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Received dose variability after administration of I-131 for treatment of hyperthyroidism in cats

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Abstract

Background: Injectable radioactive iodine (I-131) frequently is used to treat hyperthyroidism in cats. In human medicine, residual activity after injection of radionuclides has been reported, and the actual quantity administered is recorded after administration.

Objective: Our aim was to evaluate actual administered dose variability after administration of preprepared I-131 single unit doses for the treatment of hyperthyroidism in cats.

Animals: Twenty-seven cats with hyperthyroidism treated with I-131 between April 2017 and March 2019.

Methods: Retrospective observational study of cats treated with preprepared single unit I-131 doses. For each dose, the measured activity before administration and residual activity were recorded. The measured dose and the actual dose administered were compared to the prescribed dose.

Results: Measured activity before administration ranged from 88.4% to 103.3% of the prescribed dose. Mean residual activity was 5.2 ± 3.0 MBq (ranging from 1.5% to 15% of the prescribed dose). The actual dose administered (measured activity − residual activity) ranged from 79.1% to 100.2% of the prescribed dose. Seventeen of 28 (60.7%) of the actual administered doses differed between 10% and 20% of the prescribed dose. One administered dose had a >20% difference compared to the prescribed dose (79.10% of the prescribed dose).

Conclusion and Clinical Importance: Our study identified variability in the residual and actual administered activity of I-131 as compared to the prescribed dose, which should be taken into consideration when treating cats with (predrawn) I-131.

KEYWORDS
dosimetry, feline, radio-iodine therapy, residual activity

1 | INTRODUCTION

Hyperthyroidism is the most commonly diagnosed endocrine disorder in older cats and generally is caused by benign adenomatous disease of the thyroid gland (or rarely thyroid carcinoma).[1-5] Radioactive iodine has been reported to be a safe and effective treatment, with a >95% success rate after a single treatment for cats with mild-to-moderate hyperthyroidism.[4,6-13]

Different doses have been reported in the veterinary literature for the treatment of hyperthyroidism in cats, ranging from 1.5 to 40 mCi (55.5-1480 MBq).[4,6,7,9-12,14-17] The required dose can be prepared on-site or individual radioactive iodine (I-131) unit doses can be

ordered from a centralized radionuclide pharmacy. In human medicine, it has been estimated up to 80% of radiopharmaceutical doses in the United States are dispensed by a central radionuclide pharmacy.[18] Considerations for this central approach include cost-effectiveness, increased quality control of radiopharmaceuticals, and pressure to decrease man power within health care institutions.[18,19] This option may be suitable for veterinary practices where no controlled area is available to allow for the safe preparation of radiopharmaceuticals such as I-131. Furthermore, single unit doses can be a cost-effective alternative if only a small number of patients is treated.

In human medicine, it is recognized that, for logistical reasons such as postinjection residual activity, considerable variation may occur between the prescribed and administered activity of radiopharmaceuticals.[20-35] This variation potentially can lead to inadequate dosing and treatment failure. Several local guidelines and consensus statements for human patients were consulted to identify recommendations regarding acceptable dose discrepancies between the prescribed and administered dose in nuclear medicine.[20,21,28,34] Based on these local guidelines, the dispensed, measured, and administered quantity of radioactivity is recommended to be within 10%, 5% to 10%, and 10% to 20% of the prescribed activity, respectively.[20,21,28,34] No such guidelines exist in veterinary medicine and, despite wide use clinically, dose variability after I-131 administration has not been evaluated in veterinary medicine.

The standard practice at our facility since 2017 was derived from the standard practice at the regional human hospital. After publication of the most recent local guidelines for humans, cases were reviewed retrospectively to assess if the current standards of care for cats treated with I-131 at our institution were in line with the nuclear safety guidelines and recommendations used in humans.[20,21,28,34]

Our primary objective was to obtain data on dose activity variability of the actual administered dose of I-131 as compared to the prescribed activity and to assess at which level in the workflow the discrepancies occurred. We hypothesized the variability would be within 20% of the prescribed activity as recommended by guidelines used for human patients. Discrepancies between the prescribed and administered dose were suspected to occur mainly because of prepatient factors.

2 | MATERIALS AND METHODS

2.1 | Study design

A retrospective observational study was conducted to investigate administered dose variability after treatment with I-131 unit doses.

2.2 | Patient selection

The electronic medical records of all cats treated with I-131 unit doses at the Massey University Veterinary Teaching Hospital (MUVTH), between April 2017 and March 2019 were reviewed. For each patient, the prescribed I-131 dose, measured activity before injection, and residual I-131 activity in the syringe were evaluated.

2.3 | Unit doses

All I-131 unit doses were purchased from a single provider. The doses were ready to inject, and the dose activity was calibrated by the provider for the time and date of treatment. The required volume was delivered in predrawn disposable syringes. In all cases, a 3-mL plastic syringe with an attached 23-gauge needle was used. The doses were prepared by a distant pharmacy on Mondays. After arrival at our facility, the I-131 unit doses were stored at room temperature in the provided lead container until the time of treatment.[35]

The provider guaranteed that the activity of the unit doses differed by <10% from the ordered activity at the exact time and date of treatment. Before administration to the patient, the activity of the I-131 unit doses was determined using a dose calibrator. Assessment of the doses before treatment was performed at the scheduled day and time of administration (Thursdays at 12.00 pm).

The I-131 unit dose analysis was performed using a radioactivity calibration system (ATOMLAB 100 plus dose calibrator, Biodex Medical Systems Inc, Shirley, New York) in MBq immediately before administration.

The clear plastic chamber well liner was placed into the chamber well and the plastic sample holder was lowered into the liner. The 3-mL plastic syringe containing the I-131 unit dose was carefully placed into the sample holder using tongs, and then both were placed into the chamber well, near the center of the chamber. A background measurement was performed before each activity reading.

2.4 | Handling

The syringe and solution were inspected visually for particulate matter and discoloration before each administration. The radioactive iodine was administered SC in a shaved area on the left flank in all cats after assessment of the measured dose. For 1 patient, a second I-131 unit dose was ordered and administered because of failure to administer the original dose correctly. Cats were not sedated for the I-131 administration. Residual dose measurements after administration were performed as described above, immediately after injection. All cats were housed in isolation for 14 days after treatment.

A radiopharmaceutical record was maintained that included batch number, time, date, patient name and number, name of the clinician administering the dose, prescribed dose, calculated dose, measured activity before injection, residual activity, and actual administered activity as defined in Table 1. The number of doses for which the measured dose differed >10% from the prescribed dose and the number of administrations for which the actual administered dose differed by >20% from the prescribed dose were recorded. Results were compared to the previously described recommendations for humans.[20,21,28,34]

A Code of Safe Practice has been produced by the Office of Radiation Safety (ORS) to ensure the safe use of I-131 for treatment of cats with thyroid disorders using radioactive iodine (I-131).[35] Both users of radioactive materials had an appropriate license under the Act for the purpose of Veterinary Therapy under the Radiation Protection Act 1965.

2.5 | Statistical analysis

Descriptive statistics were performed. The actual administered and residual activity were calculated as defined in Table 1.

TABLE 1 Definitions

Definitions	
Unit dosage	Dosage prepared for medical use for administration as a single dosage to a patient without further manipulation of the dosage after it is initially prepared[28]
Prescribed dose	The intended and ordered activity as specified by the authorized clinician
Calculated dose	The activity calculated by the nuclear pharmacy for the time and date of administration
Measured dose	The activity measured in the on-site dose calibrator, immediately before administration
Residual syringe dose	The remaining activity in the syringe was measured, and the percentage of residual activity was calculated using the following equation: $\text{Residual activity}\,(\%) = \frac{\text{Residual activity (MBq)}}{\text{Measured activity (MBq)}} \times 100$
Actual administered dose	Administered dose (MBq) = measured activity (MBq) − residual activity (MBq) $\text{Administered dose}\,(\%) = \frac{\text{Administered activity (MBq)}}{\text{Prescribed activity (MBq)}} \times 100$

3 | RESULTS

All I-131 unit doses administered as treatment for cats with hyperthyroidism during the study period were included in the study. Twenty-eight I-131 unit doses were administered to 27 cats during the study period at the scheduled day and time of administration.

A fixed dose of 100 MBq calculated for the time of calibration (Thursday 12.00 pm) was ordered for 23 patients. For 1 patient, a second dose of 100 MBq was ordered because of misadministration of the original dose. For 2 patients, a lower dose of 75 MBq was ordered, based on the scoring system for selection of the I-131 dose as described previously and based on relatively mildly increased serum total thyroxine concentrations (44.0 nmol/L and 60.9 nmol/L, respectively; reference range, 10.4-42.0 nmol/L) measured before treatment.[4,6,13] A higher dose of 115 MBq was ordered for 2 cats with serum total thyroxine concentrations of 223.90 nmol/L and 483.0 nmol/L, respectively.

The total dose calculated by the provider ranged from 75 to 122 MBq (mean ± SD, 100.5 ± 8.5 MBq). The measured activity of the I-131 unit doses ranged between 66.7 and 111 MBq (mean ± SD, 93.3 ± 8.2 MBq). The measured activity before administration ranged from 88.4% to 103.3% of the prescribed dose, and 5 of 28 samples (17.9%) differed between 10% and 20% from the prescribed activity (mean ± SD, 6.1% ± 3.5%) at the time of administration.

TABLE 2 Possible sources of administered dose variability (adjusted from Ref. 28)

	Source of dose variability	Variability
Prescribed/ordered dosage		
↓		
Dosage calculated by compounding nuclear pharmacy to account for radiochemical breakdown during transport and storage	Human error	
↓		
Unit-dose preparation	Technique/human error	Unknown
↓		
Measured dosage	Calibrator accuracy Variations in geometry within the chamber Difference between the dosage calibration time and dosage administration time Volume of the patient dose Storage temperature and material	% of prescribed dosage ±5% [21,28] to 10% [20 a]
↓		
Residual activity	Syringe-Needle Dead space volume Syringe type Properties of the radiopharmaceutical Injection technique/care and awareness Adsorption to Vessel Wall Retention time Demeanor of the patient	Approximately up to 6%[28]
↓		
Administered dosage		% of prescribed dose ±10%[28] to 20%[34 a]

[a]Recommended maximum.

The postinjection residual activity in the syringe was measured immediately after administration and ranged from 1.5 to 15 MBq (mean ± SD, 5.2 ± 3.0 MBq) corresponding to 1.5% to 15% of the prescribed dose (mean ± SD, 5.2 ± 2.9 MBq).

The administered dose ranged between 79.1% and 100.2% of the prescribed dose (mean ± SD, 88.80% ± 4.4%). For 60.7% of the administrations (17/28), the actual dose administered differed between 10% and 20% from the prescribed dose. One cat (3.6%) received a dose that differed by >20% of the prescribed dose (79.1% of the prescribed dose).

4 | DISCUSSION

Syringe activity before administration and residual activity are not standardly reported in the veterinary literature. Instead, dosing recommendations generally are based on the intended I-131 dose (the prescribed activity) and the expected clinical outcome.

In human medicine, it is recognized that there may be a considerable variation between the prescribed activity and the actual administered activity of radionuclides. Verification of the administered activity by means of a dose calibrator is recommended to ensure the total activity does not deviate substantially from the prescribed activity, and the measured value should be recorded.[21] Consensus recommendations on the activity difference that is considered substantially different appear to be lacking.

In our study, the actual administered dose ranged from 64.3 to 100.22 MBq and, in 64.3% of patients, the actual administered dose was >10% lower than the prescribed dose. Several possible sources of dose variability during different stages of dose delivery have been considered (Table 2).

Postinjection residual activity has been reported for various drugs, including several radiopharmaceuticals. The residual activity is generally small at 1% to 9%, but some reports suggest residual activity can reach levels up to 80% for specific radionuclides.[22-25,32,33] In addition to an expected dead space residual volume, storage temperature, storage material, plunger type, and retention time in the syringe have been described to affect the residual activity.[25,32,33,36] Because of the logistics of delivery, residence time in the syringe was substantial during our study (>48 hours). Iodination of plastic vials used for shipping of I-131 capsules previously has been reported, with I-131 activity of the plastic container ranging from 0.5% to 2.4% of the total activity in the vial measured 1 day before calibration.[26] The results indicated that measurements of capsule activity in the plastic vials used for storage may lead to overestimation of the administered dose, especially for capsules that have been stored for several days.[26,27] The average residual activity in our study was 5.2% of the prescribed dose. Further assessment of the effect of the residence time and the material of the syringe on the residual activity of I-131 could be valuable and would add to our understanding of I-131 dosing.

In addition to the prepatient factors, the behavior of the cats could have affected the actual administered dose variability in our study, because I-131 administration was performed in conscious animals with different behavior and temperaments. Administration of I-131 unit doses in sedated patients potentially could improve repeatability and minimize this aspect of the dose variability.

Our study was initiated based on guidelines for humans and we hypothesized that similar dose variability could exist in cats. Considerations that should be taken into account include a different method of administration. Encapsulated I-131 is the primary treatment form in human health care, whereas liquid I-131 is used for PO administration in selected cases.[20,37] The SC administration of I-131 differs from the PO administration of I-131 using capsules, where syringes are used to fill the capsules in a controlled environment. Furthermore, because of the geographical location of our institution, there was a prolonged retention time in the syringe, which could have contributed to the residual activity.

Although information on the residual activity and injection technique in veterinary medicine is limited, we assume other studies, including those used for I-131 dose references, might have encountered similar issues during workflow leading to discrepancies between the prescribed and actual administered dose. Although the actual administered dose may be lower than assumed based on the published prescribed dose recommendations, for most patients the anticipated therapeutic end point is achieved with >95% of cats reported to have normal serum thyroid hormone concentrations by 3 to 6 months after treatment.[6,9] In recent years, even lower doses of I-131 have been described in the veterinary literature with possible benefits including lower radiation exposure to the patient and personnel, decreased incidence of iatrogenic hypothyroidism, and decreased costs.[6,38] Future studies investigating discrepancies between prescribed and actual administered doses and possible issues encountered during the workflow could add to our current understanding and further optimize I-131 dosing and administration recommendations for the treatment of hyperthyroidism in cats.

Our study had several limitations. The main limitations were the retrospective nature of the study and the small sample size. Furthermore, the calibration, administration, and measurement of the residual dose were performed by 2 clinicians. However, the injection technique and measurements were performed according to an identical protocol. Another limitation was caused by the fact that each sample was measured only once at each timepoint, because the exposure was meant to be limited in accordance with the "As Low As Reasonably Achievable" (ALARA) principle.[39]

Discrepancies in dose calibrator assays among various packagings of I-131 have been reported in the literature.[40] All I-131 doses in our study were prepared by a single supplier, prescribed across a narrow dose range, and therefore consisted of a narrow range of volumes. In addition, all doses were provided in a single size and type of syringe and needle. Therefore, our data should be interpreted with care and the ability to extrapolate this data to other settings might be limited.

Moreover, long-term outcomes of dose variability between the prescribed and actual administered dose could not be evaluated, and prospective, longer-term studies are required to evaluate possible long-term consequences.

The potential radiation hazard to staff is the main disadvantage of I-131 treatment. The use of I-131 unit doses can be a safer and more cost-effective option for certain practices that treat veterinary patients with hyperthyroidism. Therefore, our intent is not to discourage use of I-131 unit doses, but rather to investigate potential dose variabilities that may occur when using this treatment modality in practice because this issue concerning the treatment of hyperthyroidism in cats has not been reported previously in the veterinary literature.

5 | CONCLUSION

Our study raises several points of concern regarding variability in the actual administered activity when treating cats with I-131 unit doses. Based on our results, residual dose assessment is recommended as part of routine quality control. In addition, it is postulated that actual administered activity and not only preinjection syringe activity should be considered when evaluating patient response after treatment. However, additional studies are required to confirm this data and investigate possible long-term consequences of dose variability. A better understanding of the administered dose activity could help to increase awareness of possible dose variability, improve quality control and radiation safety, recognize reasons for an unexpected treatment response, and optimize the dose and administration technique in cats.

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CONFLICT OF INTEREST DECLARATION

Authors declare no conflict of interest.

OFF-LABEL ANTIMICROBIAL DECLARATION

Authors declare no off-label use of antimicrobials.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) OR OTHER APPROVAL DECLARATION

Authors declare no IACUC or other approval was needed.

HUMAN ETHICS APPROVAL DECLARATION

Authors declare human ethics approval was not needed for this study.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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