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Research Article

Reno Cardiologist Confirms FMTVDM – Opening New Opportunities for Nuclear Cardiologists.

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Abstract

Background: A quantitative myocardial perfusion imaging (MPI) and oncologic - including molecular breast imaging (MBI) - utility patent (FMTVDM*) previously validated at experienced MPI and MBI centers was independently tested for clinical application at a private practice Reno, Nevada cardiologists office.

Methods: Using FMTVDM, a private practice cardiologist independently investigated forty-four regions of interest (ROI) in 12-women with varying transitional levels of breast changes – including breast cancer.

Results: Using FMTVDM, a nuclear cardiologist without prior experience in MBI was able to easily measure changes in women's breast tissue differentiating inflammatory and cancerous breast tissue from *normal* using the same camera used for MPI. These measured changes provided diagnostically useful information on cellular metabolism and regional blood flow changes (RBF) – the same properties which differentiate ischemic coronary artery disease (CAD) on myocardial perfusion imaging (MPI).

Conclusions: Quantitative MBI using FMTVDM allows differentiation of tissue types through measurement of enhanced regional blood flow and metabolic differences. Nuclear cardiologists have previously reported cases of breast cancer while conducting MPI studies. This investigation demonstrated that nuclear cardiologists can independently conduct MBI in addition to MPI studies using the nuclear cameras they currently use for MPI.

Key words: FMTVDM; breast cancer; nuclear cardiology

Running title: Reno Cardiologist confirms FMTVDM.

Introduction

Qualitative mammography for screening and diagnostic purposes has proven to have little value in women with dense breasts and according to the Canadian National Breast Screening Study [1], provided no survival benefit for women in general. Accordingly, efforts to quantify changes in tissue – including breast - associated with cancer and inflammation have resulted in the patented development of a method for quantitatively measuring changes in regional blood flow and metabolism, associated with these different types of tissue [2,3].

Following more than 1000 women and men previously studied using FMTVDM [2-4], an independent, private practice cardiologist, with no prior experience in molecular breast imaging (MBI) investigated if - using the same equipment used for myocardial perfusion imaging (MPI) –it was possible to measure changes in breast tissue using FMTVDM.

Methods

Patient enrollment: Twelve women, all previously identified as having breast irregularities, volunteered to undergo FMTVDM testing, the results of which were compared with the information already known about the extent of breast changes. All components of FMTVDM are already FDA approved - including the enhancement of regional blood flow (RBF) and metabolic differences, isotopes and camera. Each woman signed an informed consent agreeing to participate in the nuclear imaging using the FMTVDM protocol. All personal identifying information was redacted to protect patient identification.

FMTVDM: Prior to imaging, the nuclear technologist, who was familiar with MPI, but unfamiliar with MBI, calibrated the Siemens' Orbiter camera according to patent instructions to guarantee quantitative calibration of the camera in addition to customary qualitative controls.

Patients arrived in the overnight fasting state and were prepared for imaging with placement of an intravenous catheter through which a vasodilator (enhancement) was given, followed by the imaging isotope as previously described [2,4].

Patient records: Patients provided *inter alia* detailed medical records, including prior biopsy results, mammography results, family history of cancer, any prior false positive or false negative (FPFN) results from prior testing including but not limited to mammography, smoking history, current medications, and any diagnosis of dense breasts.

Measurement of Maximal Count Activity (MCA): An individual with no prior medical or technical training, received instructions on how to draw regions of interest (ROI) around the acquired breast images and obtain the measured scintillation activity used for diagnosis following completion of the imaging.

Results

The diagnostic information obtained from these 12-women and 44-regions of interest based upon imaging and patient medical records/information are shown in Table 1.

Initial-Breast	MCA	Tissue Data	Other
1-R	54	Lumps	Implants, Not Dense
1-L	74	Lumps	Implants, Not Dense
2-R	91	No CA	Nothing reported
3-L	92	No CA	Breast Implant
4-R	103	None CA Lumps	?, Breast Implant (Right Only)
5-R	142	Breast Lumps-Not CA	No, FP, smoker
2-L	143	No CA	Nothing reported
3-L	144	No CA	Breast Implant
6-L	146	Irregularities	Dense Breasts, Implants
7-R	154	Cysts	Dense Breasts
5-R	156	Breast Lumps-Not CA	No, FP, smoker
3-R	158	No CA	Breast Implant
8-L	158	No CA	Dense Breasts, FP
9-L	160	No CA	Dense Breasts, FP
10-R	163	No CA	FP
11-R	167	No CA	Nothing reported
10-L	171	No CA	FP
4-L	173	Non-CA Lumps	Breast Implant, Taking HT
7-R	178	Cysts	Nothing reported
1-L	180	Lumps	Implants, Not Dense
11-L	184	No CA	Nothing reported
7-L	184	Cysts	Dense Breasts
9-R	185	No CA	Dense Breasts, FP
10-R	186	No CA	FP
2-R	191	No CA	Nothing reported
10-L	194	No CA	FP
8-L	201	No CA	Dense Breasts, FP
9-L	203	No CA	Dense Breasts, FP
5-L	204	Breast Lumps-Not CA	No, FP, smoker
9-R	213	No CA	Dense Breasts, FP
8-R	222	No CA	Dense Breasts, FP
3-L	232	No CA	Breast Implant
8-L	237	No CA	Dense Breasts, FP
3-R	238	No CA	Breast Implant
1-R	245	Lumps	Implants, Not Dense
6-L	259	Irregularities	Dense Breasts, Implants
7-L	264	DCIS	DCIS, Dense Breasts
12-R	270	Not tested yet	?
6-R	290	CA with marker left	Dense Breasts, Implants
4-L	297	Lumps	?
12-R	348	Not tested yet	No Implants, DB-?
12-L	396	Breast Cancer Dx	No Implants, DB-?
6-R	417	CA with marker left	Dense Breasts, Implants
12-L	444	Breast Cancer Dx	No Implants, DB-?

Table 1. Patient data and diagnostic information.
DB = Dense Breasts (Yes, No, ?=Uncertain), FP=incorrect mammogram, HT=Hormone Therapy

This included one woman who smoked and another woman taking hormone treatment. Four (one-third) had breast implants and four (one-third) had dense breasts. Only one of the women with dense breasts had breast implants. Four of the women (one-third) had incorrectly been told they had breast cancer (false positives - FP), two of which were told they had dense breasts.

Table one provides specific details for each region of interest (ROI) measured, along with the patient number and breast involved. The maximal count activity (MCA) for each ROI is shown, along with tissue information, the presence or absence of breast implants, dense breasts and FP mammography results.

Figure 1 shows an example of MBI and measurements obtained at a nuclear imaging lab with experience in MBI (top) and the results obtained in this independent laboratory without (bottom) prior MBI experience.

(Top) – Experienced MBI Center (Bottom) – Nuclear Cardiologist's Center without prior MBI experience.

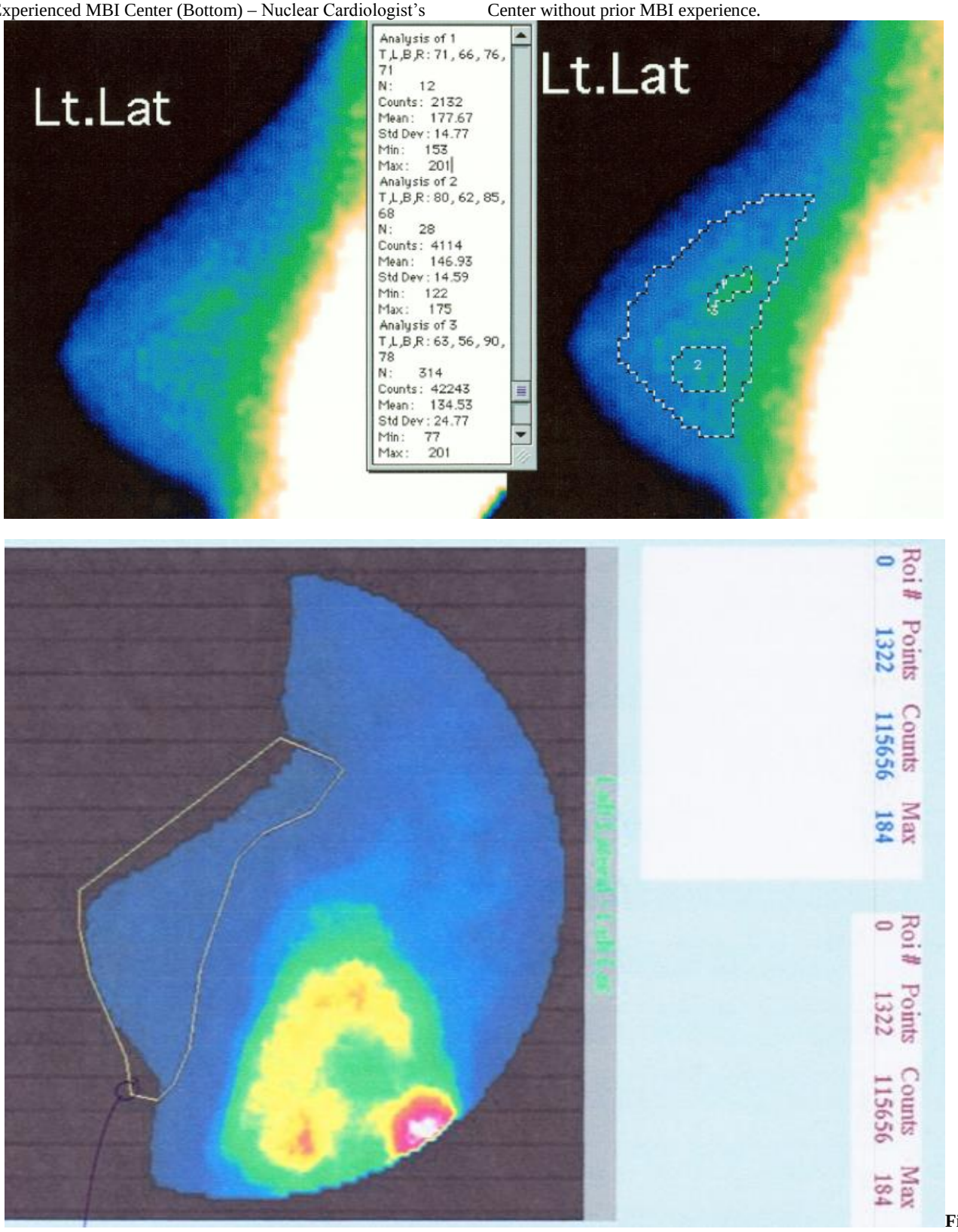

Figure 1.

Images and MCA values obtained at an experienced (top) and inexperienced (bottom) MBI laboratory.

Discussion

While the sample size was relatively small, it provided more than adequate information to demonstrate the use of FMTVDM by Nuclear Cardiologists. In this group of women, multiple ROIs were obtained matching the available medical information provided by the women and their medical records including tissue, false positive (FP) mammograms, use of hormone therapy, smoking, and family history.

The study demonstrated that nuclear cardiologists can also conduct MBI studies - using the same nuclear cameras they already use for MPI – given the use of FMTVDM to calibrate and measure differences in breast tissue metabolism and RBF differences using ROIs to obtain FMTVDM measurements.

While the appearance of imaging results were not as eloquent (Figure 1) as those obtained in centers with MBI experience, the calibration of the nuclear cameras and the ability to quantify the tissue based upon drawn ROIs, demonstrated that the utility patent makes possible accurate measurement of breast tissue health, independent of human skill or qualitative interpretation – thereby removing the human error element.

Conclusions

With little or no additional training, nuclear cardiologists are able to independently conduct MBI using FMTVDM using the same equipment they use for MPI, increasing the potential role of nuclear cardiologists.

*FMTVDM = The Fleming Method for Tissue and Vascular Differentiation and Metabolism

Acknowledgments: FMTVDM is a utility patent issued to first author. All figures reproduced with expressed consent of first author. The authors wish to thank David L Prothro, MD of Nevada Arrhythmia Services Inc. in Reno, Nevada for independently conducting these patient studies and providing the results.

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