CRC IRB Protocol
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STUDY DESCRIPTION

1. Study Purpose and Rationale

Cardiovascular imaging has become increasingly common in aiding clinical decision-making. One of these modalities is radionuclide myocardial perfusion imaging (rMPI). Ionizing radiation is used in the form of single photon emission computed tomography (SPECT), with administration of technetium-99m (Tc99m) and/or thallium-201 (Th-201) as common radiopharmaceutical agents.

The volume of rMPI increased from less than 3 million in the United States in 1990 to 9.3 million in 2002.[1] With this advance, there has been concern over the increasing radiation burden on patients as radiologic testing of all kinds have become more common. Aside from therapeutic uses of radiation in oncology, rMPI is the single test with the highest radiation burden, accounting for 22% of cumulative effective dose from medical sources.[2]

A recent retrospective cohort study at Columbia Presbyterian Medical Center (CPMC) in 2006 looked at 1097 consecutive patients undergoing rMPI and calculated the cumulative effective dose of radiation by summing up all the radiation the patient had been exposed to from other radiologic studies in addition to the rMPI.[3] The study found that patients underwent a median of 15 procedures involving radiation exposure, of which 4 were high-dose procedures (≥3 mSv; ie, 1 year's background radiation), including 1 MPI study per patient. A total of 344 patients (31.4%) received cumulative estimated effective dose from all medical sources of more than 100 mSv. Multiple MPIs were performed in 424 patients (38.6%), for whom cumulative estimated effective dose was 121 mSv.

Standard practice protocols for rMPI include (1) single day studies, which use 30±5 mCi for stress images and 8-10mCi for rest images, (2) dual isotope studies, which use 30±5 mCi for stress images and 3mCi Th-201, and (3) two day studies, reserved for patients over 250 pounds, which uses 30±5 mCi of Tc-99m for both stress and rest images. This protocol has remained unchanged for at least the last 20 years, though technology has been evolving and moving towards faster acquisition times and the capability of using lower doses of radiation.

Over the years, it had been observed that Tc99m had a propensity to stick to the plastic syringe, resulting in a residual dose whereby the actual dose delivered varied unpredictably from the dose initially drawn. It was understood that patients received less than the original dose drawn, but to what degree has not been formally studied. Factors to consider include accounting for decay during the time in between when the dose is drawn and administered, and the residual dose in the syringe. These factors are particularly pertinent to Tc99m, which has a 6-hour half-life, as opposed to Th-201 which 73-hour half-life.

The primary goal of this study is to calculate the actual delivered dose of radiation.

The secondary goal is to correlate actual dose delivered with image quality on a 5 point scale (1 – poor, 5 – excellent) as determined by experienced nuclear cardiologists to show that at least 90% of scans at doses 18-20mCis are of 4-5 quality as compared to 100% of scans at doses 25-30mCis.

Given that recent data has shown the detrimental affects of radiation, that rMPIs are contributing to the increasing radiation exposure to patients, the goal as per the general radiation safety paradigm known as ALARA (As Low As Reasonably Achievable), and given the advanced nature of clinical practice at Columbia, the data from this study is expected to make a useful contribution to this benchmark.

2. Study Design and Statistical Procedures.

Myocardial perfusion scans performed between 6/3/10-7/22/10 performed at Columbia University Medical Center/New York-Presbyterian Hospital will be analyzed.

The process begins by colleting dose information from the logs in the nuclear lab (time drawn, amount drawn), patient demographics (age, sex, height, weight), injection times of the radiopharmaceuticals, and residual dose in the syringe with time this is assayed. This information is routinely recorded by the technicians in the nuclear cardiology lab. The decay equation, $N_t = N_o e^{-[(\ln 2 * t)/t1/2]}$, will be used to determine the actual dose delivered.

To assess image quality, scans will be deidentified, and two senior nuclear cardiology attendings will rate an image based on a 5 point scale, with 1 being low quality and 5 being excellent quality. To account for inter-reader variability, if there is a discrepancy between two readings of the same image, the attendings will confer with one another to reach an agreement.

The cohort of patients includes all-comers who received either an exercise stress test or a pharmacological stress test during the above time period.

The data will be analyzed using standard descriptive statistics. The independent variable is dose delivered (high or low), and the dependent variable is the image quality (4-5, or not 4-5). As such, a Chi-square test is the most appropriate to show equivalence.

In using Chi-square test to determine power calculations, assuming 100% of high dose scans are of 4-5 out of 5 in quality, and at least 90% of lower dose scans are 4-5 out of 5 in quality, 94 scans are needed in each arm to prove the null, that there is in fact no difference in image quality.

3. Study Procedures

Procedural information and patient demographics will be retrieved from the nuclear medicine/nuclear cardiology data logs, and other data systems that include lists of patients who have undergone myocardial perfusion scans. These data logs will be used to identify patients. A list of patients who have had scans at Columbia University Medical Center/New York Presbyterian Hospital will be generated.

4. Study Drugs or Devices

There are no study drugs or devices.

5. Study Questionnaires

Not applicable. This investigation requires no patient contact.

6. Study Subjects

Data will be retrospectively collected from patients who have undergone a myocardial perfusion scan during the time period 6/3/10-7/22/10.

Patients with ambiguous or missing key data (e.g. dose drawn, injection time, residual dose) will be excluded.

7. Recruitment

Data will be retrospectively collected from the records of patients who have undergone a nuclear myocardial perfusion scan between the time periods of 6/3/10-7/22/10.

Exclusion criteria are those patients who are missing data, namely dose drawn, injection times, or residual dose.

8. Confidentiality of Study Data

Data confidentiality will be maintained as per HIPAA standards. Any data discussed outside the confines of the investigators will be de-identified. Identified data will be stored in password-protected files on password-protected devices. Only the study investigators will know file passwords.

9. Potential Risks

There are no patient risks that can be attributable to this data collection.

10. Potential Benefits

Because this study is limited to a retrospective chart review, there are no benefits to the individual patients in this study, but the statistical analysis of the data collected will be of value in evaluating the current standard practice of using high doses of radiopharmaceuticals during stress imaging. In showing that low dose image quality is equivalent to those images obtained at higher doses, this study may be the beginning of establishing a new standard of care, especially given that technology has emerged in the last year that reduces acquisition time and has potential for a low dose protocol, which will reduce associated radiation risks in future patients.

11. Alternatives

This study provides otherwise unavailable information. The alternative is not to know.