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13. ABSTRACT (Maximum 200 Words)

Lymphedema of the arm is a common, yet dreaded consequence of breast cancer treatment that can result in substantial functional impairment and distress in affected women. Axillary surgery and radiation treatment are known risk factors for lymphedema. However, other potentially modifiable characteristics or behaviors that may influence risk of this condition have not yet been studied. In this study, we will assess whether modifiable factors, including body weight, physical activity, smoking and breast reconstruction, influence risk of arm lymphedema among women treated for breast cancer. Women aged 21-74 years diagnosed with a first primary invasive breast cancer will be identified through a population-based cancer registry. Enrollment will be limited to women who have had axillary node dissection, as the occurrence of lymphedema is most common in these women. The incidence and timing of arm edema following breast cancer will be assessed using physical measures (arm volume) and self-report of symptoms, at regular intervals throughout the study. Each time they undergo arm measurement, women will complete questionnaires detailing and updating information on the exposures of interest and potential confounding factors. The study will be conducted over a 4-year period.

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MODIFIABLE RISK FACTORS FOR LYMPHEDEMA IN BREAST CANCER SURVIVORS

INTRODUCTION

Lymphedema of the arm is a common, yet dreaded consequence of breast cancer treatment that can result in substantial functional impairment and distress in affected women. Axillary surgery and radiation treatment are known risk factors for lymphedema. However, other, potentially modifiable characteristics or behaviors that may influence risk of this condition have not yet been studied. In this study, we will assess whether modifiable factors, including body weight, physical activity, smoking, and breast reconstruction, influence risk of arm lymphedema among women treated for breast cancer. Women aged 21-74 years diagnosed with a first primary invasive breast cancer will be identified through a population-based cancer registry. Eligible women will be residents of King County, Washington. We will include 500 women in the study cohort. Enrollment will be limited to women who have had axillary node dissection, as the occurrence of lymphedema is most common in these women. The incidence and timing of arm edema following breast cancer will be assessed using physical measures (arm volume) and self-report of symptoms, at regular intervals throughout the study (every 6 months for the first 18 months after study enrollment, and annually thereafter until the end of the study). Each time they undergo arm measurement, women will complete questionnaires detailing and updating information on the exposures of interest and potential confounding factors. The study will be conducted over a 4-year period.

BODY

Research Accomplishments associated with tasks outlined in the Statement of Work are as follows:

Task 1. Develop Plan for Initial and Follow-up Interviews and Measurements, Months 1-3.

a. Final IRB approval will be obtained.

IRB approval has been obtained from the Fred Hutchinson Cancer Research Center and from the DOD.

b. Tracking system will be created to track patient contacts, recruitment, and interviews.

The tracking system for this study has been developed and is in use.

c. Cohort ascertainment through the CSS tumor registry will be initiated.

We are actively identifying potential study participants through the CSS tumor registry. Case-finding through the registry is updated every month.

d. Enrollment questionnaire will be developed, piloted and finalized.

The enrollment questionnaire has been developed, piloted and finalized. It is now in use.

e. *Interviewer will be trained on study procedures, measurement, and interview administration.*

Interviewer training on all study procedures, including measurement and interview administration, has been completed.

Task 2. Subject Recruitment and Initial Data Collection, Months 4-18
The funding period for this study began on October 1, 2002. The DOD approval to involve human subjects in the research was received in April, 2003. Hence, we did not begin activities related to Task 2 until May, 2003 (month 8) and anticipate that the subject recruitment period will be extended further into the study period than was originally planned.

a. Potential study subjects will be contacted, and physician notification will be performed.
These procedures are now ongoing. The first set of contacts with physicians and study subjects occurred after all Human Subjects were obtained in May, 2003. As of mid-August, 2003, we had identified 69 eligible women. The status of these women in the study is as follows:

Deceased:	1
Physican notification/ response in process:	14
Physician refusal:	5
Study subject refusal:	5
Subjects contacted, not yet enrolled:	27
Subjects contacted, enrollment interview scheduled:	8
Subjects contacted, enrollment interview complete:	8

b. Participant enrollment interviews and initial measurements will be conducted.
See part a, above. We have begun the enrollment interview and measurement procedures and as yet have completed 8 enrollment interviews.

c. Follow-up questionnaires will be developed, piloted and finalized.
The development of the follow-up questionnaire is currently in process.

d. Data management and programming to create analytic data files for the enrollment questionnaire and arm measurement data will be performed.
The first step of these procedures, i.e., development of the data entry system, is currently in process and nearing completion.

Task 3. Follow-up Interviews and Data Collection, Months 10-45
Because the first enrollment interview was not completed until June, 2003 (month 9), we will not begin conducting the follow-up interviews until month 15 (i.e., 6 months after a participant's enrollment interview). This is related to our not receiving Human Subjects approval until month 8, as described above.

Task 4. Data Analysis and Report Writing, Months 37-48.
These tasks will be conducted during the appropriate months of the study.

KEY RESEARCH ACCOMPLISHMENTS

To date, the accomplishments of this study include:

- Receipt of necessary Human Subjects approvals;
- Development of the enrollment questionnaire and methods for arm measurement;
- Development and implementation of the study tracking system;
- Development and implementation of methods for case ascertainment through the CSS tumor registry;
- Interviewer training;
- Initiation of all procedures for participant enrollment in the study.

REPORTABLE OUTCOMES

None to date.

CONCLUSIONS

In this early phase of the study, there are no completed research results.

REFERENCES

None

APPENDICES

None