

AD_____

Award Number: DAMD17-01-1-0650

TITLE: Quantification of the Benefits of Pendent Mammography

PRINCIPAL INVESTIGATOR: Catherine W. Piccoli, M.D.

CONTRACTING ORGANIZATION: Thomas Jefferson University
Philadelphia, PA 19107

REPORT DATE: October 2005

TYPE OF REPORT: Final Addendum

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-10-2005		2. REPORT TYPE Final Addendum		3. DATES COVERED (From - To) 20 Sep 2004 - 19 Sep 2005	
4. TITLE AND SUBTITLE Quantification of the Benefits of Pendent Mammography				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER DAMD17-01-1-0650	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Catherine W. Piccoli, M.D. E-Mail: cwpiccoli@aol.com				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Thomas Jefferson University Philadelphia, PA 19107				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT: The purpose of this study was to test the benefits of pendent mammography by imaging women and acquiring both conventional (erect) and pendent mammograms. We performed quantitative analysis of the mammograms, to determine the effect of leaning on the amount of breast tissue imaged, the compression obtained, and the dose to the breast. Additionally, we assessed the preferences of radiologists for pendent images as compared to erect positioned images. Our hypothesis was that pendent mammography provided superior images since gravity fro leaning forward aids in pulling the breast away from the body, thereby increasing the amount of retroglandular breast tissue evident on a mammogram. Overall, we found that erect mammography was superior to pendent mammography, imaging more total breast tissue area and delivering a smaller radiation dose. Additionally, radiologists' preferences for the images, based on ACR criteria for clinical technical quality, were similar although they preferred the positioning with the erect mammography. While the findings from this study reject our initial hypotheses, it brings to light the problems with positioning the breast with pendent mammography.					
15. SUBJECT TERMS Breast Cancer, Mammography, Pendent Mammography					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	7	19b. TELEPHONE NUMBER (include area code)

Table of Contents

Cover.....	
SF 298.....	2
Table of Contents.....	3
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	7
Reportable Outcomes.....	7
Conclusions.....	7
References.....	7

Introduction

High quality mammographic images enhance the radiologist's ability to interpret mammograms. Image quality is dependent upon adequate visualization and inclusion of tissue, adequate exposure, contrast and resolution; and proper compression. Meeting these criteria is essential to detection of cancer, since 73% of cancers are located in the peripheral or retroglandular fat. Pendent mammography, is a procedure whereby the patient leans forward 15 to 25 degrees during mammography. The thought is that gravity aids in pulling the breast away from the body, thereby increasing the amount of retroglandular breast tissue evident on a mammogram. Thus, pendent mammography should simplify positioning making adherence to these criteria simpler and more frequent, as well as allowing better and less painful compression. There have been no published studies to quantify the benefits of pendent mammography. There was anecdotal evidence that pendent mammography provides superior images of the breast by including more tissue near the chest wall. In routine clinical practice at Thomas Jefferson University Hospital (TJUH) we believed that 0.5 to 1.0 cm of additional breast tissue was seen when pendent mammography was used. We also believed that it was more common to see the posterior margins of the glandular tissue when pendent mammography was used over the erect positioning. In this study, we tested the benefits of pendent mammography by imaging women and acquiring both conventional and pendent mammograms. We performed quantitative analysis of the mammograms, to determine the effect of leaning on the amount of breast tissue imaged, the compression obtained, and the dose to the breast. Additionally, we assessed the preferences of radiologists for pendent images as compared to erect positioned images.

Body

Statement of Work

- 1) Develop a detailed clinical trial protocol, applicable forms, etc.
- 2) Enroll and image 250 women with both pendent and erect mammography
- 3) Perform a reader study of the resultant images
- 4) Perform a physical analysis of the resultant images
- 5) Perform a statistical analysis
- 6) Report results

1) Develop a detailed clinical trial protocol, applicable forms, etc.

An open-label, non-randomized trial was designed to be conducted at Thomas Jefferson University Hospital Jefferson Breast Screening Center (BSC), which houses an imaging system that is capable of pendent mammography. The BSC exclusively performs screening studies, and thus excluded women who have experienced problems with their breasts (e.g., pain, nipple discharge, surgery, breast augmentation, pregnancy, etc.), and women less than 35 years of age. The protocol was designed to have all subjects undergo both a clinically indicated standard erect screening mammogram and a research pendent mammogram with CC and MLO views of both breasts.

2) Enroll and image 250 women with both pendent and erect mammography

Fifty-one patients were enrolled in the study after giving informed consent, with the first patient being enrolled on July 30, 2003. The population consists of 36 Caucasian females, 12 African-American females, 2 Asian females, and 1 Hispanic female. Ages of the subjects ranged from 30 to 88, and are summarized below.

<u>AGE</u>	<u># subjects</u>
30 – 39	3
40 – 49	17
50 – 59	17
60 – 69	11
70 – 79	2
80 – 89	1

We fell short of our goal of enrolling 250 patients, due to logistic problems in the BSC. Additionally, more patients than we anticipated did not want to participate in the study. All patients tolerated the study procedures well and there were no adverse events. There were no withdrawals from the study.

3) Perform a reader study of the resultant images

Subjective analysis was performed to assess technical quality according to the criteria of ACR mammographic accreditation. The erect and pendent studies were reviewed retrospectively by three radiologists to determine the clinical benefits of the pendent mammography. This evaluation involved a direct comparison of the erect and pendent mammograms for the same patient. The erect and pendent studies were hung on an 8-panel viewbox with either the erect or pendent study randomly assigned to the upper panels. The radiologists were blinded to the patient position and patient information, by applying black tape to the identification region of each film. The films of each method were randomly assigned a letter A or B. The radiologists were asked to state their preference for each film in terms of the ACR criteria for clinical technical quality, namely

- 1) Compression
- 2) Exposure
- 3) Contrast
- 4) Sharpness, and
- 5) Noise

The radiologists were also asked which method (A or B) produced the best overall image quality for the study, and the best depiction of the clinical content. The data will be recorded on a protocol specific case report form.

4) Perform a physical analysis of the resultant images

The pendent and non-pendent mammograms were digitized in the x-ray imaging physics laboratory at the University of Pennsylvania under the direction of Dr. Andrew Maidment. Software was developed to analyze the images in terms of: 1) shortest distance from nipple to chest wall edge of film (CC); 2) distance from nipple to chest wall (orthogonal to pectoral muscle – MLO); 3) length of axillary tail (MLO); 4) area of breast in the image; 5) area of the glandular tissue in the image; and 6) area of the pectoral muscle in the image. In addition, we recorded kVp, mAs, compressed breast thickness, compression force, tilt angle and rotation angle. Mean glandular dose was estimated from the kVp, mAs and the physical characteristics of the x-ray unit.

5) Perform a statistical analysis

The primary objective of this study was to demonstrate that pendent mammography results in improved diagnostic mammographic images.

The hypotheses were:

H₁: Mammograms acquired in a pendent position result in significantly more breast tissue being imaged than conventional mammograms acquired with the patient erect.

H₂: Mammograms acquired in a pendent position result in better compression of breast tissue than conventional mammograms acquired with the patient erect.

H₃: Mammograms acquired in a pendent position result in a smaller dose of radiation to the patient than that required for conventional mammograms acquired with the patient erect.

The data was analyzed statistically to determine whether in the pendent images: (H₁) more breast tissue is visible; (H₂) the breast is better compressed; and (H₃) the dose of radiation is lower. Pairwise comparisons were performed using linear models to test all hypotheses.

6) Report results

The hypotheses for this study were based on the theory that by having the patient lean forward 15 to 25 degrees during mammography, gravity would aid in pulling the breast away from the body, thereby increasing the amount of retroglandular breast tissue imaged and simplifying positioning. However, our analysis revealed that erect mammography is superior to pendent resulting in the total area of tissue being imaged and exposure to a smaller radiation dose. Although the length of pectoralis muscle was greater with erect imaging in our study, the width was greater with pendent, resulting in the total area of pectoralis muscle imaged being greater with pendent positioning, although not statistically significant. All other physical characteristics were superior on erect imaging, with statistically significant difference at an alpha-level of 0.05 detected for all except rotational angle and kVp. When a Bonferroni correction for multiple comparisons is applied, bringing the alpha-level to 0.004, erect mammography is statistical significance for compressed breast thickness, width of breast in image, length of axillary tail in image, and length of pectoralis muscle in image. The pendent positioning remains statistically significant for the width of pectoralis muscle in image.

<u>Mean and standard deviation of physical characteristics</u>			
	<u>Erect</u>	<u>Pendent</u>	<u>p-value</u>
Rotational Angle	23.77 (22.65)	24.28 (23.76)	0.06
kVp	29.30 (1.94)	29.34 (2.05)	0.41
mAs	140.15 (64.74)	145.23 (64.78)	0.03
Mean glandular dose	300.12 (174.02)	314.93 (180.82)	0.04
Compressed breast thickness	6.08 (1.13)	6.20 (1.20)	<0.01
Total area of breast in image	149.54 (46.24)	145.93 (44.75)	0.04
Width of breast in image	10.77 (2.27)	10.45 (2.23)	<0.01
Length of axillary tail in image	18.40 (1.94)	17.78 (1.90)	<0.01
Total area of pectoralis muscle in image	33.57 (13.68)	33.83 (12.72)	0.83
Length of pectoralis muscle in image	13.01 (2.53)	11.55 (2.37)	<0.01
Width of pectoralis muscle in image	5.08 (1.17)	5.67 (1.28)	<0.01
Shortest distance from nipple to chest wall	10.87 (2.10)	10.68 (2.09)	0.04

Our initial proposal also hypothesized that radiologists would subjectively prefer the pendent images to the erect, believing that the pendent imaging would simplify positioning, and thereby providing better image quality from better positioning. Based on a direct comparison of the erect and pendent mammograms for the same patient performed retrospectively by three blinded radiologists, there was no preference for erect imaging. The radiologists rated the clinical image quality to be similar in both the erect and pendent imaging. By conventional standards, the erect imaging was statistically significant for better positioning, yet when a Bonferroni correction is applied, bringing the alpha-level to 0.007, statistical significance is lost. Additionally, there was no statistical significance in the measurement of the distance from the nipple to the pectoralis muscle.

<u>Mean and standard deviation of clinical image quality</u>			
	<u>Erect</u>	<u>Pendent</u>	<u>p-value</u>
Position	0.31 (0.51)	0.24 (0.45)	0.03
Compression	0.07 (0.25)	0.06 (0.24)	0.89
Exposure	0.04 (0.19)	0.04 (0.20)	0.60
Contrast	0.05 (0.22)	0.04 (0.20)	0.51
Sharpness	0.05 (0.21)	0.04 (0.20)	0.74
Noise	0.04 (0.19)	0.03 (0.18)	0.85
Distance from nipple to pectoralis muscle	107.71 (21.15)	106.96 (20.76)	0.09

Key Research Accomplishments

- successful recruitment, enrollment, and imaging of 51 women with both pendent and erect mammography
- erect mammography positioning images more total breast area than pendent ($p=0.04$)
- erect mammography positioning delivers a smaller radiation dose than pendent ($p=0.04$)
- radiologists prefer positioning from erect mammography as compare to pendent ($p=0.03$)
- radiologists rated clinical image quality to be similar for erect and pendent mammography

Reportable Outcomes

There were no manuscripts, abstracts, or presentations based on the results obtained from this award.

Conclusion

Pendent mammography, a procedure in which the patient leans forward 15 to 25 degrees during mammography, was thought to increase the amount of retroglandular breast tissue evident on a mammogram. With no published studies to quantify the benefits of pendent mammography, it was assumed that to simplify positioning, allowing better and less painful compression and providing superior images of the breast by including more tissue near the chest wall. In this study, we tested the benefits of pendent mammography by imaging women and acquiring both conventional and pendent mammograms. Overall, erect mammography was found to be superior to pendent mammography, imaging more total breast tissue area and delivering a smaller radiation dose. Additionally, radiologists' preferences for the images, based on ACR criteria for clinical technical quality, were similar although they preferred the positioning with the erect mammography. While the findings from this study reject our initial hypotheses, it brings to light the problems with positioning the breast with pendent mammography. Future studies should be aimed at improving positioning on pendent mammography, to thereby take advantage of the potential benefits that may be possible with pendent mammography from gravity aiding in pulling the breast away from the body.

References

Not applicable