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Technetium Tc 99m Generator
Secondary shield to further reduce radiation

5cc and 10cc elution vials
Elution vial shield
Adaptors for various elution vials
Sterile needle pack and labels furnished with each generator

20ml elution vials available on request
Technetium Tc 99m Generators for the Production of Sodium Pertechnetate Tc 99m

DESCRIPTION: The Technetium Tc 99m Generator is prepared with fissile produced Molybdenum Mo 99 absorbed on alumina in a lead-shielded column and provides a means for obtaining sterile pyrogen-free solutions of Sodium Pertechnetate Tc 99m in sodium chloride injection. The eluate should be crystal clear. With a pK of 4.5 to 5.5, hydrochloric acid and/or sodium hydroxide may have been used for pH adjustment. Over the life of the generator, an elution will contain a yield of 80% to 100% of the theoretical amount of Technetium Tc 99m available from the Molybdenum Mo 99 on the generator column.

Each eluate of the generator should not contain more than 0.15 microcurie of the Molybdenum Mo 99 per millicurie of Technetium Tc 99m per administered dose at the time of administration, and not more than 50 microcuries of aluminum per millicurie of the generator eluate, both of which must be determined by the user before administration.

INDICATIONS AND USAGE: Sodium Pertechnetate Tc 99m is used IN ADULTS as an agent for brain imaging including cerebral radionuclide angiography, thyroid imaging, salivary gland imaging, placenta localization, blood pool imaging including radionuclide angiography, and urinary bladder imaging (direct isotope cystography) for detection of vesico-ureteral reflux.

Sodium Pertechnetate Tc 99m is used IN CHILDREN as an agent for brain imaging including cerebral radionuclide angiography, thyroid imaging, blood pool imaging including radionuclide angiography, and urinary bladder imaging (direct isotope cystography) for detection of vesico-ureteral reflux.

CONTRAINDICATIONS: None known.

WARNINGS: Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in children than in adults. In general, the younger the child the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

PRECAUTIONS: As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to ensure minimum radiation exposure to occupational workers.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m may affect fertility in males or females.

Pregnancy Category C: Animal reproductive studies have not been conducted with Technetium Tc 99m. It is also not known whether Technetium Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be given to a pregnant woman only if the expected benefits to the mother outweigh the potential hazards to the fetus. Evidently, examinations using radiopharmaceuticals, especially those effective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Technetium Tc 99m is excreted in human milk during lactation, and therefore formula feedings should be substituted for breast feedings.

ADVERSE REACTIONS: Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

HOW SUPPLIED: Sodium Pertechnetate Tc 99m is supplied as a Molybdenum Mo 99/Technetium Tc 99m generator in sizes from 300 milliliters up to 16,600 milliliters (in approximately 25-milliliters increments) of Molybdenum Mo 99 as of 10:00 P.M. Eastern Time of the day of calibration. The TECHNOGENIC Tc 99m GENERATOR consists of (1) sterile generator, (2) Sodium Chloride Injection source, (3) 10 cc sterile evacuated vials, (4) sterile needles, (5) elution vial sheet, (6) finished drug labels. Elution vials in 5 cc and 20 cc sizes are available upon request.

Initial order only: The TECHNOGENIC Tc 99m GENERATOR should not be used after sixteen (16) days from the date and time of calibration.
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Space/time quantitative thallium imaging

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Associate Clinical Professor of Radiology
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Ernest V. Garcia, PhD
Director, Nuclear Medicine Computer Sciences
Cedars-Sinai Medical Center
Adjunct Assistant Instructor of Radiology
University of California, Los Angeles
School of Medicine

Jamshid Maddahi, MD
Director, Nuclear Cardiac Stress Testing
Cedars-Sinai Medical Center
Assistant Professor of Medicine
University of California, Los Angeles
School of Medicine

At Cedars-Sinai Medical Center, we have developed a computerized technique for analyzing both the regional myocardial distribution and the washout of thallium-201. The technique combines some of the most useful aspects of previously described quantitative approaches to thallium imaging with certain unique display features. Our studies so far have convinced us that the method yields objective, highly accurate results and, more important, provides valuable information that often cannot be obtained by visual inspection alone of thallium-201 scintigrams.

Space/time quantitation

The method we have developed for simultaneous spatial and temporal quantitation of myocardial thallium distribution uses a computer to

- perform interpolative background subtraction of the images. This approach to myocardial background subtraction—first described by Goris and colleagues—and modified by Watson et al—appears to provide the most satisfactory approximation of the true background contribution.
- generate and display maximal circumferential profiles representing the myocardial distribution of thallium in the immediate-postexercise and 4-hour delayed images. Following the approach suggested by Burow et al and Vogel and associates, the profiles are constructed by the computer for the postexercise images from the maximal-count-per-pixel values along 60 radii spaced at 6° intervals.
- generate and display washout circumferential profiles. These profiles are computer-constructed by subtracting, point for point, the 4-hour distribution profile from the initial postexercise profile, and then dividing by the initial profile. This yields a percent washout rate for each region around the myocardium.
- compare both the initial distribution profile and the percent washout profile with previously established normal profiles. Our normal profiles are drawn from a population of patients with less than a 1% likelihood of coronary disease on the basis of Bayesian analysis. This approach avoids the pitfalls inherent in defining as normals either patients with normal coronary arteriography (who, in fact, may have nonatherosclerotic ischemic disease) or "normal volunteers" (who may have occult coronary disease).

Operator interaction is confined to selecting the ventricular region of interest for background subtraction; visual determination of the center of the ventricle (and thus the maximum radius to which the computer will search); and locating the apex. Of these three operator-dependent steps, location of the apex is most critical. The computer automatically assigns the selected apex to the 90° position for comparison of the curves for washout calculation and for comparison of patient results with our normal values.

Displaying the data

Finally, the computer displays the quantitative data in a way that is very easy to comprehend and interpret. In addition to curves of initial distribution, 4-hour distribution and percent washout for the anterior, 45° LAO and 70° LAO views, the display shows a series of three concentric ellipses that permits immediate identification of segments with abnormal perfusion and/or washout.

The innermost of these three ellipses is a reference indicating the position of the myocardium. The middle ellipse corresponds to initial postexercise thallium distribution, and the outer ellipse to the percent washout for each region. Consecutive unbroken ellipses in each view suggest a normal study—with no regions of perfusion deficit or abnormal washout. Gaps in the middle ellipse represent abnormal regional perfusion; gaps in the outer ellipse represent abnormal regional washout. Regional abnormalities are determined by the computer by comparison with the lower limits of normal established for both perfusion and washout from our normal population.

Improved thallium imaging

We believe that our program overcomes some of the limitations associated with reliance on visual interpretation of thallium-201 images. The first of these, as most experienced observers would admit, is the subjectivity of visual analysis and the consequent variability of reported sensitivity and specificity values. In our recently reported study, the sensitivity
Quantitative thallium study demonstrating significant three-vessel coronary disease. On visual inspection, the study was read as normal. The unbroken middle ellipses in all views suggest no perfusion defects—consistent with the visual interpretation. However, gaps in the outer ellipses indicate washout abnormalities in the distribution of each of the major coronary arteries. Angiography revealed 90% stenoses of each of the proximal arteries.

and specificity for detection of coronary artery disease were 93% and 90%, respectively—compared to 91% and 86% for visual interpretation. More important, interobserver agreement was 93% with the quantitative technique—higher than reported for visual interpretation, and suggesting that high sensitivity and specificity values could be routinely obtained in every nuclear cardiology laboratory.

Another reported problem is the relative insensitivity of visual analysis for identifying individual-vessel coronary lesions. Visual reading relies on the fact that the initial myocardial distribution of thallium reflects relative, not absolute, differences in uptake between ischemic and nonischemic regions. Thus, in a patient with multivessel disease, some areas with diminished perfusion may appear relatively normal compared with a more severely hypoperfused region. In the worst case, significant three-vessel disease with balanced reduction in blood flow may not be seen as abnormal by visual inspection of the images.

Our technique overcomes this limitation by quantifying regional thallium washout, thus permitting us to compare each region with itself over time rather than with other regions. Because ischemic regions demonstrate altered washout, we can thus identify areas supplied by stenosed vessels which might be undetected by visual region-to-region comparison alone.

How successful have we been in identifying individual diseased vessels? In our recent study, we detected left anterior descending disease with a sensitivity of 80% (compared to 56% for visual inspection), left circumflex disease with a sensitivity of 63% (compared to 34%) and right coronary disease with a sensitivity of 94% (compared to 65%). In addition, our sensitivity for distinguishing coronary arteries with moderate disease was 70%, compared to 35% by visual inspection.

Clinical implications

The increased sensitivity and specificity of our program, and the enhanced interobserver agreement, have important implications not only for detection of coronary disease, but also for patient prognosis. We know from angiographic studies that the likelihood of major cardiac events may be related to the location and extent of a patient's coronary disease. The ability to identify individual-vessel disease—especially in patients with multiple-vessel involvement—that we have demonstrated with our quantitative approach to thallium imaging suggests that such potentially prognostic information can now be obtained noninvasively, with the attendant advantages of reduced patient inconvenience and lower cost.

References


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TI 201

INDICATIONS AND USAGE: Thallous Chloride TI 201 may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction. It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom myocardial infarction or ischemia is known or suspected, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedure. Exercise stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

PRECAUTIONS: Data are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as is found in diabetes mellitus) on the quality of thallium TI 201 scans. Attention is directed to the fact that thallium is a potassium analog, and since the transport of potassium is affected by these factors, the possibility exists that the thallium may likewise be affected.

Thallous Chloride TI 201, as all radioactive materials, must be handled with care and with appropriate safety measures to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

Carcinogenesis, Mutagenesis, Impairment of Fertility. No long-term animal studies have been performed to evaluate carcinogenic potential or whether Thallous Chloride TI 201 affects fertility in males or females.

Pregnancy Category C. Animal reproductive studies have not been conducted with Thallous Chloride TI 201. It is also not known whether Thallous Chloride TI 201 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Thallous Chloride TI 201 should be given to a pregnant woman only if clearly needed.

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Nursing Mothers. It is not known whether this drug is excreted in human milk. As a general rule nursing should not be undertaken when a patient is administered radioactive material.

Pediatric Use. Safety and effectiveness in children below the age of 18 have not been established.

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The expiration date for Thallous Chloride TI 201 is a maximum of five days post-calibration.

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Best results with thallium imaging performed in conjunction with exercise stress testing appear to be obtained if the thallium is administered when the patient reaches maximum stress and when the stress is continued for 30 seconds to one minute after injection. Imaging should begin within ten minutes post-injection since target-to-background ratio is optimum by that time. Several investigators have reported significant decreases in the target-to-background ratios of lesions attributable to transient ischemia two hours after the completion of stress testing.

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Published quarterly.

Volume 1, No. 1, January, 1984.
Larry D. Greenfield MD FAMWA, Editor

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John B. Selby, Journal of Nuclear Medicine,
Vol. 24, No. 2, February, 1983

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