J of Nuclear Medicine Technology, first published online April 24, 2019 as doi:10.2967/jnmt.118.224725

Evaluation of the use of a modular detector system to collect data in real-time to detect and assess injection quality

Authors:

Shelley N. Acuff
Dustin Osborne

University of Tennessee Graduate School of Medicine, University of Tennessee Medical Center, Department of Radiology, Knoxville, TN

Corresponding Author
Shelley Acuff
University of Tennessee Graduate School of Medicine
Molecular Imaging & Translational Research Program
1924 Alcoa Hwy
Knoxville, TN 37920
865-305-6312
865-305-8694
Sacuff@utmck.edu

(1521)

Running Title: Real Time Injection Monitoring

No Financial Support for the Research

Abstract

A modular radiation detector system has been developed by Lucerno Dynamics, LLC. Today's version of the device collects data during the entire uptake portion of a molecular imaging study and then the data can be visualized and assessed for signs of infiltration. The objective of this study is testing the feasibility of this device for real-time assessment of the injected dose rather than the current mechanism that allows retrospective analysis of the acquired data. Real-time counts were collected manually from the device on twenty patients having a clinical PET scan. Time-activity curves were created from the manual real-time data and compared to the time-activity curve given from the device. The R^2 value calculated for the averages across the two curves was 0.93 (93%) meaning the two curves did match. An external detector device may be used to ascertain that an injection is sufficient within only a 60-second acquisition.

Keywords: Infiltration, PET/CT, Lara®, 18F-FDG

Introduction

Dynamics, LLC. The detector is a class 1 exempt medical device listed with the Food and Drug Administration. It was intended to dynamically measure the presence of a radiopharmaceutical in an organ or body region during uptake as part of a nuclear medicine procedure. It is now indicated for use as a tool to help assess whether a radiopharmaceutical injection remains near the injection site rather than circulating in the vascular system. Since the beginning of molecular imaging, infiltration of the radiotracer has been known to cause false positive lymph node uptake (*1*). This detector system could play a role in observation of an infiltration. The current version of this device offers four detectors for use, and a digital screen to display step by step instructions for setup and collection of data. (See Figure 1) Data is collected during the uptake time and then is uploaded to a server where it can be visualized and assessed for signs of infiltration. Upon uploading the data, the device will give the injection a score and display time-activity curves that have been corrected for radioactive decay, temperature, and other specific detector effects. A score less than 200 suggests a negligible presence or no presence of radiotracer was left near the injection site. Scores over 200 indicate the possibility that radiotracer remained near the injection site, allowing clinicians to decide if the patient should be rescheduled. If a significant infiltration were indicated, the patient could be rescheduled prior to undergoing imaging. The objective of this study is to test the feasibility of using this device for real time assessment of the injected dose as opposed to the current mechanism that allows only retrospective analysis of the acquired data.

Materials and Methods

This research was reviewed by our institutional review board and the activity does not meet the definition of human research found at 45 CFR 46 and the need for informed consents

was waived. Twenty PET/CT patients were connected to the detector device prior to their 18F-FDG injections. Two small detectors were placed on the patients with one on the injection arm proximal to the injection site, and the other placed on the opposite arm in the same area to serve as a control. (See Figure 2) During the delivery of the tracer, counts from seven time points were manually captured from the detector device: 5sec, 10sec, 20sec, 30sec, 40sec, 50sec, and 60sec post-injection. Using this data, predictions were made on whether activity remained at the injection site or on how rapidly the counts decreased to typical baseline values of 200-400 counts that were given by the control arm sensor.

The standard automated data collection using the device continued from the time of injection until the completion of the patient uptake time (approximately 60 minutes). The data were then uploaded to the device server to obtain the complete time-activity curves and associated score.

The manually collected curves were compared to the device collected curves to assess if the data converged, and if so, how rapidly. (See Figure 3) Convergence rates were compared to the scoring system to determine if manual predictions were accurate, and at what minimum times could real-time assessments provide a reasonable determination of an infiltration. The data points for automatic and manual assessments were averaged across all twenty patients and R-squared (R^2) values were calculated between automated and manual data collection methods to see if the time-activity curves using each technique matched.

Results

All twenty patients received a score from the Lara® device under 200 indicating a negligible presence or no presence of radiotracer was left near the injection site. After the completion of each patient scan, the images were visually reviewed for evidence of activity at the

injection site. All twenty scans showed no evidence of activity present and determined no infiltrations. Based on manual, real-time data collection, baseline threshold values were reached within approximately 60 seconds for each patient. Within this timeframe, it was possible to observe the peak in counts detected from the bolus injection passing over the sensor and watch this drop back to the observed baseline values. (Table1) R^2 value was calculated between the real-time data time-activity curve and the automated time-activity curve. R^2 value simply gives a percentage of how well the manual real-time data curve matched the automated time-activity curve from the device. The R^2 value calculated for the averages across the two curves was 0.93 (93%) meaning the two curves did match.

Discussion

Current methods for monitoring injections and potential infiltration requires injection of the entire patient dose and then assessing the injection site following the 60-minute uptake time either using the PET/CT system or the external detector device. The problem with those methods is the patient has already sat for the entire uptake period and now will have to return on a subsequent day to repeat their imaging study. If the injection site activity were monitored in real-time and the presence of lingering activity was detected within the first 60 seconds, the patient could be rescheduled without needing them to wait the entire uptake period. There were no infiltrations captured within these twenty patients that real-time data was gathered, which is a limitation to the study. However, we have collected injection monitoring results and reviewed them retrospectively. Table two shows the count values of an injection with no radioactivity remaining at the injection site and the count values of an injection with radioactivity remaining at the injection site. This shows how the count values and

the curves would differ between a suspected high-quality injection and a suspected low-quality injection.

Conclusions

An external detector device may be used to ascertain that an injection is sufficient within only a 60-second acquisition. Although less accurate than being able to analyze a longer and more complete set of time-activity curves, significant infiltrations would take much longer to reach baseline compared to non-infiltrated injections. The standard method for using this device is to inject the entire patient dose and then assess the injection quality following the full uptake time of 60 minutes. With the use of real-time monitoring, injections with activity remaining at the injection site would be captured within the first 60 secs and the patient could be rescheduled at that time. This would result in time savings for the patient and imaging center.

Acknowledgment

I would like to thank Chris Carr CNMT, RT(R) and Erica Carrol CNMT for their assistance with this project.

Disclosure

No Financial information to disclosure. UT was engaged with Lucerno in a quality improvement study during the time this research was performed.

References

1. Shreve PD, Anzai Y, and Wahl RL. Pitfalls in oncologic diagnosis with FDG PET imaging: physiologic and benign variants. *Radiographics*. 1999;19: 61-7.

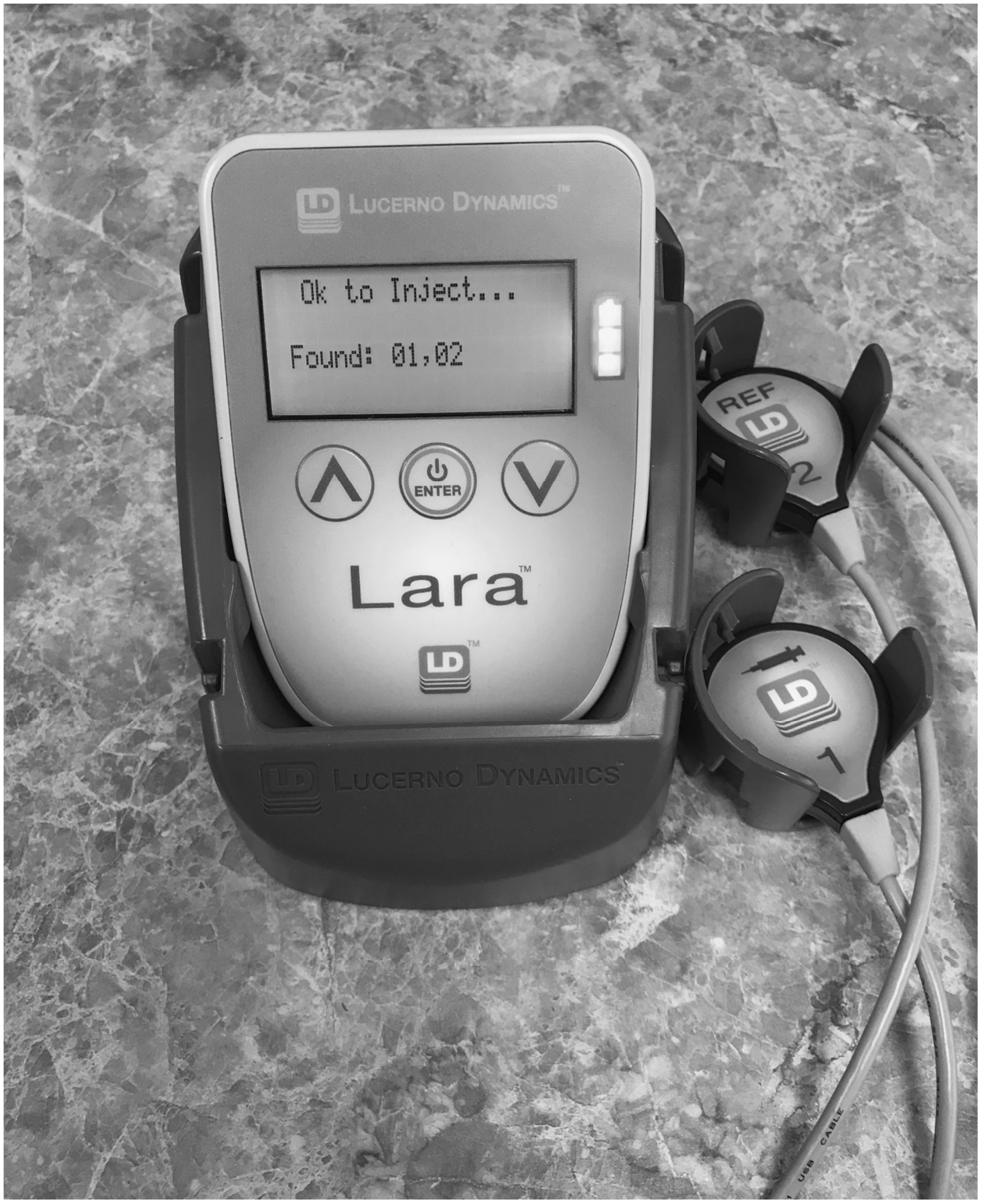

Figure 1: Modular detector device (Lara ®). The digital screen and two of the four detectors shown.

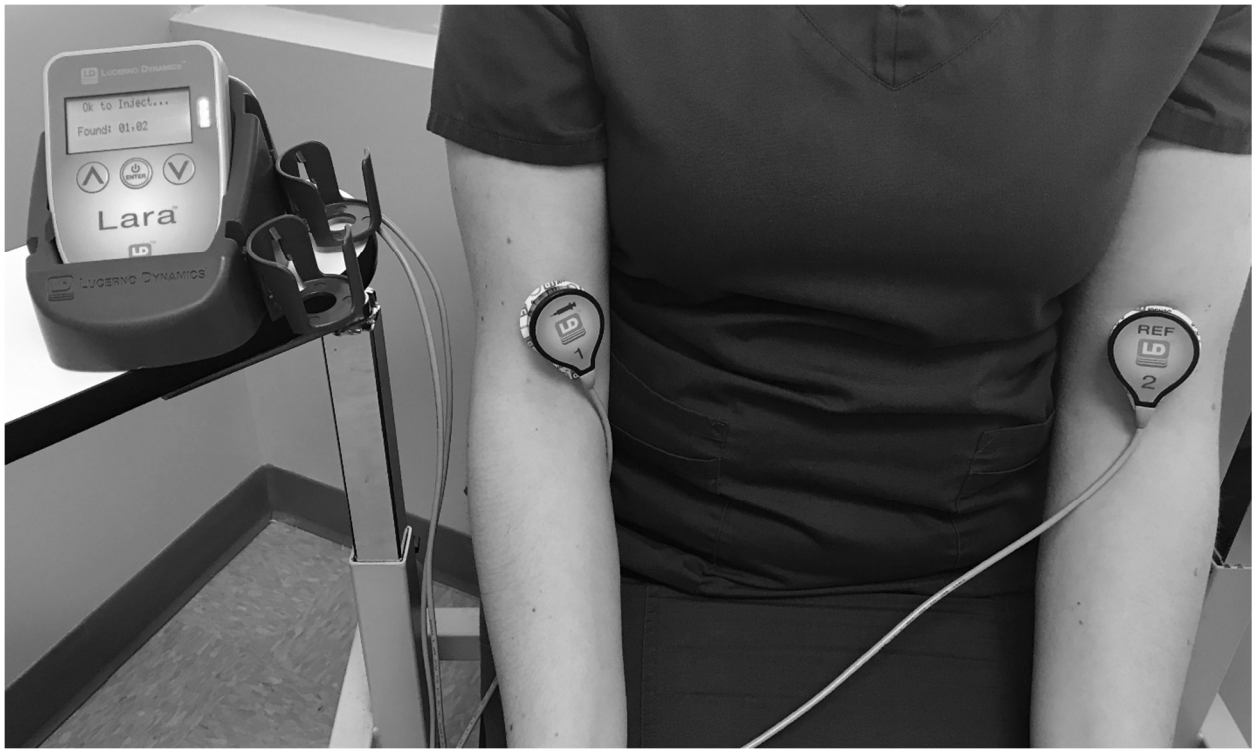

Figure2: Modular detector device (Lara ®). The digital screen and two of the four detectors shown.

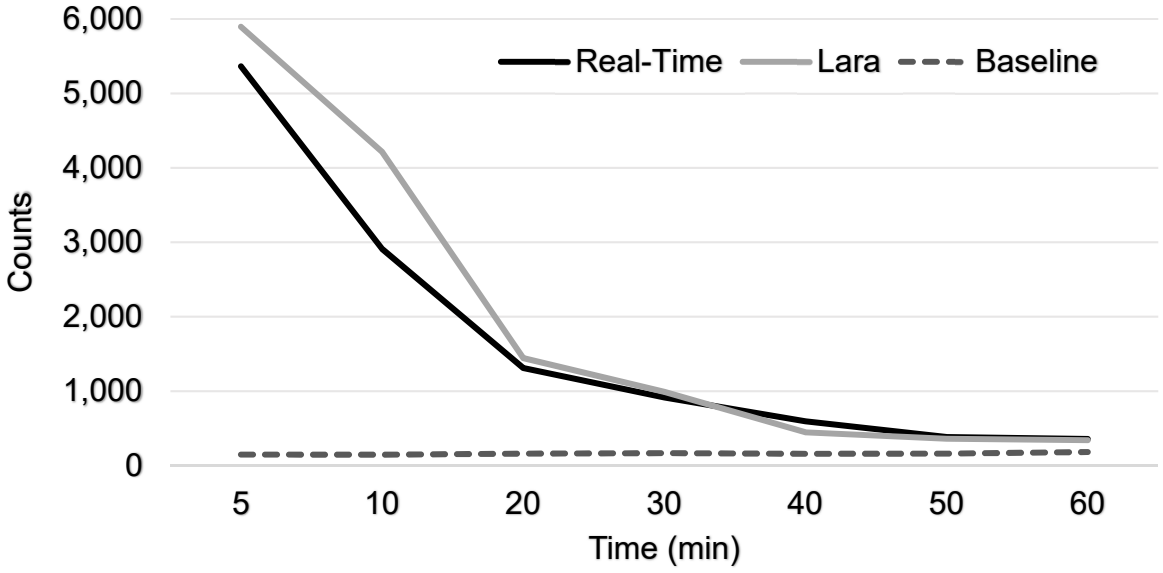

Figure 3: The manually collected (real-time) curve compared to the device collected (Lara©) curve and baseline curve to assess if the data converged.

TABLE 1

Time	Real-Time counts from a Good injection Device Score -223
5 sec	5312
10 sec	3006
20 sec	601
30 sec	433
40 sec	379
50 sec	359
60 sec	329
Baseline at 60 sec	210

TABLE 2

Time	Real-Time counts from a Good injection Device Score -223	Real-Time counts from a Bad injection Device Score +3795
5 sec	5312	2279
10 sec	3006	3742
20 sec	601	3064
30 sec	433	2926
40 sec	379	2636
50 sec	359	2736
60 sec	329	2693
Baseline at 60 sec	210	373