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Yttrium-90 SIR Sphere Spills: A Pilot Study to Determine Efficient Clean-up Practices

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Running Title: 90Y SIR-Sphere Clean up Practices

Abstract

Rationale:

Yttrium-90 (90Y) SIR-Spheres are Selective Internal Radiation Therapy (SIRT) agents encased in microscopic resin spheres, then suspended in water for injection. SIR-Spheres (SIRTeX) include recommended clean-up procedures for contamination spills. However, after a recent clinical incident, the efficiency of recommended clean-up procedures was explored. The aim of this investigation is to demonstrate the effectiveness of different cleaning procedures and compare these to the recommended procedure.

Methods:

Controlled spills of 90Y SIR-Spheres were placed in the middle of 10 independent one ft^2 tile sections of an existing vinyl tile floor. Each one ft^2 area was surrounded by absorbent pads, and further contained within 3 ft^2 ¾ inch thick plywood box enclosures. Three cleaning methods were implemented: damp paper towel (recommended procedure), adhesive paper, and a Swiffer™ (Procter and Gamble) wet mop (SWM). A calibrated Geiger counter was used to determine the maximum pre-cleaning and maximum post-cleaning exposure within the tile sections. Percent exposure reduction was calculated for each cleaning trial, and due to low sample size, non-parametric exact Kruskal-Wallis tests were used to determine differences in percent exposure reduction among cleaning types. All statistical tests were conducted assuming a 5% chance of a type 1 error, using SAS 9.4 (Cary NC).

Results:

Both the damp paper towel and SWM methods were superior to the adhesive paper method. (p=0.0006, p=0.0005 respectively). There was no difference between the damp paper towel and SWM methods, nor was the variability of the clean-up methods different. (p=0.6826, p=0.2501 respectively)

Conclusion:

The damp paper towel and SWM methods decontaminated the controlled spills equally. This indicates that the SWM can effectively clean up 90Y contamination.

Key words: 90Y, contamination, clean-up, microspheres

Introduction

90Y resin SIR-Spheres ® (Sirtex), referred to as 90Y resin microspheres (90Y RM) for the purposes of this paper, are a form of radiation therapy used to treat liver tumors.(*1-4*) 90Y RM are biocompatible radioactive spheres about 20-60 microns (approximately ¼ the size of a human hair) in diameter, and are manufactured with approximately 40-80 million particles per vial.(*1-4*) Additionally, 90Y RM has a 64.1 hour half-life and emits pure beta emissions with a max energy of 2.27 MeV.(*1,2,4*)

A vial of 90Y RM is shipped in dosages of 3 GBq (81 mCi 90Y RM) calibrated for a particular time and suspended in 5 mL of water.(*2*) The vial can be kept at room temperature but has to be used within 24 hours after the calibration time.(*2*) At our institution, it is the responsibility of the nuclear medicine technologist to prepare and confirm the prescribed dose prior to injection. This process has the risk of contamination from an unintentional spill. Each microsphere, though embedded in resin, can roll, bounce, and if allowed to dry can even become airborne.(*4*) The inspiration behind this study came after a recent spill at a local hospital. When preparing a dose for a patient, a technologist accidentally dropped a needle cap of 90Y RM onto the hot lab floor. The technologist tried to contain the spill based on the manufacturer's recommendation, however they soon discovered it had spread into the hallway and another adjacent department. The local radiation safety officers (RSO) were contacted and discovered the 90Y RM had spread to the bottom of shoes and suspected dry spheres were being moved by air circulation. Regardless of efforts to contain the spill, the 90Y RM still spread significantly beyond the primary spill area causing widespread contamination. Although this study did not include the potential air circulation contamination, the event did inspire the question as to the best method to decontamination and clean dry 90Y RM.

Previous research has shown many methods or ideas for cleaning up radioactive contamination in the nuclear medicine department. (5-7) Some research suggests using various solutions or solvents from soap, water, Radiacwash™ (BIODEX), and even different chemicals. (5-6) Mountford recommends an extensive list of cleaning substances for radioactive contamination, including various chemicals like potassium iodide and sodium bisulphite. (7) Additionally, each recommend various cleaning methods including towels, brushes, and cloths when cleaning radioactive contamination. (5-7) However, the majority of the sparse evidence is focused on wet spill contamination. Only one, Mountford, mentions dry radioactive contamination. (7) In this article, Mountford mentions that dry contamination needs to be cleaned using a base which will speed up hydrolysis, as well as a detergent made to reduce surface tension. (7) Also, he recommends the use of a chelate made to dissolve precipitates of metal hydroxides. (7) Lastly, he mentions that the area should be mopped with disposable towels, while wiping toward the center of the contamination area. (7) However, this article was written in 1991 and does not consider 90Y RM and possible contamination from dry resin spheres.

The aim of this study was to determine the most efficient way to decontaminate dry 90Y RM no longer in suspension. The manufacturer's recommendation to decontaminate 90Y RM spills is to use damp paper towels, however the effectiveness of this method is not well published, nor explored against other cleaning methods.(*8,9*) Three different cleaning methods were investigated during this study: damp paper towels (manufacturer's recommendation), adhesive paper, and Swiffer™ (Procter and Gamble) wet mop (SWM). So, the objective of this study was to compare the percent exposure decrease for cleaning dry 90Y RM contamination using damp paper towels (manufacturer recommendation), adhesive paper, or a Swiffer™ wet mop.

Methods and Material

This project was reviewed by the University of Oklahoma Health Sciences Center (OUHSC) Institutional Review Board and the OUHSC Radiation Safety Office (#10023). The radiation safety office approved the project with stipulations for controlled and contained spills. As part of the containment, the radiation safety office required the entire laboratory floor to be covered in absorbent pads except for 10 1x1 foot commercial vinyl (Armstrong Imperial Texture Standard-Excelon) tile sections, and less than 10 μCi (370 kBq) of 90Y RM was to be used to contaminate each section. The one ft^2 tile sections were contaminated and cleaned with each different method and are referred to as contamination sites.

The laboratory approved for the project was quite small (approximately 20 ft x 20 ft) so construction of multiple half-value barriers for each contamination site was required to prevent crossover exposure readings from other contamination sites. Half-value layer calculations for 90Y RM indicate that 3/4 inch plywood would effectively block cross contamination exposure. Four sheets of 3/4 inch plywood were purchased and resources from the University of Oklahoma Tom Love Innovation Hub (Norman, OK) were used to fabricate ten 3 ft^2 plywood boxes. These boxes were made larger than the required one ft^2 contamination sites so that the entire contamination site could be cleaned without interference from the plywood. All 10 boxes were set up with absorbent paper in in the laboratory and the Radiation Safety Office (RSO) reviewed the set-up. (Figure 1)

90Y RM was donated from a local hospital, and a nuclear pharmacist drew 10 equivalent 90Y RM samples. Since a dose calibrator is difficult to use for a pure beta emitter like 90Y RM, especially for the microcurie amounts used in this investigation, doses were drawn and the mass of each dose was measured and recorded. A microbalance was used to ensure each dose contained approximately like masses, thus assuming the amount of 90Y RM in each was comparable. Each donated vial of 90Y RM had a manufacturer indicated activity concentration, which was not altered. We assumed the specific concentration of a homogeneous solution of 90Y RM in solution was approximately 1g/mL, thus an estimated activity of each syringe was calculated.

Contents of each syringe were carefully expelled into the center a corresponding contamination site from a height of 1 cm and allowed to dry overnight. The following day, after donning gowns, gloves, and protective shoe covers the investigators and RSO surveyed each contamination area with a Ludlum model 3 (SN: 171990) Geiger counter with attached Ludlum model 44-9 (SN: PR 175216) pancake probe. Survey measurements were conducted at approximately 1 cm above the contamination site. The maximum exposure rates (mR/hr) of the sites were measured and recorded as the pre-clean maximum exposure rate.

After the pre-clean exposure measurements, the contamination site was cleaned using damp paper towels by a single investigator, this individual was responsible for all cleaning throughout the investigation. Each contamination site was cleaned in a circular motion from the outside toward the center. The investigators and RSO surveyed the post-clean sites with the Geiger counter and the maximum post-clean exposure rates were recorded (mR/hr). All 10 samples from each contamination site were cleaned by the same investigator using the same cleaning method in one day. Following the clean up day, the lab was closed down, and all access was denied for 30 days for decay of the 90Y RM (10 x 64.1 hr. half-life of Y-90). Once this decay time passed, new samples of 90Y RM were weighed and the clean-up procedure was repeated using contact paper and SWM. The contact paper method consisted of a paper with an adhesive underside. This adhesive side was pressed against the center of the contamination site and repeated in a circular fashion toward the outside of the contamination site. The SWM was a common wet mop with detachable wet cleaning pads attached. A new cleaning pad was used for each contamination site, and was disposed of between contamination sites. The wet mop was placed at the edge contamination site and moved in a circular motion toward the center of the contamination site. A total of 10 samples for each cleaning method were performed.

The outcome variable of interest was the percent decrease of exposure (mR/hr) from each cleaning method. This percent decrease is defined by equation 1:

Eq 1: $$\%\, Exposure\ Decrease = \frac{Pre\ Clean\ Max\ Exposure - Post\ Clean\ Max\ Exposure}{Pre\ Clean\ Max\ Exposure} \times 100$$

Descriptive statistics for mass, estimated activity, and percent exposure decrease were computed among each cleaning method and reported. Due to low sample size, non-parametric exact Kruskal-Wallis tests were used to determine differences in percent exposure decrease among the three cleaning methods. Additionally, non-parametric Dwass, Steel, Critchlow, and Flinger (DSCF) multiple comparisons adjustments were employed to examine individual method differences. Among methods that indicated no difference in percent exposure decrease; the variability of each method was examined using non-parametric Ansari-Bradley tests of dispersion. All statistical tests were conducted assuming a 5% chance of a type 1 error, using SAS 9.4 (Cary NC).

Results

Descriptive statistics among each cleaning type are presented in table 1. The damp paper towel and SWM methods were superior to the adhesive paper method (Figure 2). Both the damp paper towels and SWM methods cleaned a higher percentage compared to the adhesive paper method ($p=0.0006$, $p=0.0005$ respectively). However there was not a significant difference between the damp paper towel and SWM methods. ($p=0.6826$, Figure 3) Additionally, there was no difference in the cleaning variability between the damp paper towels and SWM methods. ($p=0.2501$)

Discussion

Both the damp paper towels and SWM methods cleaned a higher percentage of 90Y RM compared to the adhesive paper method. However, between the damp paper towel and SWM there was not a significant difference in decontamination amount or variability of 90Y RM. This indicates that both methods consistently cleaned the same amount with little difference in the statistical variability of cleaning. However, descriptively examining the clean-up method’s box plot (Figure 3), one might conclude that with further investigation using a larger sample size, the SWM method may provide a more consistent method of clean up. The manufacturer’s recommended method cleaned well, however, we suggest the SWM could be explored further as a cleaning method as it may be a more efficient and ergonomic option for large areas, such as the one encountered at the local clinic site.

One strength of the study was that the spill was contained. Knowing where the contamination was gave the investigators the opportunity to clean the contamination to the best of our ability. This is also a major weakness to the study. Realistically, an individual may not know the spill boundaries, nor would the spill have plywood boxes surrounding the area to help keep the microspheres from bouncing or spreading. These enclosure boxes, although required to prevent cross exposure, also possibly prohibited movement of the dry spheres that may be evident in clinical situations. This could falsely elevate estimates for effective cleaning percentages. Hence, we would like to further explore the possibility of dry 90Y RM spread by air handling systems, and examine cleaning methods for that type of situation. Another limitation to the study was the low sample size; however statistically non-parametric methods were employed to limit the assumptions that parametric statistics assume with small samples. Even with nonparametric approaches to the analysis, the variability with lower sample sizes are larger, which makes differences harder to show. Post hoc power analysis indicates that we are powered between 84.5% and 99.8% for the difference test between damp paper towels and SWM methods versus the adhesive paper method. However, we are only 10-20% powered to detect differences between the SWM and damp paper towel methods, since their observed difference was so small. A sample size of 300-400 trials would be required to show a difference between the SWM and damp paper towel methods, assuming the observed variabilities. However, with both of these methods near 100%, even with this small sample we are confident these methods are adequate for clean-up. Another limitation to the study is we could not directly measure the activity of the 90Y RM. Given the low activities of 90Y–RM approved for this investigation, we were unable to measure the activity in a dose calibrator. Furthermore, charged particles like beta emitters interact constantly while inside the dose calibrator, which makes measurement of their activity difficult and prone to error.[11] Additionally, 90Y RM-is a higher-energy beta emitter meaning the particles are moving more quickly, and interacting with fewer molecules while they are in the gas chamber of a dose calibrator.[11] We did our due diligence to attempt to use the manufacturer's specified activity concentration and measured mass of the 90Y RM sample to estimate activity for each trial. However, small differences in the activity of the 90Y-RM in the contamination sites could bias results, and could not be controlled in this experiment. Another limitation was that each spill did not contain exactly the same amount of microspheres in solution. Having the same number of microspheres in each solution would add less variability to each trial, but would be difficult, if not impossible, to attain. Lastly, we are limited to the environment in the lab at the time of clean up. We decided to decontaminate each sample area with the same method on one day. This methodology could have opened the door to unmeasured and unknown environmental issues for that particular set of observations. We made this decision based on radiation safety requirements and simplicity for data collection while working with these safety requirements. Unknown environmental confounders could bias estimates in either direction, thus limiting to the study design.

This study could be re-created and performed with Theraspheres, which are Yttrium-90 glass microspheres. The study could also be performed with a larger sample size, and test different cleaning methods from those used in this investigation. The idea that 90Y RM could be spread through air circulation when out of solution could be explored further.

Conclusion

The results of this investigation demonstrate damp paper towels and the SWM methods are superior to the adhesive paper clean up method for decontaminating dry 90Y RM no longer in suspension. These findings help to confirm the manufacturer's recommendation. Additionally, these findings indicate a possible alternative, the SWM, to the manufacturer's recommendations. This evidence of effective cleaning methods, including the manufacturer's recommendation, should be considered when establishing department protocols for decontamination procedures.

Table 1: Descriptive Statistics for Each 90Y RM SIR Spheres Cleaning Method Used

Cleaning Method	Label	n	Mean	Std	Median	Min	Max
Damp Paper Towels: Control	Measured Mass (mg)	10	64.9	5.2	64.0	58.0	76.0
	Estimated Activity (uCi) of Spill	10	1.8	0.1	1.7	1.6	2.1
	Percent Exposure Decrease	10	98.1	2.5	99.0	91.7	99.9
	Pre-Clean Exposure (mR/hr)	10	102.0	59.2	70.0	50.0	200.0
	Post-Clean Exposure (mR/hr)	10	1.8	1.9	1.0	0.1	5.0
Adhesive Paper	Measured Mass (mg)	10	119.3	8.0	118.0	107.0	135.0
	Estimated Activity (uCi) of Spill	10	2.2	0.1	2.1	1.9	2.5
	Percent Exposure Decrease	10	72.8	20.8	78.2	29.6	92.5
	Pre-Clean Exposure (mR/hr)	10	105.0	24.9	105.0	55.0	140.0
	Post-Clean Exposure (mR/hr)	10	29.7	27.5	17.5	6.0	95.0
SWM	Measured Mass (mg)	10	115.3	12.5	116.5	90.0	130.0
	Estimated Activity (uCi) of Spill	10	1.8	0.2	1.9	1.4	2.1
	Percent Exposure Decrease	10	98.7	1.8	99.2	93.8	99.9
	Pre-Clean Exposure (mR/hr)	10	81.4	28.8	77.5	48.0	150.0
	Post-Clean Exposure (mR/hr)	10	1.0	1.5	0.5	0.1	5.0

Figure 1: 3ft^2 Plywood Sample Boxes and Absorbent Pads Ready for Controlled 90Y RM Spill

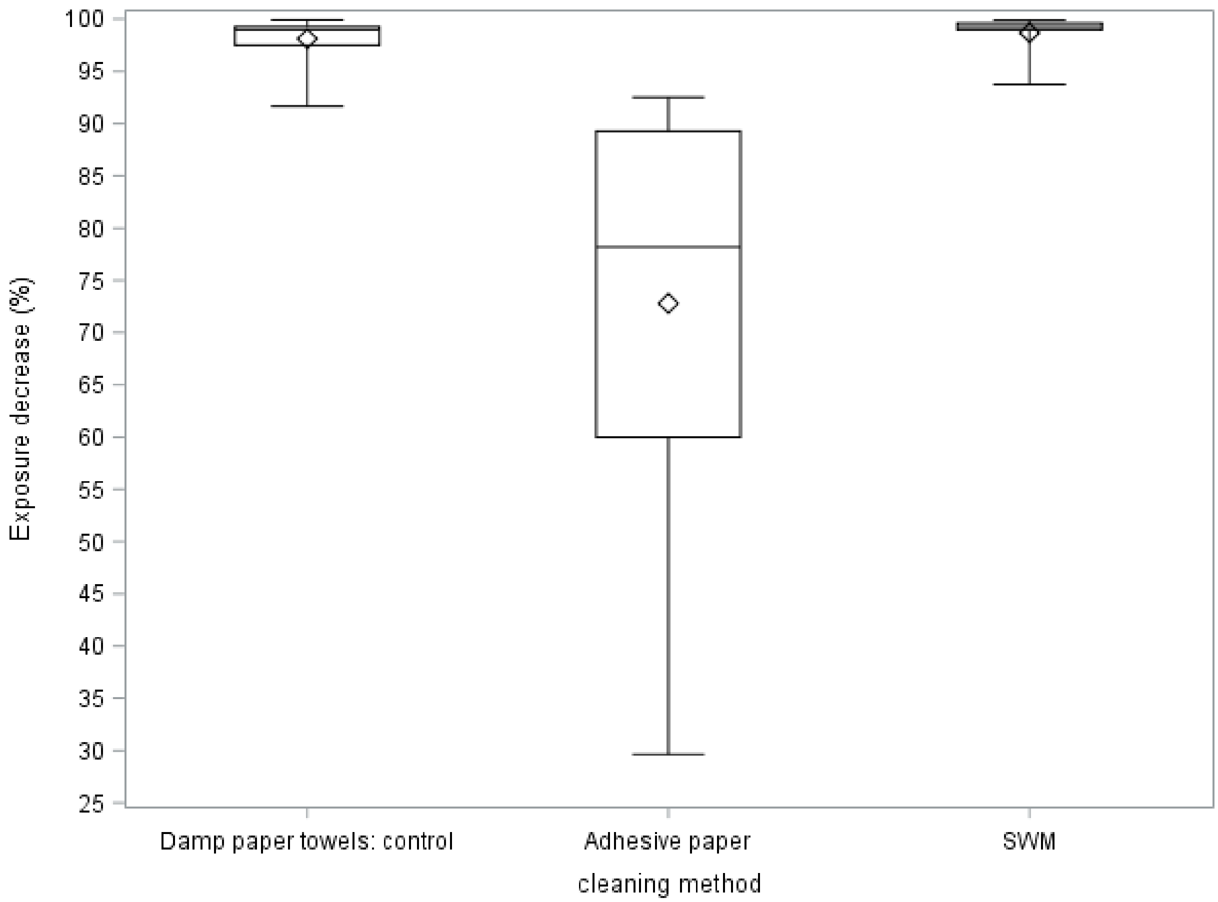

Figure 2: Percent Exposure Decrease Among All 90Y ~~RM~~ SIR Sphere Cleaning Methods.

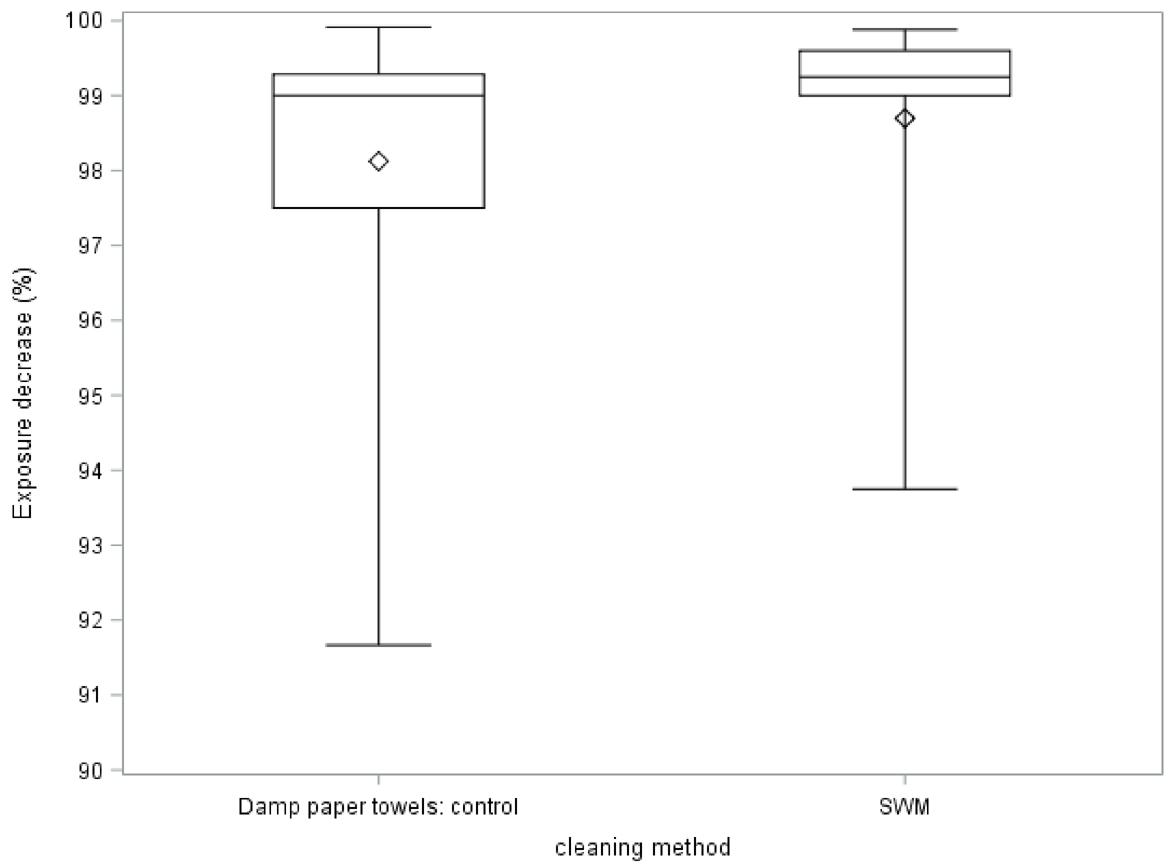

Figure 3: 90Y RM SIR-Spheres Post-decontamination Percent Exposure Decrease Among Damp Towels and Wet Mop Methods (Wilcoxon p=0.6826, Ansari-Bradly p=0.2501)

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