

A Clinical Evaluation of an Automated Software Program (P3T™ Cardiac) for Patient Specific Contrast Injection During Chest CTA to Exclude Pulmonary Embolism

Christopher R Deible MD, PHD¹, Jacob Alexander MD¹, Iclal Ocak MD¹, Maryam Ghadimi Mahani MD¹, John Kalafut BS, MS², Janet E Durick MD¹, Carl R Fuhrman MD¹, Darlene Frasher RN, MSN¹, Karen M Pealer BA, CCRC¹, Michael P. Federle MD¹, Joan M Lacomis MD¹ Department of Radiology, University of Pittsburgh Medical Center, Pittsburgh, PA¹, MEDRAD, INC., Pittsburgh, PA²

INTRODUCTION

The role of CT angiography (CTA) has been well established in the detection of pulmonary thromboembolism. According to the PLOPED II study, CTA overall sensitivity and specificity is 83% and 96% respectively (1, 2). Optimizing contrast injection and scanning parameters has become of increased importance with the faster multidetector scanners to achieve diagnostic quality images (2-6).

The purpose of our study is to assess if a prototype automated software program for patient specific contrast injection, P3T Cardiac (MEDRAD, INC., Pittsburgh, PA), is comparable to or offers advantages over our site specific standard protocol used for chest CTA to exclude pulmonary embolism (PE).

METHODS AND MATERIALS

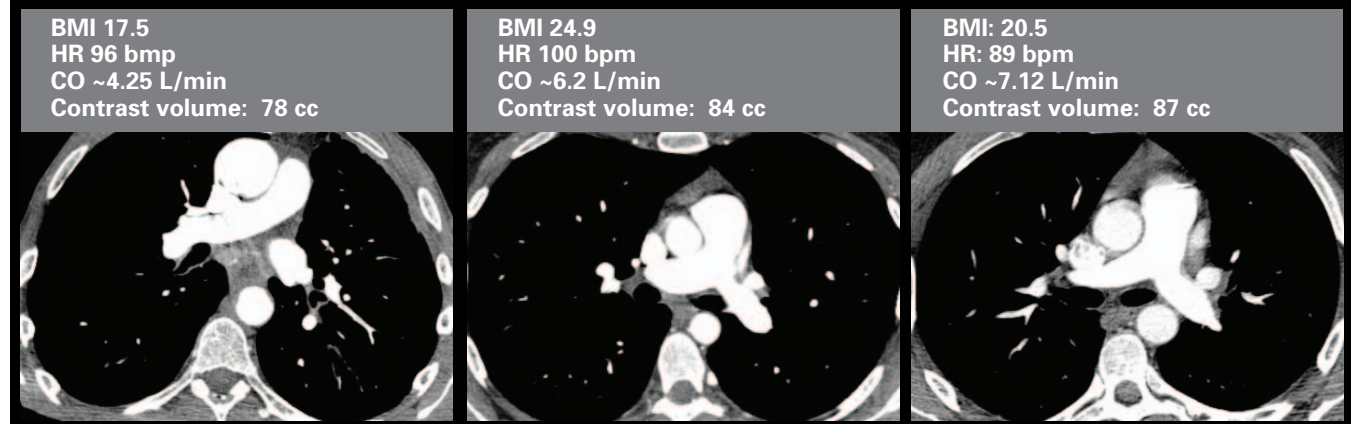
62 emergency department patients referred for chest CTA to exclude PE underwent informed consent for this study & were randomized to P3T Cardiac versus Standard (control) groups. All had 18 gauge IV access, received the contrast agent Ioversol (350mg/ml iodine; Mallinckrodt, St Louis, MO) & were scanned on one 64 slice CT scanner (VCT, GE Healthcare; Milwaukee, WI) by selected technologists monitored by selected investigators (JL, CD, JA). Scan parameters: 0.625 mm collimation; 0.24 pitch; 9.6 mm/sec table speed; 350 msec rotation time; 120 kV; 280 - 550 mAs. Recorded patient parameters: height, weight, age, sex, heart rate.

CTA Standard Group: Test bolus = 20cc contrast/50cc saline flush @ 4cc/sec to time for main pulmonary artery (MPA). Scan delay = time to contrast peak MPA + 9 seconds. Scan bolus = 80cc contrast/50cc saline flush @ 4cc/sec.

CTA P3T Cardiac Group: As a safety measure, a default max allowed injection rate of 6cc/sec was pre-selected. Height, weight, age, sex, heart rate & scan duration were entered into P3T Cardiac which generated test bolus parameters. From the test bolus, time to peak & peak density (HU) in the MPA were entered into P3T Cardiac which generated scan bolus & scan delay parameters.

Data Collection/Analysis: Two readers, blinded to injection method, jointly measured density (HU) of main (MPA, RPA, LPA) & segmental pulmonary arteries (bilateral upper & lower lobes), & SVC. Three other blinded readers qualitatively scored scans compared to an "adequate" example for image quality to assess for PE, noting limitations: poor contrast, motion, quantum mottle, SVC streak artifact. The mean and standard deviation for each group was calculated separately. Statistical analysis was performed with the t, Wilcoxon rank sum, & hypothesis tests.

Figure 2: P3T Cardiac Scans



Estimated cardiac output was computed using standard look-up tables

**Table 1:
Comparison of PA Enhancement (t test)**

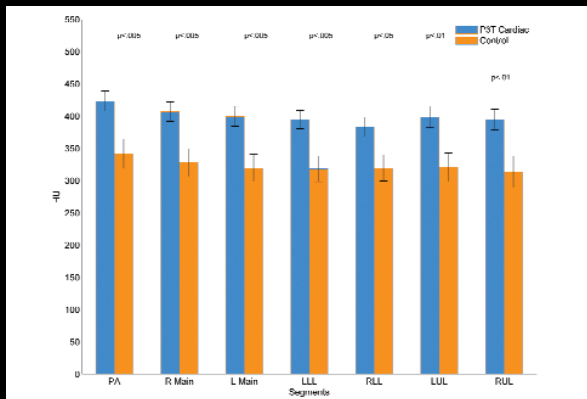
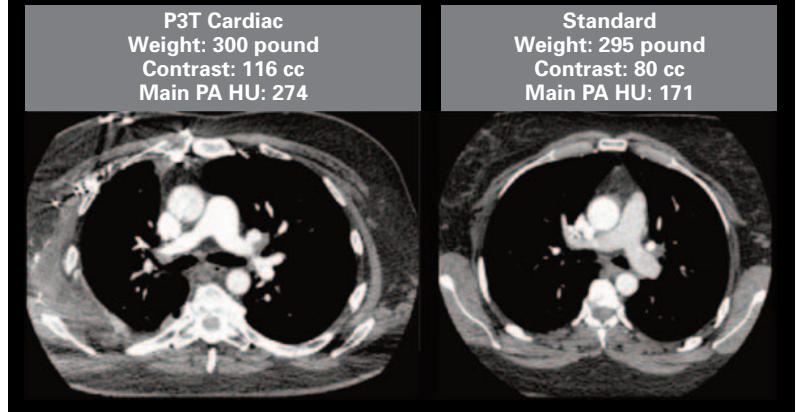


Figure 3: P3T Cardiac versus Standard



RESULTS

- P3T Cardiac population: 20 women, 11 men
 - Age: mean 43.7 yrs (range: 20-76)
 - Weight: mean 180 lbs +/- 59, median 172 lbs
 - BMI: mean 29 +/- 9, median 26
- Standard population: 22 women, 9 men
 - Age: mean 44.4 yrs (range: 19- 89)
 - Weight: mean 181 lbs +/- 75, median 185 lbs
 - BMI: mean 30 +/- 10, median 29
- Higher average image quality score of P3T Cardiac exams (mean 4.2 +/- 0.8) vs. Standard exams (mean 3.6 +/- 1.2) (p<0.05; Wilcoxon rank sum)
- Higher percentage of exams ranked as diagnostic without limitation (positive or negative for PE) in the P3T Cardiac exams (100%) vs. Standard exams (73%*) (p < 0.05 Wilcoxon rank sum)
 - * Contrast related problems (63%) were most frequent factors cited for scan limitation
- Better contrast enhancement of pulmonary arteries in P3T Cardiac exams vs Standard exams (p < 0.01 to p < 0.005, Wilcoxon rank sum) (Table 1) (Figure 3)
- Average contrast dose (test + scan) for P3T Cardiac scans was higher (114mls +/- 12mls: range 76-152) vs Standard scans (100 mls) (z-score 6.6,p<.001,1 sample z-test)

CONCLUSIONS

In this small study, the prototype P3T Cardiac automated software program for patient specific contrast injection offered improved, more consistent contrast enhancement of the target pulmonary arteries over a variety of patient specific parameters. There was a higher percentage of diagnostic quality exams albeit at a slightly higher contrast dose than our site's standard protocol used to exclude PE.

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MEDRAD, INC.
One Medrad Drive
Indianola, PA 15051-0780 USA
412-767-2400

www.medrad.com
For more information:
info@medrad.com

Customer Service/Orders
1-800-MEDRAD-1
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