quality in action

Assessing and Reducing Positron Emission Tomography/Computed Tomography Radiotracer Infiltrations: Lessons in Quality Improvement and Sustainability

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abstract

PURPOSE Accurate administration of radiotracer dose is essential to positron emission tomography (PET) image quality and quantification. Misadministration (infiltration) of the dose can affect PET/computed tomography results and lead to unnecessary or inappropriate treatments and procedures. Quality control efforts ensure accuracy of the administered dose; however, they fail to ensure complete delivery of the dose into the patient's circulation. We used new technology to assess and improve infiltration rates and evaluate sustainability.

METHODS Injection quality was measured, improved, and sustained during our participation in a multicenter quality improvement project using Define, Measure, Analyze, Improve, Control methodology. Five technologists monitored injection quality in the Measure and Improve phases. After seven new technologists joined the team in the Control phase, infiltration rates were recalculated, controlling for technologist- and patient-level correlations, and comparisons were made between these two groups of technologists.

RESULTS In the Measure phase, five technologists monitored 263 injections (13.3% infiltration rate). Nonantecubital fossa injections had a higher probability of infiltration than antecubital fossa injections. After implementing a quality improvement plan (QIP), the same technologists monitored 278 injections in the Improve phase (2.9% infiltration rate). The 78% decrease in infiltration rate was significant ($P < .001$) as was the decrease in nonantecubital fossa infiltrations ($P = .0025$). In the Control phase, 12 technologists monitored 1,240 injections (3.1% infiltration rate). The seven new technologists had significantly higher rates of infiltration ($P = .017$).

CONCLUSION A QIP can significantly improve and sustain injection quality; however, ongoing monitoring is needed as new technologists join the team.

JCO Oncol Pract 16. © 2020 by American Society of Clinical Oncology

INTRODUCTION

Accurate and complete administration of the radiotracer dose as a bolus is essential to positron emission tomography (PET) image quality and quantification.[1] An infiltration is the inadvertent paravenous administration of the radiotracer into the soft tissue surrounding the vein. ^{18}F-labeled fluorodeoxyglucose (^{18}F-FDG) dose infiltrations are not uncommon and can negatively affect image quality and quantification. They may adversely affect patient management, including incorrect staging and treatment decisions.[2]

There is no routine quality control to ensure complete delivery of the ^{18}F-FDG dose into the patient's circulation. Infiltrations may be seen on the static images (approximately 60-70 minutes postinjection) but may be underestimated because they can resolve over the course of the uptake period.[3] In addition to the resolving nature of infiltrations, injection sites are often outside the imaging field of view.[4] A literature review identified six studies (2006-2017) from three centers with a total of 2,804 patients and 425 infiltrations (15.2%).[4-9] These centers used routine static images to identify infiltrations that may have underestimated the true infiltration rate. The impact of infiltrations on PET/computed tomography (CT) images, including underestimation of the standardized uptake value, has been previously described in the literature.[4]

Carilion Clinic participated in a multicenter quality improvement project using new technology (Lara System; Lucerno Dynamics, Cary, NC) to help to assess and improve infiltration rates. Rates of infiltration from the seven participating PET/CT centers ranged from 2% to 16%, and individual technologist's rates ranged from 0% to 24%.[10,11] Specific aims of this project were to monitor injection quality, use analysis of factors that contribute to infiltrations to guide improvements, remeasure rates in a similar number of patients, and evaluate sustainability of the intervention.

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Accepted on January 6, 2020 and published at ascopubs.org/journal/op on February 11, 2020: DOI https://doi.org/10.1200/JOP.19.00302

METHODS

Our institutional review board determined that the project was not research as defined by the US Department of Health and Human Services Protection of Human Subjects[12] and that it qualified as a quality assurance/quality improvement activity. Define, Measure, Analyze, Improve, and Control (DMAIC) methodology was followed to assess infiltration rates, measure improvement, and evaluate sustainability.

Define

After a review of the literature on radiotracer infiltrations, an opportunity was identified to evaluate and improve radiotracer injection quality at PET/CT centers, and a quality improvement project was designed. Five certified nuclear medicine technologists at our center with experience ranging from 13 to 28 years (mean, 18.4 years) were trained on the project and the use of the Lara System, a class 1 exempt medical device that uses scintillating crystal technology to identify presence of radiotracer at the injection site.

Measure

Injection quality was evaluated on adult and pediatric patients (n = 263) undergoing routine PET/CT. After gaining venous access and before the ^{18}F-FDG injection, the technologist attached Lara sensors to the patient's skin using atraumatic adhesive pads. One sensor was placed approximately 7 cm proximal to the injection site, and the other, which functioned as a reference, was placed in the mirrored location on the contralateral arm (Fig 1). Utilization of the system was tracked on a weekly basis.

Data were recorded by the system during the radiolabeled tracer uptake period (approximately 45-60 minutes). After removal of the sensors, patient- and procedure-specific variables were uploaded to the system's web application, which then produced time-activity curves (TACs). These curves were used to help to determine injection quality and overall infiltration rate. Our center was initially blinded to the TACs to encourage technologists to perform injections per their usual practice.

Analyze

After 263 injections were monitored, statistical analyses were performed and included by constructing binary decision trees using 20-fold cross validation with inverse prior weights as the assessment measure (SAS Enterprise Miner 14.1; SAS Institute, Cary, NC). Logistic regression using the Bayesian information criterion as the selection criterion was also used (SAS 9.4). Both methods were used in tandem to identify contributing factors. Rates presented are unadjusted unless otherwise stated. Results of the analyses were shared with the Carilion team.

Improve

A quality improvement plan (QIP) was created on the basis of the analysis of contributing factors and discussion with our technologists, managers, and nuclear medicine physician. The QIP included three components: addition of an auto-injector (Medrad Intego PET Infusion System; Bayer HealthCare, Whippany, NJ) to provide consistent infusion and flush parameters across injections, adjustment of uptake room setup to allow for improved access to both sides of the patient, and refresher training for venous access and injection technique. After implementing the QIP, a similar number of injections were monitored (n = 278). TACs were visible to the technologists during this phase. QIP adherence was assessed, and weekly utilization continued to be tracked to ensure consistent use of the system.

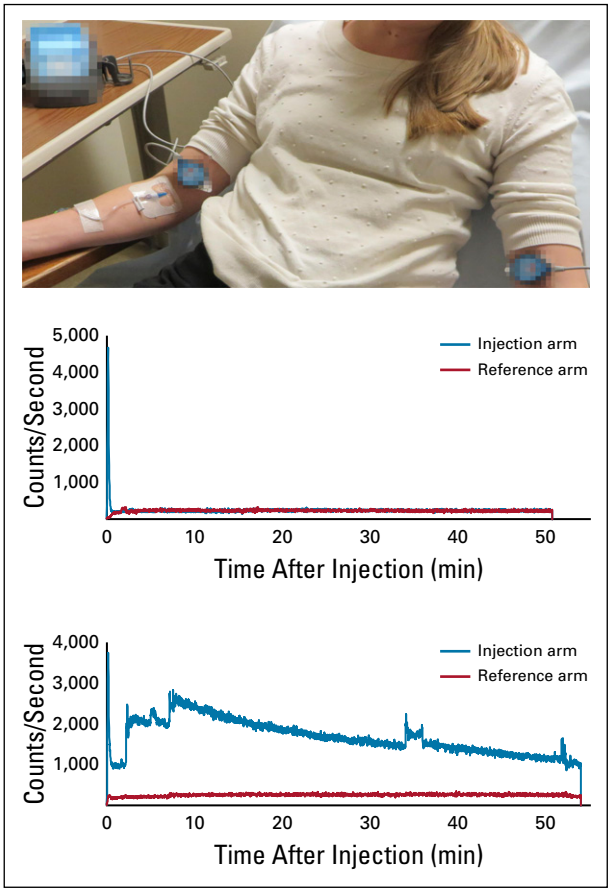

FIG 1. The Lara System (Lucerno Dynamics, Cary, NC) consists of 2 scintillation sensors, 2 pads, a reader, and a docking station. Sensors are placed on the injection arm and the contralateral arm. Time-activity curve (TAC) is provided after data are uploaded. The first TAC represents an ideal injection, and the second TAC shows significant presence of radiotracer at the injection site.

Control

Injection quality monitoring continued for approximately 1 year to assess sustainability of the intervention. During this time, seven new technologists joined the team. These new technologists received our standard onboarding training but were not present for the refresher training done in the earlier Improve phase; however, both the new and the

original technologists experienced the same auto-injector and uptake room conditions during this phase. Infiltration rates were re-assessed. Comparisons were then made between the results from the five technologists who participated in the Measure/Improve phases and the results from the seven new technologists.

RESULTS

Measure and Improve Phases

In the Measure phase, 263 injections were monitored over 13 weeks with a 93% average utilization and an overall infiltration rate of 13.3%. Nonantecubital fossa injections (hands, wrists, forearms) were associated with increased probability of infiltration. Infiltration rates for nonantecubital fossa (n = 63) and antecubital fossa injections (n = 200) were 28.6% and 8.5%, respectively. QIP adherence was estimated to be high; the auto-injector was used 65% of the time, uptake chairs were repositioned, and refresher training was conducted. In the Improve phase, 278 injections were monitored over 12 weeks with an average utilization of 85% and an overall infiltration rate of 2.9%. The 78% decrease in overall infiltration rate was significant ($P < .001$; Fig 2).

The infiltration rate for nonantecubital fossa injections (n = 71) decreased from 28.6% to 7.0%, demonstrating a significant reduction ($P = .0026$). In antecubital fossa injections (n = 207), infiltration rates also had a significant ($P = .0039$) reduction from 8.5% to 1.5%. Use of the auto-injector resulted in 1 infiltration out of 180 injections (0.6%), while 98 manual injections resulted in 7 infiltrations (7.1%).

Control Phase

Monitoring continued for approximately 1 year (n = 1,240 injections), with a resulting infiltration rate of 3.1% (Fig 2). Utilization of the system remained consistent with prior rates on the basis of reported weekly patient volume. Model-based analysis revealed a higher and significantly different ($P = .017$) adjusted infiltration rate for the seven new technologists compared with the original five technologists (Table 1). Larger needles (< 22 gauge) and not using an auto-injector were significantly associated with higher predicted probability of infiltrations for injections administered by the seven new technologists.

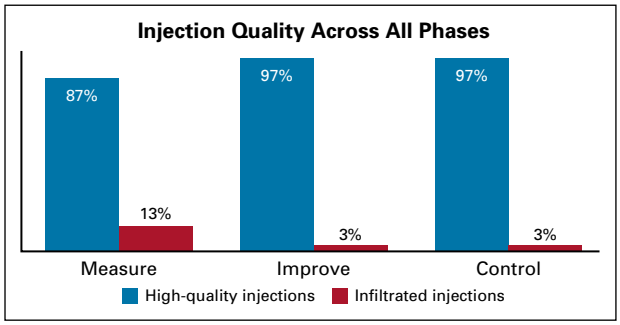

FIG 2. The 78% decrease in infiltration rate in the Improve phase was significant ($P < .001$) and was maintained in the Control phase.

DISCUSSION

We were able to create a tailored QIP specifically for our center that led to improved overall injection quality. In addition to the overall benefit of improved injection quality, we were able to enhance our clinical practice. Before this quality improvement project, our facility scanned all patients' arms to assess the injection site for infiltrations. We also repeated PET/CT studies if large infiltrations were observed on static images. Use of injection monitoring technology allows us to image patients with arms over their head as needed and provides additional insight into the quality of the injection during the uptake period, which aids in our clinical assessment of whether to repeat PET/CT studies. We intend to assess the effect of future interventions by evaluating the overall rate of repeat PET/CT studies.

While the overall improvement project was successful, we experienced several challenges. A facility relocation negatively affected utilization early in the Improve phase. Utilization was 68% over 12 scanning days, with an infiltration rate of 4.8%, as technologists adjusted to a new patient flow and room setup. Utilization during the remaining 10 weeks was 91% (Measure phase, 93%) with an infiltration rate of 2.5%, indicating that the lower utilization early in the Improve phase did not favorably bias the results. In addition, a key component of the QIP, the auto-injector, was not available 100% of the time. Finally, we observed during the Control phase that additional training would be needed for the technologists who did not participate in the retraining in between the Measure and Improve phases.

New monitoring technology to drive radiotracer injection quality improvement was easily incorporated into our routine clinical practice and allowed us to significantly reduce infiltration rates and sustain improvement. Ongoing monitoring allows us to repeat DMAIC cycles to ensure that new and existing technologists achieve and maintain high injection quality. One of our satellite facilities with a mobile unit PET/CT also used the technology as part of the multicenter quality improvement project. This facility experienced similar results, which suggests successful implementation beyond our own center. The mobile team created a customized QIP (which did not include an

TABLE 1. Original Five Technologists Versus Seven New Technologists (Control Phase)

Technologists	Infiltration Rate, %	SE (95% CI)
Original five	2.1	0.0055 (0.83 to 3.26)
Seven new	6.1	1.31 (3.19 to 8.97)

auto-injector), reduced infiltration rates, and sustained improvements. We anticipate inclusion of appropriate DMAIC learnings in our onboarding process and dissemination of the technology and quality initiative to our general nuclear medicine practice, where we expect similar results. Through quality improvement processes, infiltration rates can be reduced. However, ongoing monitoring is needed to ensure that injection quality remains high and that factors that contribute to infiltrations are continually evaluated and addressed.

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PRIOR PRESENTATION

Presented at the 2018 ASCO Quality Care Symposium, Phoenix, AZ, September 28-29, 2018.

SUPPORT

Supported in whole or part by the North Carolina Biotechnology Center.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

Disclosures provided by the authors and data availability statement (if applicable) are available with this article at DOI https://doi.org/10.1200/JOP.19.00302.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Assessing and Reducing Positron Emission Tomography/Computed Tomography Radiotracer Infiltrations: Lessons in Quality Improvement and Sustainability

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Speakers' Bureau: Cardinal Health, Advanced Accelerator Applications
Patents, Royalties, Other Intellectual Property: Patent submitted 4/15/2019 for a new method for delivering radioactive material (Inst), submitted patent for a new dose monitoring device (Inst)

No other potential conflicts of interest were reported.