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Statistical Demonstration that FMTVDM is Superior to Mammography

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Abstract

Using statistical chi-square analysis it is possible to calculate how many participants are required to determine if there is a statistically significant difference between two tests used to diagnose breast cancer. Using this calculation, a sample size of 1000 women would produce a p-value of less than 0.0001. The outcomes of the published data include 1000 women and 4 men, providing statistical evidence of FMTVDM superiority over mammography for the detection of breast cancer. Additional advantages of FMTVDM include the ability to measure transitional changes in tissue resulting in the development of breast cancer.

Keywords: FMTVDM, Breast Cancer, Breast Inflammation, Transitional Changes, Health-Spectrum

Introduction

A determination of the sample size required to statistically demonstrate significant differences between two tests for breast cancer can be calculated based upon the observed outcomes of those two tests. In this instance we compare mammography with The Fleming Method for Tissue and Vascular Differentiation and Metabolism (FMTVDM), using biopsy results to compare outcomes obtained with mammography and FMTVDM nuclear imaging. We present the statistical calculation demonstrating the required number of studies needed to verify clinical diagnostic significance has been reached. The comparison studies published to date exceed the required numbers to achieve statistical significance to prove FMTVDM superiority to mammography.

Methods

The Fleming Method for Tissue and Vascular Differentiation and Metabolism (FMTVDM, patent #9566037) provides the first and only quantitative patented method which (A) quantitatively calibrates nuclear imaging devices, (B) enhances regional blood flow differences resulting from tissue gene expression and metabolic differences and (c) quantitatively measures those differences. A total of 1000 female and 4 male imaging study results have been published to date comparing FMTVDM with mammography and biopsy results, validating the patented process including diagnostic and therapeutic measurement outcomes [1-22]. Having already demonstrated and published the outcomes of these 1004 studies, the remainder of this paper looks at whether this is an adequate number to state unequivocally that FMTVDM is superior to mammography for breast cancer diagnostic purposes.

Determining the Sample Size Required to Demonstrate FMTVDM Superiority to Mammography for Breast Cancer Diagnosis [23]

Overview of sample size comparisons

The determination of breast cancer has previously been evaluated using qualitative mammography and quantitative FMTVDM imaging. These studies have compared results with biopsy data, allowing for the accurate evaluation of each method. Based upon this information, FMTVDM demonstrated the quantitative ability to accurately, consistently and reproducibly measure the regional blood

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Table 1: Chi-square analysis is the result of comparing the observed pathology results with the expected mammography and FMTVDM results; with mammography (M) denoted in black font and FMTVDM (F) denoted in red font.

	Cancer Detected by "M" or "F" (+)	Cancer Not Detected by "M" or "F" (-)	
Cancer Present (+)	77 111	34 0	111 111
Cancer Absent (-)	142 0	747 889	781 889
	219 111	781 889	1000 1000

flow and metabolic differences differentiating "normal" breast tissue from breast cancer and the transitional changes associated with breast cancer.

When reduced to qualitative terms, FMTVDM demonstrated a 100% sensitivity and specificity in detecting breast cancer. Mammography demonstrated a sensitivity of 69% and specificity of 84% presuming that women included in the original studies did not have breast cancer when mammography reported they had none (*viz.* a 0% false negative rate). When only women who received biopsies were studied, the specificity dropped to 66%. No cases of breast cancer were identified in women by mammography which were not also identified by FMTVDM; however, mammography missed 31% of the women who had breast cancer and were detected using FMTVDM [1-22].

Is a sample size of 1000 sufficient to prove differences in detection of breast cancer?

Current data shows 1 in 9 women will develop breast cancer. Given a sample size of 1000, 111 potentially could have breast cancer. Given the published research findings to date, data comparisons between the mammography and FMTVDM imaging are possible. Given the best possible sensitivity for mammography (69%), of the 111 women, 77 with breast cancer would be detected while 34 would not. Quantitatively these 111 women are measureable using FMTVDM.

Of the 889 women without breast cancer, using the most optimistic mammography result of 84% specificity, 747 would be told they do not have breast cancer, while 142 women without cancer would be told they have something "suspicious" and require further evaluation and/or testing. In contrast FMTVDM accurately measures the absence of cancer and perhaps more importantly, gives vital measurements to warn of transitional changes occurring, which lead to breast cancer upon which clinicians could act. The result of the incorrect mammogram reports would be 142 women without breast cancer, being referred for additional procedures, prolonged stress and costs for "abnormalities" on their mammograms, which in fact are not cancer.

Chi-square analysis. (χ^2= E (O–E)2/E)

Using chi-squared analysis and the published data on mammography and FMTVDM, we can calculate the statistical differences between these two tests. This is a simple nominal/categorical data analysis; viz. the presence or absence of disease detection (Table 1).

Therefore,

$X^2=[(77-111)^2\div(111)]+[(142-0)^2\div(0)]+[(34-0)^2\div(0)]+[(747-889)^2\div(889)]=33.10$

The statistically significance [23] difference between mammography and FMTVDM is $p \leq 0.0001$, when used in 1000 studies. This demonstrates a statistically significant difference five times that necessary to statistically show FMTVDM superiority to mammography for the detection of breast cancer.

Discussion

A discussion about applicable diagnostic testing for breast cancer requires a consideration of whether the test is qualitative or quantitative [24]. Above and beyond that, the introduction of a new diagnostic test requires that it be shown to be superior to that currently used. To do such a comparison requires that we not only show a diagnostic difference but that such a diagnostic difference is statistically significant. The determination of how many comparisons between the current (mammography) and new (FMTVDM) diagnostic testing is required, is a statistical one; i.e. does it truly make a difference which is clinically valuable? Here we have looked at the required number of study comparisons between mammography and FMTVDM, which are needed to statistically make such a decision. The published data exceeds that which is required to demonstrate that FMTVDM is superior to mammography in the detection of breast cancer.

Conclusion

FMTVDM is statistically superior to mammography in the diagnostic ability to find breast cancer when present and to exclude it when absent.

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