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Weight-based contrast administration in the computerized tomography evaluation of acute pulmonary embolism

Challenges in optimizing imaging quality

Lisa Laurent, MD, MBA, CPE[a,*], Ina Zamfirova, MS[b], Suela Sulo, PhD[b], Pesach Baral, BA[c]

Abstract

Compare individualized contrast protocol, or weight-based protocol, to standard methodology in evaluating acute pulmonary embolism.

Retrospective chart review was performed on patients undergoing computed tomography angiography with standard contrast protocol (n = 50) or individualized protocol (n = 50). Computerized tomography images were assessed for vascular enhancement and image quality.

Demographics were comparable, however, more patients in the individualized group were admitted to intensive care unit (48% vs 16%, $P = 0.004$). Vascular enhancement and image quality were also comparable, although individualized protocol had significantly fewer contrast and motion artifact limitations (28% vs 48%, $P = 0.039$). Fifteen percent decrease in intravenous contrast volume was identified in individualized group with no compromise in image quality.

Individualized contrast protocol provided comparable vascular enhancement and image quality to the standard, yet with fewer limitations and lower intravenous contrast volume. Catheter-gauge flow rate restrictions resulting in inconsistent technologist exam execution were identified, supporting the need for further investigation of this regimen.

Abbreviations: ATA = ascending thoracic aorta, HU = Hounsfield unit, LLL = left lower lobe, LPA = left pulmonary artery, LUL = left upper lobe, MPA = main pulmonary artery, RLL = right lower lobe, RML = right middle lobe, RPA = right pulmonary artery, RUL = right upper lobe, SD = standard deviation.

Keywords: computerized tomography, optimizing imaging quality, pulmonary embolism, weight-based contrast administration

1. Introduction

Pulmonary embolism (PE) is the third most common cause of cardiovascular death and affects almost 600,000 people in the United States every year.[1] Mortality can be reduced through early diagnosis and treatment, although clinical manifestations can often be nonspecific, necessitating accurate and efficient imaging. The role of computed tomography angiography (CTA) has been well established in the detection of PE with the estimated incidence of reported PE, increasing from 62.1 to 112.3 per 100,000 cases.[2,3]

Pulmonary CTA poses a familiar quandary of achieving maximum luminal enhancement of target vessels while minimizing mediastinal and perivascular streak artifact from undiluted contrast material in neighboring venous structures. Optimized contrast injection protocols are critical in accurately identifying acute PE. However, several factors may interfere with proper contrast delivery and scan timing (e.g., washout of contrast into the central circulation, contrast administration rate, catheter gauge flow rate limitations, technologist protocol adherence, etc.).[4–7]

Studies aimed at optimizing chest CTA protocols for the assessment of acute PE have focused on the timing of the contrast injection rather than on the amount of contrast,[4,7,8] in addition to using patient weight to tailor contrast injection protocols.[5,6] The development of the personalized CTA protocols investigated here for the evaluation of acute PE was based on research originally conducted on coronary CTA which combined custom injection protocols with scan timing for each patient, patient and procedure data gathered by healthcare personnel, an individualized algorithm for protocol generation, and DualFlow technology.[9] Compared with standard injection protocols, weight-based protocols optimize contrast volumes and improve coronary and pulmonary artery enhancement during chest CT.[5,6]

The purpose of the study is to compare an individualized contrast protocol to the use of a standard protocol and to identify factors that influence the clinical utility, contrast usage, and limitations in process consistency when performing chest CTA for the evaluation of acute PE.

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[a] Department of Radiology, [b] James R. and Helen D. Russell Institute for Research & Innovation, Advocate Lutheran General Hospital, Park Ridge, [c] Rosalind Franklin University, Chicago Medical School, North Chicago, IL.

[*] Correspondence: Lisa Laurent, Advocate Lutheran General Hospital, Park Ridge, IL (e-mail: lisa.laurent@advocatehealth.com).

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2. Materials and methods

2.1. Study population

A retrospective chart review of 100 randomly selected adult patients with no specific morphologic characteristics who underwent chest CTA for the evaluation of acute PE in the emergency room at a 538-bed level 1 trauma center between June and December 2013 was conducted. Fifty patients received the standard contrast protocol, and 50 patients received the individualized, or weight-based protocol.

2.2. Individualized algorithm

The personalized contrast protocol software tested in this study (P3T, Bayer Healthcare LLC, Whippany, NJ) customizes a triphasic injection protocol for each patient and procedure using patient weight, scan duration, contrast concentration, and attributes of a test bolus scan with an ROI placed in the pulmonary artery. The P3T software adapts the Iodine delivery rate (gI/s) based upon a nonlinear relationship between patient weight and scan duration. For scan durations typical on a GE Lightspeed VCT 64 to rule out PE (~5 seconds), the Iodine administration rates for 50, 80, and 118 kg patient weights are 1.60, 2.00, and 2.30 gI/s, respectively (corresponding to Iodine dosing coefficients of 0.500, 0.375, and 0.310 gI/kg). The volumetric flow rate for all contrast phases varies as a function of the patient weight and the Iodine concentration of the contrast.

The coefficients relating the patient weight, contrast concentration, and Iodine delivery rate were determined by performing multiobjective optimization (Gembicki weighted goal attainment method)[10] using a goal of 350 Hounsfield units (HU) in the left heart compartment. Iterative numerical simulations of the Bae-Heiken-Brink full-body pharmacokinetic model[6] of contrast medium propagation were used in the optimization. A target of 350 HU throughout the coronary vasculature was chosen during the design of the software based upon clinical practice patterns and the clinical literature. For example, Cademartiri et al demonstrated higher diagnostic accuracy at coronary computed tomography angiography when opacification in the coronaries exceeds 326 HU.[10] A key principle in rationale contrast protocol design is ensuring the injection duration of the contrast bolus is sufficient to anticipate the dispersive effects of the cardiopulmonary system. The P3T software sets the injection duration of the contrast-only portion of the triphasic protocol as the sum of the scan duration plus N seconds, where N is a configurable integer ranging between 0 and 10 seconds. The default setting in the software is N equal to 4 seconds. For fast data acquisitions typical at high-pitch CTA (~5 seconds), the software restricts the injection duration of the contrast-only phase to a configurable minimum value, ranging between 6 and 16 seconds. The setting used in this study was 10 seconds. The saline phase of the protocol is fixed at 30 mL and is delivered with the same volumetric flow rate of the contrast.

A per-patient scan delay is computed as a function of the test bolus arrival time, the patient weight, and the scan duration. The scan delay is the arrival time of contrast in the regions of interest (ROI) set in the pulmonary artery plus *M* seconds, where *M* is an integer ranging between 1 and 6 seconds, depending on the patient's weight, the time to peak contrast enhancement of the test bolus, the injection duration of the contrast-only phase of the injection, and the scan duration. With knowledge of the scan delay and the scan duration, simple heuristics are applied, such as preventing the injection of contrast beyond the end of the scan by finishing the split-bolus phase at least 3 seconds prior to the end of the scan.

Unique subject identifiers and a data collection tool created and pilot tested by the investigators were used to record patient demographics. Contrast protocol parameters, diagnostic quality, and quantitative measurements were recorded for: the ascending and descending intrathoracic aorta, main pulmonary artery (MPA), right and left pulmonary arteries, and segmental pulmonary arterial branches including: right upper lobe (RUL) —apical segment; right middle lobe (RML) —medial segment; right lower lobe (RLL)—posterior basal segment; left upper lobe (LUL) —anterior segment; lingula—superior segment; and left lower lobe (LLL)—posterior basal segment. This study was approved by the facility's Institutional Review Board with a waiver of consent for accessing patients' charts.

2.3. CTA scan protocols

Upon implementation of the new CTA Individualized Protocol at our institution, all patients seen after this implementation received the new protocol. Our chart review comprised of a random selection of 50 patients from the time period immediately before CTA Individualized Protocol and 50 patients randomly selected from the time period following new protocol employment.

All selected imaging studies were acquired on a GE HD 750 64-slice CT scanner (VCT; General Electric, Milwaukee, WI). Scanning was performed in a nongated, helical acquisition mode during a single breath-hold. The scan protocol entailed the capture of a series of image sets, with the 1.25 mm × 1.25 mm axial CT slices being used.

2.3.1. CTA standard protocol. Depending on the site of injection, no smaller than a 20-gauge needle was used to inject 100 cc of the contrast agent Isovue-370 (Bracco Diagnostics Inc, Monroe Township, NJ) or Omnipaque-350 (GE Healthcare, Princeton, NJ) into the antecubital fossa at a rate of 4 cc/s. The first cine image was acquired after an upfront 8-second delay. After the first blush of contrast was observed in the MPA, the CT scan was initiated and the image was acquired during an approximate 3- to 5-second breath-hold. The total delay time before imaging ranged from 13 to 18 seconds.

2.3.2. CTA individualized protocol. Using the PA scout image, the patient weight and diagnostic scan parameters (scan duration) were entered into the Certegra (P3T) software (Bayer HealthCare, LLC, Whippany, NJ). The software's formulaic algorithm generated a personalized timing protocol for the contrast bolus. The single-level dynamic imaging sequence was used to determine the time to peak enhancement within the MPA. The patient weight, diagnostic scan parameters, and timing data for the contrast bolus were entered into the software generating a personalized diagnostic imaging protocol which provided: scan delay from IV contrast delivery, recommended contrast and saline volumes, and recommended flow rate.

2.4. Image review

Three board-certified, fellowship-trained radiologists specializing in either cross-sectional imaging or interventional radiology were recruited to quantitatively and qualitatively assess the axial CT images. The radiologists were blinded to patient data and any imagery associated with the contrast injection protocol.

2.5. Vascular enhancement

One radiologist quantitatively assessed the pulmonary vasculature enhancement by drawing ROI cursors in the ascending and descending intrathoracic aorta, as well as in the 9 PA structures identified in the *Individualized Algorithm* section above as the MPA, right and left pulmonary arteries, and segmental pulmonary arterial branches including: RUL— apical segment; RML—medial segment; RLL—posterior basal segment; LUL—anterior segment; lingula—superior segment; and LLL—posterior basal segment. Assessments were focused on the branches distal to the main and lobar PAs, which have clinical significance in the diagnosis and treatment of acute PE.[11] The mean HU, standard deviation (SD), and ROI were reported for each region.

2.6. Image quality

Two radiologists independently assessed the diagnostic image quality as: "diagnostic without limitation," "diagnostic with limitation," or "nondiagnostic." Diagnostic limiting factors identified within a region were categorized as either: technical (related to contrast administration such as streak/streaming artifact and/or poor enhancement or patient-related (motion artifact, surgical resection, and/or presence of synchronous disease states such as malignancy, pneumonia, or congestive heart failure). When discordance existed between the readers, the third radiologist served as the adjudicator in resolving the discordance.

2.7. Statistical analysis

The mean HU value for the individualized protocol was determined with previously collected pilot data from the most diagnostically relevant region, PA, and was used to calculate the sample size necessary to achieve a statistical power of 80%. A total of 100 patients (50 in each group) was required to distinguish a 15% difference between the protocols with a β of 20% and α of 0.05.

Descriptive statistics were calculated on all patient characteristics. Continuous patient variables and quantitative measures (vascular enhancement, HU) were compared between the groups with the Independent Student *t* test. Categorical patient variables and qualitative measures (image quality) were compared with the Pearson χ^2 or Fisher exact tests. Kappa (*k*) values were calculated to assess the level of agreement in image quality between the readers. Interobserver agreement was classified as poor ($k=0$–0.20), fair ($k=0.21$–0.40), moderate ($k=0.41$–0.60), good ($k=0.61$–0.80), or excellent ($k=0.81$–1).[12] Analyses were performed using SPSS for Windows, version 22.0 (SPSS Inc, Chicago, IL).

3. Results

3.1. Demographic characteristics of study population

The demographic data and the total contrast volume for both groups are presented in Table 1. Patients in this study were generally older adults with a mean age of 61.06 years (SD = 15.58, range = 16–94). Patient demographics were comparable between the groups; however, more patients in the individualized group were admitted to the intensive care unit (ICU) (48% vs 16%, $P=0.004$). Most of the patients had a negative radiologic diagnosis; however, 14% of patients in the standard protocol group and 6% in the individualized group were diagnosed with acute PE. The total contrast volume recorded by the technologists was statistically significantly higher in the standard protocol group (97.51 mL vs 82.78 mL, $P<0.001$).

Table 1

Comparison of overall patient characteristics and total contrast volume between the CTA standard and individualized groups.

Characteristic	Standard group (n = 50)	Individualized group (n = 50)	*P* value
Age, y*	61.66 (14.32)	60.46 (16.87)	0.702
Weight, kg*	86.62 (22.39)	78.82 (21.49)	0.083
Height, m*	1.68 (0.10)†	1.67 (0.12)‡	0.660
BMI, kg/m^{2,*}	30.50 (5.97)†	28.12 (5.75)‡	0.135
Sex			0.161
Male	30 (60)	23 (46)	
Female	20 (40)	27 (54)	
ICU	8 (16)	24 (48)	0.004§
Radiological diagnosis			
Negative	43 (86)	40 (80)	0.424
Cancer	0 (0)	2 (4)	0.495
Congestive heart failure	0 (0)	5 (10)	0.056
Pulmonary embolism	7 (14)	3 (6)	0.182
Total contrast volume, mL*	97.51 (17.72)	82.78 (10.10)	0.000‖

Unless otherwise specified, data are numbers of participants, with percentages in parentheses. Statistical tests performed included Student *t* test, χ^2, and Fisher exact test.
CTA = computed tomography angiography, ICU = intensive care unit.
* Data are mean, with standard deviations in parentheses.
† Data available for 41 patients.
‡ Data available for 20 patients.
§ $P<0.01$.
‖ $P<0.001$.

3.2. Vascular enhancement

The comparative results for vascular enhancement for the different anatomic structures are outlined in Fig. 1.

Table 2 presents the comparison of image diagnostic limitations between the 2 groups. With the exception of 3 studies, all the scans were considered diagnostic and acceptable in

Table 2

Comparison of image diagnostic qualifications between the CTA standard versus individualized groups.

Characteristic	Standard group (n = 50)	Individualized group (n = 50)	*P* value
Overall			
Accurate diagnosis without qualification	48 (96)	49 (98)	1.00
Limitations (overall)	24 (48)	14 (28)	0.039*
Contrast limitations (streak/poor enhancement)	15 (62.5)	12 (85.7)	0.160
Motion/resection limitations qualification	9 (37.5)	2 (14.3)	0.160
ICU patients	8 (16)	24 (48)	
Accurate diagnosis without limitation	3 (37.5)	18 (75)	0.088
Limitations (overall)	5 (62.5)	6 (25)	0.088
Contrast limitations (streak/poor enhancement)	2 (40)	5 (83.3)	0.242
Motion/resection limitations	3 (60)	1 (16.7)	0.242

Unless otherwise specified, data are numbers of participants, with percentages in parentheses. Percentages may not add up to 100% because of rounding. Statistical tests performed included Student *t* test, χ^2, and Fisher exact test.
CTA = computed tomography angiography, ICU = intensive care unit.
* $P<0.05$.

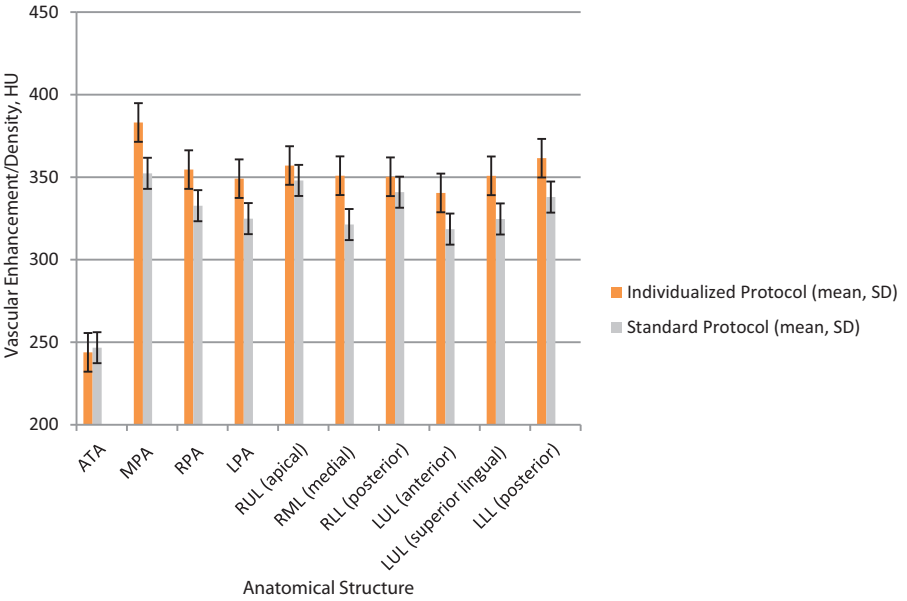

Figure 1. Quantitative comparisons among the studied anatomical structures between the study protocols. Graph illustrates means and standard deviations for the quantitative outcomes for the selected anatomical regions. Statistical test performed included Student *t* test. $^{*}P > 0.05$ deemed to be statistically significant.

interpretability (without the need for qualification) despite the presence of either technical and/or patient-related limitations. Although the percent of accurate diagnosis without limitation was comparable between the groups, statistically less overall limitations were identified in the individualized protocol patients compared with the standard protocol patients (28% vs 48%, $P = 0.039$). This is primarily due to the lower percentages of patient-related limitations for the individualized protocol overall and in the ICU cohort. However, technical limitations (streak/stream artifact and/or poor enhancement) were higher within the individualized group overall (85.7%) as well as for the ICU patients (83.3%) compared with the corresponding standardized groups (62.5% and 40%, respectively). Although not statistically significant, more ICU patients receiving the individualized protocol had an accurate diagnosis without limitation (75%) compared with ICU patients receiving the standardized protocol (37.5%). This is thought to be due to the relatively fewer patient-related limitations identified when the individualized protocol was used (16.7%) versus when the standardized protocol was implemented (60%). Technical limitations associated with the individualized protocol were, in fact, higher than those associated with the standardized protocol (5 [83.3%] out of 6 patients vs 2 (40%) out of 5 patients, respectively). The reason for this is that these limitations were based on anecdotal observation, the significance of which is unclear and related to motion and or contrast artifact.

The breakdown of the kappa values used to assess the interobserver agreement for the anatomical structures evaluated for qualitative luminal enhancement and interpretative value are depicted in Table 3. The interobserver agreement for image quality ranged between 0.51 and 0.90, with the highest level of agreement reported for the MPA region ($k = 0.90$), and the lowest agreement reported for the segmental left lower lobe region ($k = 0.51$).

Table 3

Interobserver agreement for image quality of studied anatomical structures.

Characteristic	*K* value
Main pulmonary artery	0.90
Right upper lobe—apical	0.81
Right middle lobe—medial	0.73
Right lower lobe—posterior	0.57
Left upper lobe—anterior	0.68
Lingula—superior	0.55
Left lower lobe—posterior	0.51
Subsegmental right upper lobe	0.57
Subsegmental right middle lobe	0.57
Subsegmental right lower lobe	0.55
Subsegmental left upper lobe	0.65
Subsegmental lingula	0.68
Subsegmental left lower lobe	0.60

Anatomical structures presented are structures qualitatively evaluated by the radiologists.

4. Discussion

Despite the recognized advantages and high diagnostic accuracy of multidetector CT imaging, chest CTA for the assessment of acute PE is among the most challenging cross-sectional examinations to standardize for reliable interpretation.[11–13] The breadth of patient comorbidities including cardiovascular disease, respiratory disorders, and cancer has historically challenged CT technology to produce a consistent and reliable diagnostic examination with the desired maximum opacification of the target PA vessels.[11] One of the proposed advantages to a personalized algorithm for IV contrast delivery compared with the more conventional "cookbook" approach would be to obtain this desired effect while retaining image quality and conserving iodinated contrast. We propose that the validity or strength of the individualized technology could be determined by the maximum attenuation achievable of the target vessel under a wide range of clinical conditions that otherwise serve to degrade image quality when assessing for acute PE (e.g., presence of comorbid disease,

motion artifact related to respiratory distress). How useful the technology is for the interpreting radiologist to render an accurate and reliable reading in the presence of a "less than perfect" scan is paramount and consequently the cornerstone of this investigation.

The randomly selected study groups were well matched and basically equivalent with respect to multiple demographics and scanning parameters (with the exception of patients admitted to the ICU). No statistically significant difference in the diagnostic interpretability was found between the 2 assessed protocols; acceptable image quality that allowed the interpreting radiologist to make a diagnosis without qualification was reported in 96% of patients in the standard protocol group versus 98% in the individualized protocol group. In general, we considered patients admitted to the ICU following the CT study as being "sicker" or more critically ill for a variety of reasons. An anecdotal observation was that more patients in the individualized contrast group admitted to the ICU shortly after receiving the CT. Although contrast administration-related issues were present in 5 of the total 24 ICU patients, these limitations did not affect the overall interpretability of the scans. We would therefore propose that despite this small cohort number, the individualized contrast protocol may be capable of overcoming significant technical challenges inherently associated with the more seriously ill patient without compromising image quality. Similarly, regardless of the clinical condition of the patient and/or the presence of comorbidities (e.g., pneumonia, congestive heart failure, cancer), the individualized protocol provided the radiologist with a reliably interpretable study.

Finally, the use of an individualized contrast protocol resulted in an approximate 15% decrease in total IV contrast volume needed to execute a diagnostic chest CT angiogram. This is a key factor in potentially decreasing dose-dependent adverse reactions and overall cost for contrast use.

4.1. Challenges and limitations

A limitation of this study is the not representative cohort of patients studied. This prohibits formulating a strong argument in favor of using a personalized IV contrast delivery system (in lieu of the more conventional standardized protocols commonly in use) despite its capability to generate diagnostic image quality regardless of the patient's clinical condition. As the flagship institution within the largest integrated delivery network in Illinois, our hospital was the first to implement this alternative contrast delivery software. Consequently, there was widespread interest in learning of our initial results.

During the course of analyzing the results, we discovered that the computer-generated algorithm was not consistently implemented by the CT technologists in approximately 25% of the cases and specifically when catheters smaller than 18-gauge were used. To match these outlier examinations to the qualitative assessments in an effort to formulate a reasonable conclusion is an issue to be explored with future study. The flow rates calculated by the software were manually reduced by the technologist to avoid exceeding the flow rate recommendations in the catheter system package insert. This introduced lower flow rates than desired which we feel compromised the effectiveness of target vessel enhancement. This is a legitimate concern when imaging larger patients requiring higher iodine concentrations via maximum contrast volume and delivery velocity.[14] Despite the questionable significance of this limitation, the outcomes with respect to vessel opacification were nearly identical for the 2 assessed protocols. Although the difference in enhancement did not reach statistical significance, a slight advantage observed with the individualized contrast protocol is worth noting. These observations suggest that a true advantage, as demonstrated by Deible et al,[15] may exist with strict adherence to the algorithm using a larger-sized catheter system.

The results of this study, although not conclusive, are nevertheless promising. Potential variability in study parameters and patient acuity levels inherent to the utilization of retrospective design limit standardization and therefore the ability to collect complete information on study patients. Our findings would support the advantage in using individualized protocols in the CTA evaluation for acute PE phenomenon when all other scan technique variables are kept constant and a large bore needle is used. The challenges encountered are not unique to this study, have been and will continue to be investigated as the multidetector CT technology continually evolves.

Future research is indicated in quantifying the combined positive effects of individualized contrast administration and larger gauge catheters (and therefore higher flow rates), under specific conditions of multidetector CTA in the evaluation of acute PE from both a clinical and cost effectiveness perspective. Prospective studies utilizing larger sample sizes and matched cases (based on relevant demographic and clinical characteristics) are needed to assess the relationship between weight-based IV contrast volume administration and decreased occurrence of dose-dependent adverse reactions such as renal toxicity in at-risk patients.

4.2. The role of transformational change

The technologists in our CT department underwent intensive training during the implementation of the individualized weight-based IV contrast delivery system. This was commensurate with learning a brand new CT scanner and advanced reiterative reconstruction dose reduction algorithms. Consequently, all protocols had to be modified and the conventional way CT scans were performed in the assessment for acute PE completely changed. Despite these challenges, 100% adherence in utilizing the new software algorithm across all shifts was achieved in 6 months due to the collaborative efforts of the technologists, radiologists, and managers. This scenario is not unique to our institution, but instead underscores the need for sensitivity and multidisciplinary engagement when introducing a new methodology that can potentially impact process and procedure work flows. Stringent adherence to protocols and standardization whenever feasible are mandatory in creating a high reliability imaging environment. Therefore, we view this paper as the stepping stone for further in-depth study into the role behavioral and attitudinal change affects patient outcomes.

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