BIOGRAPHICAL SKETCH

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NAME: Giuliano, Armando E

eRA COMMONS USER NAME (credential, e.g., agency login): giulianoae

POSITION TITLE: Chief, Surgical Oncology; Associate Director, Surgical Oncology, Cedars-Sinai Medical Center

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Fordham University, New York	BA	6/69	Pre-Medicine
University of Chicago, Illinois	MD	6/73	Medicine
University of California - San Francisco	Residency	6/76	Surgery
University of California - Los Angeles	Fellowship	6/78	Surgical Oncology and Tumor Immunology
University of California - San Francisco	Residency	6/80	Surgery

A. Personal Statement

I have over forty years' experience and interest in cancer research and have been involved on the national and international level in clinical and translational research. I have the expertise, leadership, knowledge and experience necessary to successfully perform research projects evaluating treatments for breast cancer. I have conducted prospective observational and randomized trials in the management of breast cancer and am institutional principal investigator for the Alliance for Clinical Trials in Oncology group. I have had papers selected as classics in breast cancer and the "best of the best" in cancer surgery. My experience in clinical research has taught me the conduct of clinical studies, the importance of protocol adherence and accurate data collection, and the practical and ethical considerations of human clinical experimentation.

1. Giuliano AE, Hawes D, Ballman KV, Whitworth PW, Blumencranz PW, Reintgen DS, Morrow M, Leitch AM, Hunt KK, McCall LM, Abati A, Cote R. Association of occult metastases in sentinel lymph nodes and bone marrow with survival among women with early-stage invasive breast cancer. JAMA 306(4): 385-93, 2011.
2. Giuliano AE, Ballman KV, McCall L, Beitsch PD, Brennan MB, Kelemen PR, Ollila DW, Hansen NM, Whitworth PW, Blumencranz PW, Leitch AM, Saha S, Hunt KK, Morrow M. Effect of axillary dissection vs no axillary dissection on 10-year overall survival among women with invasive breast cancer and sentinel node metastasis: The ACOSOG Z0011 (Alliance) Randomized Clinical Trial. JAMA 12;318(10):918-926, 2017.
3. Schnitt SJ, Moran MS, Giuliano AE. Lumpectomy margins for invasive breast cancer and ductal carcinoma in situ: Current guideline recommendations, their implications and impact. J Clin Oncol. 2020 Jul 10;38(20):2240-2245. doi: 10.1200/JCO.19.03213. Epub 2020 May 22.

B. Positions and Honors

Positions

1988 – 1991 Assistant Dean, Office of Student Affairs, UCLA School of Medicine, Los Angeles
1990 – 1991 Professor of Surgery, University of California, Los Angeles
1991 – 2011 Clinical Professor, Department of Surgery, UCLA School of Medicine
1991 – 2011 Chief, Surgical Oncology, John Wayne Cancer Institute (JWCI), Santa Monica, CA
1993 – 2011 Director of Breast and Endocrine Program and Director of the Breast Center, JWCI
2006 – 2011 Chief, Science and Medicine, JWCI
2011 – 2020 Executive Vice Chair of Surgery, Department of Surgery, Cedars-Sinai Medical Center (CSMC)
2011 – pres Chief, Surgical Oncology, Cedars-Sinai Medical Center
2011 – pres Associate Director, Surgical Oncology, Samuel Oschin Comprehensive Cancer Institute, CSMC
2011 – pres Program Director, Cedars-Sinai Medical Center Breast Oncology Fellowship
2012 – pres Program Director, Cedars-Sinai Medical Center Complex Surgical Oncology Fellowship

Other Experience and Professional Memberships

1998-2003 Executive Committee, American College of Surgeons – Oncology Group
1998-2003 Chair, Breast Organ Site Committee, American College of Surgeons – Oncology Group
2005 Consultant, Center for Drug Evaluation and Research, Food and Drug Administration
2005 Member, Oncologic Drugs Advisory Committee, Food and Drug Administration
2003-2011 Chairman, Breast Fellowship Program Directors Committee, Society of Surgical Oncology
10/2009-pres Member, Board of Persian American Cancer Institute (PACI)
2011-2013 President, International Sentinel Node Society
3/2013-3/2016 Secretary, Society of Surgical Oncology
2013-present Chair, Membership Committee, Society of Surgical Oncology
2014-present American College of Surgeons Board of Governors
3/2016-3/2017 Vice President, Society of Surgical Oncology
3/2017-3/2018 President-Elect, Society of Surgical Oncology
3/2018-3/2019 President, Society of Surgical Oncology

Honors

1991 Golden Scalpel Award for Teaching Excellence, Department of Surgery, UCLA School of Medicine
1996 Three M. Tyler Award for Outstanding Service
1996 Pathbreaker Award, The National Alliance of Breast Cancer Organizations
1997 The Best of the Best 1997 - Archives of Surgery
2001 Classic Papers - Journal of Clinical Oncology
2004 Maurice D. and Lois Schwartz Humanitarian Award, Center for Healthy Aging
2004 Outstanding Medical Advances in Breast Cancer - Sentinel Node Biopsy for Breast Cancer, National Summit on Breast Cancer
2005 Fellowship ad hominem of the Royal College of Surgeons of Edinburgh
2008 Umberto Veronesi Award - International recognition of contributions to field of breast cancer
2009 Honorary Member of the Brazilian Society of Surgical Oncology
2011 Susan G. Komen for the Cure® Brinker Award for Scientific Distinction in Clinical Research
2011 Glenn-Robbins Award, New York Metropolitan Breast Cancer Group, New York, NY
2011 Castle Connolly 2011 National Physician of the Year Award for Clinical Excellence
2011 Lynn Sage Distinguished Lecturer
2013 Society of Surgical Oncology James Ewing Lecturer
2014 American Society of Breast Surgeons, Keynote Address
2016 Impact Award, National Consortium of Breast Centers
2016 The American-Italian Cancer Foundation Prize for Scientific Excellence in Medicine
2018 OncLive Giant of Cancer Care® Award in Surgical Oncology
2019 Sociedad Espanola de Senologia y Patologia Mamaria Medalla de Oro (Gold Medal)

C. Contributions to Science

1. **Establishing the sentinel node concept and technique in the treatment of breast cancer**. In 1991, we began to investigate the role of sentinel node biopsy in the management of breast cancer. My colleague Don Morton had been working on establishing the technique for melanoma, and we began to investigate the safety and feasibility for the management of carcinoma of the breast. By investigating injection technique, timing of injection, location of injection, and tumor characteristics, we established a practical technique to identify sentinel nodes in breast cancer. Most importantly, we established the proof of principle by comparing sentinel lymph nodes evaluated with multiple sections and immunohistochemistry to entire axillary dissection lymph nodes similarly evaluated. In this study, we showed that regardless of the extent of non-sentinel node sampling, the sentinel node accurately predicted axillary status with high accuracy. When the sentinel node was tumor-free, all non-sentinel nodes would be tumor-free. The proof of principle has been widely referred to and clearly established the rationale and accuracy of the technique.

    a. Giuliano AE, Kirgan DM, Guenther JM, Morton DL. Lymphatic mapping and sentinel lymphadenectomy for breast cancer. Ann Surg 220(3):391-401, 1994.
    b. Giuliano AE, Dale PS, Turner RR, Morton DL, Evans SW, Krasne DL. Improved axillary staging of breast cancer with sentinel lymphadenectomy. Ann Surg 222(3):394-401, 1995.
    c. Giuliano AE, Jones RC, Brennan M, Statman R. Sentinel lymphadenectomy in breast cancer. J Clin Oncol 15(6):2345-2350, 1997.
    d. Giuliano AE, Ballman K, McCall L, Beitsch P, Whitworth PW, Blumencranz P, Leitch AM, Saha S, Morrow M, Hunt KK. Locoregional recurrence after sentinel lymph node dissection with or without axillary dissection in patients with sentinel lymph node metastases: Long-term follow-up from the American College of Surgeons Oncology Group (Alliance) ACOSOG Z0011 Randomized Trial. Ann Surg. 2016 Sep;264(3):413-20.

2. **Investigating Nodal Micrometastases in Breast Cancer**. With the increased use of sentinel node biopsy and enhanced histopathologic analysis, sentinel nodes were found to frequently contain micrometastases or isolated tumor cells detected usually with immunohistochemistry. Previous literature was controversial regarding the clinical relevance of these micrometastases. Numerous studies supported no clinical significance to the findings of these small clusters of tumor cells, and others showed decreased survival and increased breast cancer recurrence when micrometastases were detected in lymph nodes. We first performed a prospective institutional study evaluating the clinical significance of micrometastases in the sentinel node. This study showed no clinical relevance associated with this detection and was used as the basis for a prospective multi-institutional study supported by the NIH through the American College of Surgeons Oncology Group Protocol Z0010 entitled “A multicenter prognostic study of sentinel node (SN) and bone marrow (BM) micrometastases in women with clinical T1/T2 N0 M0 breast cancer.” As the author and principal investigator for this study, I supervised its conduct and analyzed its results. This prospective study, in which sentinel node findings were blinded to the patient and the clinician, showed micrometastases in lymph nodes have no clinical relevance whereas micrometastases in bone marrow, although unusual, may be significant. This study helped establish the omission of axillary node dissection for women with micrometastases or isolated tumor cells in the sentinel node and changed the surgical management of these patients.

    a. Giuliano AE, Kelemen PR. Sophisticated techniques detect obscure lymph node metastases in carcinoma of the breast. Cancer 83(3):391-393, 1998.

b. Chen SL, Hoehne F, Giuliano AE. The prognostic significance of micrometastases in breast cancer: A SEER population based analysis. Ann Surg Oncol 14(12):3378-84, 2007.
c. Hansen N, Grube B, Ye X, Turner R, Brenner J, Sim MS, Giuliano AE. The impact of micrometastases in the sentinel node of patients with invasive breast cancer. J Clin Oncol 27(28): 4679-84, 2009.
d. Giuliano AE, Hawes D, Ballman KV, Whitworth PW, Blumencranz PW, Reintgen DS, Morrow M, Leitch AM, Hunt KK, McCall LM, Abati A, Cote R. Association of occult metastases in sentinel lymph nodes and bone marrow with survival among women with early-stage invasive breast cancer. JAMA 306(4): 385-93, 2011.

3. **Changing the surgical treatment for patients with macrometastases in lymph nodes**. It had been assumed patients with lymph node macrometastases require axillary lymph node dissection for regional control and improved survival. However, an early study by the NSABP, Protocol B-04, showed extended local treatment did not impact survival. This study examined the role of radical mastectomy compared to less radical procedures. The management of axillary nodes was also investigated but often overlooked. The result of this study showed no value to treatment of axillary lymph nodes either with irradiation or with resection. These findings were overlooked in part because of the introduction of adjuvant systemic therapy for high-risk node-positive women. Over the years the choice of systemic therapy became more frequently based on tumor factors such as estrogen/progesterone receptors and HER2 overexpression, rendering axillary nodal status of less prognostic significance. For this reason, I designed and conducted American College of Surgery Oncology Group Protocol Z0011, "A randomized trial of axillary node dissection in women with clinical T1-2 N0 M0 breast cancer who have a positive sentinel node." This study was a prospective randomized multi-institutional study where women with hematoxylin-and-eosin-detected sentinel node metastases were randomized to axillary dissection or no axillary dissection. Adjuvant systemic therapy was based on tumor factors and the patient's medical condition. This study showed statistically significant non-inferiority for the omission of axillary lymph node dissection and changed the paradigm of the surgical management of patients with early metastatic breast cancer at major institutions worldwide.

a. Giuliano AE, Haigh PI, Brennan MB, Hansen NM, Kelley MC, Ye W, Glass EC, Turner RR. Prospective observational study of sentinel lymphadenectomy without further axillary dissection in patients with sentinel node-negative breast cancer. J Clin Oncol 18(13):2553-2559, 2000.
b. Grube BJ, Giuliano AE. Observation of the breast cancer patient with a tumor-positive sentinel node: Implications of the ACOSOG Z0011 trial. Semin Surg Oncol 20(3):230-237, 2001.
c. Guenther JM, Hansen NM, DiFronzo LA, Giuliano AE, et al. Axillary dissection is not required for all patients with breast cancer and positive sentinel nodes. Arch Surg 138(1):52-6, 2003.
d. Giuliano AE, Ballman KV, McCall L, Beitsch PD, Brennan MB, Kelemen PR, Ollila DW, Hansen NM, Whitworth PW, Blumencranz PW, Leitch AM, Saha S, Hunt KK, Morrow M. Effect of axillary dissection vs no axillary dissection on 10-year overall survival among women with invasive breast cancer and sentinel node metastasis: The ACOSOG Z0011 (Alliance) Randomized Clinical Trial. JAMA 12;318(10):918-926, 2017.

Complete List of Published Work in MyBibliography:

https://www.ncbi.nlm.nih.gov/myncbi/10_9xMIW6BdAD/bibliography/public/

D. Additional Information: Research Support and/or Scholastic Performance

ACTIVE SUPPORT:

W81XWH-18-1-0058

(GRANT12427492, DOD Breakthrough Award, awarded) Tanaka (PI)
04/01/2018-03/31/2021
Title: DNA palindrome as a novel tumor marker in extracellular vesicles from liquid biopsy
The ultimate goal of our project is to develop a novel, highly sensitive assay to identify tumor-specific chromosome aberrations in plasma from liquid biopsies in women with very early stages of breast cancer. To accomplish the goal, we will apply our method to enrich a form of structurally aberrant DNA (DNA palindromes)
Role: Collaborator

NIH/NCI R01CA151610 Cui (PI) 02/14/11 - 01/31/23
Title: The Role of FOXC1 in Basal-like Breast Cancer
The major goal of this project is to examine the signaling pathways induced by FOXC1 and to uncover the biological basis for the cellular traits and phenotypes of basal-like breast cancer.
Role: Collaborator

DOD/BCRP W81XWH-18-1-0067 Cui (PI) 04/01/18-03/31/21
Title: Modeling Estrogen-Induced Genomic Alteration in BRCA1-Mutant Mammary Cells Using iPSCs
The goal of this study is to determine how estrogen affects genomic changes in derived normal breast cells and tissue to uncover the genetic mechanisms and hallmarks for BRCA1mut-specific effects on breast cancer development.
Role: Collaborator

R01 CA149385-06 (National Cancer Institute) Tanaka (PI) 09/01/2018- 08/31/2022
Title: Mechanisms of genomic amplification in human cancer
Our long-term goal is to control aggressive tumors by elucidating genomic amplification mechanisms. Results from our project may reveal that oncogene amplification is driven not only by a fitness advantage delivered from activated oncogenes but also by a specific interaction between local genomic context and amplification mechanisms. Such results will provide a novel direction in cancer susceptibility research and previously undefined therapeutic targets against aggressive tumors.
Role: Collaborator

AFT-025(COMET): Comparison of Operative to Monitoring and Endocrine Therapy (COMET) Trial for Low Risk (DCIS: A Phase III Prospective Randomized Trial
Alliance Foundation Trials, LLC
Purcella Jennings pjennings@partners.org 7/10/2017 – 4/13/2021
Goals: This study looks at the risks and benefits of active surveillance (AS) compared to guideline concordant care (GCC) in the setting of a pragmatic prospective randomized trial for low risk DCIS. Our overarching hypothesis is that management of low-risk Ductal Carcinoma in Situ (DCIS) using an AS approach does not yield inferior cancer or quality of life outcomes compared to GCC.
Role: Institutional Principal Investigator

ACOSOG Master Agreement
American College of Surgeons Oncology Group
Sylvia Hrbek shrbek@alliancectn.org 12/1/2011 – 2/28/2021
Budget based on patient accrual
Goals: Master agreement for the participation of the institution in ACOSOG clinical trials. Multiple studies roll up under this master agreement and are tracked separately.
Role: Institutional Principal Investigator – Effort as needed (clinical trial)