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Circle Reader Service No. 132
The rule of thumb in stress perfusion imaging

In myocardial perfusion imaging, the quality of information is directly related to the level of exercise, as measured by the percentage of maximal predicted heart rate achieved by the patient at the time of tracer injection. This is because myocardial oxygen demand is mainly determined by the heart rate. When oxygen demand is increased by exercise, the disparity in coronary blood flow caused by the presence of significant CAD produces perfusion defects, which allow for lesion detection. This provides valuable physiological information for CAD diagnosis.1,2

A rule of thumb governs the exercise stress test. Patients are asked to exercise to 85% of their maximal predicted heart rate. This rule has been determined from a review of exercise ECG studies where diagnostic information has been considered inconclusive at heart rates below 85% of the maximal predicted heart rate.3,4

When to bend it

However, not all patients will achieve 85% of their maximal predicted heart rate. Some may reach diagnostic endpoints in testing. Others will have physical limitations or may be on beta blockers that prevent them from achieving the optimal level.

To maximize diagnostic certainty and avoid the risk of false-negative test results, suboptimal stress should be avoided.

Pharmacologic stress: The measure of success in imaging after suboptimal exercise

In images taken after patients have failed to reach 85% of their maximal predicted heart rate, defects may go undetected.5,6 I.V. Persantine® (dipyridamole USP) can help salvage potentially non-diagnostic perfusion studies where patients have achieved suboptimal exercise levels. This form of pharmacologic stress, administered when the patient's heart rate has returned to baseline, allows for reliable results and may result in a higher yield of useful imaging information.6

In addition, I.V. Persantine offers a proven safety record,7,8 gradual onset, and a convenient, easy-to-follow protocol. In pharmacologic stress, it's the rule by which all other agents are measured. In perfusion imaging, anything less diminishes diagnostic certainty.

Ask questions about pharmacologic stress with I.V. Persantine. Call the Du Pont Pharma Nuclear Cardiology Infoline at 1-800-343-7851 for further information.

*Serious adverse reactions associated with the administration of I.V. Persantine have included fatal and non-fatal myocardial infarction, ventricular fibrillation, symptomatic ventricular tachycardia, transient cerebral ischemia, and bronchospasm. Severe adverse events have occurred infrequently (0.3%) in a study of 2011 patients. Patients with a history of unstable angina may be at a greater risk for severe myocardial ischemia. Patients with a history of asthma may be at a greater risk for bronchospasm.

Persantine® is a registered trademark of Boehringer Ingelheim International GmbH. I.V. Persantine® is manufactured and distributed by Du Pont Pharma under license from Boehringer Ingelheim Pharmaceuticals, Inc.

Please see brief summary of prescribing information on reverse for contraindications, warnings, and adverse reactions.


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Brief Summary of Precautionary Information

CONTRAINDICATIONS: Hypersensitivity to dipyridamole.

WARNINGS: Serious adverse reactions associated with the administration of intravenous Persantine® (dipyridamole USP) have included fatal and non-fatal myocardial infarction, ventricular fibrillation, symptomatic ventricular tachycardia, transient cerebral ischemia, and bronchospasm.

In a study of 3911 patients given intravenous Persantine as an adjunct to thallium myocardial perfusion imaging, two types of serious adverse events were reported: 1) four cases of myocardial infarction (0.10%); two fatal (0.05%); and two non-fatal (0.05%); and 2) six cases of severe bronchospasm (0.20%). Although the incidence of these serious adverse events was small (0.10% of 3911), the potential clinical information that might be gained through use of intravenous Persantine thallium imaging must be weighed against the risk to the patient.

Patients with a history of urticaria angina may be at the greatest risk for severe myocardial ischemia. Patients with a history of asthma may be at a greater risk for bronchospasm during IV Persantine use.

When thallium myocardial perfusion imaging is performed with intravenous Persantine, parenteral amphotophylline should be readily available for relieving adverse events such as bronchospasm or chest pain. Vital signs should be monitored during, and for 15-30 minutes following, the intravenous infusion of Persantine and an electrocardiographic tracing should be obtained using at least one chest lead. Should severe chest pain or bronchospasm occur, parenteral amphotophylline may be administered by slow intravenous injection (50-100 mg over 30-60 seconds) in doses ranging from 50 to 250 mg. In the case of severe hypotension, the patient should be placed in a supine position with the head tilted down if necessary, before administration of parenteral amphotophylline. If 250 mg of amphotophylline does not relieve chest pain symptoms within a few minutes, sublingual nitroglycerin may be administered. If chest pain continues despite use of amphotophylline and nitroglycerin, the possibility of myocardial infarction should be considered. If the clinical condition of a patient with an adverse event permits a one minute delay in the administration of parenteral amphotophylline, thallium-201 may be injected and allowed to circulate for one minute before the injection of amphotophylline. This will allow intrathallic perfusion imaging to be performed before reversal of the pharmacologic effects of Persantine on the coronary circulation.

PRECAUTIONS: See WARNINGS.

Drug Interactions: Oral maintenance theophylline may abolish the coronary vasodilatory effects of Persantine® (dipyridamole USP) administration. This could lead to a false negative thallium imaging result.

Cardiogenic, Metabolic, Impairment of Fertility: In studies in which dipyridamole was administered in the feed to rats of up to 75 mg/kg/day (3.4 times), the maximum recommended daily human oral dose in mice up to 128 weeks and in males and up to 142 weeks in females and rats (up to 111 weeks in males and females), there was no evidence of drug related cardiogegusity. Mutagenicity tests of dipyridamole with bacteria and mammalian cell systems were negative. There was no evidence of impaired fertility when dipyridamole was administered to male and female rats at oral doses up to 500 mg/kg/day (63 times), the maximum recommended daily human oral dose. A significant reduction in number of corpora lutea with consequent reduction in implantations and live fetuses was, however, observed at 1250 mg/kg/day.

Calculation based on assumed body weight of 50 kg.

Pregnancy Category: Reproduction studies performed in mice and rats at daily oral doses of up to 125 mg/kg (16.5 times) and in rabbits at daily oral doses of up to 20 mg/kg (2.5 times) the maximum recommended daily human oral dose) have revealed no evidence of impaired embryonic development due to dipyridamole. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Calculation based on assumed body weight of 50 kg.

Nursing Mothers: Dipyridamole is excreted in human milk.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Adverse reactions to Persantine® (dipyridamole USP) is derived from a study of 3911 patients in which Intravenous Persantine was used as an adjunct to thallium myocardial perfusion imaging and from spontaneous reports of adverse reactions and the published literature.

Serious, adverse events (fatal and non-fatal myocardial infarction, severe ventricular arrhythmias, and serious CNS abnormalities) are described previously (see WARNINGS).

In the study of 3911 patients, the most frequent adverse reactions were chest pain/angina pectoris (19%), electrocardiographic changes (most commonly ST-T changes) (15.9%), dyspnea (12.2%), and dizziness (8%).

Adverse reactions occurring in greater than 1% of the patients in the study are shown in the following table:

<table>
<thead>
<tr>
<th>Incidence (%) of Drug-Related Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest/Pain/Anxia Pectoris</td>
</tr>
<tr>
<td>Headache</td>
</tr>
<tr>
<td>Dizziness</td>
</tr>
<tr>
<td>Electrocardiographic Abnormalities/ST-T changes</td>
</tr>
<tr>
<td>Electrocardiographic Abnormalities/Extrastyles</td>
</tr>
<tr>
<td>Hypetension</td>
</tr>
<tr>
<td>Nausea</td>
</tr>
<tr>
<td>Flushing</td>
</tr>
<tr>
<td>Electrocardiographic Abnormalities/Tachycardia</td>
</tr>
<tr>
<td>Oedema</td>
</tr>
<tr>
<td>Pain Unspecified</td>
</tr>
<tr>
<td>Blood Pressure Lability</td>
</tr>
<tr>
<td>Hyperetension</td>
</tr>
<tr>
<td>Paresthesa</td>
</tr>
<tr>
<td>Fatigue</td>
</tr>
</tbody>
</table>

Less common adverse reactions occurring in 1% or less of the patients within the study included:

Cardiovascular System: Electrocardiographic abnormalities unspecified (0.8%), atrial relationship unspecified (0.6%), palpitation (0.3%), ventricular tachycardia (0.2% see WARNINGS), bradycardia (0.2%), myocardial infarction (0.1% see WARNINGS), AV block (0.1%), syncope (0.1%), orthostatic hypotension (0.1%), atrial fibrillation (0.1%), supraventricular tachycardia (0.1%), ventricular arrhythmias unspecified (0.03% see WARNINGS), heart block unspecified (0.03%), cardiomyopathy (0.03%), edema (0.03%).

Central and Peripheral Nervous System: Hypotension (0.5%), hypopnea (0.3%), nervousness/irritability (0.2%), insomnia (0.1%), abdominal cramp (0.03%), somnolence (0.03%), dizziness (0.03%), vertigo (0.03%).

Gastrointestinal System: Dyspepsia (1.0%), dry mouth (0.8%), abdominal pain (0.7%), flatulence (0.6%), vomiting (0.4%), cramping (0.1%), dysphagia (0.03%), tenesmus (0.03%), appetite increased (0.03%).

Respiratory System: Pharyngitis (0.3%), bronchospasm (0.2% see WARNINGS), hyperventilation (0.1%), rhinitis (0.1%), coughing (0.03%), pleural pain (0.03%)

Other: Myalgia (0.5%), back pain (0.5%), injection site reaction unspecified (0.4%), dyspnoea (0.1%), asthma (0.1%), malaise (0.3%), arthralgia (0.3%), injection site pain (0.1%), rigor (0.1%), earache (0.1%), tinnitus (0.1%), vision abnormalities unspecified (0.1%), dysgeusa (0.1%), thirst (0.03%), genital irritation (0.03%), eye pain (0.03%), micturition (0.03%), perineal pain (0.03%), breast pain (0.03%), intermittent claudication (0.03%), leg cramping (0.03%).

OVERDOSAGE: No cases of overdose in humans have been reported. It is unlikely that overdosage will occur because of the nature of use (i.e., single intravenous administration in controlled settings). See WARNINGS.

Caution: Federal law prohibits dispensing without prescription.
IN A FOG??

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Breakthrough in cancer detection...
OncoScint® CR/OV
Satumomab Pendetide (1mg/2mL)

A new diagnostic tool that can assist decision making in patients with colorectal or recurrent ovarian adenocarcinoma.

Please see last page for brief summary of prescribing information.
NEW

OncoScint® CR/OV
Satumomab Pendetide (1mg/2mL)

To enhance decision making in the management of patients

The first monoclonal antibody-based in determining both the location and

Reveals malignancy with tumor-targeted accuracy—
specifically targets the cell-surface antigen, TAG-72, common to colorectal and ovarian adenocarcinomas, making it possible—with the use of existing nuclear medicine equipment—to detect extrahepatic abdominal and pelvic lesions.

Provides information beyond the scope of standard diagnostic modalities—when interpreted in conjunction with a review of information obtained from other appropriate tests

Found to be beneficial in these difficult situations:

- determining the source of a rising serum tumor marker in patients with an otherwise-negative workup
- determining extrahepatic abdominal and pelvic involvement in patients thought to have isolated and resectable recurrence
- differentiating disease from postsurgical or postradiation anatomic changes

OncoScint is a registered trademark of CYTOGEN Corporation.

Please see last page for brief summary of prescribing information.
with colorectal or recurrent ovarian cancer...

imaging agent effective extent of disease

Assists decision making in patient management\(^2\text{-}^5\) —
enhanced medical/surgical management in difficult colorectal\(^3\text{-}^4\) and recurrent ovarian cases.\(^2\text{-}^5\)

Excellent safety profile* —
with generally minor and transient side effects occurring in less than 4% of patients studied (most frequently reported: fever, chills and clinically insignificant changes in blood pressure).\(^7\)

*See Adverse Reactions section of brief summary on following page.

For further information, please call 1-800-833-3533.

ONCOScint® CR/OV
Satumomab Pendetide (1mg/2mL)
Tumor-targeted cancer detection
OncoScint® CR/OV Kit
(satumomab pendetide)

Kit for the Preparation of indium In 111 satumomab pendetide
For Intravenous Use Only

Brief summary of prescribing information

INDICATIONS AND USAGE
OncoScint® CR/OV-In (indium In 111 satumomab pendetide) is a diagnostic imaging agent that is indicated for determining the extent and location of extracellular malignant disease in patients with known colorectal or ovarian cancer. Clinical studies suggest that this imaging agent should be used after completion of standard diagnostic tests when additional information regarding disease extent could aid in patient management. The diagnostic images acquired with OncoScint® CR/OV-In should be interpreted in conjunction with a review of information obtained from other appropriate tests. OncoScint® CR/OV-In is not indicated as a screening test for ovarian or colorectal cancer.

Administration of OncoScint® CR/OV-In may result in falsely elevated values from in vivo immunodiagnostiX, including tests for carcinoembryonic antigen (CEA) and CA 125. Because this interference may persist for months, the clinical laboratory should investigate for assay interference in patients who develop elevated CE A or CA 125 subsequent to imaging with OncoScint® CR/OV-In (see Drug/Laboratory Test Interactions).

Due to insufficient safety and efficacy data regarding repeat administration of this product, this imaging agent is limited to single use only.

CONTRAINDICATIONS
OncoScint® CR/OV-In (indium In 111 satumomab pendetide) should not be used in patients who are hypersensitive to this or any other product of murine origin or to indium In 111 chloride.

WARNINGS
Allergic reactions, including anaphylaxis, can occur in patients who receive murine antibodies. Although the reactions of this type have not been observed in clinical trials after OncoScint® CR/OV-In (indium In 111 satumomab pendetide) administration, medications for the treatment of hypersensitivity reactions should be available during administration of this agent.

PRECAUTIONS
General
The components of the kit are sterile and pyrogen free and contain no preservative. OncoScint® CR/OV-In (indium In 111 satumomab pendetide) should be used within 8 hours after radio labeling. It is essential to follow the directions for preparation carefully and to adhere to strict aseptic procedures during preparation of the radiolabeled product. Each OncoScint® CR/OV kit is a unit of use package.

The contents of the kit are to be used only to prepare OncoScint® CR/OV-In; un labeled OncoScint® CR/OV should NOT be administered directly to the patient. After radio labeling with indium-111, the entire OncoScint® CR/OV-In dose must be administered to the patient for whom it was prescribed. Reducing the dose of either component may adversely impact imaging results, and, therefore, is not recommended.

Information for Patients
Murine monoclonal antibodies are foreign proteins, and their administration can induce human anti-murine antibodies (HAMA). While limited data exist concerning the clinical significance of HAMA, the presence of HAMA may interfere with murine antibody based immunodiagnostiX, could compromise the efficacy of diagnostic or therapeutic murine antibody-based agents, and may increase the risk of adverse reactions. For these reasons, patients should be informed that the use of this product could affect the future use of other murine-based products, including OncoScint® CR/OV-In, and should be advised to discuss prior use of murine antibody-based products with their physicians (see Heterologous Protein Administration). Heterologous Protein Administration Murine monoclonal antibodies (MAbs) are heterologous proteins, and their administration can induce human anti-murine antibody-based agents (HAMA).

OncoScint® CR/OV-In has been shown to induce HAMA in murine IgG after single administration in about 40% of patients in tumor imaging trials. HAMA levels became negative (detectable < 0.05 or < 400 ng/mL) in approximately half of such patients at 4 to 12 months after infusion.

While limited data exist concerning the clinical significance of HAMA, detectable HAMA levels can alter the clearance and biodistribution of MAbs. In patients who develop persistently elevated serum HAMA levels, the efficacy of diagnostic or therapeutic murine antibody-based agents may be compromised. When considering the administration of OncoScint® CR/OV-In to patients who have previously been administered murine antibodies products, physicians should be aware of the potential for HAMA to alter clearance and biodistribution. The quality or sensitivity of the imaging study may be compromised. Therefore, prior to administration of murine antibody-based agents, including OncoScint® CR/OV-In, physicians should consider the patient history to determine whether the patient has previously received such products. Preliminary data are available from repeat-administration studies of OncoScint® CR/OV-In in 69 patients who have received 105 repeat doses. However, there are insuf- cient data to determine the safety and efficacy of this product after repeat administration. Drug/Laboratory Test Interactions: The presence of HAMA in serum may interfere with two-site murine antibody-based immunodiagnostiX, including assays for carcinoembryonic antigen (CEA) and CA 125. When present, this interference generally results in falsely high values. If HAMA is known or suspected, the clinical laboratory should be notified and appropriate measures taken to avoid this interference. These methods include the use of non-murine immunodiagnostiX, or HAMA removal by adsorption, blocking, or heat inactivation.

Carcinogenesis, Mutagenesis, Impairment of Fertility Long-term animal studies have not been performed to evaluate the carcinogenic or mutagenic potential of OncoScint® CR/OV-In or to evaluate its effect on fertility in male or female rats.

Pregnancy Category C Animal reproduction studies have not been conducted with OncoScint® CR/OV-In. It is also not known whether OncoScint® CR/OV-In can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. OncoScint® CR/OV-In should not be administered to a pregnant woman unless, in the opinion of the physician, the information to be gained outweighs the potential risks. MAB 872.3 has been shown to react with fetal gastrointestinal tissues. In general, examinations using radiopharmaceuticals, in which the childbearing potential should be performed during the first few days (approximately 10) following the onset of menses.

Nursing Mothers and/or Lasting Women It is not known whether OncoScint® CR/OV-In is excreted in human milk and, if so, for how long. Because many drugs are excreted in human milk, caution should be exercised when OncoScint® CR/OV-In is administered to a nursing woman. OncoScint® CR/OV-In has not been administered to lactating females and therefore should not be administered to nursing women unless, in the opinion of the physician, the information to be gained outweighs the potential risks. In such cases, formula feedings should be substituted for breast feedings.

Pediatric Use The safety and effectiveness of OncoScint® CR/OV-In in children have not been established.

Now, to assist decision making in the management of patients with colorectal or recurrent ovarian cancer...

New
OncoScint® CR/OV
Satumomab Pendetide (1mg/2mL)
Effective in determining both the location and extent of disease

Please refer to complete prescribing information before using OncoScint® CR/OV.

Additional adverse reactions after 105 repeat administrations of OncoScint® CR/OV-In in 69 patients included two reports of fever, one complaint of abdominal pain, and two cases of non-serious, readily reversible reactions characterized primarily by flank pain.

OVERDOSE
The maximum amount of OncoScint® CR/OV-In (indium In 111 satumomab pendetide) that can be safely administered has not been determined. In clinical trials, single doses of 20 mg of OncoScint® CR/OV-In were administered to 64 patients with various types of epithelial carcinomas; the type and frequency of adverse reactions at this dose were similar to those observed with lower doses.

DOSAGE AND ADMINISTRATION
The dose of OncoScint® CR/OV (satumomab pendetide) is 1 mg radiolabeled with 5 mCi of indium In 111 chloride. Each dose is administered intravenously over 5 minutes and should be mixed with 0.9% saline or D5W. The solution becomes slightly cloudy during the administration. The patient dose of the radiolabeled should be measured in a dose calibrator prior to administration. Each OncoScint® CR/OV kit is a unit dose package. After radiolabeling with indium-111, the entire OncoScint® CR/OV dose should be administered to the patients. Reducing the dose of either component may adversely impact imaging results, and, therefore, is not recommended.

NOW SUPPLIES
The OncoScint® CR/OV kit (NDC No. 0044-0579-01) for the preparation of indium-111 labeled OncoScint® CR/OV includes one vial containing 1 mg of satumomab pendetide per 2 mL of sodium phosphate buffered saline and 1 mL of vial of sodium acetate buffer solution, 0.5 M. These solutions are sterile and pyrogen free and contain no preservative. Each kit also includes one sterile 0.25 mm Millex® GV filter, preserving information, and two identification labels.

U.S. Patent Nos. 4,671,858 and 4,741,900
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References
CELEBRATE NUCLEAR MEDICINE WEEK

Nuclear Medicine Week—October 3 through 9—is the prime time to demonstrate pride in your profession—and to make the profession’s presence known both among the public and other health care professionals.

Under the sponsorship of the Society of Nuclear Medicine and SNM’s Technologist Section, Nuclear Medicine Week offers an excellent opportunity to educate, to stimulate, and to promote the successes of nuclear medicine. This week also gives you a specific time to spotlight your facility to referring physicians, potential patients, and to anyone else in your community who could benefit from nuclear medicine.

To help enhance the visibility of nuclear medicine facilities, Mallinckrodt Medical, in association with the Technologist Section, has designed a striking new poster to mark this year's event. Buttons, stickers, and guidelines are also available to assist you with your celebration. We guarantee that this year's sensational design—carried over on all three items—will draw attention and spur positive comment.

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NUCLEAR MEDICINE WEEK

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Payment must be enclosed with your order. Payments must be made in U.S. dollars drawn on U.S. banks. No foreign funds will be accepted. Make checks payable to:

The Society of Nuclear Medicine

Orders will be sent out by 1st class mail or UPS. Orders received after September 1, 1993 will be assessed a 15% surcharge, payable before shipment, to ensure timely delivery.

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Model | Strip Chart | CRT Monitor | HR/R-R Int | Trigger
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3L | | | | 
4L | | | | 

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Circle Reader Service No. 133
Computers in Nuclear Medicine: A Practical Approach

Kai Lee, PhD

Computers have become an indispensible tool in nuclear medicine. This is the book for those who wish to acquire a basic understanding of how computers work and the processing techniques used to obtain diagnostic information from radionuclide images. The text gives a thorough description of the hardware components of a nuclear medicine computer system and explains the principles behind many common image processing techniques. The following topics are discussed in detail:

- Functions and components of a computer system
- Mass storage devices
- Input and output devices
- Computer software
- Nuclear Medicine image acquisition methods
- Methods of qualitative image analysis
- Quantitative image analysis
- Nuclear cardiology
- Quantitative data analysis
- Single-photon emission computed tomography
- Selecting a computer for nuclear medicine

The book is illustrated throughout to help the reader conceptualize the topics as they are discussed.

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Custom Radioisotope Shielding

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Mini-PACS

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