CT Predicts Pulmonary Embolism Outcomes

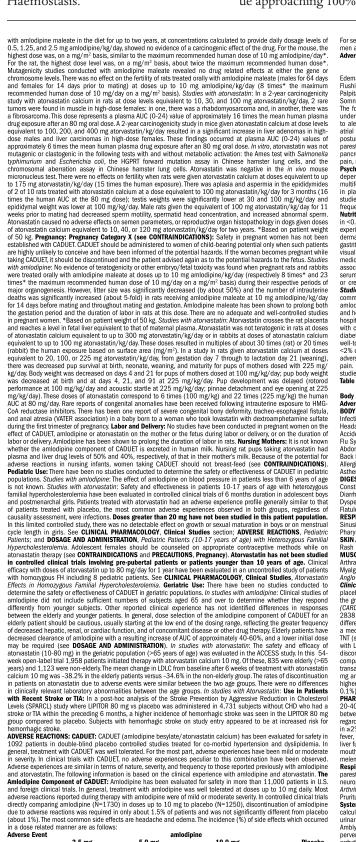
BY NEIL OSTERWEIL

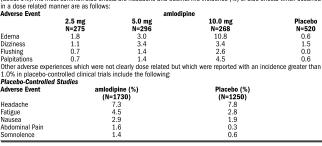
BOSTON — In patients who experience an acute pulmonary embolism, CT assessment of right ventricular ejection fraction appears useful for identifying which patients are most likely to have a good clinical outcome, investigators reported at a meeting of the International Society on Thrombosis and Haemostasis.

Among 114 patients who had an acute pulmonary embolism (PE), a right ventricular ejection fraction (RVEF) lower than 47% as assessed by ECG-synchronized multidetector-row CT (MDCT) was significantly predictive of adverse cardiac events, said Dr. Frederikus A. Klok from Leiden (the Netherlands) University Medical Center.

The test had a negative predictive value approaching 100%, suggesting that it may be most useful in identifying patients with very low risk for adverse outcomes following an acute PE.

ECG-synchronized MDCT is a novel imaging technique that allows assessment of right ventricular end-diastolic and end-systolic volumes, as well as ejection fraction. After acquisition of cardiac images, the investigators digitally trace the end-diastolic and end-systolic endocardial contours for both the left and

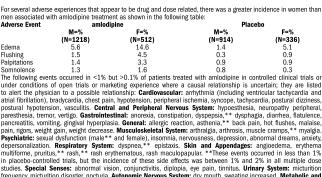




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Flushing
1.5
4.5
0.3
0.9

Palpitations
1.4
3.3
0.9
0.9

Somnolence
1.3
1.6
0.8
0.3

The following events occurred in <1% but >0.1% of patients treated with amilodipine in controlled clinical trials or under conditions of open trials or marketing experience where a causal relationship is uncertain; they are listed to alert the physician to a possible relationship: Cardiovascular: arrhythmia (including ventricular, apostural dizziness, postural hypotension, vasculitis. Central and Peripheral Nervous System: hypoesthesia, neuropathy peripheral, paresthesia, termor, vertigo. Gastrointestimal: anorexia, constpation, dyspepsia,** (sysphagia, diarhea, flatulence, pancreatitis, vomiting, gingkal hyperplasia. General: allergic reaction, asthenia,** back pain, hold tushes, malaise, pain, rigors, weight gain, weight decrease. Musculoskeletal System: athraliga, arthrosis, muscle cramps,** myalgia.

Psychiatric: sexual dysfunction (male** and fenale), insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization. Respiratory System: dyspnea,** epistaxis. Skin and Appendages: angioedema, erythema unitforme, pruttus,** rash,** trash erythematous, rash maculopapular.** These events occurred in less than 1% in placebo-controlled trials, but the incidence of these side effects was between 1% and 2% in all multiple dose studies. Special Senses: antomari Vision, conjunctivitis, diplopia, eye pain, tinnitus, Uninary System: incluriton frequency, micturiton disorder, nocturia. Autonomic Nervous System: dry mouth, seveating increased. Metabolic and in <0.1% of patients treated with amiloipine in controlled clinical trials or unarketing experience: cardia calinure, pusces, hista,

Body System/ Adverse Event		atorvastatin			
	Placebo N=270	10 mg N=863	20 mg N=36	40 mg N=79	80 mg N=94
BODY AS A WHOLE					
Infection	10.0	10.3	2.8	10.1	7.4
Headache	7.0	5.4	16.7	2.5	6.4
Accidental Injury	3.7	4.2	0.0	1.3	3.2
Flu Syndrome	1.9	2.2	0.0	2.5	3.2
Abdominal Pain	0.7	2.8	0.0	3.8	2.1
Back Pain	3.0	2.8	0.0	3.8	1.1
Allergic Reaction	2.6	0.9	2.8	1.3	0.0
Asthenia	1.9	2.2	0.0	3.8	0.0
DIGESTIVE SYSTEM					
Constipation	1.8	2.1	0.0	2.5	1.1
Diamhea	1.5	2.7	0.0	3.8	5.3
Dyspepsia	4.1	2.3	2.8	1.3	2.1
Flatulence	3.3	2.1	2.8	1.3	1.1
RESPIRATORY SYSTEM					
Sinusitis	2.6	2.8	0.0	2.5	6.4
Pharyngitis	1.5	2.5	0.0	1.3	2.1
SKIN AND APPENDAGES					
Rash	0.7	3.9	2.8	3.8	1.1
MUSCULOSKELETAL SYSTEM	1				
Arthralgia	1.5	2.0	0.0	5.1	0.0
Myalgia	1.1	3.2	5.6	1.3	0.0

Hass
0.7
3.9
2.8
3.8
1.1

MUSLOUSKELETAL SYSTEM
Attinagia
1.5
2.0
0.0
5.1
0.0

Antinagia
1.1
3.2
5.6
1.3
0.0

AngleScandinavian Cardiac Outcomes Trial (ASCOT): In ASCOT (see CLINICAL PHARMACOLOGY, Clinical Studies, Clinical Studies, Olinical Studies, Studies with Atorvastatin in omgable to that of he group treated with placebo during a median of 3.3 years of follow-up. Collaborative Atorvastatin Dimostation in working the group treated with placebo (n=5.137), the safety and tolerability profile of the group treated with placebo (n=1410), there was no difference in the overall frequency of adverse events or serious adverse events between the treatment groups during a median follow-up of 3.9 years. No cases of thatodomyoips were reported. Freating to New Targets Study (NPI): INT (see CLINICAL PHARMACOLOGY, Clinical Studies) involving 1.0.001 subjects with clinically evident CHI threated with placebre events in the high-dose atorvastatin group (St. 1.3%; 497, 9.9%, respectively) as or placebo (n=5.137), there were more serious adverse events and incoming threated with placebre events in the high-dose atorvastatin group (St. 1.3%; 497, 9.9%, respectively) as or placebo (n=5.137), but there were the overall frequency of adverse events in the high-dose atorvastatin group (St. 1.3%; 497, 9.9%, respectively) as or placebo (n=5.137), but there were the rest of the low-dose group (B, 1.4%; 404, 8.1%, respectively) during a median follow-up of 4.9 years. Presistent on the high-dose atorvastatin group (B, 1.3%; droppadle (B-1.3%) (Didviduals with atorvastatin target (B-1.4%), but were the varianting the greates or placebo (n=5.137), but there the high-dose ato



right ventricles, allowing them to determine ventricular volumes.

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The study included consecutive inpatients and outpatients with clinical suspicion of acute PE who were hemodynamically stable and who had an indication for CT pulmonary angiography. The patients with confirmed PE then underwent low-radiation-dose ECG-synchronized MDCT for assessment of right ventricular function. Right ventricular failure is the primary cause of death after acute PE, Dr. Klok noted.

Right ventricular dysfunction was defined as an ejection fraction less than 47%, which was previously established as the lower limit of the 95% confidence interval of normal RVEF in a large population-based cohort.

Patients were followed for 6 weeks. End points were all-cause mortality, resuscitation, admission to an ICU with

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mechanical ventilation requirement and/or use of inotropic agents, and thrombolytic therapy.

Of 464 patients with suspected PE, ECG-synchronized MDCT confirmed embolism in 114 and ruled it out in 350. Of those with confirmed PE, 51 (45%) had a determination of right ventricular dysfunction and 63 (55%) were deemed to have normal ventricular function.

Of the patients with acute PE, 10 (8.8%) went on to experience an adverse event. There were four deaths, four resuscitations, one ICU admission, and one thrombolytic therapy administration. By the end of the 6 weeks of follow-up, seven of these patients had died, with four of the deaths attributable to PE.

ECG-synchronized MDCT had identified right ventricular dysfunction in 9 of the 10 patients with adverse events. The remaining patient, who had an RVEF above 47%, experienced a major bleeding complication requiring admission to an ICU, but this patient eventually recovered.

For the identification of patients at risk for adverse outcomes, ECG-synchronized MDCT evaluation of RVEF less than 47% had an associated odds ratio of 13.3, sensitivity of 90% (56%-99.8%), specificity of 60% (50%-70%), negative predictive value of 98% (92%-99.9%), and positive predictive value of 18% (8.4%-31%).

Dr. Klok acknowledged that given the low positive predictive value and high negative predictive value, the test would likely be more useful for predicting outcomes in low-risk patients than in highrisk patients.

Dr. Klok said that neither he nor his colleagues had conflicts of interest relative to the study.