tissue after thyroidectomy.

Table 1. Other studies on liquid I-131 administration

| Study | Summary | Similarities with Case 1 | Differences with Case 1 |
|-----------------------|---|--------------------------------------|---|
| Rini et al. [11] | Capsular I-131 tracers expose patients to higher-than-intended amounts of radiation, compared to liquid I-131 tracers | N/A | Inclusion criterion: Graves' disease, radiation uptake compared |
| Al Aamri et al. [7] | Several capsule-related mishaps are cited here (i.e. Perspex tube adherence, swallowing difficulty, radiation exposure) | Pill dysphagia | Radioactive mishandling and misuse described |
| Cheen Hoe et al. [14] | Case series of 144 RAI patients, documents minimal fluid intake for speedy recovery | N/A | High dose solid I-131 therapy |
| Shields & Johnson [8] | Novel presentation (2011) of capsular I-131 administration via endoscopic stomach implantation | Successful pill dysphagia workaround | Endoscopy required, capsule I-131 administered |

Table 2. Other studies on oral I-131 administration for dialysis patients

| Study | Summary | Similarities with Case 3 | Differences with Case 3 |
|-----------------------|---|---|---|
| Vermandel et al. [13] | Six ESRD patients were administered reduced RAI formulae to treat thyroid cancer. Their bone marrow toxicities were analyzed to define optimal dosimetry. | ESRD, successful removal of I-131 remnants | Dosimetry used to minimize toxicity |
| Magné et al. [12] | Hemodialysis was safe and effective during oral I-131 RAI treatment of differentiated thyroid carcinoma | ESRD, Metastases, successful excretion | Papillary thyroid carcinoma, metastases in 9/16 cervical nodes |
| Mercutt et al. [10] | Safe hemodialysis techniques and protocol is shared here for 1) minimizing radiation risks and 2) maintaining RAI treatment | ESRD, Successful excretion, patient interaction minimized | N/A |
| Bhat et al. [9] | Radioactive ablation in ESRD patient post complete thyroidectomy saw successful treatment, now 4 y post treatment. | ESRD, history of hypertension, diagnostic pre-scan with I-123 | Goiter, presented with shortness of breath, post left-thyroidectomy |