I-131 Patient Release Criteria based on Measured Data

Presentation by:
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Study Objective

- Develop a method to demonstrate compliance with regulatory release limits for outpatient radioiodine therapy that is:
  - More accurate than current methods
  - Easier to perform
  - Less expensive
Outline

► Primer on Radioiodine Therapy
► Approach using Regulatory Guide 8.39
► Approach using NCRP Report No. 155
► Approach using Patient-Specific Measured Data
Thyroid Diseases

► Thyroid Cancer
  ▪ Papillary and/or mixed papillary/follicular ~ 78%
  ▪ Follicular and/or Hurthle cell ~ 17% Medullary ~ 4%
  ▪ Anaplastic ~ 1% (Most aggressive)

► Hyperthyroidism
  ▪ Diffuse Toxic Goiter
  ▪ Toxic Nodular Goiter
  ▪ Subacute Thyroiditis

► Hypothyroidism
Radioiodine is used to determine thyroid uptake.

- Isotopes used include I-123 and I-131.
- Normal uptake 15-25%
- Hypo - <10%
- Hyper - >30%
Thyroid Uptake Value

- Thyroid uptake of radioiodine can be used to:
  - Determine the therapeutic dose.
  - Determine if the patient is “releasable” according to regulatory limits.
Thyroid Uptake Measurements

Uptake measurements for thyroid cancer patients are performed by:

- Counting pills (up to 2 millicuries of I-123) under gamma camera,
- Administering pills to patient,
- Imaging the patient’s neck region using a gamma camera at 24 hours post administration, and
Thyroid Uptake Measurements

- quantifying uptake by
  - drawing a region of interest around the thyroid region,
  - subtracting background,
  - decay correcting to time of administration, and
  - dividing by the measured pill counts obtained prior to administration.
Iodine-131 Therapy

► Used to ablate thyroid cancer remnants including metastatic disease after surgical removal of the thyroid.

► Used to reduce thyroid function for hyperthyroid patients

► Typical administered doses are:
  ▪ Thyroid cancer – 30 to 400 millicuries
  ▪ Hyperthyroidism – 5 to 20 millicuries
Patient Release Criteria

► Regulatory Guide 8.39
► NUREG 1556 Vol. 9, Appendix U

Patient release can be determined by one of four methods:

1. Administered activity
2. Retained activity
3. Measured dose rate
4. Patient-specific dose calculation
Patient Release Criteria

Release based on:

- Administered activity (< 33 millicuries)
- Retained activity (< 33 millicuries)
- Measured dose rate (< 7 millirem/hr at 1 meter)
- Patient specific release criteria using
  - Effective half-life
  - Patient uptake
  - Public occupancy values
- Member of public must be < 500 millirem
Appendix A, Equation A.11

\[ E_{\text{lim}} = 34.6 \sum_{j=1}^{m} T_{r_j} \dot{K}_a (r_j,0) (E \cdot K_a^{-1}) \sum_{i=1}^{n} T_{e_i} F_{i e} \left( -0.693 \left( t_{\text{release}} \right)_{\text{lim}} \right) / T_{e_i} \]
<table>
<thead>
<tr>
<th>Group</th>
<th>Distance (m)</th>
<th>Occ. Factor</th>
<th>Dose Limit cSv</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family member</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonsleeping partner</td>
<td>1</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>All activities except sleeping with patient</td>
<td>1</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>Sleeping with patient</td>
<td>0.3</td>
<td>0.33</td>
<td>0.5</td>
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<tr>
<td>General Public</td>
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<td>0.33</td>
<td>0.1</td>
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</table>
This goes on for:

- Dose to pregnant woman as sleeping partner and nonsleeping partner
- Dose to pregnant coworker
- Dose to Children, holding or not holding

Each has its own distance, occupancy factor and dose limit.
Equations allow for

- Equations allow from one to three exponential components.
- HOWEVER, recommends the value for residence time be “taken from literature.”
- Also, makes use of “Zero-time Exposure Rates” at:
  - one meter from an upright patient and
  - one foot from a supine patient
New Approach

► Use the Siemens MK2 Electronic Personal Dosimeter
MK2 Specifications

- **Dose rate linearity**
  - Hp(10) 137Cs
    - ±10% <0.5Sv/h (<50 rem/h)
    - ±20% 0.5Sv/h to 1Sv/h (50 to 100 rem/h)
  - Photon, Hp(10)
    - ±50% 15keV to 17keV (ref. 137Cs)
    - ±20% 17keV to 1.5MeV (ref. 137Cs)
    - ±30% 1.5MeV to 6MeV (ref. 137Cs)
    - ±50% 6MeV to 10MeV (ref. 137Cs)
Critical Feature

Dose profile history: settable interval from 2 seconds to 35 hours, stores transitions of Hp(10) and Hp(0.07) at a resolution of 1μSv (0.1mrem); will store up to 579 records for transitions up to 127μSv or less
Using Mk2

- Determine patient-specific effective half-life
- Measure dose rate for calculating dose at other distances.
- Use these values for precise calculations of dose to individuals of concern as specified in NCRP Report No. 155
Dose Measurement

I need to figure out:

- Can I accurately determine the effective half-life by measuring exposure rate using the Mk2?
- Can I extrapolate the dose measured on contact with the patient using the Mk2 to distances of 1 foot and 1 meter?
Measurement One

- Measurement One: Determine the half-life of a radionuclide using the Mk2.
  - Obtained pills of Iodine-123
  - Placed in a neck phantom
  - Placed the Mk2 on contact with the phantom
  - Collect total dose measurements for 24 hours
  - Use the dose measurements to calculate the half-life of the radionuclide
  - Compare to published value of I-123 half-life
Half-Life Determination

Results

Cumulative Dose versus Time Using the Mk2
Half-Life Determination

Results

- Half-life of I-123 from Plot
  13.30 hours

- Published Half-life (BNL)
  13.22 hours

- Difference 0.6%
Measurement Two

Measurement Two: Extrapolating dose measured on contact of patient with Mk2 to one foot and 1 meter

- Used ion chamber to measure exposure rate at 0.75 ft, 1.75 ft, and 4 ft from patient administered I-131
- Measured dose rate on contact with patient using the Mk2
- Extrapolate data from Mk2 to 1.75 ft and 4 ft
Important Factor!

- If thyroid cancer localized, dose to distance relationship followed inverse square rule.

- If thyroid cancer metastatic, dose to distance relationship followed inverse to 1.6 power, which shows body as a cylindrical source rather than point source.
Sample Dose to Distance Relationship for a patient

Relationship between Time post administration and Distance/Exposure Rate

- Time post administration (hrs)
- Distance/Exposure Rate
On Contact Dose Rate Multiplier for Different Disease Types

<table>
<thead>
<tr>
<th>Distance</th>
<th>Thyroid Only</th>
<th>Metastatic Disease</th>
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<tbody>
<tr>
<td>On contact</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>One foot</td>
<td>0.250</td>
<td>0.330</td>
</tr>
<tr>
<td>One meter</td>
<td>0.028</td>
<td>0.057</td>
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Dose Rate Extrapolation Measurement Results

Patient data based on gamma camera counts using I-131 diagnostic scan

\[ y = 0.9658e^{-0.0007x} \]

\[ R^2 = 0.9941 \]

Effective Half-Life = 16.5 hours
Dose Rate Extrapolation
Measurement Results

Patient Effective Half Life using Mk2

Cumulative dose per Hour

Effective half-life = 17.20 hours

\[ y = 708.81e^{-0.0403x} \]

\[ R^2 = 0.883 \]
Dose Rate Extrapolation Measurement Sample Result

- Effective Half-Life using Whole Body scan by dual head gamma camera
  16.5 hours
- Effective Half-Life using Mk2
  17.20 hours
- Difference 4%
Dose Rate Extrapolation Measurement Results

- Dose rate measurements on contact with patient using Ion Chamber and compared to Mk2 results were within 10%.

- Sample Result: Dose rate measured on contact with patient using Ion Chamber was 90 millirem/hr, and distance corrected Mk2 measured 92 millirem/hr.
Summary of Results

Using the Mk2 we can accurately measure:

- Patient-specific effective half-life for radioiodine
- Patient-specific biological removal rate constant for radioiodine
- Dose rate (and cumulative dose) on contact and at distances from the patient
Direct Measurement Method

1. Administer diagnostic activity to patient
   - If I-123, make correction to I-131
   - If I-131, measured values are normalized to one millicurie

► Obtain cumulative dose data over 24 hours
► Determine $\lambda_e$ and extrapolate cumulative dose data using prescribed therapeutic dose of I-131 to distances of one foot and one meter applying different factors.
Cumulative Dose

CumDose = \frac{D_0}{\lambda_e} \left( e^{-\lambda_e t_1} - e^{-\lambda_e t_2} \right)

- $D_0$ is the expected dose cumulated in the first hour post administration.
- Where $t_1$ and $t_2$ are the beginning and ending time point post administration of the therapeutic dose. If infinity, first exp = 1, and second = 0.
<table>
<thead>
<tr>
<th>Time Post Administration t1 (days)</th>
<th>One foot</th>
<th>One Meter</th>
<th>One Foot</th>
<th>One Meter</th>
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<tr>
<td>1</td>
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<td>2</td>
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<td>9</td>
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Limitations

- **Regulatory Guide 8.39**
  - Uses one size fits all approach with respect to biokinetics
  - Requires nuclear medicine equipment

- **NCRP Report No. 155**
  - Cumbersome equations
  - Disease type not considered
  - Requires nuclear medicine equipment

- **Proposed Method**
  - Requires purchase of dosimeter
Strengths

► Regulatory Guide 8.39
  ▪ Simple approach – easy to calculate

► NCRP Report No. 155
  ▪ Allows patient specific data to be used
  ▪ Promotes use of dose to multiple populations

► Proposed Method
  ▪ Uses patient-specific measured data
  ▪ Allows use of dose to multiple populations
  ▪ Easy to do with EPD
  ▪ Does not require expensive gamma camera time
Future Research

- Mk2 Method will be used and compared against “gold standard” for effective half-life determinations, and
- Mk2 Method release/dose to public results will be compared to Regulatory Guide 8.39 and NCRP 155 release/dose to public estimates