The Royal Wolverhampton
NHS Trust

Nuclear Medicine Department

Section of Medical Physics and Clinical Engineering Department

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The Fab Nuclear Medicine Team
We Instigate and Develop, We Share
We Collaborate, We ask
We are Fab!!

Fabulous Practice

Development of a ^{223}Radium Dichloride (Xofigo) Patient Pathway for Metastatic Castrate-Resistant Prostate Cancer (mCRPC) that Present to the The Royal Wolverhampton NHS Trust Following an Alert by the Medicines and Healthcare Products Regulatory Agency (6th August 2018)

Authors: Jo Weekes, I. Sayers, M. Foley. The Royal Wolverhampton NHS Trust; Email joanneweekes@nhs.net

Introduction

Nobody knows the exact number in the UK, but approximately 90% of the prostate cancer deaths per year in this country are from cancer that has metastasized to bone.

There are various possible sequences of therapy available for these patients, however following an alert from the European Medicines Agency and the Medicines and Healthcare Products Regulatory Agency (6th August 2018) the Clinical Oncology and Medical Physics Departments have had to revise the ^{223}Radium Dichloride Patient Pathway to ensure that we are following the most up to date best practice for our patients.

Aim / Objectives

The remit of the ^{223}Radium Dichloride Therapy Group (RDTG) was to devise a simple pathway for clinicians/referrers to follow thereby ensuring the patient has a tailored therapy approach following the best known available practice at this time depending on their presentation.

Design

There are 4 main pharmacological options that are available as front-line therapies for patients that present with mCRPC:-

1. Docetaxel (Taxotere, Sanofi-Aventis).
2. Abiraterone (Zytiga, Janssen Biotech)
3. Enzalutamide (Xtandi, Astellas/Medivation)
4. ^{223}Radium Dichloride (Xofigo, Bayer)

There is also a fifth pharmacological therapy that needs to be taken into consideration in this patient pathway and that is, Cabazitaxel (Jevtana, Sanofi-Aventis). However, this must only be prescribed post docetaxel therapy.

Following the Alert from the European Medicines Agency and the Medicines and Healthcare Products Regulatory Agency (6th August 2018) the RDTG reviewed our existing practice taking into account the reports findings "A possible increased risk of fracture associated with the use of ^{223}Radium Dichloride"

From this review the RDTG formulated two simple flow diagrams to show the patient pathways for symptomatic referrals not just from The Royal Wolverhampton NHS Trust but for external referrals as well.

Figure 1 we produced as an aid-memoir for referring clinicians highlighting the inclusion and exclusion criteria plus noting any relevant clinical information that needs to be taken into account when referring a patient for ^{223}Radium Dichloride therapy and Figure 2 delineating the available pharmacological treatment pathway for mCRPC.

From the production of these pathways we are ensuring that all patients referred for ^{223}Radium Dichloride therapy are following best practice and that we are providing a safe radionuclide therapeutic service.

Figure 1: Aid for Referring Clinicians

Patient Presents with Symptomatic Bone Metastases (>6 metastases) and No Known Visceral Metastases

Inclusion Criteria
- ^{223}Radium Dichloride only to be used as a monotherapy or in combination with luteinising release hormone (LHRH)
- Received two prior lines of systemic therapy for mCRPC other than LHRH analogues, or are ineligible for any systemic mCRPC treatment
- Recent skeletal scintigraphy to evaluate bone status and distribution / number of skeletal metastases (6 > mets)
- Recent CT to ensure no visceral disease
- Recent blood profile to include ALP (ALP > 220 U/L)

Exclusion Criteria
- Patient taking abiraterone

Relevant Clinical Information that Needs to be Taken into Account

Figure 2: mCRPC Treatment Pathway

mCRPC Treatment Pathway: Disease Progression within 6 months of completion of Docetaxel → Cabazitaxel; Docetaxel; Abiraterone / Enzalutamide; Patient not a candidate clinically for further systemic therapy other than LHRH; Patient presents on Review with Symptomatic Bone Metastases (>6 metastases and No Known Visceral Metastases

Inclusion Criteria for ^{223}Radium Dichloride Therapy
- ^{223}Radium Dichloride only to be used as a monotherapy or in combination with luteinising release hormone (LHRH)
- Received two prior lines of systemic therapy for mCRPC other than LHRH analogues, or are ineligible for any systemic mCRPC treatment
- Recent skeletal scintigraphy to evaluate bone status and distribution / number of skeletal metastases (6 > mets)
- Recent CT to ensure no visceral disease
- Recent blood profile to include ALP (ALP > 220 U/L)

^{223}Radium Dichloride → Cabazitaxel (If not been previously prescribed)

Conclusion

These simple flow diagrams can be used to demonstrate to the patient and family the various therapy options available and their sequencing, and they also aid in ensuring the best available treatment options are delivered to the patient thus improving patient experience and outcomes.

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Presented at RWT Research 2018 and British Nuclear Medicine Society Conference 2019

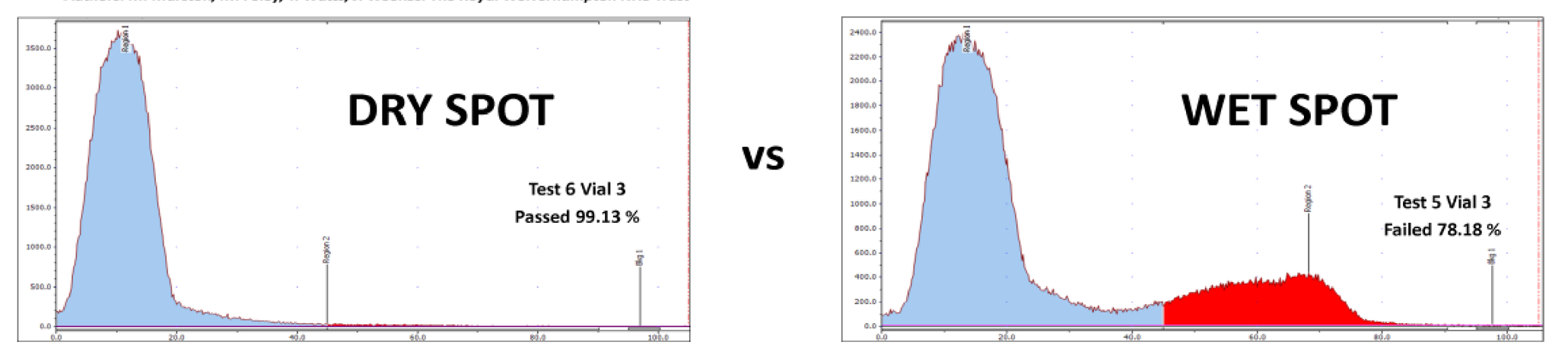
A comparison of half time and full time Myocardial Perfusion Scintigraphy using a cardiac phantom and clinical assessment

The Royal Wolverhampton Hospitals NHS Trust
Authors: T. Watts, V.A. Smith, P.J. Turner, P.D. Strouhal.

Presented at European Association of Nuclear Medicine 2018

Radiochemical purity testing of Hepatobiliary Iminodiacetic Acid (HIDA)

The Royal Wolverhampton NHS Trust
Authors: M. Marston, M. Foley, T. Watts, J. Weekes. The Royal Wolverhampton NHS Trust



Purpose and investigation.

After preparation of a HIDA kit a Radiochemical purity test (RCP) is performed to check labelling efficiency (Percentage of Technetium bound HIDA). A test failed at around 82%. Therefore a decision was made to investigate.

The RCP sample was taken within 10 minutes of manufacture but it states in the summary of product characteristics (SPC) to invert the vial a few times to dissolve the freeze-dried product, and then allow to stand for 30 minutes at ambient temperature. Initial thoughts were that the sample was taken too early from the kit not allowing the chemical bonding to be completed.

The study investigates the effects on the following during the RCP

- The time the sample was taken from the vial after manufacture, 10 minutes, 30 minutes and 45 minutes.

- Wet sample spot vs dry sample spot.

New Cross Hospital's HIDA RCP Method

Prepare the strips and solvent.
Use Whatman 1 strips 10 cm long x 1.5 cm wide (in duplicate)
Mark with a pencil 1 cm up from the bottom (origin)
Mark with soluble ink a line at 9 cm up from the bottom (solvent front line)
Pour approximately 10 ml of Methylethylketone (2- Butanone) into the chromatography tank to a level of 0.5 cm deep and cover with large tank to create an atmosphere.

Procedure
Place a spot of the sample on the pencil mark (origin) of both strips.
Place one strip immediately into the solvent (wet) and leave the other strip for 10 minutes to allow the spot to dry and then place it into the solvent (dry).
On both strips, allow the solvent to run up to the 9 cm mark (solvent front) and then take out of the solvent and leave to dry.

Once dry measure the strips using the SCAN RAM and input regions of interest following the SPC to calculate the percentage of free technetium (^{99m}Tc)

$$\% \text{ free } ^{99m}Tc = \frac{\text{Activity of strip for RF} = 0.5 - 1.0}{\text{Total activity of strip}} \times 100$$

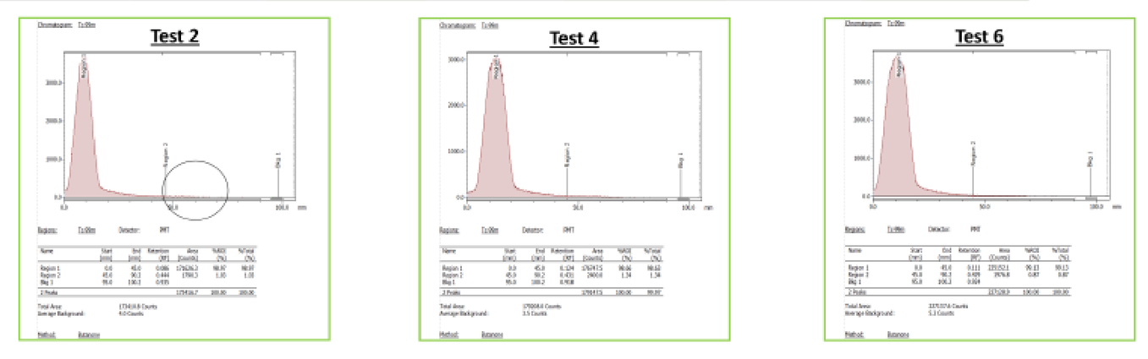
Calculate the percentage of bound Technetium (^{99m}Tc) (radiochemical purity):
% bound ^{99m}Tc = 100 % - % of free ^{99m}Tc
The percentage of bound ^{99m}Tc (radiochemical purity) should be more than 95 %
The first region of interest is from 0.0 mm to 45.0 mm (RF = 0.0 - 0.5)
The second region of interest is from 45.0 mm to 90.0 mm (RF = 0.5 - 1.0)
A background region can be applied at 95.0 mm to 100.0 mm if required, as the solvent hasn't reached this far up the strip therefore can only be the background level.

Three Vials of HIDA were used with two different batch numbers. Each vial was manufactured on a different day. Six strips were used per vial resulting in a total of 18 strips; three dry sample spots and three wet sample spots from each vial were analysed at different times the sample was taken. The time the sample was taken from the kit had no observable effect. The main effect noticed was whether the sample spot was dry or wet.

Test	Time between kit manufacture and RCP sample being taken (minutes)	Dry/Wet Spot	Vial 1 Free ^{99m}Tc (%)	Pass/Fail	Vial 2 Free ^{99m}Tc (%)	Pass/Fail	Vial 3 Free ^{99m}Tc (%)	Pass/Fail
1	10	Wet	78.95	Failed	76.06	Failed	78.28	Failed
2	10	Dry	99.07	Passed	98.87	Passed	98.97	Passed
3	30	Wet	71.43	Failed	79.22	Failed	78.62	Failed
4	30	Dry	98.77	Passed	98.20	Passed	98.63	Passed
5	45	Wet	73.85	Failed	73.76	Failed	78.18	Failed
6	45	Dry	99.19	Passed	99.07	Passed	99.13	Passed

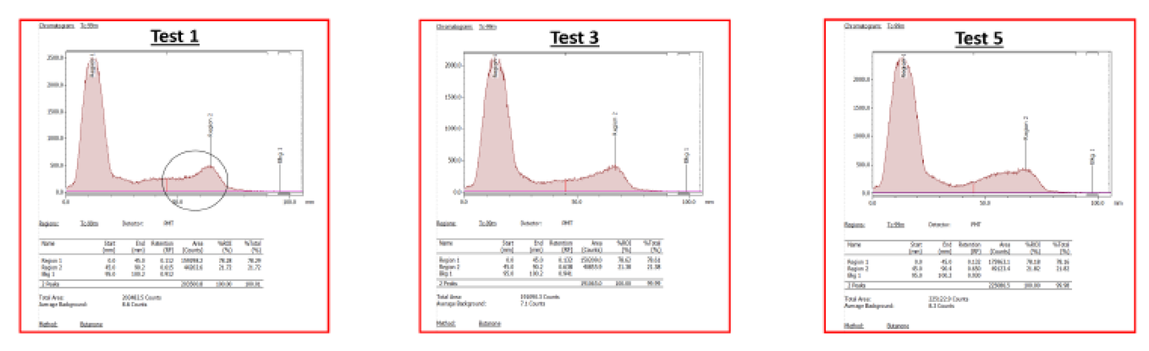
Test results from vial 3 can be seen in these graphs.

3 Dry sample strips
All passed



All the results from each vial show the same pattern as on the graphs shown here. Notice the circled area on the graph for test 2 where there are very low impurities in region 2, this was the same for all dry tests. Compare this to the circled area on the graph for test 1 where there are higher levels of impurities in region 2, this was the same for all the wet tests.

3 Wet sample strips
All failed



Conclusion—*Always allow sample spot to fully dry before placing into the solvent.*

In total there were 18 tests performed, 9 with a dry spot and 9 with a wet spot. Every time the spot was left to dry the RCP passed, every time the spot was wet the RCP Failed. The time taken for the spot to dry on the strip increased with the volume of the sample placed on the strip, therefore a consistent spot sample size was used to ensure it was dry after 10 minutes. These results suggest that the most important part of the RCP process is to make sure the sample spot is dry before placing it in to the solvent. The time between the kit being manufactured and the RCP sample being taken did not make any significant difference to the result of the test.

Reference: SPC CHOLEDIAM HIDA PL 22879/0001

Acknowledgements: All staff in Nuclear Medicine — New Cross Hospital.

Presented at RWT Research 2018

A Follow Up Dose-rate Measurement Strategy for Patients Post ^{131}Iodine Ablation Therapy. Can We Improve the Post Treatment Restrictions Applied to the Patient on Discharge?

Authors: Jo Weekes, M. Foley, D. Tripathi. The Royal Wolverhampton NHS Trust; Email joanneweekes@nhs.net

Introduction

^{131}Iodine Ablation Therapy is used in the treatment of some thyroid cancers, specifically papillary and follicular thyroid cancer. The patients are referred post thyroidectomy, for post-operative radioactive iodine ablation to destroy any residual functioning thyroid tissue or metastases.

The full nature and consequences of the treatment and need for hospitalisation must be explained to the patient and written consent obtained before proceeding with arranging the treatment. The Radiotherapy Consultant, with ARSAC approval, will prescribe the ablation dose of ^{131}I required and complete the consent form.

The radioactivity administered (ranges from 1100—7400 MBq) is dependent on the patient's staging. All patients receiving ^{131}Iodine Ablation Therapy have to be admitted to one of the specially constructed patient rooms on Deanesly Ward due to the radiation risk.

Patients on discharge post ^{131}Iodine Ablation Therapy are issued with radiation precautions (restrictions) depending on their remaining radiation dose-rate measured.

These applied restrictions can have a huge influence on their family / work / life balance post discharge due to the need to:-

1. Sleep separately from partner and children
2. Keep a certain distance from family members and public. This can vary between 1-3 metres depending on the age of the child.
3. Avoid close contact for any period of time (3 metres minimum distance) with pregnant females
4. Apply super hygiene methods in place to avoid spread or contamination of excreted ^{131}I
5. Be signed off from work (economic effect).

The duration of restrictions put in place on patient discharge can span up to 27 days post discharge. As well as family life being affected, it can also have a considerable financial impact to the patient if they are unable to work during this period.

Aim / Objectives

The remit of this study was to investigate the social and economic effects on patient's by providing a follow up dose-rate measurement service post ^{131}Iodine Ablation Therapy.

Design

A re-measurement service (15 minutes of staff time) was offered to 42 patients (male 31%, female 69%, age range 17-79, mean age 46 years old) that received ^{131}I Ablation Therapy between 01/04/17 to 31/03/18 at The Royal Wolverhampton NHS Trust. 37 patients (88%) returned for their re-measurement on average 4 days post discharge.

Results

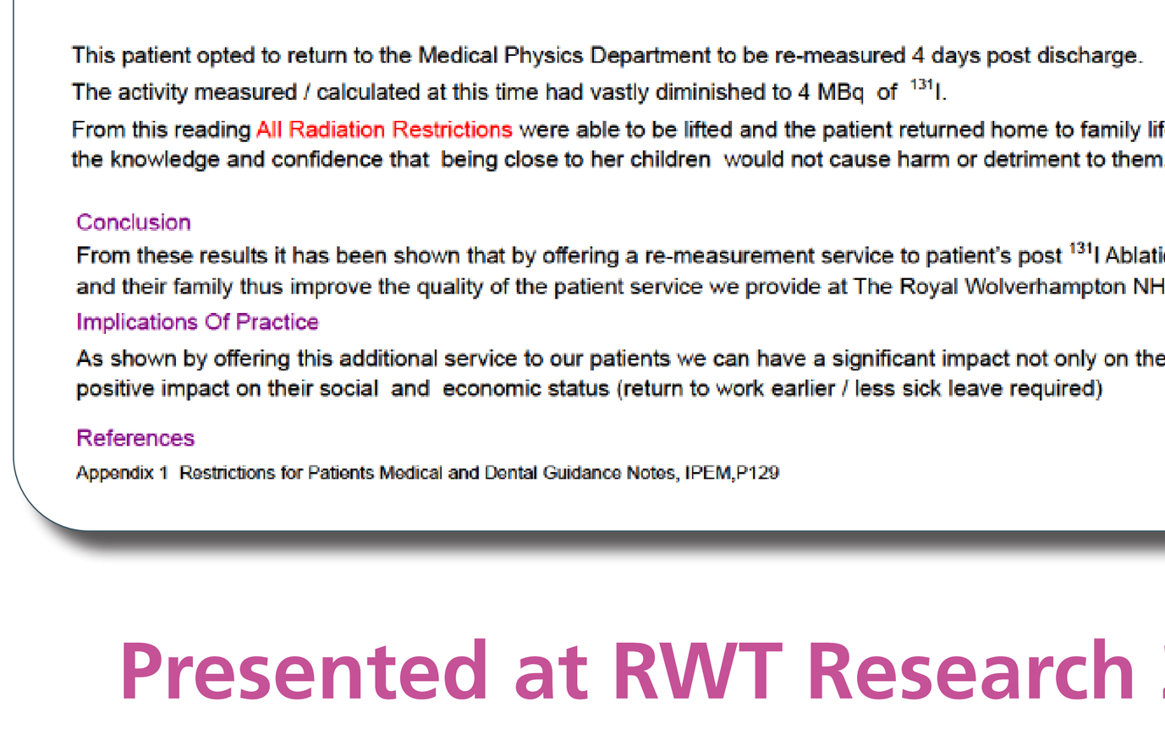
28 patients (76%) on day 4 post discharge had all their radiation restrictions lifted completely. 9 patients (24%) on day 4 post discharge had their restrictions reduced to a maximum of 4 further days thus dramatically reducing the original restrictions that were applied on discharge.

Patient Case Example

Female patient aged 33 years old admitted for ^{131}Iodine Ablation Therapy on Deanesly Ward post thyroidectomy (Papillary Thyroid Cancer). Patient married and has two children aged 6 and 2 years, lives with husband and children.

Day of admission patient was administered with 3670 MBq Na^{131}I capsule orally. From this point the patient was isolated due to the risk of radiation dose to staff and public.

Patient 's radioactivity doserate (µSv/hr) were measured at 4, 20 and 24hrs post administration and converted to demonstrate the activity (MBq) remaining within the patient.



Following Appendix 1 Restrictions for Patients Medical and Dental Guidance Notes, IPEM,P129 patients that have received ^{131}Iodine Ablation Therapy can be discharged once their activity remaining is below 800 MBq or a minimum admission of 24hrs.

This patient was discharged 24 hrs post administration with the following restrictions

Sleep Alone for 13 nights
Keep 1 metre away from adults and children over 5 years for 13 days
Keep 1 metre away from children 3—5 years 19 days
Keep 3 metres away from pregnant women and children under 3 years of age for 24 days

Due to the age of the patient's children and the concern she had Re: Radiation Exposure to her family the lady once discharged did not go to her family home but went to stay at her parents so as not to cause distress to her and her children during this period

"Thank you for offering this service to me. I can now go back home. I feel it would have been too distressing for me and my children to keep apart for so long as they are not of the age to understand why"

Time 120 Hrs Post Administration
4 MBq

This patient opted to return to the Medical Physics Department to be re-measured 4 days post discharge.

The activity measured / calculated at this time had vastly diminished to 4 MBq of ^{131}I.

From this reading All Radiation Restrictions were able to be lifted and the patient returned home to family life with the knowledge and confidence that being close to her children would not cause harm or detriment to them.

Conclusion

From these results it has been shown that by offering a re-measurement service to patient's post ^{131}I Ablation Therapy we can show a significant benefit to the patient and their family thus improve the quality of the patient service we provide at The Royal Wolverhampton NHS Trust.

Implications Of Practice

As shown by offering this additional service to our patients we can have a significant impact not only on their family life post ^{131}Iodine Ablation Therapy but it can also have an positive impact on their social and economic status (return to work earlier / less sick leave required)

References

Appendix 1 Restrictions for Patients Medical and Dental Guidance Notes, IPEM,P129

Presented at RWT Research 2018, British Nuclear Medicine Society Conference 2019 and European Association of Nuclear Medicine 2019

Iodine Restricting diet Prior to Radioiodine Therapy (RAI) for Hyperthyroidism- does it help?

Society for Endocrinology
Syed Assad Nabi, Joanne Weekes, S. Krishnasamy, Harit Buch
Endocrinology and Medical Physics Department,
New Cross Hospital (NXH) Wolverhampton and Walsal Manor Hospital

Background

- Radioiodine is being increasingly used as first line therapy for Graves' disease.
- Aim is to destroy sufficient thyroid tissue to make patient either euthyroid or hypothyroid.

Factors Affecting post RAI outcome
- Several factors have been studied but now generally agreed that no single factor reliably predicts the outcome.
- Individual radio-sensitivity, poorly defined and impossible to quantify, may be a major determinant of the outcome

Role of Iodine Restriction
- Iodine restriction has been recommended at some centres for many years with a view to increasing the thyroid RAI uptake. This is based on the theory that high iodine pool could hinder the uptake of RAI in hyperthyroidism.
- Most of the evidence available for iodine restriction prior to RAI is from studies done on thyroid caner patients.

Concerns with the Dietary Restriction of Iodine
- Compliance with the low-iodine diet is usually poor
- Low iodine levels in the body prior to the treatment result in a higher whole body radiation due to higher I blood concentration.

Dose and indications for RAI therapy at NXH
- We administer RAI (400 or 550 MBq) for (a) Toxic nodular disease (b) Relapsing Graves' disease (c) Primary therapy in Graves' disease intolerant to antithyroid drugs
- The cure rate is 85-90% at the end of 6/12

Objective

To compare post RAI outcomes in the following 2 groups of patients receiving RAI therapy for hyperthyroidism.

- No restriction of dietary iodine
- Severe restriction of dietary iodine including
  - All seafood, fish, fish oils
  - Kelp
  - Vitamins
  - Cough medicines
  - Iodized salt
  - Red coloured processed foods
  - Dairy products such as eggs, cheese, milk and milk products

Patients and Methods

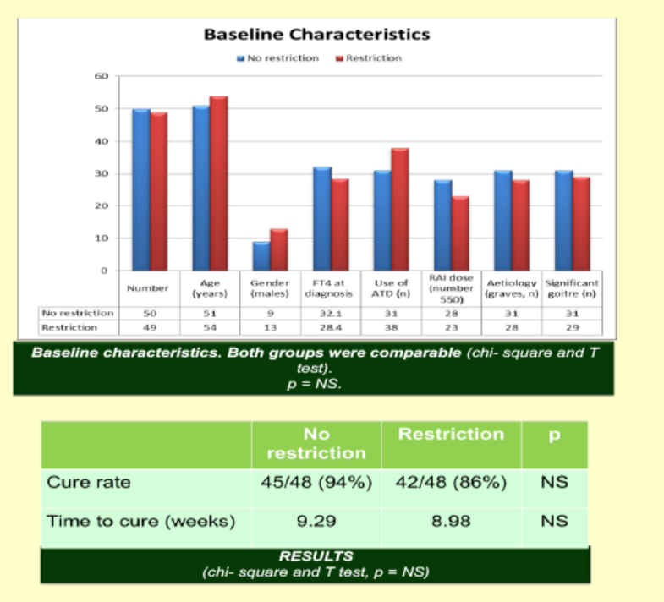
Patient Selection
A change in the policy of severe iodine restriction was brought in by Medical Physics in Jan 2017 with a view to reducing the rate of re-dosing, but was discontinued in July 2017 after wider discussion. This provided us with the opportunity to assess the impact of Iodine restriction prior to RAI therapy.

We retrospectively identified 50 consecutive patients without iodine restrictions and 50 with severe restriction for 2 weeks pre-RAI.

Outcomes studied
- Percentage cure of hyperthyroidism in both groups
- Time taken to achieve the cure

Definition of "Cure"
- Euthyroidism or hypothyridism when assessed 4 months post-RAI

Results



Baseline characteristics. Both groups were comparable (chi- square and T test). p = NS.

	No restriction	Restriction	p
Cure rate	45/48 (94%)	42/48 (86%)	NS
Time to cure (weeks)	9.29	8.98	NS

RESULTS (chi- square and T test, p = NS)

Conclusion

Strict iodine restriction prior to administration of RAI for the management of hyperthyroidism is inconvenient for patients and does not improve the cure rate or the time to achieve cure in a clinical setting.

We have not been able to assess the compliance rate for Iodine restriction, as the study design was retrospective. However this would not influence the comparative assessment in the two groups in a "real-life" context.
We have now reverted to the position of not restricting dietary iodine.

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British Endocrine Society Conference 2018

Bio distribution Mapping of ^{223}Radium Dichloride during the course of Treatments 2 to 6. A Patient Case Study

Authors: I. Sayers, Jo Weekes, M. Foley. The Royal Wolverhampton NHS Trust; Email joanneweek-

Introduction

Prostate cancer is diagnosed in over 47,000 men per year in the UK and caused 11,631 deaths in 2016 (1). 90% of men with the disease have bone metastases (2), and in 80% these cause debilitating pain or other symptoms (3).

^{223}Radium Dichloride has been shown to improve both survival and reduce the rate of symptomatic bony events in a large phase III Research Clinical Trial (4)
The physical half-life of ^{223}Radium is 11.4 days and initial studies in rats showed a preferential uptake in bone (5).

Human studies have confirmed a preferential uptake in bone and described the elimination pattern of single administration (6).

Studies on the bio distribution pattern changes in response to treatment over multiple administrations have yet to be published

Methodology

With fully informed consent and active initiation of this study after his first ^{223}Radium Dichloride Therapy administration "Patient X" a retired academic acquired daily measurements of radiation using a scintillation counter. These measurements were taken at a defined distance for defined anatomical sites(36) anteriorly and posteriorly. A background radiation level was also recorded at this time and subtracted from the results obtained. Measurements were obtained over a range of 22 to 35 days post ^{223}Radium Dichloride administration. This variation in time the measurements were acquired for was due to observing the post analysis of the data after administrations 2—4. It was decided with Patient X to extend the time of measurements post administration to see if any further information could be gained by this.

This process was repeated and the results recorded for the subsequent administrations 3—6.

Validation of the scintillation counter used was carried out prior to use by Public Health England, Radiation Protection Services (Leeds).

The resulting data was recorded by the patient in 12 Excel files.

Statistical analysis was retrospectively performed with the programming language "R" to plot elimination and assess the significance of any trends

Results

Treatment Number	Site with shortest half-life	Estimated Effective half life (days)
2	diaphragm/liver	3.438
3	diaphragm/liver	3.613
4	diaphragm/liver	3.767
5	diaphragm/liver	4.718
6	diaphragm/liver	4.876

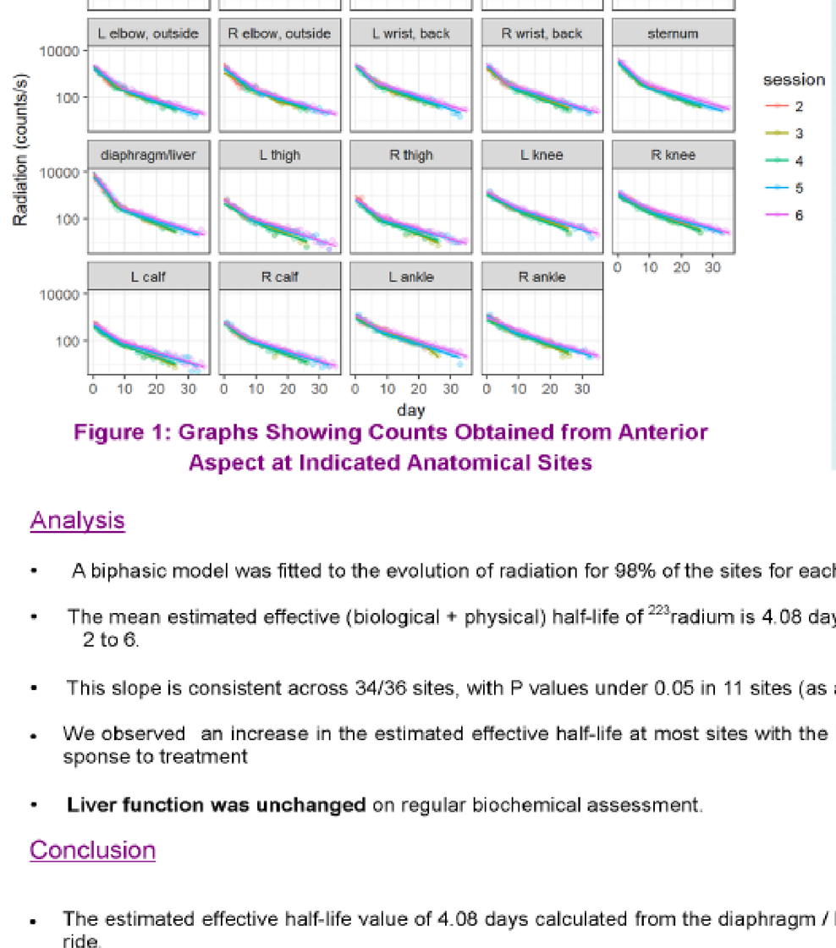
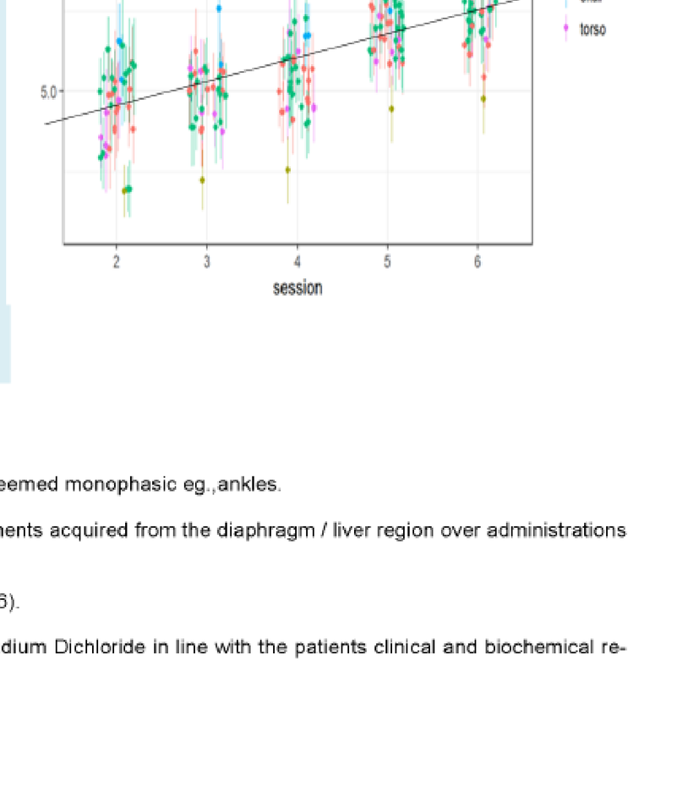


Figure 1: Graphs Showing Counts Obtained from Anterior Aspect at Indicated Anatomical Sites

Table 1: Slope of the Evolution of the Decaying Slope over Sessions

location	Site	Slope	P value
front	R wrist, back	0.000	0.853
front	R calf	0.000	0.763
front	R shoulder	0.000	0.735
back	R knee, back	0.001	0.701
front	skull	0.001	0.592
back	L knee, back	0.001	0.587
front	L ankle	0.001	0.529
front	R ankle	0.000	0.469
front	L thigh	0.001	0.444
back	R elbow, inside	-0.001	0.392
front	sternum	0.001	0.232
front	diaphragm/liver	0.001	0.205
front	L calf	0.001	0.164
back	L elbow, inside	0.001	0.158
back	L wrist, inside	0.003	0.138
front	R elbow, outside	-0.001	0.127
front	R knee	0.002	0.09
back	R hip	0.005	0.088
back	R ankle, back	0.002	0.08
front	L knee	0.001	0.071
back	L hip	0.004	0.069
back	skull	0.003	0.067
front	L shoulder	0.002	0.065
front	R thigh	0.002	0.061
back	spine, C7	0.002	0.057
back	R wrist, inside	0.003	0.05*
back	R shoulder	0.002	0.046*
front	L elbow, outside	-0.002	0.04*
front	R hip	0.003	0.037*
back	L shoulder	0.002	0.032*
front	L hip	0.003	0.024*
front	L wrist, back	0.002	0.021*
back	spine, lumbar	0.002	0.019*
back	L ankle, back	0.001	0.011*
back	spine, sacral	0.003	0.006*
back	spine, thoracic	0.003	0.005*

Figure 2: ? Increase in Estimated Effective Half Life with Administration Number



Analysis

- A biphasic model was fitted to the evolution of radiation for 98% of the sites for each administration. Only a few were deemed monophasic eg.,ankles.
- The mean estimated effective (biological + physical) half-life of ^{223}radium is 4.08 days as calculated from the measurements acquired from the diaphragm / liver region over administrations 2 to 6.
- This slope is consistent across 34/36 sites, with P values under 0.05 in 11 sites (as assessed across administrations 2-6).
- We observed an increase in the estimated effective half-life at most sites with the increase in administrations of ^{223}Radium Dichloride in line with the patients clinical and biochemical response to treatment
- **Liver function was unchanged** on regular biochemical assessment.

Conclusion

- The estimated effective half-life value of 4.08 days calculated from the diaphragm / liver region can be used to plan radiation protection precautions in patients treated with ^{223}Radium Dichloride.
- The increase in the estimated effective half-life at the majority of anatomical sites measured indicates a change in pharmacokinetics with treatment.
- We propose there is an increase in osteoblastic action at these sites with increasing administrations of ^{223}Radium Dichloride.
- The clinical implication is that with increasing administrations of ^{223}Radium Dichloride results in a greater proportion of the administered activity being delivered to metastatic sites within the bone.

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In Relation to this Poster, I declare that there are No Conflicts of Interest

Presented at British Nuclear Medicine Society Conference 2019 and European Association of Nuclear Medicine 2019

Author Acknowledgement: M Foley, I Sayers, H Buch, T Watts, A Cartwright, M Marston and D Tripathi

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