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Review Article

Definitive Human Studies Showing Indisputable Proof of Clinically Significant Sestamibi Redistribution

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Key words

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Abstract

The manufacturers and distributors of Sestamibi have long held that two doses of isotope are required for Myocardial Perfusion Imaging (MPI), based upon their representation to physicians, hospitals, clinics, insurance companies including Medicaid and Medicare, the FDA and the Federal Courts, that Sestamibi does NOT redistribute. If these corporations are correct, then the initial and sequential images displayed here, will by virtue of having “no redistribution,” be easily “qualitatively” matched by the reader, as they will have to be “identical” to each other for each individual patient. If; however, the reader is unable to “match” those images, which must be “identical” by virtue of the corporations “no redistribution” representation, then the evidence speaks for itself; Sestamibi redistributes and the corporation’s representations to physicians, hospitals, clinics, insurance companies including Medicaid and Medicare, the FDA and the Federal Courts is fraudulent.

Introduction

For decades the backbone of Myocardial Perfusion Imaging (MPI) has been the “qualitative” comparison of two different images obtained sequentially. Thallium-201(Tl-201) provided a single injection of isotope following efforts to change a patient’s blood flow by “stressing” them; a method well understood to put increased demand on

the heart and increase coronary artery blood flow along with iso-tope, which is then delivered to myocardium for imaging. The pharmacokinetics and pharmacodynamics ofTl-201 required an hour before the initial image (called “stress”) could be obtained. There distribution characteristics of Tl-201 required three additional hours for a comparison image (called “redistribution”) to be obtained. The advantage was the use of a single dose of Tl-201, while the drawback was the amount of time required and a 72-hour half-life limiting the amount of Tl-201, which could be given in the single injection.

During the late 1980’s newer isotopes, with shorter physical half-lives (6-hours)allowed for higher millicurie (mCi)or European equivalent (mBq) doses, of the isotope to be given, improving

“qualitative” appearance. The manufacturers and distributors of one of these agents, Sestamibi, a technetium-99m (Tc-99m) based compound have long held that Sestamibi, unlike Tl-201, does NOT redistribute and for that reason, two doses of the drug are required to look for evidence of MPI defects, comparing what would become commonly, albeit incorrectly [1,2], known as “stress” and “rest” imaging.

To convince physicians, hospitals, clinics, insurance companies including Medicaid and Medicare, the FDA and the Federal Courts, that these two injections are required to obtain serial im-ages for comparison, the companies selling Sestamibi, directed physicians to begin “stress” imaging one-hour after Sestamibi in-jection, even though the companies have always maintained in the package insert that initial uptake of the isotopic compound begins as early as 5-minutes after injection. The “resting” [1, 2] image acquisition can either be performed before or after the “stress” imaging is completed and there are various protocols pro-posed; all of which require a second dose of

Sestamibi pursuant to the “Sestamibi does NOT redistribute” statements of the pharmaceutical companies which have sold

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Sestamibi.

Multiple papers [1-75] have now been published showing Sestamibi does in fact "redistribute". Despite the abundance of evidence to the contrary [1-75], of which these references are not inclusive of all the published material available the corporations, which sell Sestamibi have refused to correct the record. If the corporations are correct, and Sestamibi does not redistribute, then sequential images obtained after only a single injected dose of Sestamibi, completed in less than 4-hours, must be identical. If the images are not identical, i.e. if the "defects" noted on the first and second images obtained following a single injected dose of Sestamibi are different, then Sestamibi MUST be redistributing or the images could not "qualitatively" be different, and consequently the pharmaceutical companies have been and continue to misrepresent the information they have been submitting to physicians, hospitals, clinics, insurance companies including Medicaid and Medicare, the FDA and the Federal Courts.

Ten Patient Studies Following Single Injection Showing Sestambi Redistribution

It would be too easy to provide the sequential images for people to compare and then listen to justifications as to why the images really are the same. To establish the truthas to SESTAMIBI REDISTRIBUTION, we are presenting the reader with 10-patients,each with an initial and sequential image for comparison. A letter of the English alphabet represents the initial image. An English number represents the sequential image.

If there is no redistribution, then the reader should have no difficulty matching each initial image (A-J) with the corresponding sequential image (1-10). Such matching types of questions are not uncommonly used in testing scenarios to determine what students have and have not learned. For those who have been trained in how to

"read" MPI, and given the companies representation that the initial and sequential images must be identical given "no Sestamibi redistribution" then this should be an easy examination. If however Sestamibi redistributes, then the matching will be more problematic; at least for those trained to read MPI. Unlike cross-word puzzles, where the

reader can find the correct answers by looking for them on another page, the correct answer s will not be provided in this particular paper.

Should the readers wish to submit their answers to the primary author, he will tally the results and report the findings in a future paper. One thing is clear, either Sestamibi Redistributes or it doesn't. If it doesn't, the reader should have no difficulty matching the images. Let the games begin!

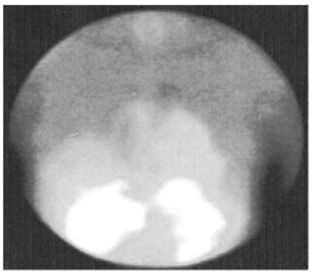


Figure A

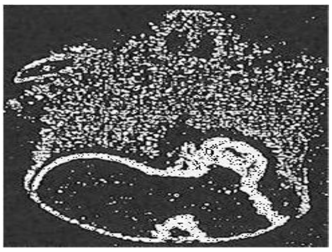
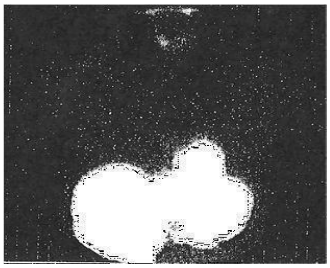


Figure B



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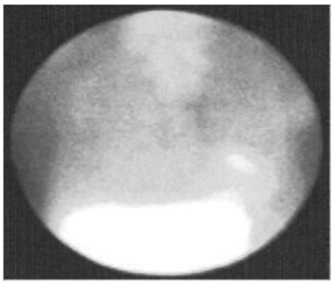
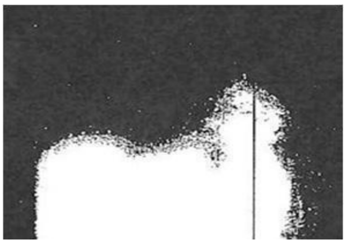


Figure D



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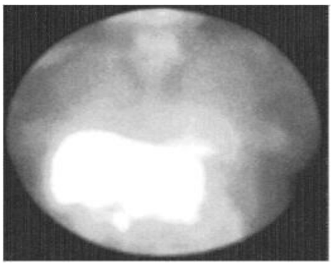

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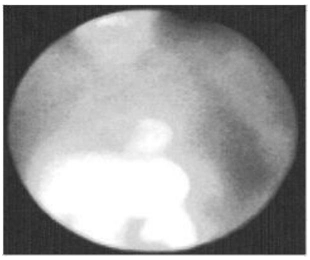

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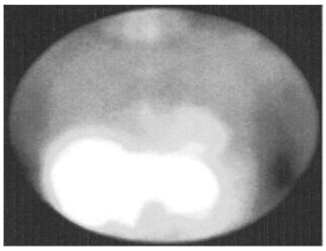

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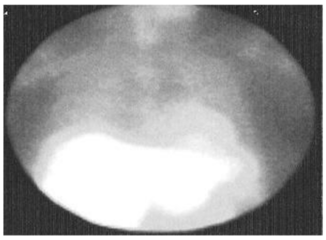
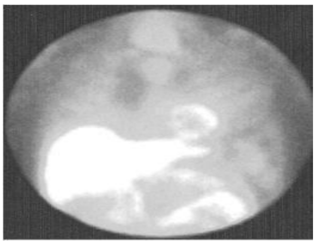


Figure I



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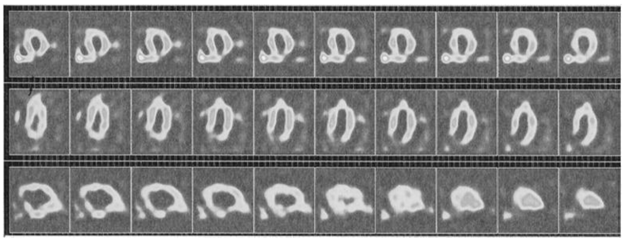

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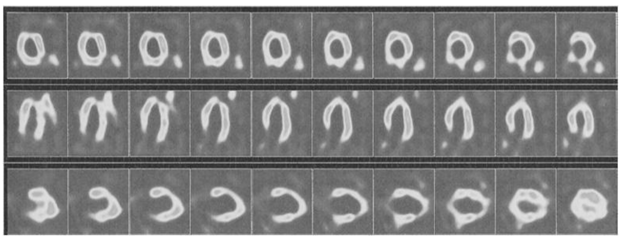

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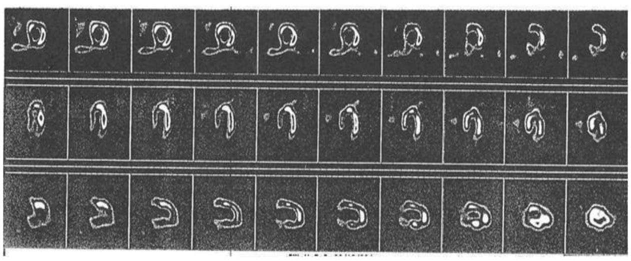

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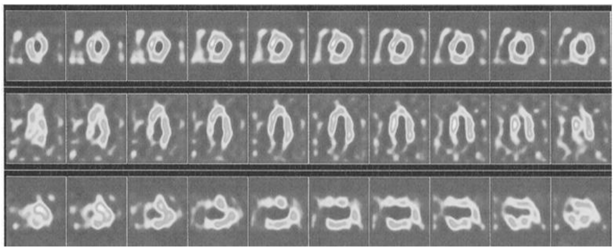

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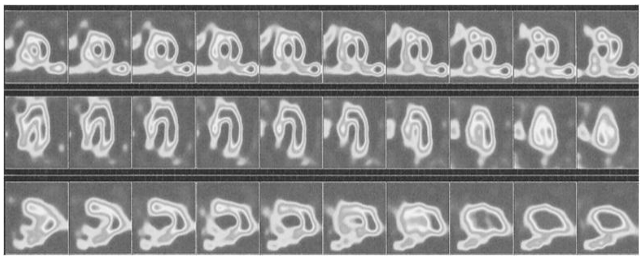

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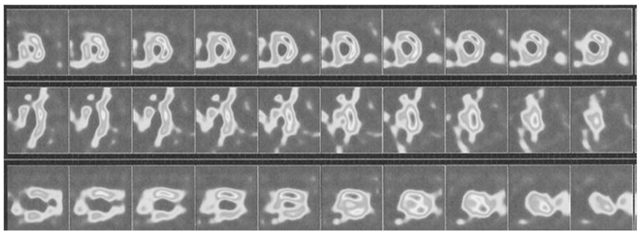

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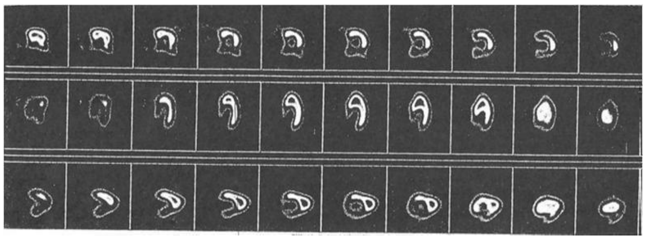

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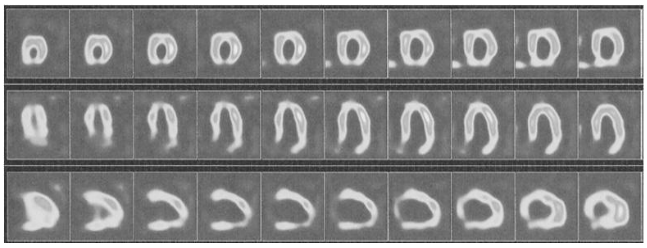

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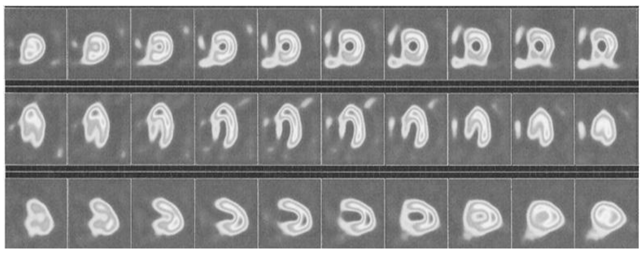

Figure 9

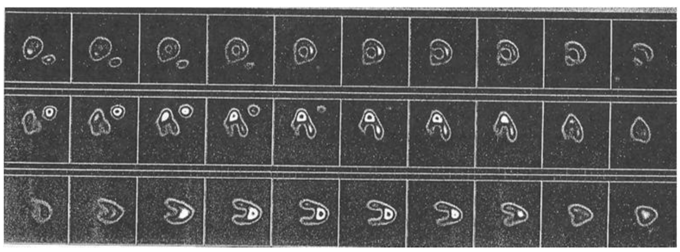

Figure 10

Conclusion

The results of this demonstration will only be available after you submit your answers to the matching of these initial and sequential images. While the literature is replete with evidence [1-75] that Sestamibi and the other Tc-99m isotopes redistribute, the results of this paper will be the first of its kind to reveal to Physicians, Hospitals,

Clinics, insurance companies including Medicaid and Medicare, the FDA and the Federal Courts, whether those trained in MPI agree or disagree with Sestamibi redistribution and the representations being made by the corporations marketing and selling Sestamibi.

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