PRECISION IN BREAST CANCER & CARING FOR THE SURVIVOR

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• How we treat breast cancer 2018
  • Model of precision
  • Less is more
  • Honing in on tough subtypes
  • New frontier
• How do we care for women surviving after breast cancer
  • After math of therapy
  • Preventing Recurrence
  • Combatting side effects
  • Young women
FACTS

• 1 in 8 women BCA
• Incidence increases with age
• Greater prevalence in whites, blacks higher mortality
• Young women <40 make up 7% of BCA
• Men make up 1% of BCA
• 70% of BCA ER+
• Most women will go on to survive their cancer
MULTIDISCIPLINARY APPROACH

Comprised of radiologists, pathologists, radiation oncologists, medical oncologists, breast surgeons, genetic counselors, psychologists, & nurse navigators

• **Multidisciplinary clinic**
  • Clinical evaluation

• **Tumor board review**
  • Films
  • Pathology
  • Surgical approach
  • Chemotherapy/hormones
  • Radiation therapy
LOOKING BACK

ER+ Disease

Her2 Neu

Grade, proliferation % ER positivity

Multigene Molecular Subtyping

Next Generation Sequencing
MOLECULAR FINGERPRINT
ONCOTYPE DX

Intermediate Risk 18-30
Low Risk <18
High Risk ≥31

NSABP-B20: T1-T3, Node Negative, N1mic

PROLIFERATION:
Ki67 STK-15
Survivin Cyclin-B1
MYBL2

Estrogen: ER PR Bcl2 SCUBE2
HER2: GRB7 HER2

INVASION:
Stromelysin 3, Cathepsin L2

Proliferation:
Ki67 STK-15
Survivin Cyclin-B1
MYBL2

HER2:
GRB7 HER2

PROLIFERATION:
Ki67 STK-15
Survivin Cyclin-B1
MYBL2

Her2:
GRB7 HER2

GSTM1 BAG1 CD68

Reference:
Beta-actin GAPDH RPLPO GUS TFRC

SHIFT IN TREATMENT PARADIGM

• 37% change adjuvant treatment recommendations
• Observed shift: chemo & endocrine → endocrine alone
• 20-84% reduction in chemo use after RS from prior recommendation based on clinicopathologic tumor characteristics
• Spared long-lasting chemo effects
• Decreased financial burden

"We've found a mass. The good news is we have weapons of mass destruction."
• ER+ Tumors: Magnitude of chemo benefit?

• SWOG-8814: Post Menopausal Node (+) 1-3
  • RS low=NO benefit vs. RS high recurrence/death at 5yr

• NCCN: “consider” oncotype 1-3+ LN

• USA survey: > half of US physicians changed reccs after RS, reflecting a reduction in tx intensity
8TH EDITION: INCLUDES BIOLOGY!

- Two staging systems: TNM & Prognostic staging
- Prognostic staging includes ER, PR, Her2, grade & multigene panel analysis

**Table 8. Examples of Revisions to Breast Cancer Staging Using Biomarkers and Oncotype DX**

<table>
<thead>
<tr>
<th>T</th>
<th>N</th>
<th>M</th>
<th>G</th>
<th>HER2</th>
<th>ER</th>
<th>PR</th>
<th>SEVENTH EDITION ANATOMIC STAGE/PROGNOSTIC GROUP</th>
<th>EIGHTH EDITION PROGNOSTIC STAGE GROUP</th>
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<tbody>
<tr>
<td>Biomarkers</td>
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<td>–</td>
<td>IA</td>
<td>IIA</td>
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<tr>
<td>1</td>
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<td>3</td>
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<td>IA</td>
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<tr>
<td>3</td>
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<td>0</td>
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<td>+</td>
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<td>+</td>
<td>IIIA</td>
<td>IB</td>
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<tr>
<td>Oncotype DX recurrence score &lt; 11 for ER-positive tumors</td>
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<tr>
<td>2</td>
<td>0</td>
<td>0</td>
<td>Any</td>
<td>–</td>
<td>+</td>
<td>Any</td>
<td>IIA</td>
<td>IB</td>
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<tr>
<td>1-2</td>
<td>1</td>
<td>0</td>
<td>Any</td>
<td>–</td>
<td>+</td>
<td>Any</td>
<td>IIA/MIB</td>
<td>IB</td>
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<tr>
<td>0-2</td>
<td>2</td>
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<td>1-2</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>IIIA</td>
<td>IB</td>
</tr>
</tbody>
</table>

Abbreviations: –, negative; O+, positive; ER, estrogen receptor; G, grade; HER2, human epidermal growth factor receptor 2; M, metastasis classification; N, lymph node classification; PR, progesterone receptor; T, tumor classification.
## Table 3. Survival Outcomes of Patients With T1a,bN0 Breast Cancer, NCCN 2000-2009

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No Chemotherapy or Trastuzumab</th>
<th>Chemotherapy With or Without Trastuzumab</th>
<th>No Chemotherapy or Trastuzumab</th>
<th>Chemotherapy With or Without Trastuzumab</th>
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<tbody>
<tr>
<td></td>
<td>5-Year Estimate (%)</td>
<td>95% CI</td>
<td>Total No. of Events</td>
<td>5-Year Estimate (%)</td>
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<tr>
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<tr>
<td>HR-positive/HER2-negative</td>
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<tr>
<td>OS</td>
<td>96</td>
<td>90 to 94</td>
<td>96</td>
<td>96</td>
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<tr>
<td>BCSS</td>
<td>99</td>
<td>90 to 99</td>
<td>100</td>
<td>99</td>
</tr>
<tr>
<td>IDFS</td>
<td>96</td>
<td>96 to 96</td>
<td>41</td>
<td>96</td>
</tr>
<tr>
<td>DRFS</td>
<td>100</td>
<td>100</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>HR-positive/HER2-positive</td>
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<tr>
<td>OS</td>
<td>95</td>
<td>88 to 98</td>
<td>8</td>
<td>95</td>
</tr>
<tr>
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<td>96</td>
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<tr>
<td>DRFS</td>
<td>100</td>
<td>100</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>HR-negative/HER2-positive</td>
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<tr>
<td>OS</td>
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<td>DRFS</td>
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<td>80 to 96</td>
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<td>93</td>
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<tr>
<td>HR-negative/HER2-negative</td>
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<tr>
<td>OS</td>
<td>94</td>
<td>88 to 98</td>
<td>9</td>
<td>94</td>
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<tr>
<td>BCSS</td>
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<td>89 to 99</td>
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<td>IDFS</td>
<td>96</td>
<td>95 to 97</td>
<td>13</td>
<td>96</td>
</tr>
<tr>
<td>DRFS</td>
<td>93</td>
<td>94 to 97</td>
<td>10</td>
<td>93</td>
</tr>
</tbody>
</table>

**Abbreviations:** BCSS, breast cancer-specific survival; DRFS, distant relapse-free survival; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; IDFS, invasive disease-free survival; NCCN, National Comprehensive Cancer Network; OS, overall survival.
1 chemo drug
Paclitaxel
+ Trastuzumab
Vs.
Combination chemo drugs + Trastuzumab (ACTH or TCH)

APT Trial: ≤3cm tumors node (-) Her2neu (+)

LESS IS MORE

Outcome: Survival free from invasive disease at 3yrs

WHO ARE WE NOT DOWN-SIZING?

- TNBC- worst prognosis, high propensity for metastasis, least understood
- De-escalation for stage I may be reasonable however stage II & III not ready yet
- **WHO NEEDS MORE?**
- Response to Neoadjuvant Chemo: prognostic information!
- Absent PCR 10-20% risk of recurrent disease
- Interest in **escalating** therapy to improve outcome
CREATE-X TRIAL

Adapted from Soo Jung Lee's slides @SABCS 2015
Masuda et al. NEJM 2017
DEMystifying Triple Neg Ca

- **LAR**: Androgen receptor, Cell Surface Mucin (MUC1)
- **MES**: Growth Factor Receptor A (PDGF), C-KIT
- **BLIS**: Immunosuppressing molecule aka (VTGN1)
- **BLIA**: Stat signal transduction molecule & cytokines
**FUTURE PATHWAYS**

- Biclutimide (AR Antagonist) resulted in 19% 6mo clinical benefit rate
- Enzalutimide in bone-only MBCA showed clinical activity. Future combo w/ Taxol

**CK 4/6 Inhibition (Palbociclib): Those RB+ have 10-15% response**

- IGF1, Prostaglandin Inhibitors exist
- Pembrolizumab (anti programmed cell death ab) and VTCN1 antibody
- STAT inhibitors & anti CTLA-4 like Ipilimumab
HARNESSING IMMUNE SYSTEM

- Immune cells in microenvironment~ good prognostic indicator!
- Triple Neg & Her-2 neu enriched TILS
- Prognostic~ survival even in those not receiving chemotherapy (+/-) trastuz
- Predictive more robust response in those receiving chemotherapy

ON THE HORIZON - IMMUNE THERAPY

• Incorporation into prognostic models
• TIL count/gene signatures predictors for response to immunotherapy
• Met setting:
  • CTLA-4ab +Al= stable ds
  • Pembrolizumab/Avelumab/Atezolizumab: 19% rr in those with PDL-1 expression
  • Atezolizumab+abraxane 42% RR in triple neg
MOLECULAR EVOLUTION

Adapted from Dr. Nikhil Wagle’s slides DFCI symposium

Genomic Landscape of ER+ Metastatic Breast Cancer

Tumor Evolution: Transition to TNBC

2011:
- Diagnosed with metastatic disease
- Core biopsies
- Breast & liver

2011:
- Mastectomy & lymph node dissection

2015:
- glutathione mass biopsy

Tamoxifen/Lupron
Fulvestrant
ganetespib
Letrozole
PI3K
Capetitabine
Eribulin
Palbociclib
SERD
Taxol
Pembrolizumab

ER+ / PR+ / HER2-
- ESR1 WT
- RB1 WT
- PTEN WT
- CDH1 nonsense + LOH

ER- / PR- / HER2-
- ESR1 single-copy deletion
- RB1 nonsense + LOH
- PTEN homozygous deletion
- CDH1 nonsense + LOH

Adapted from Dr. Nikhil Wagle’s slides DFCI symposium
FOUNDATION TESTING & MATCH TRIAL

Evaluate for mutations

TRIAL MATCH

Trial #1

Trial #2

Trial #3
CELL-FREE DNA

- NEJM 2013: **CFDNA** vs. CTC vs. CA15-3
  - Detected at a greater frequency
  - Greater correlation to tumor burden
  - Earliest measurement of treatment response
- Future:
  - Monitor cancer burden & response to Tx
  - Non-invasive way to identify genomic alterations
- Shown beneficial in identifying ESR-1 mutations

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SURVIVING BREAST CANCER
HOT BUTTON TOPICS
AFTER THE STORM

- Peripheral edema
- Alopecia
- Hyperpigmentation
- Nail changes
- Fatigue
- Neuropathy
- Periods
RECURRENCE

Follow clinically & breast imaging, healthy living
  • No tumor markers, scans, labs
• Her2 neu/Triple Neg ds
  • 2-5 year window
• Hormone positive disease
  • Analogous ~chronic ds
  • Late relapse 20 yrs out
  • Endocrine back bone

Table 1: Risk of Distant Recurrence 10 to 20 Years After Diagnosis and Discontinuation of Endocrine Therapy at 5 Years

<table>
<thead>
<tr>
<th>Tumor Subgroup</th>
<th>10 Years</th>
<th>15 Years</th>
<th>20 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1N0</td>
<td>4%</td>
<td>9%</td>
<td>14%</td>
</tr>
<tr>
<td>T1N1 (1–3 nodes)</td>
<td>8%</td>
<td>15%</td>
<td>23%</td>
</tr>
<tr>
<td>T1N2 (4–9 nodes)</td>
<td>16%</td>
<td>30%</td>
<td>41%</td>
</tr>
<tr>
<td>T2N0</td>
<td>8%</td>
<td>14%</td>
<td>21%</td>
</tr>
<tr>
<td>T2N1 (1–3 nodes)</td>
<td>12%</td>
<td>20%</td>
<td>29%</td>
</tr>
<tr>
<td>T2N2 (4–9 nodes)</td>
<td>20%</td>
<td>35%</td>
<td>47%</td>
</tr>
</tbody>
</table>

HORMONAL THERAPY

BENEFITS
• Decrease risk of recurrence & improve survival in Invasive cancer
• Prevent contralateral cancer 50%
• Tam promotes bone health
• AI no endo CA or VTE risk

RISKS

Aromatase Inhibitors: Anastrazole
• Joint aches & stiffness (35%)
• Vaginal dryness
• Bone density loss (6-7%)
• Fracture risk (2.93% yearly, 11%)
• Mild hair thinning

SERM: Tamoxifen
• Hot flashes (35%)
• Vaginal discharge (13%)
• Endometrial Ca (0.8%)
• VTE (2-5%)

INCREASED MORTALITY WITH EARLY DISCONTINUATION/NON-ADHERENCE

Breast Cancer Res Treat. 2011 Apr; 126(2): 529–537.
TACKLING JOINT ACHES

• Most common reason for aromatase inhibitor discontinuation

Recommendations:

• **EXERCISE!!**
  • Reduction of arthralgia by 30% with exercise combination of strength training and aerobic at least 150 mins per week

• **Acupuncture**
  • 2x/wk for 6 wks, then 1x/wk for 12 improvement in msk symptoms compared to sham

• Vitamin D thus far no large benefit

• Glucosamine Chondroitin (tx vs. unblinided-?mod improvement in n=53)

• AI rotation

Irwin, M etal. J Clin Oncol; 2014
Hershman SABCS 2018-SWOG
VAGINAL DRYNESS

- Fissures, dyspareunia, UTIs
- Moisturizers, lubricants **First-line**
  - Liqui beads
  - Over-the-counter agents
  - Coconut, Avocado, olive oil
  - Replens weekly with taper
  - Vitamin E
- Estrogen preparations
• **Mayo clinic systematic review:** increased systemic estrogen levels with estrogen preparations

• **Am Coll of Obgyn Consensus 2018:** Not felt to increase risk of breast cancer recurrence

• Patient should be counseled on absorption & current consensus

• **AVOID** oral estrogen
SEXUAL HEALTH

• 64% of BCA survivors report reduced sexual desire & >50% long-term dysfunction
• Chemotherapy: greater sexual dysfunction lasting up to 5 years
  • Vaginal sequelae, lubrication, sexual pain, arousal, orgasm
  • Increased severity in younger women
• Vaginal atrophy therapy: lubricants, oils, replens
• Viscous Lidocaine to vulvar vestibule
• Vaginal Dilators
• Maintenance of sexual activity
• Pelvic physical therapy & prescribed devices
• Sexual health clinic

Carter et al. J Sex Med 2011; 8; 549-559
Burwell et al. J Clin Oncol 24:2815-2821
BONE LOSS

HUGE IMPACT ON QOL IN SURVIVORS!

Estrogen inhibits rank-ligand (promotor of osteoclastic activity)

- Premenopausal s/p chemo 3-8% BMD loss L-spine
  - Aromatase Inhibition & ovarian suppression in premenopausal=bone loss
- Post menopausal 1-10% loss of BMD s/p 1yr of chemo (limited data)
  - AI: Decrease BMD, increase fractures
  - Tamoxifen promotes stabilization in BMD

*ADJUVANT THERAPY TO TREAT BONE LOSS MOST STUDIED IN THIS POPULATION!

BONE MODIFICATION

- 2017 Meta-analysis: SOC Bisphosphonate
  - Zometa 4mg IV q6 mo
  - Post-menopausal women improve survival & reduce recurrence in bone
- ABCSG-18: Denosumab 60mg 2x/yr premenopausal BCA
  - Decreased risk of fracture (p=0.0001), improves bone health, no added toxicity
  - Improved DFS
BONE MODIFICATION

- **Benefits**: 50% decreaser fractures denosumab, DFS 2% at 5yrs, 3% 7-10yr, mortality 2-3% benefit
- **Risks**: MC joint, muscle aches, F/N (flu-like)
  - less common hypocalcemia (dose-adjusted), renal toxicity, 1% risk osteonecrosis of jaw
- ~2 years of therapy
- Monitoring: DEXA q 2 years on therapy
- Recommend: Vitamin D, Calcium in Diet, Weight bearing exercise, reduction of tobacco
- Improvement seen in BMD after therapy w/ similar rates of fractures to controls
HOT FLASHES

Improve w/ Time!

- Avoid Triggers: alcohol, caffeine, spicy food!
- Fan at bedside, decrease ambient temp
- Slow breathing
- Down pillow, moisture-wicking pajamas, sheets
- Dress in layers
- Exercise/stretching
- **NO** convincing evidence for: acupuncture, yoga, Chinese herbs, dong quai, evening primrose oil, ginseng, kava, soy or red clover extract
- **NOT** recommend phytoestrogens, black cohosh, or oral estrogen
- Meds: Venlafaxine, SSRIs, Gabapentin

www.cooljams.com  www.wickedsheets.com

Table 3. Major Drug Classes Divided by Known CYP2D6 Inhibition Activity

<table>
<thead>
<tr>
<th>Class</th>
<th>Moderate-to-Potent Inhibitors With Clear Demonstrated or Expected in Vivo Inhibition*</th>
<th>Weak-to-Moderate Inhibitors That Have Demonstrated or Could Potentially Have Some in Vivo Effect*</th>
<th>Alternative Drugs Expected to Have Little in Vivo Inhibition*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSRIM/NRIs</td>
<td>Paroxetine*</td>
<td>Sertraline*</td>
<td>Venlafaxine*</td>
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<tr>
<td></td>
<td>Fluoxetine*</td>
<td>Citalopram</td>
<td>Desvenlafaxine</td>
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<tr>
<td></td>
<td>Bupropion</td>
<td>Fluoxetine</td>
<td>Reboxetine</td>
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<td></td>
<td>Duloxetine</td>
<td></td>
<td>Escitalopram</td>
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<td>Tricyclic antidepressants</td>
<td>Clomipramine</td>
<td>Desipramine</td>
<td>Mirtazapine</td>
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<td></td>
<td>Doxepin</td>
<td>Imipramine</td>
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<td></td>
<td>Desipramine</td>
<td>Amitriptyline</td>
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<td>Imipramine</td>
<td>Amoxapine</td>
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<td></td>
<td>Amitriptyline</td>
<td>Nor-lortylax</td>
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<td>Antipsychotics</td>
<td>Thioridazine</td>
<td>Chlorpromazine</td>
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<td>Perphenazine</td>
<td>Phentolamine</td>
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<td></td>
<td>Pimozide</td>
<td>Haloperidol</td>
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<td>Cardiac medications</td>
<td>Clofibrate</td>
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<td>Ticlopidine</td>
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<td>Olanzapine</td>
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<td>Ticlopidine</td>
<td>Olanzapine</td>
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<tr>
<td>Medications for Infectious diseases</td>
<td>Tobramycin</td>
<td>Thalidomide</td>
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<td></td>
<td>Gentamicin</td>
<td>Mitomycin</td>
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<td>Tetracycline</td>
<td>Hydroxychloroquine</td>
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<td>H2 blockers</td>
<td>Cimetidine</td>
<td>Ranitidine</td>
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<td>H1 blockers</td>
<td>Clemastine</td>
<td>Diphenhydramine</td>
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<tr>
<td>Miscellaneous medicines</td>
<td>Cisapride</td>
<td>Cetirizine</td>
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</tr>
</tbody>
</table>

ASCO Clinical Practice Guidelines:

- Despite accumulating evidence of drug-drug interactions, the data remains LIMITED & INDIRECT linking the interactions.
- Those with clear benefit from CYP2D6 drugs may want to avoid Tam bc of potential Pharm interactions & vice versa.
GYNECOLOGIC HEALTH ON TAMOXIFEN

• Agonist at endometrium=proliferation, hyperplasia, polyp formation, invasive carcinoma, sarcoma

• Risk in postmenopausal ONLY

• Consensus statement: Does **NOT** recommend a screening endo u/s unless high risk (ie. hx of polyps, fam hx)
  • Gynecologic yearly monitoring for hyperplasia, uterine bleeding
  • GYN f/u if vaginal bleeding
  • Reconsider Tamoxifen if atypical hyperplasia on drug

• Premenopausal patients:
  • Break-through bleeding
  • Recommend birth control (ie. Condoms, copper IUD)

ACOG committee opinion 2017 revised
PREVENTION

• Alcohol <3 drinks per week
  • Lace trial: ≥6 grams of alcohol daily~ higher rates recurrence ([HR] 1.35, 95% CI 1.0-1.83) & BCA death (HR 1.51, 95% CI 1.0-2.29) vs. <0.5 grams daily. Overweight & postmenopausal women > harm of recurrence

• Exercise
  • Modest exercise tends to reduce the risk of breast cancer in post-menopausal women
  • BMI ≤24
  • Largely Mediterranean diet w/ olive oils, nuts supported
SURVEILLANCE

• Breast Cancer: (q6mos x 2years)
  • Yearly mammography (4% risk recurrence I/L, surveillance C/L)
  • MRI alt w/ mammography q6mos (BRCA, fam/hx)
  • B/l mastectomies & implants, autologous reconstruction: PE
  • Mammography in survivors (older women), reduction of death from BCA

• Metastatics
  • No mammograms….endocrine (+) probably?
  • No routine cancer screening…endocrine (+) probably?
• 6-7% of BCA is diagnosed in women ≤40 yo
• Growing population in US > women at risk!
• Leading cause of cancer related death
• Survival inferior in young women compared to older women
• More aggressive subtypes w/ unfavorable features
• Present more advanced ds
DIFFERING NEEDS

- Body Image
- Psychosocial Distress, Depression
- Fertility
- Sexuality/menopausal sxs
- Genetic implications
- Child care, education
YOUNGER WOMEN: REPRODUCTIVE & LATE HEALTH EFFECTS

• High level of physical functioning in younger women
• However social & emotional functioning, and vitality lowest amongst youngest women
• More depressive symptoms and more negative affect in youngest women
• Experience of menopausal transition w/ treatment was associated with lower mental health in youngest women

Ganz et al JCO 2003
PREGNANCY AFTER BREAST CANCER

• **Data:**
  - Retrospective study, multi-centered, cohort study
  - 333 pregnant pt ER(+) to 874 non-preg controls (686 ER+)
  - No difference in ER (+) DFS (p=0.55)
  - Pregnancy is NOT detrimental or protective, but SAFE.

• **Recommendations:**
  - Wait 2-3 yrs to get through early risk period, optimal endo therapy

• **POSITIVE TRIAL:** prospective trial ph II evaluate safety & pregnancy outcomes in interrupting ET in those who desire pregnancy
Most retrospective studies do NOT report preterm birth, low birth weight, congenital abnormalities or neonatal death.

No negative impact of breast feeding on survivors.

Christinat A et al. maturitas 73 (2012)191-196
YOUNG FIGHT STRONG PROGRAM

For women 45 years old and younger with breast or gynecological cancer

Care
- Stream-lined care to specialists
- Assessments of depression & sexual function
- Social Network, Live

Research
- New Research Opportunities
- Financial, Child care, meals

Support
- Activities: healthy lifestyle, body image
- Team building, peer programs

Education

Young Fight Strong
Addressing practical needs for young women with breast or gynecological cancer

We want to demonstrate the kind of impact that providing services specific to young women has on the experience of cancer treatment

"This is an incredible opportunity to not only do something good for a young woman with cancer, but to also study the impact services can have on the cancer experience."

— Don Dizon, MD, Director of Women’s Cancers, Lifespan Institute, Director Medical Oncology RIH, Associate Professor of Medicine, The Warren Alpert Medical School of Brown University

DONATE HERE:
https://consano.org/projects/addressing-practical-needs-for-young-women-with-breast-or-gynecological-cancer/

Summary
Distress is common in women with young children facing a new diagnosis of breast and gynecologic cancer. Studies have shown parenting to be a concern in these young women; having responsibility for dependent children under the age of 18 may heighten distress and diminish quality of life in this group. We are hoping to offer supports to these young women in hopes of alleviating some of the stressors at the time of treatment. We would like to conduct a feasibility trial evaluating the utilization of provided child care in young women undergoing IV chemotherapy for a diagnosis of breast/gynecologic cancer. We intend to enroll women who have children 12yr or under and see if it is feasible to provide this service. We would also like to measure their psychosocial distress and parenting concerns prior to receiving the service and how they are impacted when child care is provided. We would also like to evaluate whether women can complete their planned chemotherapy treatments on time at the expected intervals as we know that adherence to chemotherapy schedule is important for treatment benefit.