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

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INTRODUCTION

The role of CT angiography (CTA) has been well established in the detection of pulmonary thromboembolism. According to the PIOPED 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® PA (Pulmonary Angiography), 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

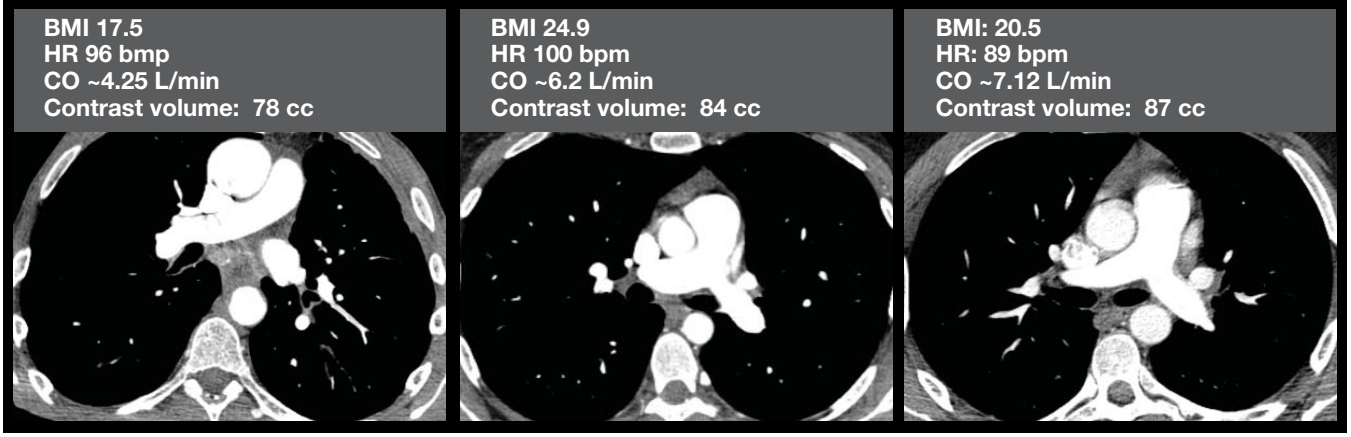
62 emergency department patients referred for chest CTA to exclude PE underwent informed consent for this study and were randomized to P3T PA versus Standard (control) groups. All had 18 gauge IV access, received the contrast agent Ioversol (350mg/ml iodine; Mallinckrodt, St Louis, MO) and were scanned 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 and 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 PA Group: As a safety measure, a default max which allowed injection rate of 6cc/sec was pre-selected. Height, weight, age, sex, heart rate and scan duration were entered into P3T PA which generated test bolus parameters. From the test bolus, time to peak and peak density (HU) in the MPA were entered into P3T PA which generated scan bolus and scan delay parameters.

Data Collection/Analysis: Two readers, blinded to injection method, jointly measured density (HU) of main (MPA, RPA, LPA) and segmental pulmonary arteries (bilateral upper and lower lobes), and 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 and artifact. The mean and standard deviation for each group was calculated separately. Statistical analysis was performed with the Student's t-test, and the Wilcoxon rank sum test.

Figure 2: P3T PA Scans



Estimated cardiac output was computed using standard look-up tables

Table 1:
Comparison of P3T PA Enhancement (t-test)

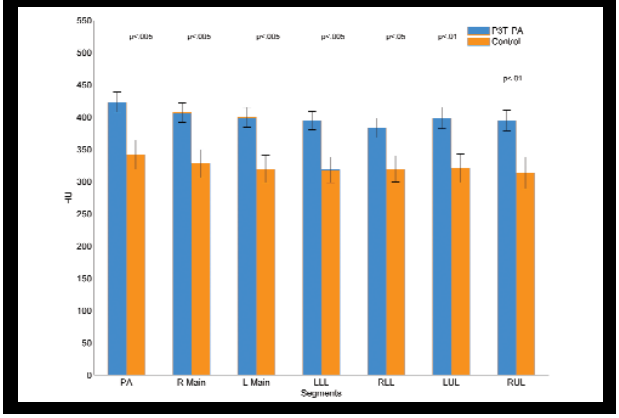
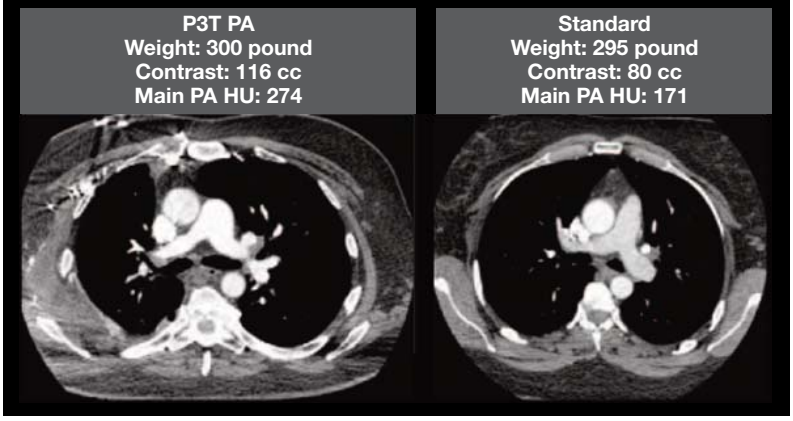


Figure 3: P3T PA versus Standard



RESULTS

- P3T PA 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 PA 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 PA 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 PA 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 PA 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 PA 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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