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An analysis of three common Cardiogen Rb-82 Infusion System injection methods and their impact on clinical volume and image counts.

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Abstract

In the wake of the FDA recall, many clinics have had to reduce their exam volumes to meet the new generator volume usage requirements. This review tests three common infusion methods and how they affect patient dose, generator volume usage, image counts, and generator volume limits.

Methods

Three common configurations of the Cardiogen Rb-82 Infusion system settings, Standard 50mL, Volume Limiting, and Bolus Method, were tested to determine how they affect patient dose, generator volume, and image counts. Each injection configuration was tested daily for the duration of 3 consecutive generators by injecting into separate vials. Each injection configuration was also infused into a beaker and imaged to determine the impact of image counts for each method. The total estimated volumes for multiple exam and QA clinical situations were simulated to observe the use of each method relative to the new FDA volume alert and expirations limits.

Results

Vial tests confirm that the Bolus method uses the least amount of volume per infusion and stays the most consistent throughout the life of the generator. The Bolus method also produces a lower patient dose after ~10 days of use. The beaker tests in the scanner showed the Standard

50mL method produced the greatest number of total counts for the flow and uptake images. Based on the estimated total volume simulations, the Bolus Method allows for the most exams over the life of the generator while staying within the new FDA limits.

Conclusions

All three methods for augmenting the Rb-82 Cardiogen Infusion system will produce different outcomes for patient dose, image counts, and total generator volume use. The Standard 50mL method will assure the maximum amount of counts available for imaging throughout the life of the generator. The Bolus method will provide a consistent and predictable amount of volume use. The Volume Limiting method falls somewhere in the middle of volume predictability and count preservation.

Introduction

In the wake of the FDA recall, many clinics have reduced their patient volumes in order to meet the new generator volume usage requirements for preventing unintended radiation exposure of Sr-82 and Sr-85 (1). This review of 3 different infusion methods shows how those methods affect patient dose, generator volume usage, image counts, and generator volume limits.

Materials and Methods

Infusion Methods

There are multiple infusion settings on the Rb-82 Cardiogen Infusion system. By the Cardiogen User Tools manual, the Elution Volume and Infusion Rate (1) should never be changed from 99mCi and 1mCi/sec respectively. However, Patient Volume (20-50ml) and Patient Dose (10-60mCi) may be changed (2). Three common configurations of these two settings were tested to determine how they affect patient dose, generator volume, and image counts.

Standard 50mL Protocol. – The Patient Volume is set for 50mL and the Patient Dose is set for 50mCi for the life of the generator. Referred to as "50mL" here after and in graphs.

Volume Limiting 30mL Protocol - This protocol has been recently recommended by Bracco to reduce the total volume per injection thereby allowing more patient exams per generator. However, its effect on

generator volumes has not been reported. The Patient Volume is set for 30mL and the Patient Dose is set for 50mCi. Referred to as “30mL” here after and in graphs.

Bolus Protocol – The goal here is timing to include only the volume of the bolus of activity delivered by the generator excluding portions of the infusion with activity under ~0.5mCi. The Patient Volume is set for 50mL and the Patient Dose is changed daily based on the generator output. Referred to as “Bolus” here after and in graphs.

In Vitro Vial Test

Each infusion method was tested daily by collecting eluate in separate 50mL glass QA vials. The Patient Dose at the end of the infusion and the Elution Volume was recorded from the printed strip for each infusion for 3 consecutive generators.

Beaker Scan Test

In the first ten days of a generator, the three protocols yield very similar activity and volumes per injection. However, after ten days as generator yield starts to decline, the different protocols yield increasingly different results that we also examined. Accordingly, in order to quantify the greatest expected differences among the three protocols as proof of concept, we selected day 34 of a subsequent generator to examine two imaging scenarios – a two minute image followed by a five minute image corresponding to our early two minute arterial input image and subsequent

five minute myocardial uptake image since both are needed for quantifying perfusion in cc/min/gm.

Using a 500mL glass beaker filled with tap water. Rb-82 was infused into the beaker according to each of the three infusion protocols and imaged for 2 minutes starting as soon as counts appeared in the scanner field of view in order to capture time/activity curves. Time was allowed for the beaker to decay to background between infusions. The dose, total counts, and time/activity curves were collected for this “early arterial image” for all infusion methods.

For the “late uptake” phase, the beaker was prepared in the same way. Following infusion completion and 90 sec delay, the beaker was imaged for 5 min after each infusion method; this delay is typical for standard relative uptake imaging where arterial input and absolute perfusion in cc/min/gm are not measured. The dose, total counts, and time/activity curves were collected for this “late uptake” image for all infusion methods.

RESULTS

In vitro Vial Test Results

TABLE 1 AND FIGURE 1 confirm that the Bolus protocol uses the least amount of volume per infusion and remains the most consistent throughout the life of the generator. Over the lifetime use of the generator,

the average total volume for the Bolus protocol in generator 1 was 31% and 12.9% less than the 50mL and the 30mL protocols respectively, for generator 2 was 34.2% and 19.3% less, and for generator 3 was 33.9% and 13.4% less than the 50ml and 30ml protocols.

However, the Bolus protocol also produced a slightly lower patient dose after ~10 days of use. TABLE 2 and FIGURE 2 display the dose range data throughout the usage of the generators. The differences in dose ranged from 0-7.5% less than the 50mL protocol and 0-5.7% less than the 30mL method, for generator 1. For Generator 2 dose differences were 0-9.9% and 0-9% less than the 50mL and 30mL protocols and for generator 3 was 0-16.2% and -0.1-14.5% less than the 50mL and 30mL protocols respectively.

Beaker Scan Results

The Standard 50mL protocol produced the greatest number of total counts for the “early arterial” and “late uptake” images compared to somewhat less for the 30mL protocol and substantially less for the Bolus protocol seen in TABLE 3 AND FIGURE 3. For the “early arterial” images, activity injected into the beaker for the Standard 50ml protocol was 4% higher than the 30ml protocol and 23% higher than the Bolus protocol. The total acquired counts for the “early arterial” Standard 50ml protocol were 21% greater than the 30ml protocol and 50% greater than the Bolus protocol.

For the “late uptake” images the activity injected into the beaker for the Standard 50ml protocol was 4% higher than the 30ml protocol and 23% higher than the Bolus protocol. The total acquired counts for the “late uptake” Standard 50ml protocol were 11% greater than the 30ml protocol and 37% greater than the Bolus protocol.

Generator Volume Limits

Current volume limits for the Rb-82 Cardiogen Infusion system are 14 liters as an alert limit and 17 liters for expiration. In this study, days of use are defined as days QA was completed and patients scanned. 24 days (5 calendar weeks) was the longest this site used a generator during this study, so that generator’s lifespan was chosen to extrapolate theoretical patient usage volumes in Figure 4. The actual Daily QA and the vial injection volumes were used to simulate total generator volume for each method.

As shown in Figure 4, using a volume of 204 exams plus QA volume over 24 days of use, the bolus method would be above the alert limit on day 21, but would not reach the 17L expiration limit. The 30mL and 50mL method would both hit the expiration volume limits before the end of 24-day usage. The 30mL would expire on day 22 and the 50mL on day 19.

Using 180 exams plus QA volume over 24 days of use, the 30mL method would not expire for the entire 24-day period, the 50mCi method would expire on day 20, and the bolus method would reach the alert limit on day 23.

And lastly, the maximum volume that could be done to prevent the 50mL method from expiring in 24 days of use is 138 exams plus QA volume. (FIGURE 4)

Discussion

All three methods for augmenting the Rb-82 Cardiogen Infusion system will produce different outcomes for patient dose, image counts, and generator volume use. The Standard 50mL method will assure the maximum amount of counts available for imaging throughout the life of the generator. The Bolus method will provide a consistent and predictable amount of volume use. The Volume Limiting 30mL method represents a compromise between volume predictability and count preservation.

Conclusions

Each infusion method impacts patient dose, image counts, and total generator volume use. Each infusion method should be reviewed internally to determine which meets the needs of the individual patient care setting based on the past or expected patient volume at each site.

We currently use the 50mL method to produce images with the greatest amount of statistics.

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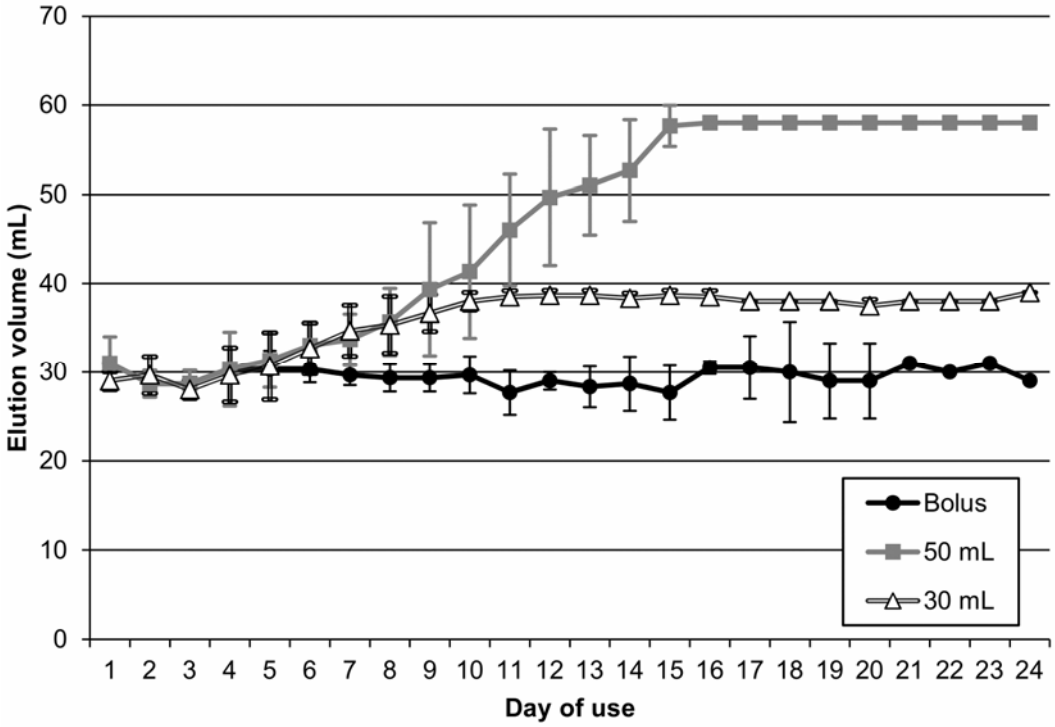


FIGURE 1: Depicts graphically the average daily volume differences between each method for all 3 generators. Error bars represent one standard deviation for each infusion method. Note: Generator 2 was used for 20 days and Generator 3 for 15 days.

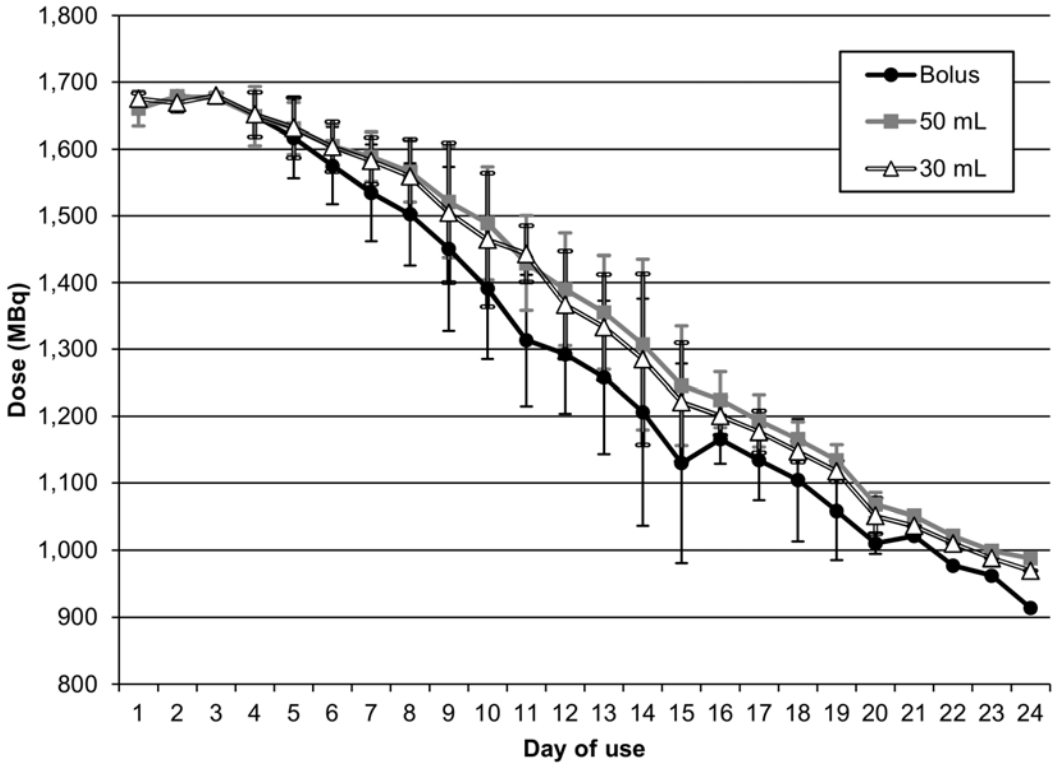
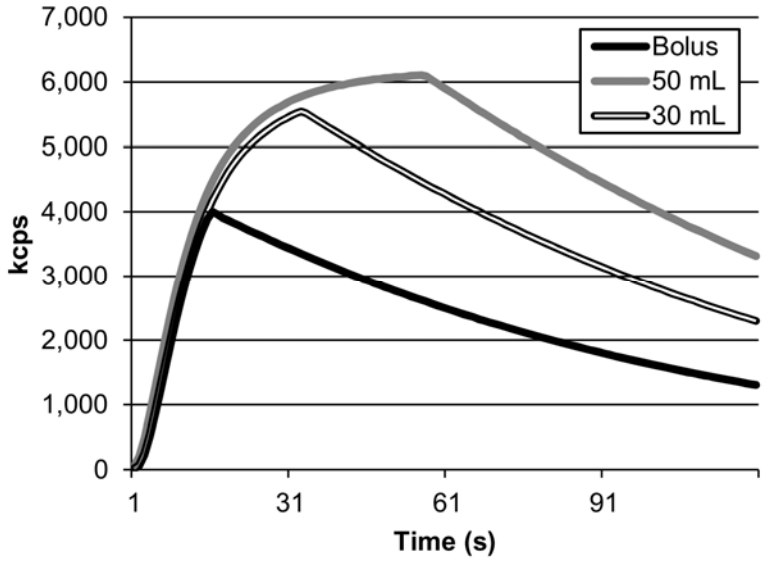


FIGURE 2: Depicts graphically the average daily dose differences for each method across all 3 generators. Error bars represent one standard deviation for each infusion method. Note: Generator 2 was used for 20 days and Generator 3 for 15 days.

A



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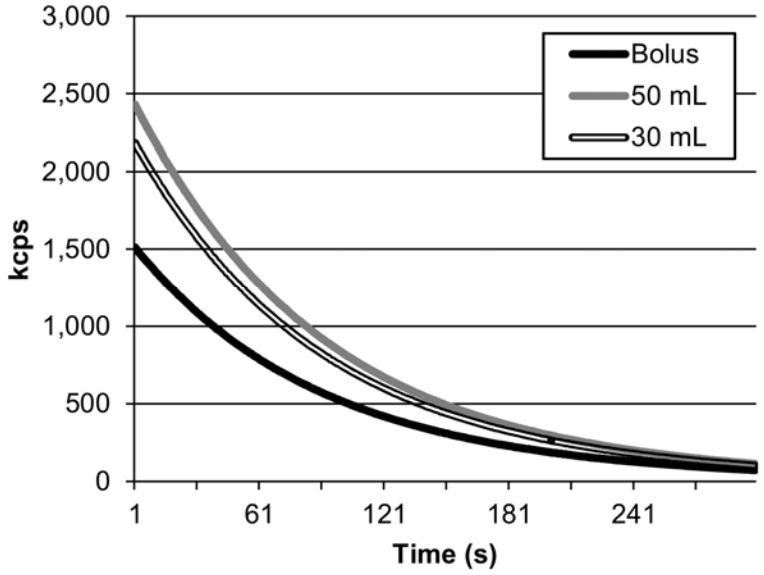

FIGURE 3: Displays the difference in counts/sec for each method for early arterial and late uptake acquisitions. A. 2 min Flow, B. 5 min Uptake

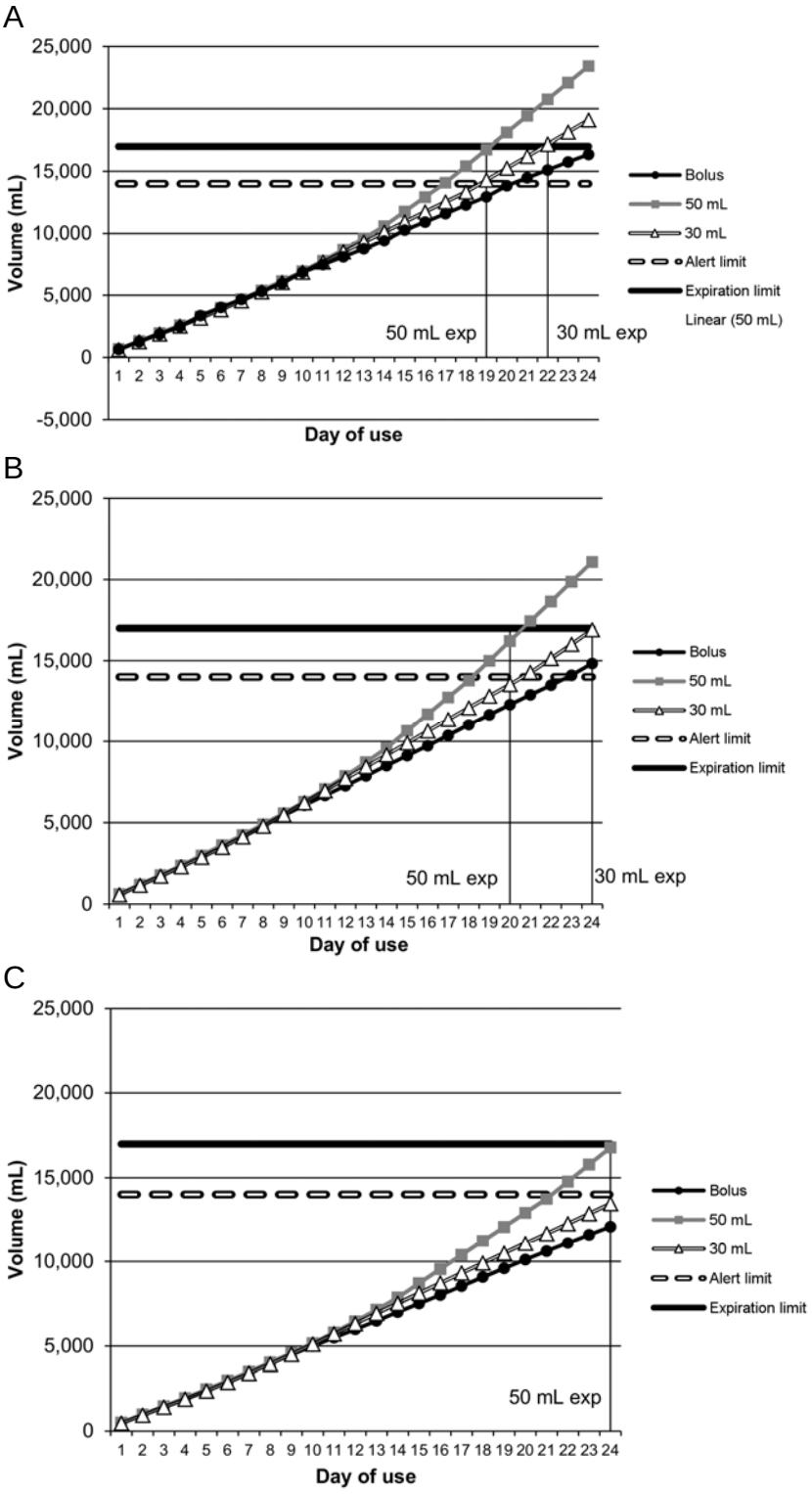

FIGURE 4: Displays the total estimated volume use for each exam volume and QA simulation. A. 204 exams, B. 180 exams, C. 138 exams

TABLE 1: Vial test volume in mL.

	Generator 1 Total Volume	Generator 2 Total Volume	Generator 3 Total Volume
Bolus	744	555	436
50mL	1079	843	660
30mL	854	688	504

TABLE 2: Dose Ranges

	Generator 1	Generator 2	Generator 3
	MBq (mCi)	MBq (mCi)	MBq (mCi)
50mL	1665 - 987.9 (45 - 26.7)	1683.5 - 1080.4 (45.5 - 29.2)	1631.7 - 1143.3 (44.1 - 30.9)
30mL	1665 - 969.4 (45 - 26.2)	1665 - 1069.3 (45 - 28.9)	1679.8 - 1121.1 (45.4 - 30.3)
Bolus	1665 - 913.9 (45 - 24.7)	1683.5 - 999 (45.5 - 27)	1631.7 - 958.3 (44.1 - 25.9)

TABLE 3: Imaged activity

Scanner Results:	Early Counts (2min) E+08	Dose MBq (mCi)	Late Counts (90 sec post) E+08	Dose MBq (mCi)
50mL	5.6	1121.1 (30.3)	2.19	1121.1 (30.3)
30mL	4.4	1076.7 (29.1)	1.96	1076.7 (29.1)
Bolus	2.8	862.1 (23.3)	1.37	858.4 (23.2)