

Part I: Proposed New Standards of Care for the Work up of Chest Pain and Breast Lumps

¹Richard M. Fleming, PhD, MD, JD, ¹Matthew R. Fleming, BS, NRP, ²Tapan K. Chaudhuri, MD, ³William C. Dooley, MD

¹FHHI-OmnificImaging-Camelot El Segundo, CA, USA

²Eastern Virginia Medical School Norfolk, VA, USA

³Oklahoma University Health Science Center Oklahoma City, Oklahoma

Abstract

Heart disease and cancer are the number one and two causes of death in the United States. Their evaluation and treatment account for a tremendous amount of time and resources being spent in both the Emergency Department and Primary Care offices throughout the country. The current tests utilize qualitative multi-step algorithms flawed with errors, both missing disease (sensitivity) and resulting in unnecessary testing (specificity) increasing the expenditure of resources –including mental, emotional, physical and financial. We propose two new protocols for the diagnosis and treatment of patients with chest pain and breast lumps, which will provide the new standard of care.

We present here the first Part of a two Part Proposed New Standards of Care for the Work up of Chest Pain and Breast Lumps for the Emergency Department and Primary Care Physician, now made possible by our ability to quantitatively measure changes in tissue through the use of The Fleming Method for Tissue and Vascular Differentiation and Metabolism (FMTVDM). In this paper, we will compare the older approach with this new method, which allows us to accurately measure coronary artery disease (CAD).

Keywords: FMTVDM, Standard-of-Care, Emergency Department, Primary Care, Chest Pain, Breast Lump.

Introduction

According to the U.S. Department of Health and Human Services – the Centers for Disease Control – and the National Center for Health Statistics¹, there were 145.6 million Emergency Department Visits in 2016, with 12.6 million admissions, 2.2 million of which

were to critical care units. Chest pain and related symptoms was the number 2 cause for evaluations in both men and women, 15-64 years of age.

While it is not entirely clear how many women see their physician for breast lumps, what we do know is that 80% of all breast lumps are not cancer. Given the statistics by the Komen Foundation², there are expected to be 268,600 new cases of breast cancer for women and 2,670 new cases of breast cancer for men, in 2019. If we back project from this number, and presume for ease of calculation, that each of these are associated with a breast lump, knowing that (a) there are people diagnosed with breast cancer without lumps and (b) there are people with lumps that do not present for evaluation and therefore there is no data to work with; then we can calculate a potential 1,356,350 breast lumps which are evaluated each year in the U.S.; many by their primary care physician.

The current methods for evaluating chest pain³ and breast lumps⁴ are flawed and require a multi-step approach. The errors made in detecting (sensitivity) and correctly excluding (specificity) both coronary artery disease (CAD) and breast cancer, using the

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***Corresponding author:** Richard M. Fleming, Director and Chair FHHI-OmnificImaging-Camelot El Segundo, Los Angeles, CA, USA. Email: DrRichardMFleming@gmail.com

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currently employed approaches are undoubtedly well known to the reader and are discussed elsewhere^{5,11}. Notwithstanding the obvious medico-legal concerns that accompany these flawed methods, are the more important physical, mental, emotional and financial costs to patients, their families and friends and an already over burdened health care system.

Based upon the diagnostic and therapeutic benefits of the ability to quantitatively measure¹² where patients truly exist on a health-spectrum⁴, from healthy to critical disease, we propose the following changes to be implemented immediately for the purposes of diagnostic and treatment decision making in both the Emergency Department and Primary Care Physicians office.

Emergency Department Evaluation of Chest Pain

Upon arrival in the Emergency Department, patients should be taken to a cardiac room for further evaluation and treatment. The diagnostic work up should include the History and Physical, along with venous access and initiation of the following *Chest Pain Protocol*.

Initial 12-lead electrocardiogram, and when applicable additional leads based upon cardiac anatomy and rhythm. Blood work should continue to include cardiac enzymes, including troponin and creatine kinase levels with fractionation (MM, MB, BB). Assessment of the applicable pharmacologic agent to enhance regional blood flow differences^{13,15}, followed by a selected isotope to be imaged beginning^{3,5} minutes after isotope injection, dependent upon the nuclear imaging equipment available at the hospital.

Since, angina is the result of regional blood flow differences¹⁶ and given that *pharmacologic stress*, augments delivery of coronary blood flow to regions capable of increasing coronary flow reserve¹⁷, without an equivalent consequential increase in blood flow to regions with CAD (impaired coronary flow reserve – CFR), and given that the initial delivery and uptake of isotope is dependent upon (a) regional blood flow and (b) cellular viability, *pharmacologic stress* will differentiate regions of impaired coronary flow, without decreasing coronary flow in impaired regions, below the baseline levels present upon arrival in the Emergency Department.

Following the applicable time (55-minutes for technetium isotopes), based upon isotope redistribution properties¹⁸, a second image acquisition is obtained and compared with the first. Quantitative measurements of the change in isotope redistribution,

the percent diameter stenosis (% DS) and coronary flow reserve can be calculated¹².

Figure 1 details these steps from beginning to end. Changes are dependent upon the specific type of nuclear cameras and isotopes available for the Emergency Department to use.

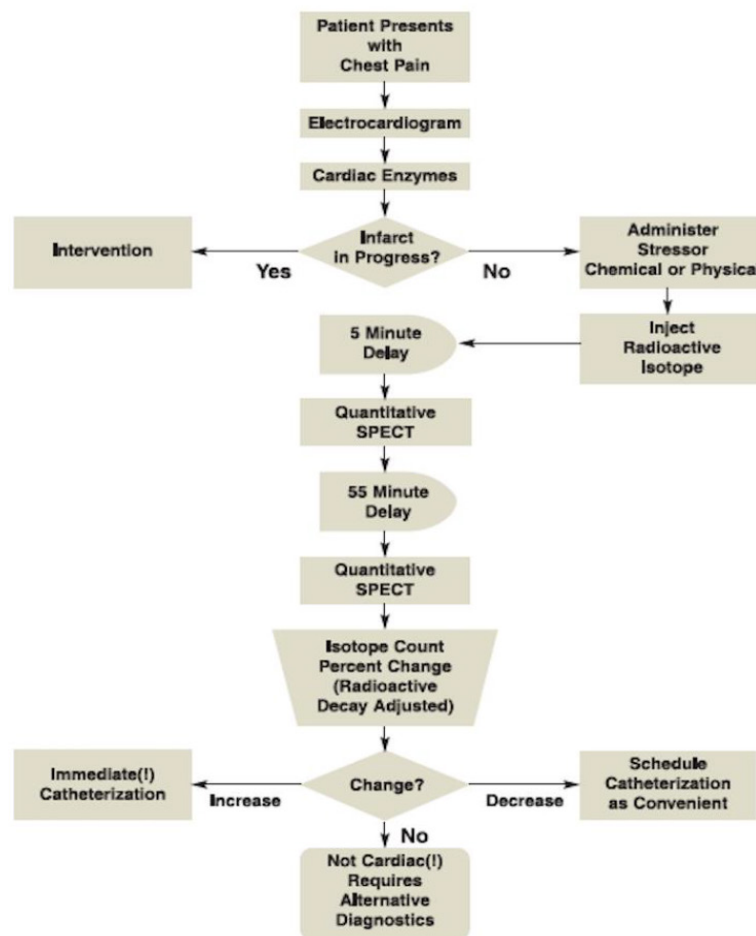


Figure 1. Proposed FMTVDM Emergency Department Algorithm for the Evaluation and Treatment of Chest Pain [3].

Using *The Fleming Method for Tissue and Vascular Differentiation and Metabolism* (FMTVDM), the extent of ischemia/infarction can be determined and patients can be discharged (no measured CAD), scheduled for further coronary arteriography and potential intervention, emergently taken for coronary intervention, or evaluated for non-cardiac causes. Clearly if the initial electrocardiogram shows acute myocardial infarction, treatment should be initiated immediately based upon the Emergency Department and Hospital protocol.

In Part II of this series, we will look at the evaluation of breast lumps, which may present either as concerns in the Emergency Department, or more commonly in the primary care or specialist's office setting.

Acknowledgements: FMTVDM was issued to the first author. The figure is reproduced with the expressed consent of the first author.

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