

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

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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 second 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 breast cancer and the transitional changes leading up to it.

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

Introduction

In Part I of this series of papers, we looked at the problems inherent in the currently utilized approach to evaluating patients in the Emergency Department, who present with chest pain.

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In the second part of this series, we will see how quantitatively measuring changes in breast tissue, will allow the Primary Care Physician and Specialist, to accurately diagnose and treat the woman, or man, who presents with breast lump(s), through the measurement of changes in metabolism and regional blood flow.

Evaluation of Breast Lump

The diagnosis of breast cancer, independent of reported improvement in treatment outcomes, remains a major concern for women everywhere. As we have already noted, breast cancer is not just a concern for women, but for men as well. While it is frequently not addressed, the smaller the amount of breast tissue that exists, either due to naturally occurring smaller breasts, prior surgical interventions (mastectomy, partial mastectomy, etc.) or being male, there is less breast tissue for a cancer to grow through before it can metastasize^{1,3}.

Based upon the demonstration that quantitative measurements of differences in breast tissue can be made⁴ and given the failure of screening mammography to provide a survival benefit in women⁵, the following protocol is being proposed for implementation by Primary Care physicians, as well as others.

Women and men are encouraged to routinely examine themselves for any irregularities, including breast lumps, retractions, discharge, et cetera. Any such noted abnormalities should be brought to the attention of the patient's physician without delay.

Currently a series of steps are taken, including one or more mammogram, ultrasound, and/or biopsy (open or closed). During this amount of time, patients and their families undergo considerable mental, physical, emotional and financial stress related to the uncertainty incorporated into the process. While the two extremes are either a missed cancer (sensitivity error) with delay in diagnosis and increased morbidity and mortality, or the agony of working through a suspicious area (specificity problem) only to find out there was no cancer to begin with; each is devastating to the patient, their family and friends, and quite frankly the physician and staff.

Given what we know about the differences between cancers and the transitional changes, which must occur to eventually develop cancer⁶, it is clear that we must change our approach to quantitatively measure these differences to find changes earlier⁷. By doing so, we open new treatment options, with less potential toxicity to healthy tissue. We also open the ability to measure treatment outcomes sooner than later, saving time, money and lives⁸.

As shown in Figure 1, a component of FMTVDM, called Breast Enhanced Scintigraphy Test (BEST), a specialized molecular breast imaging (MBI) method, can be used to independently measure these tissue changes, based upon metabolic and regional blood flow differences. Once measured, the patients actual health status can be determined placing them on their health-spectrum, from which patient, family and doctor can make treatment decisions; including no treatment, alternative treatments – including diet, lifestyle, and other options up to the discretion of those involved – medication, surgery, chemotherapy, radiation treatment, immune therapy, et cetera.

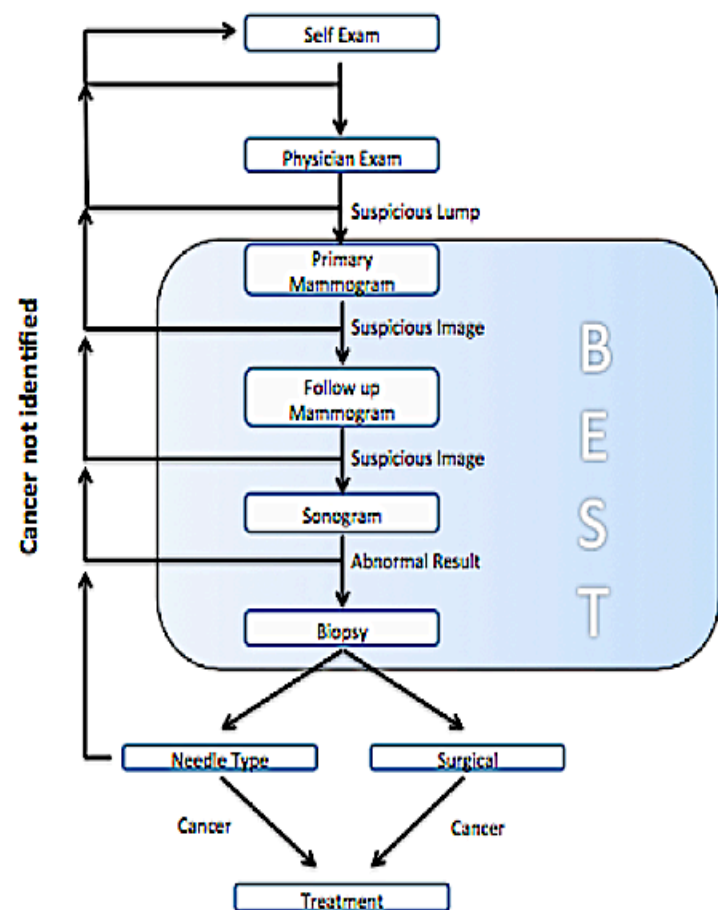


Figure 1. Proposed FMTVDM (BEST) Physician Algorithm for the Evaluation and Treatment of a Breast Lump [4].

Conclusion

Heart disease is the number one cause of death in both men and women in the United States and account for 23.5% of all deaths as of 2017, with 647,457 deaths⁹ and are the second most common reason for emergency department visits¹⁰. The number two cause of death in the U.S. is cancer, responsible for 599,108 deaths, or 21.3% of all deaths¹⁰. While lung cancer kills more women than breast cancer, breast cancer remains the most commonly diagnosed cancer in women and will continue to drive primary care visits.

While patients continue to deal with the emotional, mental, physical and financial costs of heart disease and cancer, it is also true, that physicians and our staff, are also bearing the emotional, mental, physical and yes, financial costs of diagnosing and treating heart disease and breast cancer. The utilization of outdated qualitative imaging and multi-stepped approaches to

working through the diagnosis and treatment plans of correctly identifying heart disease and breast cancer, not only is impairing our ability to correctly diagnose and help people, but it is also continuing to produce a burden on a health care system already near the breaking point.

The implementation of these quantitative protocols for the diagnosis and treatment of heart disease and breast cancer, not only will enhance our ability to timely see, diagnose and treat patients; it will reduce costs, time and enhance lives saved.

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