**Title: Perspectives on geriatric oncology research presented at the 2019 San Antonio Breast Cancer Symposium**

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## 1. Introduction

The 2019 San Antonio Breast Cancer Symposium (SABCS) brought together an international audience of researchers and healthcare professionals to discuss the latest in breast cancer research. This year we saw much progress with practice-changing trials that could mean better treatment for patients with breast cancer. Here, we highlight research which we consider having the highest relevance to Geriatric Oncology.

## 2. Geriatric oncology specific research

Two presentations focused on treatment for early-stage breast cancer in older adults.

In an oral presentation, Cardoso and colleagues on behalf of the Microarray in Node-Negative and 1 to 3 Positive Lymph Node Disease May Avoid Chemotherapy (MINDACT) investigators evaluated the impact of integrating age with clinical and genomic risk to guide clinical decision-making in adjuvant chemotherapy in early luminal breast cancer.[1] MINDACT was a randomized phase III study that enrolled 6,693 women with early breast cancer and classified their genomic risk utilizing the 70-gene signature, comparing this to their corresponding clinical risk as determined by a modified version of Adjuvant! Online. In patients with high clinical (CH) risk but low genomic (GL) risk, there was no statistical difference in the 5-year distant metastases free survival (DMFS) in those receiving adjuvant chemotherapy versus those who did not (94.5% versus 95.9% respectively). In this retrospective, exploratory, unplanned sub-group analysis, 452 and 865 estrogen receptor (ER)-positive human epidermal growth factor receptor 2 (HER2)-negative patients aged ≤50 and >50 years respectively were identified CH/GL; approximately 50% of patients in each group received adjuvant chemotherapy. All received adjuvant endocrine therapy thereafter. In patients ≤50 years, there was a 3% absolute difference in DMFS favoring the receipt of adjuvant chemotherapy (96.1% versus 93.1% respectively). In those aged >50 years there was no DMFS difference in the adjuvant chemotherapy versus the no adjuvant chemotherapy group (95.2% versus 95.4% respectively). Although underpowered, this subgroup analysis suggests that adjuvant chemotherapy, may

potentially be avoided in patients aged >50 years with a node positive (1-3 nodes) or node negative CH/GL ER-positive HER2-negative early breast cancer.

In a poster discussion, Sedrak and colleagues investigated factors associated with decreased relative dose intensity (RDI) in older adults with Stage I-III HER2-negative early breast cancer receiving neo/adjuvant chemotherapy.[2] In this prospective multicenter cohort trial, 321 patients aged ≥65 years underwent a pre-chemotherapy clinical assessment (CA) and geriatric assessment (GA). CA included sociodemographic, laboratory, tumor and treatment variables, whilst GA included functional status, comorbidity, cognition, psychological state, social activity and support and nutritional status. A decreased RDI was defined as <85%. A bivariate regression and stepwise selection were utilized to identify independent variables associated with decreased RDI. 79.5% received neo/adjuvant chemotherapy at the optimum RDI, with majority receiving either anthracyclines (46%) or docetaxel/cyclophosphamide (47%). Significantly more patients developed grade 3-5 toxicities and were hospitalized if they received a RDI >= 85% (p<0.001). Factors associated with decreased RDI were stage II & III (odds ratio [OR] 2.14, p=0.04), presence of heart disease (OR 2.50, p=0.03), Anthracycline and CMF regimens (OR 2.76, p=0.002) and Karnofsky Performance Scores (PS) <90 (OR 5.50, p<0001). This study highlights the need for further research investigating the relationship between decreased RDI on outcomes in older patients and alternative adjuvant chemotherapy dosing strategies that would better suit older patients.

## 3. Research relevant to older patients

### *3.1 New treatment paradigms for advanced HER2-positive breast cancer.*

The HER2CLIMB study presented by Murthy et al randomized 612 patients with advanced HER2-positive breast cancer previously treated with trastuzumab, pertuzumab and trastuzumab emtansine (T-DM1) to either tucatinib or placebo in combination with trastuzumab and capecitabine.[3] Interestingly, 47.5% of the overall cohort had brain metastases at baseline. Although no geriatric assessments were included in the study, 20.0% of patients assigned to the experimental arm were aged 65 years and older. The study documented a statistically significant benefit in 1-year progression-free survival (PFS) rate up to 33.1% in the experimental arm versus

12.3% in the control arm (hazard ratio [HR] for disease progression or death 0.54: 95% confidence interval [CI] 0.42-0.71) and in 2-year overall survival (OS) rate up to 44.9% versus 26.6% respectively (HR 0.66; 95% CI 0.50-0.88) which were maintained in the cohort with secondary brain involvement. Nonetheless, 80.9% of patients in the combination arm experienced any grade of diarrhea (which was grade 2 in 24.8% and grade 3+ in 12.9% of patients): since low-grade toxicities may be quite impactful in older patients,[4] these findings suggest that in this age group patients should be carefully selected for this regimen.

The use of trastuzumab deruxtecan (T-Dxd) was evaluated in the phase 2 DESTINY-Breast01 in 253 patients who had a median number of 6 lines of palliative therapy including T-DM1.[5] In this heavily pre-treated cohort, 60.9% of patients reported at least partial responses with a median duration of response (DOR) of 14.8 months. Despite patients aged up to 96 years were included and the treatment was recently approved by the Food and Drug Administration (FDA) in the United States,[6] no age-specific data were provided. 13.6% experienced any grade of interstitial lung disease which caused death in 2.2% and raises concerns about the feasibility of this treatment in a potentially more frail population of patients.

### *3.2 Controversial role of immunotherapy in the curative setting.*

The NeoTRIPaPDL1 Michelangelo trial presented by Gianni et al[7] questions further the role of immunotherapy agents in the curative setting. In a cohort of patients with cT1N1/T2N1/T3N0 or locally advanced, triple-negative disease randomized to carboplatin/nab-paclitaxel with or without atezolizumab, immunotherapy did not improve rates of pathological complete response (pCR), in clear contrast with the KEYNOTE-522 study previously presented this year.[8] Also, serious adverse event and transaminasemia rates were higher in the atezolizumab arm in the intention-to-treat (ITT) population. This trial enrolled patients aged up to 79 years, which obviously makes the role of immunotherapy even more uncertain in this age group and in a curative setting.

### *3.3 Validity of radiotherapy de-escalation for lower risk patients.*

Meattini et al presented the 10-year follow-up results of the randomized APBI IMRT Florence trial which confirmed that external accelerated partial breast irradiation (APBI) is a valid approach to treat low-risk patients following breast conserving surgery

(BCS).[9] The study randomized 520 patients aged over 40 years with node-negative tumors smaller than 25mm and clear surgical margins to APBI (30Gy in 5 non-consecutive fractions) versus conventional fractionation whole breast irradiation (WBI), involving 50Gy in 25 fractions plus 10Gy boost. More than one fifth of patients were aged over 70 years. On APBI there were low rates of ipsilateral breast, locoregional and distant recurrences which did not differ compared with patients receiving WBI and similar survival outcomes. However, toxicities favored PBI which confirms that this is a very appropriate strategy to de-escalate locoregional treatments in an older population of patients.

### *3.4 No role for de-escalation of breast-conservation based on response to neoadjuvant therapy.*

Basik et al reported the findings of the NRG-BR005 study which evaluated the accuracy of image-directed tumor bed biopsies in predicting pCR in patients with clinical and radiological complete response after neoadjuvant chemotherapy, which would be an appealing strategy to de-escalate surgical approaches.[10] The study included 98 evaluable patients with cT1-3, stage I-IIIA tumors and imaging involved mammography, ultrasound and magnetic resonance. Thirty-six patients were found to have residual invasive or non-invasive disease at surgery and therefor the addition of biopsy to tri-modality imaging assessment did not achieve the cut-off of negative predictive value of 90% chosen *a priori*. These findings do not support the omission of surgery here although more research is warranted on this topic.

## 4. A focus on supportive care research

This year's symposium featured 41 sessions which included supportive and palliative care including toxicity, tolerability, and cost. Rocque et al analyzed the real world quality of life (QoL) evidence in 522 patients (median age 64y) with advanced HR+/HER2- breast cancer receiving palbociclib and reported a stable to improved QoL on the EORTC QLQ-C30 from baseline to 6 months on palbociclib.[11] Hershman et al highlighted the value of integrating patient reported outcomes (PROs) to improve adherence with long-term AI use based on 724 patients (median age 60.9y) enrolled on SWOGS1105.[12] Baseline factors associated with AI non-adherence at 36 months

were not age or race/ethnicity, but rather were baseline symptom burden (measured using validated PRO instruments), satisfaction with medications, and beliefs about medication, which may warrant a focused intervention to improve long-term AI adherence. Several studies on physical activity in breast cancer care included one characterizing the practices and barriers in Japanese oncology providers for physical activity promotion for survivors and another on supervised high intensity physical exercise during neoadjuvant chemotherapy.[13, 14] Finally, Dr. Eric Winer led the Conversations on Tough Topics Surrounding Cancer Care where he offered that most successful strategies often incorporate “listening, expression of empathy” as well as optimism.[15]

## 5. Posters relevant to older patients

The poster sessions included 33 presentations focusing on geriatric oncology related research which are summarized in Table 1. Research categories ranged from basic science to clinical trials, and topics covered included geriatric assessment, surgery, radiotherapy, and therapeutics.

## 6. Conclusions

Many innovative studies have been presented at the 2019 SABCS and we are excited to see the scientific community continue to improve the treatment of older adults with breast cancer. We are hopeful that continued efforts and commitment to high-quality research in Geriatric Oncology will enable us to change the landscape of precision cancer care for older adults with cancer.

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## Tables

### Table 1 - Geriatric oncology research presented at the SABCS 2019 Poster sessions.

| Abstract | Topic | Objective | Design | Demographics | Results |
|---|---|---|---|---|---|
| P2-08-15 Gulbahce et al | Epidemiology | Evaluate the Use of OncotypeDX, 21-gene recurrence score (RS) in women | Retrospective prospective cohort study (SEER registry data, 2004-15) | • 539,693 patients with ER+, stage I-III BC (Stage IV, T4 excluded)<br>• 20.35% had RS done<br>• ≥65yrs: 236,355 | • Fewer older patients had RS tested.<br>• Use of CT was associated with a lower risk of breast cancer specific death in women aged ≥65 with high risk RS (HR 0.63 (0.6, 0.67)) |
| P2-16-05 Kuemmel et al | Neoadjuvant chemotherapy | Evaluate response- and toxicity-guided NAC in older patients | Prospective multicenter study (WSG ADAPT older women sub-study) | • Planned sample size 150<br>• 83 patients aged ≥70yrs recruited<br>• Eligible Pts<br>- Oncotype RS >25 or 12-25 with a post ki67 >10% or cN2 disease<br>- Early TNBC | • Study underpowered due to sub-optimal recruitment<br>• pCR 23% in overall population<br>• Good tolerance and low toxicity of NAC<br>○ 15/459 AEs leading to treatment discontinuation<br>• 4/459 AEs due to febrile neutropenia |
| P2-14-03 Crozier et al | Adjuvant chemotherapy | Evaluate the efficacy of adjuvant CT in older women with early TNBC | Retrospective prospective PMS cohort study (NCDB Registry, 2004-2014) | • ≥70rs: 16,062 patients<br>• 7,485 (47.1%) patients received adjuvant CT | • Multivariate propensity score matched analysis showed adjuvant CT improved OS (HR 0.7 (0.61-0.8)), significance persisted even with stratification on LN status (LN-: 5-year OS 71 versus 74%; LN+: 5-year OS 35 versus 42%) |
| P2-14-04 Smith-Graziani et al | Adjuvant chemotherapy | Impact of delayed initiation of adjuvant CT in older patients | Retrospective prospective cohort study (SEER Data and TEXAS Cancer Registry Medicare databases, 2001-2013) | • ≥65yrs: 25,902 patients with localized or regional BC<br>• Median age: 71yrs<br>• Delayed chemo defined as ≥ 90 days after primary surgery | • CT delays occurred n 10.6% patients<br>• Delays were associated with statistically significant worse BCSS (HR 1.38 (1.24-1.52)) and OS (HR 1.32 (1.24-1.4)). |
| P2-14-08 Battisti et al | Adjuvant chemotherapy | Evaluate the interaction between systemic therapy use and toxicity and survival in older patients with EBC | Prospective multicenter UK Observational Study (2013-2018) | • ≥70yrs: 3649 patients with EBC<br>• 96.2% ECOG PS 0-1<br>• 20.2% impaired ADL | • 13.6% received adjuvant CT; 43.7% HER2+ BC patients received trastuzumab<br>• 68.95% with high risk disease and deemed fit based on geriatric parameters did not receive CT<br>• No difference in matched all-cause mortality and EBC mortality between adjuvant CT and no adjuvant CT groups. |
| P4-12-13 Zhang et al. | Radiotherapy | Analyze the effect of radiotherapy on survival in women with HR+ BC | Retrospective review | • >65yrs: 327 patients with stage I-II, HR+ BC with BCT | • Patients who received RT+HRT had better DFS, but similar OS. |

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| | | | | • 138 received RT+HRT<br>• 176 received HRT alone | • Patients with Luminal B-type tumors had improved OS when treated with RT+HRT. |
| P4-12-12<br>Waechter et al | Radiotherapy | Assess the efficacy and tolerance of exclusive radiotherapy for localized BC | Retrospective review | • 66 patients aged ≥70 who were treated with RT without surgery<br>• Median age 84.8. | • 5 year OS was 65.5%<br>• Age ≥80 and higher comorbidity index were related with survival. |
| P5-07-08<br>Wang et al. | Radiotherapy | Develop and validate a risk calculator to estimate the risk of local recurrence and mortality in older patients with EBC | Retrospective review | • 487 patients aged >65 with newly diagnosed stage I/II BC between 2001 and 2010 | • The outcome estimates projected by the tool were compatible with the observed estimates from real-world data.<br>• 5-year mortality: predicted 20% versus observed 16%, c-statistics 0.761<br>• 5-year local recurrence: predicted 3.9% versus observed 3.1%, c-statistics 0.775 |
| P3-14-02<br>Kashiwaba et al | Adjuvant treatment | Cohort study of patients with HER2+ BC who refused participation in the RESPECT RCT and were treated at physician discretion | Cohort study | • 123 older adults in the cohort<br>• 43% received adjuvant trastuzumab alone<br>• 30% received adjuvant trastuzumab + CT<br>• 27% did not get trastuzumab. | • 3 year DFS in the cohort was 89.3%.<br>• 3 year DFS in the RCT was 91.4%.<br>• DFS was improved in patients who got trastuzumab. |
| P2-18-04<br>Wei et al | Adjuvant therapy | Evaluate outcomes in older women with HR+, cN- EBC treated with adjuvant HRT +/- post lumpectomy RT | Single center retrospective cohort study (2005-2018) | • ≥65 yrs: 484 patients<br>• 92% did not receive adjuvant CT | • Older age & tumor size (>2cm) are risk factors for recurrence<br>• Older patients less likely to receive adjuvant therapy<br>• Omission of HRT & subsequent non-initiation of HRT associated with statistically significant higher risk of recurrence. |
| P4-05-08<br>Selenica et al. | Histopathology | Describe somatic mutations, mutational signatures, and mutations in HRD genes in primary and metastatic BC in older adults compared with younger individuals | Cohort study | • 290 older women.<br>• 290 younger adults. | • Older adults with primary BC had more mutations in *PIK3CA, NF1, MAP3K1* and *TBX3*, and less in *TP53* and *AKT1.*<br>• No differences in copy number alterations by age.<br>• BRCA2 alterations found at older ages in ER- patients. |
| P4-09-15<br>Chan et al | Histopathology | Investigate the PIK3CA mutation in different age groups | Cohort study | • Total 1281 patients with average age 62.9yrs | • PIK3CA mutation positivity rate: 37.5%<br>• Mutation rate increased with age:<br>  ○ 40s: 37.9%, 50s: 31.0%, 60s: 41.3%, 70s: 39.2%, 80s: 45.0% |
| P5-06-04<br>Sestak et al. | Prognostic factor | Investigate the prognostic value of EndoPredict (EPclin) and Oncotype | Retrospective review | • 928 post-menopausal women with ER+, Her2- BC<br>• <60yrs: 300 (32.3%) | • Both EPclin and RS were prognostic but with decreasing prognostic value with increasing age<br>• For age >70: |

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| | | Recurrence Score (RS) in different age groups | | • 60-70yrs: 377 (40.6%)<br>• >70yrs: 251 (27.1%) | ○ EPClin: significant prognostic ability (HR 2.02 (1.59-2.57))<br>○ RS: not significant (HR 1.22 (0.96-1.55))<br>• Tests that incorporate clinical parameters provide more prognostic value in older patients. |
| P1-19-10<br><br>Goetz et al | Advanced Disease-Therapy | Safety and Efficacy of Abemaciclib in patients ≥ 65yrs (subgroup analysis of MONARCH 2 &3) | Retrospective prospective exploratory subgroup analysis of two RCTs | • 699 patients from MONARCH 2<br>• 493 patients from MONARCH 3<br>• 3 age groups: <65yrs, 65-74yrs, ≥75yrs | • Efficacy in PFS similar in all subgroups<br>• Similar incidence of diarrhea in all age subgroups; G2-3 diarrhea higher in age ≥75 (45-55%)<br>• Grade 3/4 neutropenia similar across all age groups (18-25%) |
| P1-19-19<br>Annonay et al | Advanced Disease-Therapy | Comparison of treatments and outcomes in older women and younger women with HER2+ MBC | Retrospective cohort study | • French National Muliticentre Registry (2008-2016)<br>• 4045 women<br>• >70yrs: 814 (20.1%) | • Older patients received less 1st line treatment (76% versus 92.1%) and had poorer OS (2.9yrs versus 3.8yrs) |
| P6-11-07<br>Dabakuyo et al. | QoL | Compare HRQoL of older and younger EBC patients on CT | Multicenter prospective observational study | • Total 3079 patients<br>• Mean age at diagnosis: 53 years<br>• Aged ≥70: 7.3%<br>• Similar disease stage, histology, grade and Her2 status in aged <70 and ≥70 | • More deterioration in older women:<br>- Appetite loss: Mean difference (MD=9.65)<br>- Upset by hair loss (MD=16)<br>• Less deterioration in older women:<br>- Body image (MD=8.75)<br>- Dyspnea (MD= -6.98)<br>- Financial difficulties (MD= -7.08)<br>• No difference for the other dimensions |
| P1-17-09<br><br>Gervaso et al | Psychosocial & QoL | Evaluate the rate of CT-related cardiotoxicity and its relation to treatment discontinuation and outcomes. | Retrospective cohort study | • 128 patients aged ≥65yrs<br>○ 65-70yrs: 57 (44.5%)<br>○ 70-75yrs: 45 (35.2%)<br>○ >75yrs: 26 (20.3%) | • Cardiotoxicity in 14.8%<br>• 30% required dose reduction or discontinuation of adjuvant CT<br>• No significant difference in PFS or OS in related to dose reduction due to cardiotoxicities |
| P6-11-16<br><br>Nakayama et al. | Physicians' attitude | Investigate factors associated with physicians' attitude on treatment recommendations in older women with BC. | Survey on physicians | • 508 Japanese physicians responded to the survey, response rate: 30%<br>• 4 hypothetical cases with stage IIB BC (1 case aged 55, 3 cases aged 78) | • Physicians experience and belief affect their recommendations of treatment in older women with BC.<br>• Physicians who treated larger number of outpatients per day and those who had lower proportion of elder patients tended not to give CT in older patients with poorer PS and serious complications. |

*Abbreviations: AEs: adverse events; BC: breast cancer; BCSS: breast cancer specific survival; BCSD: breast cancer specific death; BCT: breast conservative surgery; CT: chemotherapy; cN-: clinical lymph node negative; DFS: disease free survival; EBC: early breast cancer; ER: estrogen receptor; HRD: homologous repair deficiency; HER2: human epidermal growth factor receptor 2; HR: hormonal receptor; HRQoL:*

*health related quality of life; HRT: hormonal therapy; LN: lymph node; MBC: metastatic breast cancer; NAC: neoadjuvant chemotherapy; OCSD: other cause specific death; OS: overall survival; pCR: pathological complete remission; PFS: progression-free survival; QoL: quality of life; RCT: randomized clinical trial; RT: radiotherapy.*

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