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TITLE: Outcomes by Ethnicity: Sentinel Lymph Node Status in Women with Breast Cancer

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14. ABSTRACT

It is well known by researchers that breast cancer incidence and outcomes (disease-free survival and overall survival) vary widely in women of different racial and ethnic backgrounds.1-2 Differences in health-seeking behaviors, socioeconomic disparities, cultural influences, stage at diagnosis, estrogen receptor status, treatment and tumor biology are all possible factors that could impact breast cancer outcomes for women of different racial and ethnic groups.2-6 What is not known is whether race and ethnicity affect lymph node status or if the value of promising new prognostic indicators currently under study, such as low molecular weight (LMW) cyclin E, is independent of race and ethnicity. Additional research is needed to determine how and why race and ethnicity impact breast cancer incidence and outcomes. This retrospective study seeks to further describe the differences in disease-free survival and overall survival by race and ethnicity for women with breast cancer. The study will aim to correlate Sentinel Lymph Node (SLN) status to race/ethnicity, cyclin E levels to race/ethnicity and SLN to cyclin E levels. Data for 375 women has been collected from two cohort groups. Unique data for a study-specific database include socioeconomic status, education and health-related behaviors. Data quality checks and abstraction are near completion. A final sample of 100 subjects, matched for as many factors as possible, will be equally divided into Whites/non-Hispanics and Others including Hispanics for analysis. If the prognostic accuracy of SLN status and cyclin E levels are independent of racial/ethnic factors as hypothesized, this suggests SLN status and cyclin E levels could discriminate outcomes across different racial/ethnic groups.

15. Subject Terms (keywords previously assigned to proposal abstract or terms which apply to this award)
Breast cancer, sentinel lymph node, cyclin E, race, ethnicity

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Outcomes by Ethnicity: Sentinel Lymph Node Status in Women with Breast Cancer

INTRODUCTION

It is well known by researchers that breast cancer incidence and outcomes (disease-free survival and overall survival) vary widely in women of different racial and ethnic backgrounds.[1-2] Differences in health-seeking behaviors, socioeconomic disparities, cultural influences, stage at diagnosis, estrogen receptor status, treatment and tumor biology are all possible factors that could impact breast cancer outcomes for women of different racial and ethnic groups.[2-6]

What is not known is whether race and ethnicity affect lymph node status or if the value of promising new prognostic indicators currently under study, such as low molecular weight (LMW) cyclin E, is independent of race and ethnicity. Additional research is needed to determine how and why race and ethnicity impact breast cancer incidence and outcomes. This retrospective study seeks to further describe the differences in disease-free survival and overall survival by race and ethnicity for women with breast cancer (Stages 0-IV).

BODY

Description of the Research

This award study aims to: (1) evaluate the relationship between race/ethnicity and sentinel lymph node (SLN) status in women diagnosed with breast cancer, (2) evaluate the relationship between race/ethnicity and high levels of LMW cyclin E in women diagnosed with breast cancer and (3) compare the predictive value of SLN status versus LMW cyclin E for women of different race/ethnicity who have been diagnosed with breast cancer.

During the initial award period, data has been collected for 375 women diagnosed with breast cancer who underwent sentinel lymph node biopsy (SLNB) with or without completion axillary lymph node dissection (ALND) as a component of their surgical management at the University of Texas MD Anderson Cancer Center (UTMDACC). Data was collected from existing databases and medical records abstraction.

The study's preliminary sample is comprised of women with breast cancer in cohorts referred to as Study Groups 1 and 3. Group 1 subjects were drawn from the ongoing lymphatic mapping database study (IRB# RCR01-309) and Group 3 subjects are participants in an ongoing prospective clinical trial studying cyclin E also at UTMDACC (IRB# LAB00-222). All subjects in the preliminary sample had cyclin E testing on their primary breast tumor tissue. Due to time and funding constraints, the P.I. will not pursue cyclin E testing for additional subjects from Group 1, proposed as an option in the approved Statement of Work (Tasks 4 e-g).

An additional cohort (Study Group 2) for the study includes 395 women diagnosed with breast cancer (stages I-IV) from a completed retrospective study entitled "Cyclin E and Survival in Patients with Breast Cancer." Subjects were not treated at UTMDACC and underwent surgical treatment for removal of the primary tumor as well as ALND. Sentinel node status is unknown. All subjects had LMW cyclin E testing on their breast tumor tissue. A complete data set regarding the subjects' age, race/ethnicity, lymph node status, adjuvant therapies and outcome has been imported and is available for analysis. These subjects were anonymous tissue donors treated in the United States whose identities are de-linked and no additional data is retrievable beyond what is currently archived.

Table A: Summary of Subject Population Group Data for Analysis.

Subject Population	**Race/ Ethnicity**	**Regional Node Status**	**Sentinel Node Status**	**Cyclin E Testing**	**Outcome**
Group 1 2100+ Subjects	✓	✓	✓	✳	✓
Group 2 395 Subjects	✓	✓		✓	✓
Group 3 375 Subjects	✓	✓	✓	✓	✓

✳ Some, not all, Group 1 subjects have cyclin E testing.

Sampling Considerations

A final sample of 100 subjects, matched for as many factors as possible, will be selected for descriptive analysis. The final sample will be divided into two (2) sub-groups: 50 Whites/non-Hispanics and 50 Others including Hispanics. The final sample will be comprised of subjects with the most complete data set; however, all data will be analyzed.

Possible biases in sampling and results have been previously identified. White/non-Hispanic women are diagnosed with breast cancer at an earlier stage of disease than women of other races/ethnicities including Hispanics. Stage at diagnosis and treatment delay are known factors affecting outcomes. The study's subjects will be those with cyclin E testing completed; therefore, most subjects are also LAB00-222 participants and socio-economic factors (income, access to care, education, etc.) may influence the decision to enroll in a research study as well as outcomes. In general, a greater percentage of research participants are Whites/non-Hispanics versus others. Patients at UTMDACC are predominantly White/non-Hispanic and thus, there is less access to individuals of other races/ethnicities. Finally, some subjects may have received 'different-era therapy;' that is, standard of care treatments may have changed over time thus altering outcomes.

Statement of Work Task Completion

Tasks 1 through 3 are completed. Tasks 4 & 5 are partially complete. Data collection and data quality checks have been more challenging and time-consuming than previously anticipated. These tasks must be viewed in the context of the more extensive data collection for UTMDACC's ongoing prospective study LAB00-222 from which the award study's data is derived. Similarly, laboratory procedures for LAB00-222 will provide the cyclin E score data for use in evaluating race/ethnicity and LMW cyclin E levels along with comparison of the predictive value of SLN status versus LMW cyclin E levels amongst the various races/ethnicities. The validation procedures to determine cyclin E scoring will begin June 2006 and are estimated to be completed by September 2006 per LAB00-222's P.I. It is fully expected that any data of interest collected for LAB00-222 may also be used for the award project. IRB-approved waivers for such use are on file. Data analysis and results reporting for publication (Task 6) cannot begin until Tasks 4 and 5 are fully achieved.

For these reasons, a one year no-cost extension was requested by the P.I. The extension was approved effective January 4, 2006 and extends the work period to April 22, 2007. The award study will benefit from the additional time because during this extension, all subjects will reach the 4-5 years after surgery milestone perhaps enhancing the data's significance.

Updated Scope of Data

Data queried from existing databases

- ~~UTMDACC medical record num~~ber (field MDACC)
- First name (field FName)
- Last name (field LName)
- Date of Birth (field DOB)
- Date of breast cancer diagnosis (field DOX)
- Age (field Age)
- Date entered on database (field Enterdate)
- Date of last follow-up (field LastFUdate)
- Bilateral breast cancer (field Bilateral)
- Clinical stage (field ClinicalStage)
- Pathology stage (field PathStage)
- Yes/No neo-adjuvant chemotherapy (field PreopChemo)
- Other malignancies (field OtherMalignancies)
- Type of other malignancies (field Othermalignanciestype)
- Other history of breast cancers (field OtherBreastCancers)
- Breast cancer recurrence (field Recurrence)
- Date of breast cancer recurrence (field Recurrencedate)
- Site of breast cancer recurrence (field Siterecurrence)
- Other site of breast cancer recurrence (field Othersite)
- Follow-up status (field FUStatus)

- Comments (field Comments)
- Lost to follow-up (field LOSTFU)
- Race/ethnicity (field Race)
- Estrogen receptor status (field ER_st)
- Progesterone receptor status (field PR_st)
- Her-2/neu status (field Her-2_st)
- Lymphovascular invasion on final pathology (field Final LVI)
- Date of sentinel lymph node pathology (field PBx_dt)
- Positive sentinel lymph node (field SLN Positive Histology)
- Positive non-sentinel lymph node (field NSLN Histology)

Unique data for study-specific database (uncoded)

- ~~Socio-economic status (field SE_st)~~
- Education level (field Educ)
- Breast self-exam performance (field BSE)
- Other health-related behaviors (field OtherHealthBeh)

Additional data collected since prior Annual Summary (uncoded)

- ~~Menopausal status (field meno_yn)~~
- Specific neo-adjuvant chemotherapy regimen (agent, course)
- Yes/No neo-adjuvant hormonal therapy
- Specific neo-adjuvant hormonal therapy regimen (agent, course)
- Yes/No adjuvant hormonal therapy
- Specific adjuvant hormonal therapy regimen
- Other adjuvant med. regimen (Tamoxifen, aromatase inhibitors, etc.)
- Yes/No adjuvant chemotherapy
- Specific adjuvant chemotherapy regimen (agent, course)
- Yes/No XRT
- Ki-67 (low, moderate, high)
- Ploidy
- Yes/No GCDFP-15 positive
- p53
- EGFR

Status of Data Preparation for Analysis

For Groups 1 and 3, additional data abstraction for missing data and/or verification of imported data is in progress for the fields reflecting nodal status in particular (Sentinel Node Positive Histology and non-Sentinel Node Positive Histology) in order to address the related study aims. Tables summarizing initial data tabulations for the preliminary sample (Groups 1 and 3, n=375) follow and indicate frequency of missing data. These tabulations are being crossed-checked for accuracy between the fields (for example, staging components). Assistance to contact subjects lost to follow up will be sought from UTMDACC's Medical Informatics department and the death index will be examined again. Data clean-up will accomplish the work for Tasks 4 and 5.

Data Summary Tables for Groups 1 & 3 (n=375)

Table 1: Race/Ethnicity (n=373, frequency missing = 2)

Race/Ethnicity	Frequency	Percent	Cumulative Frequency	Cumulative Percent
White	282	75.60	282	75.60
African American	22	5.90	304	81.50
Hispanic	35	9.38	339	90.88
Asian	19	5.09	358	95.98
Middle East descent	14	3.75	372	99.73
Other	1	0.27	373	100.00

Table 2-A: Clinical Staging[7] (n=375)

Clinical Stage	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0(T0,N0,M0)	1	0.27	1	0.27
0(Tis,N0,M0)	6	1.60	7	1.87
I(T1,N0,M0)	181	48.27	188	50.13
IIA(T1,N1,M0)	11	2.93	199	53.07
IIA(T2,N0,M0)	105	28.00	304	81.07
IIB(T2,N1,M0)	31	8.27	335	89.33
IIB(T3,N0,M0)	5	1.33	340	90.67
IIIA(T3,N1,M0)	9	2.40	349	93.07
IIIB(T4,N0,M0)	4	1.07	353	94.13
IIIB(T4,N1,M0)	9	2.40	362	96.53
IIIB(T4,N2,M0)	5	1.33	367	97.87
IIIC(Tx,N3,M0)	6	1.60	373	99.47
IV(Tx,Nx,M1)	1	0.27	374	99.73
Unknown	1	0.27	375	100.00

Table 2-B: Pathologic Staging[7] (n=375)

Pathologic Stage	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	7	1.87	7	1.87
I	128	34.13	135	36.00
IIA	94	25.07	229	61.07
IIB	38	10.13	267	71.20
IIIA	22	5.87	289	77.07
IIIB	3	0.80	292	77.87
IIIC	7	1.87	299	79.73
IV	1	0.27	300	80.00
Unknown	75	20.00	375	100.00

Table 2-C: Primary Tumor Size[7] (n=375)

T Stage	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Tis	7	1.87	7	1.87
T0	1	0.27	299	79.73
T1	175	46.67	182	48.53
T1mic	1	0.27	298	79.47
T2	102	27.20	284	75.73
T3	10	2.67	294	78.40
T4	3	0.80	297	79.20
Unknown	76	20.27	375	100.00

Table 2-D: Pathologic Node Classification[7] (n=375)

Pn Stage	Frequency	Percent	Cumulative Frequency	Cumulative Percent
pNX	3	0.80	3	0.80
pN0	4	1.07	7	1.87
pN0(i-)	188	50.13	195	52.00
pN0(i+)	10	2.67	205	54.67
pN1mi	27	7.20	232	61.87
pN1a	100	26.67	332	88.53
pN2a	30	8.00	362	96.53
pN3a	13	3.47	375	100.00

Table 2-E: Distant Metastasis[7] (n=375)

M Stage	Frequency	Percent	Cumulative Frequency	Cumulative Percent
M0	375	100.00	375	100.00

Table 3-A: Estrogen Receptor (ER) Status (n=373, frequency missing =2)

ER status	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Positive	276	73.99	276	73.99
Negative	87	23.32	363	97.32
Equivocal	1	0.27	364	97.59
Unknown	9	2.41	373	100.00

Table 3-B: Progesterone Receptor (PR) Status (n=373, frequency missing =2)

PR status	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Positive	232	62.20	232	62.20
Negative	122	32.71	354	94.91
Equivocal	9	2.41	363	97.32
Unknown	10	2.68	373	100.00

Table 3-C: Her-2/neu Status (n=373, frequency missing =2)

Her-2/neu Status	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Positive	64	17.16	64	17.16
Negative	264	70.78	328	87.94
Equivocal	28	7.51	356	95.44
Unknown	17	4.56	373	100.00

Table 4-A: Breast Cancer Recurrence (n=367, frequency missing =8)

Recurrence	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	32	8.72	32	8.72
No	334	91.01	366	99.73
Unknown	1	0.27	367	100.00

Table 4-B: Follow Up Status (n=367, frequency missing =8)

Follow Up Status	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Alive, Free of Disease	318	86.65	318	86.65
Alive, with Disease	22	5.99	340	92.64
Dead of Disease	16	4.36	356	97.00
Dead of Other Causes	5	1.36	361	98.37
Dead, Cause Unknown	6	1.63	367	100.00

Table 4-C: Active Follow Up Status versus Lost to Follow Up – Any Cause (n=367, frequency missing =8)

Lost to Follow Up	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Yes	47	12.81	47	12.81
No	320	87.19	367	100.00

Once completed, the data categories will be reviewed. The number of events was limited (for example 27/345 for Overall Survival) and the number of categories for some variables must be collapsed to increase the sample in each category. Cut-off points based on statistical analysis results are not reliable as they depend heavily on specific data and could be markedly different for another data set. In general, it is more easily accepted to establish cut-off points based on clinical knowledge and expertise. Therefore, the P.I. will collaborate with key breast research personnel (Mentor/study P.I., others) to establish these cut-off points.

To analyze data from study subjects who underwent ALND or for whom SLN status is unknown (Group 2 and others), our collaborating statistical analyst will construct a classifier (model) to predict SLN status based on other clinical factors. Such extrapolation has limitations and details of this tool will be addressed again in subsequent reporting.

Task 6 will begin with analysis of Groups 1 and 3 followed by inclusion of Group 2 data. The study aims should be accomplished by the end of the extended award period March 22, 2007.

KEY RESEARCH/TRAINING ACCOMPLISHMENTS

Research

Data analysis has not yet occurred; therefore, at this time there are no reportable scientific findings related to the study aims.

Training

- Collaboration at various levels with multi-disciplinary research team
- SEE Appendix A for continuing education during report period
- Career development: Advanced to Level III of RNDM (UTMDACC Research Nurse Development Model) and maintained requirements for certification as a clinical research coordinator

REPORTABLE OUTCOMES

- Study-specific database for unique study data will be generally available to other oncology researchers as authorized by UTMDACC.

- Abstracts and Posters:
  Hassett MA, Hunt KK, Keyomarsi K. Outcomes by Ethnicity: Sentinel Lymph Node Status in Women with Breast Cancer, Era of Hope Department of Defense Breast Cancer Research Program Meeting Proceedings, Philadelphia PA, June 8-11, 2005.

  Keyomarsi K, Hassett MA, Sahin A, Hunt K. Cyclin E, A Powerful Predictor of Survival in Breast Cancer – A Prospective Study, Era of Hope Department of Defense Breast Cancer Research Program Meeting Proceedings, Philadelphia PA, June 8-11, 2005.

- Presentation:
  June 16, 2005 at the University of Texas MD Anderson Cancer Center
  Audience: Department of Surgical Oncology Research Personnel
  Poster and meeting highlights from the Era of Hope Department of Defense Breast Cancer Research Program Meeting, Philadelphia PA, June 8-11, 2005.

CONCLUSIONS

Disease-free survival and overall survival rates cannot be determined for several years and thus may not be available during the award period. However, all subjects will have reached the important 4-5 years after surgery milestone at the study's end perhaps enhancing the utility of the data for continued study or future research projects. Within institutional guidelines, unique study data may be made generally available to oncology researchers.

Data analysis for a preliminary subject sample comprised of 375 subjects from 2 of the 3 study cohort groups is scheduled for July 2006. If the prognostic accuracy of SLN status and cyclin E levels are independent of racial/ethnic factors as hypothesized, this finding would suggest SLN status and cyclin E levels could discriminate outcomes across different racial/ethnic groups.

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Appendix A – Continuing Education (Start 3-23-05 to 3-22-06)

The University of Texas M.D. Anderson Cancer Center
- Skin-Sparing Mastectomy and Immediate Breast Reconstruction 3-3-06

The University of Texas M.D. Anderson Cancer Center
Nursing Professional Development & Education:
- Publishing Class 2-6-06

The University of Texas M.D. Anderson Cancer Center
Department of Surgical Oncology Grand Rounds:
- NSABP Sentinel Lymph Node Randomized Trial – Early Results 10-12-05

The University of Texas M.D. Anderson Cancer Center
Department of Surgical Oncology Research Nurse Team:
- Breast Protocol Database Roundtable with Johns Hopkins Medical Institute 11-21-05
- Electronic Medical Record (Clinic Station) 8-3-05

The University of Texas M.D. Anderson Cancer Center
Breast Center Clinical Research Conference:
- Ductal Carcinoma in Situ 6-17-05
- Breast Reconstruction and Post-mastectomy Radiation Therapy – Challenges and Opportunities 5-20-05

University of Nebraska Medical Center College of Nursing:
- Comprehensive Breast Cancer Management – Current and Emerging Treatment Strategies 4-18-05

Update in the Prevention and Treatment of DVT and PE: Factor XA Inhibitors 4-5-05

The University of Texas M.D. Anderson Cancer Center
Clinical Research Compliance:
- Protocol Management Model 1-27-06
- Introduction to the Institutional Tissue Bank 11-18-05
- Sponsor Audits 10-28-05
- Understanding Serious Adverse Event Reporting 5-19-06

The University of Texas M.D. Anderson Cancer Center
Department of Surgical Oncology
Fellows' Research Conference:
- Targeting Her2/neu & cyclin E in Breast Cancer Therapy 4-1-05

The University of Texas M.D. Anderson Cancer Center
Department of Surgical Oncology
Breast Group Research Symposium 3-31-05

The University of Texas M.D. Anderson Cancer Center
Cancer Therapy and Evaluation Program Workshop 3-31-05 to 4-1-05

Oncology Best Practices 2005 – Houston:
- Systemic Chemotherapy in Breast Cancer:
  Update from the San Antonio Breast Cancer Symposium 3-29-05

The University of Texas M.D. Anderson Cancer Center
Graduate Medical Education Core Curriculum Lecture Series:
- Introduction to Protocol Design 1-23-06
- Data Analysis 7-18-05
- Genomics 5-23-05
- Cell Cycle Regulation 3-28-05

Interdisciplinary Breast Cancer Journal Club:
- A Multigene Assay to Predict Recurrence of Tamoxifen-Treated, Node-Negative Breast Cancer 1-26-06
- Gene Profile Signature for Metastases to Lung and Bone 8-25-05
- Use of LMW Heparins in Cancer Patients 3-24-05

The University of Texas M.D. Anderson Cancer Center Breast Cancer Series:
- Bevacuzumab (Avastin) in Metastatic Breast Cancer 10-27-05
- Trastuzumab (Herceptin) Use in the Neo-adjuvant and Adjuvant Settings 9-29-05
- Update in the Management of Metastatic Breast Cancer 5-26-05
- Osteoporosis – Prevention and Treatment 5-5-05
- Complementary & Alternative Medicine (CAM) in Oncology Patients Part II 4-21-05
- Complementary and Alternative Medicine (CAM) in Oncology Patients Part I 4-7-05
- Biphosphonates in Breast Cancer 3-31-05