ESMO PRECEPTORSHIP ON BREAST CANCER

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Lisbon, 11-12 October 2019

Principles of Breast Surgery
Oncoplastic Surgery
DISCLOSURE OF INTEREST
No conflict of interest to disclose

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INESC TEC research group coordinator
EUSOMA executive committee
Surgery for breast cancer

**EBC (Estimating the magnitude of Clinical benefit of local therapies - St Gallen 2019)**
- Hereditary breast cancer
- DCIS
- Margins in conservative surgery
- Oncoplastic Surgery
- Total mastectomy vs Skin Sparing Mastectomy
- Immediate vs Delayed Reconstruction
- Surgery after primary systemic treatment (PST) – Breast
- No axillary approach vs Sentinel Node vs Axillary dissection

**ABC 4**
- The role of Surgery of the Primary Tumour in ABC (Stage IV)
Hereditary breast cancer

- Strong family history
- Patients < 40 (35) years
- Triple negative < (50) 60 years

Uptake, Results, and Outcomes of Germline Multiple-Gene Sequencing After Diagnosis of Breast Cancer

Allison W Kuriian, Kevin C Ward, Ann S Hamilton, Dennis M Deapen, Paul Abrahamse, Irina Bondarenko, Yun Li, Sarah T Hawley, Monica Morrow, Reema Jagsh, Steven J Katz

JAMA Oncology 2018 May 10

https://ask2me.org/index.php
Hereditary breast cancer

Impact that Timing of Genetic Mutation Diagnosis has on Surgical Decision Making and Outcome for BRCA1/BRA2 Mutation Carriers with Breast Cancer. Akiko Chiba et al 2016, Ann Surg Oncology
Hereditary breast cancer

- IBR – 1-2% year <7 Y
  IBR – doubles >7 Y
- CBC – 3% year BRCA1 - 2% year BRCA2

- IBR – 1-2% year
- CBC -0.5% year

NO OVERALL SURVIVAL DIFFERENCES
**DCIS**

- DCIS represents a spectrum of different situations, and should be approached accordingly.
- BCS with selective use of whole breast radiotherapy is still the optimal treatment for the majority of women with DCIS.
- Sentinel node biopsy should not be performed in patients having BCS for DCIS (exc: palpable; invasion susp).
- Ideally margins ≥2 mm. Given the limited amount of information in 1-2 mm margins or focal invasion, discuss before re-excision.
- Endocrine therapy reduces RR. Benefits/Risks. Consider BabyTam (5mg/day)
- Stratification tools can help in risk quantification and optimizing treatment strategies.
## PRINCIPLES OF BREAST SURGERY. ONCOPLASTIC SURGERY

### DCIS

#### Surveillance trials

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>Inclusion</th>
<th>Recruit</th>
<th>N</th>
<th>End points</th>
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<tr>
<td>The Low risk DCIS trial</td>
<td>45, pure, non high grade DCIS (VACB or open surgical without margins)</td>
<td>Ongoing</td>
<td>932</td>
<td>Ipsilateral invasive BC within F-UP 10 years</td>
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<td>LORIS Trial UK</td>
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<td></td>
<td>(50)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>uni or bilateral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Asymptomatic micros</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Low risk/intermediate DCIS trial</td>
<td>45, pure low and intermediate grade DCIS (VACB)</td>
<td>Ongoing</td>
<td>1240</td>
<td>Ipsilateral invasive BC or higher grade (II-III) within F-UP 10 years</td>
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<td>LORD trial - NKI</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>unilateral</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Asymptomatic micros</td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Comparison of operative to monitoring and endocrine therapy for low-risk/intermediate DCIS</td>
<td>40, pure, non high grade DCIS (VACB)</td>
<td>Ongoing</td>
<td>1189</td>
<td>Ipsilateral invasive BC or higher grade (II-III) within F-UP 5 years</td>
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<tr>
<td>COMET trial USA</td>
<td>unifocal or multifocal,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>uni or bilateral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HR positive, Her2 negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Asymptomatic micros</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Low and intermediate risk DCIS study</td>
<td>55, pure, non high grade DCIS (VACB open surgical biopsy)</td>
<td>Ongoing</td>
<td>550</td>
<td>Ipsilateral invasive BC or higher grade (II-III) within F-UP 5 years</td>
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<tr>
<td>LARRIKIN trial Australia</td>
<td>unifocal &lt; 2 cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>uni or bilateral</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
Randomized placebo controlled trial of low dose tamoxifen-Tam01

Women aged <75 yrs
With ADH or LCIS or ER+ve/unk DCIS

Tamoxifen
5 mg/day

Placebo

3 yr treatment + at least 2 yr FU

Primary endpoint: Incidence of invasive breast cancer or DCIS

- 500 participants enrolled from 14 centers in Italy
- Median follow up = 5.1 years (IQR 3.9-6.3)
- Primary events: 42

DeCensi et al. JCO 2019, in press
Margins in conservative surgery

"Sometimes patients demand a mastectomy, driven by fear and the desire of getting rid of the disease while ignoring all this new information. It is important to inform them properly that, in most cases, breast cancer can be cured maybe even better without the need to be separated from their breasts."
Contra-indications for BCT

In aggregate, in the following clinical situations the increased risk of breast relapse should be extensively discussed with the patient and breast conservation should be executed with caution:

- very young woman (<35 years),
- the presence of extensive DCIS (heralded by extensive microcalcifications) mounting up to one quarter of the breast,
- more than focally incomplete resection of an invasive or in situ cancer,
- Inflammatory Breast Cancer and LABC with poor response to PST
- and in the case that radiotherapy cannot be given.

In all other clinical situations breast conservation is a safe option, provided complete resections are achieved and good cosmetic outcome is secured.

(even multifocal and multicentric – St Gallen 2019)
Margins in conservative surgery

- Margins/need to forgo 2nd surgeries/mastectomies in three settings:
  - Invasive breast cancer – no need for additional distance in Lobular Invasive, in extensive intraductal componente, or in multifocal/multicentric breast cancer
  - Does focally invasive margin < 4 mm require additional excision?
  - After neoadjuvant therapy – no tumour on inked margins, the same as in primary surgery.

The association of surgical margins and local recurrence in women with early-stage invasive breast cancer treated with breast-conserving therapy: a meta-analysis.

Society of Surgical Oncology-American Society for Radiation Oncology consensus guideline on margins for breast-conserving surgery with whole-breast irradiation in stages I and II invasive breast cancer.
The margin status of invasive carcinoma did not influence IBTR, DM rate, or OS. Between 1980 and 2008, locoregional control after BCT remained stable with low IBTR rates, even in young patients.

**Fig. 2 IBTR-free interval by age group**


**Omitting re-excision for focally positive margins after breast-conserving surgery does not impair disease-free and overall survival.** Vos EL, Siesling S, Baaijens MHA, Verhoef C, Jager A, Voogd AC, Koppert LB.
When a resection of more than 20% of breast volume is planned oncoplastic techniques are recommended and can prevent major deformities.

Current approaches to managing partial breast defects: the role of conservative breast surgery reconstruction.

Oncoplastic Surgery

Considered a major technical improvement
- larger scars,
- increased complications
- increasing need for contralateral breast surgery
Pros
- Wider excisions - Better margins
- Less recurrences
- Overall better cosmetic outcomes

Cons
- Trained teams
- Higher cost
- Higher complication rate
- Possible delay of adjuvant treatments

Which technique to use for each case?
Total mastectomy vs Skin Sparing Mastectomy

Breast Reconstruction following Nipple-Sparing Mastectomy: Predictors of Complications, Reconstruction Outcomes, and 5-Year Trends.
Colwell AS, Tessler O, Lin AM et al.
PRINCIPLES OF BREAST SURGERY. ONCOPLASTIC SURGERY

Total mastectomy vs Skin Sparing Mastectomy

Preservation of the skin envelope in mastectomy indications (SSM)/(NSM)

- NOT in Inflammatory breast cancer even with clinical complete response to PST

Oncoplastic Breast Consortium consensus conference on nipple-sparing mastectomy.
Weber WP et Al
Breast Cancer Res Treat. 2018 Dec;172(3):523-537
Delayed Reconstruction vs Immediate Reconstruction

Is immediate autologous breast reconstruction with postoperative radiotherapy good practice?: a systematic review of the literature.
Schaverien MV, Macmillan RD, McCulley SJ.
Delayed Reconstruction vs Immediate Reconstruction
Delayed Reconstruction vs Immediate Reconstruction

- Reconstruction should be offered to all mastectomy patients and all techniques should be discussed even if not available locally.

- Immediate reconstruction can be performed in the majority of patients and does not reduce radiation efficacy.

- Patients who will probably need radiotherapy should be advised about the possibility of a poorer cosmetic outcome.

*ESTRO ACROP consensus guideline for target volume delineation in the setting of postmastectomy radiation therapy after implant-based immediate reconstruction for early stage breast cancer.*

Kaidar-Person O et al. Radiother Oncol. 2019 Aug;137:159-166
PRINCIPLES OF BREAST SURGERY. ONCOPLASTIC SURGERY

Surgery after primary systemic treatment (PST)

…..without ever forgetting the importance of each discipline
Surgery after primary systemic treatment (PST)

Pre-treatment work-up

<table>
<thead>
<tr>
<th>Comparative Accuracy Studies</th>
<th>Number Studies (2050 patients)</th>
<th>P value</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI Clinical</td>
<td>11</td>
<td>0.10</td>
<td>0.89</td>
</tr>
<tr>
<td>MRI Ultrasound</td>
<td>10</td>
<td>0.15</td>
<td>0.93</td>
</tr>
<tr>
<td>MRI Mammography</td>
<td>7</td>
<td>0.02</td>
<td>0.90</td>
</tr>
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</table>

Meta-analysis of Magnetic Resonance Imaging in Detecting Residual Breast Cancer After Neoadjuvant Therapy. 

Multimodality Imaging for Evaluating Response to Neoadjuvant Chemotherapy in Breast Cancer.
BCT after NAC is safe independently of pre-treatment multifocality/multicentricity

Retrospective analysis – 6134 Gepartrio; quattro; quinto
Breast conservation is feasible for clinically multifocal or multicentric breast cancer patients who undergo NACT without worsening LRFS if tumor-free margins can be attained or if patients achieve a pCR

Ataseven Ann Onc 2014
Factors associated to a significant increase in LRR

- Residual $> 2$ cm
- Lymphatic invasion
- Multifocal residual

Chen JCO 2004; Mittendorf Ann Surg 2013
Evaluation of the extent of residual disease/biology - MRI

Loo JCO 2011
Breast conservation is safe after NAC using the new limits (response limits)

- Caution in multifocal residual disease
- Caution in Luminal subtype
**PRINCIPLES OF BREAST SURGERY. ONCOPLASTIC SURGERY**

**New trials**

**NO SURGERY AFTER COMPLETE RESPONSE**

| Table 1: Completed, ongoing, and planned clinical feasibility trials utilizing percutaneous biopsy after neoadjuvant therapy to select patients for omission of breast cancer surgery |
|---|---|---|---|---|---|
| **Status** | **Group/author-PI** | **Eligibility criteria/lesion size criteria** | **Type of biopsy** | **No. of patients** | **Study unique characteristics** | **Performance results** |
| Completed trials | MD Anderson Cancer Center/ Kuerer et al.16 | All lesions <5 cm on imaging after NST; included only TN and HER2-amplified cases | VACB and FNA: median number sampled 12 using 9G under radiologist defined image guidance (63% by stereotactic and 37% by ultrasound) | 40 | Meticulous image guided sampling in radiology suite Subtype specific with highest probability of pCR (no invasive and in situ) | Accuracy = 99%; FNR = 5%; NPV = 95% |
| | German Breast group/Heil et al.16 | Invasive breast cancer patients; nonmetastatic; with clinical imaging after neoadjuvant chemotherapy/No lesion size criteria | Core cut (CC) and vacuum-assisted biopsy (VACB) | 164 (111 with CC and 46 with VACB) | Explorative comparison of different techniques: CC and VACB, ultrasound and mammographic guidance | Entire cohort (n = 164); NPV 71.3%; FNR 49.3%; Mammographic guided VACB (n = 16); NPV 100%; FNR 0% |
| | University of Heidelberg/ Heil et al.17 | Histologically confirmed, unilateral breast cancer; clinical partial or complete response to NST; target lesion visible by ultrasound/No lesion size criteria | Ultrasound-guided VACB | 50 | Explorative comparison of three evaluation methods of biopsy specimen pathologic representativeness | Entire cohort (n = 50); NPV 76.7%; FNR 25.9%; Histopathological evaluation of representativeness (n = 38): NPV 94.4%; FNR 4.8% |
| | University of Birmingham/ Rea-Francis et al./NOSTRA PRELIM18 | Invasive breast cancer with any receptor subtype receiving NST/No lesion size criteria | Ultrasound guided core biopsy; 4 to 6; mammography and stereotactic biopsy not utilized for malignant calcifications | 22 | Designed to inform biopsy protocol for larger study | Number of patients with a false-negative result (4/18 total patients) |


Maria-João Cardoso
Surgery of the axilla: main topics

- In patients undergoing surgery before systemic treatment
  - Omitting SLND in low-risk invasive breast cancer
  - Omitting ALND in patients with macrometastatic sentinel lymph nodes

- In patients undergoing neoadjuvant treatment
  - Indications for SLND (sufficient to predict ypN0?)
  - Indications for special approaches to SLND (e.g. >2 nodes, TAD)
  - Indications for ALND

PRINCIPLES OF BREAST SURGERY. ONCOPLASTIC SURGERY

Sentinel Node vs Axillary dissection

Sentinel node biopsy is actually considered standard of care in patients with clinically and ultrasound negative axillae

Estimating the benefit of axillary surgery

In patients undergoing surgery before systemic treatment:

- Omitting SLND in low-risk invasive breast cancer – Luminal A T1>70, comorbidities
- Omitting ALND in patients with macrometastatic sentinel lymph nodes – 1-2 nodes – Z11 /AMAROS
- Can lead to lower rates of typical side effects such as lymphedema, dysesthesia, arm/shoulder morbidity
- These benefits need to be weighed against loco-regional recurrence risk

Sentinel Node vs Axillary dissection

Recommendations

- **Recommendation 1**: Clinicians should not recommend axillary lymph node dissection (ALND) for women with early-stage breast cancer who do not have nodal metastases.

- **Recommendation 2.1**: Clinicians should not recommend ALND for women with early-stage breast cancer who have one or two sentinel lymph node metastases and will receive breast-conserving surgery (BCS) with conventionally fractionated whole-breast radiotherapy.

- **Recommendation 2.2**: Clinicians may offer ALND for women with early-stage breast cancer with nodal metastases found on SNB who will receive **mastectomy – RT NOT PLANNED**

- **Recommendation 3**: Clinicians may offer SNB for women who have operable breast cancer who have the following circumstances:
  - DCIS/mastectomy
  - Prior breast/axillary surgery

- **Recommendation 4**: There are insufficient data to change the 2005 recommendation that clinicians **should not perform SNB** for women who have early-stage breast cancer and are in the following circumstances:
  - LABC / Inflammatory
  - DCIS in BCS
LOCAL TREATMENT IN ELDERLY

Safety of Not Performing SLNB in Pts ≥70 Yrs with Clinically N₀ BC

- n=140
- cT₁-₂, N₀
- BCS

- T₁: 74%
- ER+: 86% / PR+: 73%
- HER₂+: 8%

- No CT: 98%
- No RT: 76%
- No HT: 59%

Figure: Kaplan-Meier Survival Estimates

F/U: 4.5 yrs

Approach to axillary surgery in patients undergoing primary systemic therapy

- Response can lead to lower axillary tumour burden.
- The benefits of less axillary local therapy need to be weighed against loco-regional recurrence risk and the risk of "understaging" and of overtreatment.
  - Indications for SLND
  - Indications for "SLNDplus" (e.g. >2 nodes, tailored axillary dissection)
  - Indications for ALND (e.g. in cN2 or resistance)
### Extend of axillary staging

#### Situation cN1/cN0 (40% turn over rate)

<table>
<thead>
<tr>
<th></th>
<th>FNR</th>
<th>Sentina cN1/ycN0</th>
<th>Alliance cN1/ycN0</th>
<th>SN FNAC cN1/ycN0</th>
<th>Spain cN1/ycN0</th>
<th>Meta-analyse Tee</th>
</tr>
</thead>
<tbody>
<tr>
<td>In all</td>
<td>14.2%</td>
<td>12.6%</td>
<td>8.4%</td>
<td>8.3%</td>
<td>14%</td>
<td></td>
</tr>
<tr>
<td>Dual tracer</td>
<td>8.6%</td>
<td>9.1%</td>
<td>5.2%</td>
<td></td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>&gt;2 SLN identified</td>
<td>7.3%</td>
<td>10.8%</td>
<td>4.9%</td>
<td></td>
<td>4%</td>
<td></td>
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</table>

→ **SNB is a good option for cN1/cN0 patients**

Marking the cancer positive lymph node in cN1 (Clip, SEEDS)

<table>
<thead>
<tr>
<th>Identification</th>
<th>FNR</th>
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<tr>
<td>n=100 MARI¹</td>
<td>97%</td>
</tr>
<tr>
<td>n=170 Clip²</td>
<td>6.8%</td>
</tr>
<tr>
<td>n=208 TAD³</td>
<td>2%</td>
</tr>
<tr>
<td>n=2217 combi⁴</td>
<td>100</td>
</tr>
</tbody>
</table>

Clip found in x-ray in the OR

SONO/MR pre NACT
BX/CLIP if cN1
ycNO – SNB possible

National Comprehensive Cancer Network®
Low-volume SLN disease after NAC is not an indicator of a low risk of additional positive axillary nodes and remains an indication for ALND, even when not detected on intraoperative FS.
**PROSPECTIVE TRIALS ON SURGERY IN STAGE IV BREAST CANCER AT PRESENTATION**

<table>
<thead>
<tr>
<th>Country</th>
<th>CI Tri gov ID</th>
<th>Current Name</th>
<th>Accrual Period</th>
<th>N</th>
<th>Type</th>
<th>Initial Tr</th>
<th>Radiotherapy</th>
<th>Pr End Point</th>
<th>STATUS</th>
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<tr>
<td>India</td>
<td>NCT00193778</td>
<td>Tata Memorial</td>
<td>2005-2012</td>
<td>350</td>
<td>RCT</td>
<td>ST</td>
<td>If indicated</td>
<td>TTP</td>
<td>Completed</td>
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<td>USA</td>
<td>NCT00941759</td>
<td>MSKCC</td>
<td>2009-2016</td>
<td>100</td>
<td>PO</td>
<td>ST/Surg</td>
<td>Not addressed</td>
<td>TTP</td>
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<td>Netherlands</td>
<td>NCT01302586</td>
<td>SUBMIT</td>
<td>2011-2014</td>
<td>10</td>
<td>RCT</td>
<td>Surgery</td>
<td>Not addressed</td>
<td>Survival</td>
<td>Terminated</td>
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<tr>
<td>Japan</td>
<td>JCOG1017</td>
<td>PRIM-BC</td>
<td>2011-2016</td>
<td>410</td>
<td>RCT</td>
<td>ST</td>
<td>Not addressed</td>
<td>Survival</td>
<td>Ongoing</td>
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<tr>
<td>USA/Canada</td>
<td>NCT01242800</td>
<td>ECOG</td>
<td>2011-2025 (15)</td>
<td>880(368)</td>
<td>RCT</td>
<td>ST</td>
<td>If indicated</td>
<td>Survival</td>
<td>Ongoing</td>
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<td>Turkey</td>
<td>NCT00557986</td>
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<td>2008-2012</td>
<td>281</td>
<td>RCT</td>
<td>Surgery</td>
<td>For BCT only</td>
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<td>Thailand</td>
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<td>2013-2019</td>
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<td>Austria</td>
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<td>BOMET MF 14-01</td>
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<td>RCT</td>
<td>Surgery</td>
<td>Not addressed</td>
<td>Survival</td>
<td>Ongoing</td>
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</tbody>
</table>
The role of Surgery in ABC

A retrospective cohort study using data from the SEER program. Female patients stage IV ab initio breast cancer from 1988 to 2011 (not receive radiation as part first treatment) (N = 21,372).

The median survival increased from 20 months (1988-1991) to 26 months (2007-2011).

Receipt of surgery was associated with improved survival in multivariate analysis. Account for several bias.

A large benefit for many women with stage IV breast cancer with surgery to the primary tumor is unlikely.

More potent and targeted drugs may be able to provide better control/eradication of systemic disease. Systemic therapies cannot yet manage all macroscopic disease.

Until then, local therapy with surgery to the primary tumor may offer critical disease control for select patients and could be an essential component of prolonged survival.
The role of Surgery in ABC

Primary operation in synchronous metastasized invasive breast cancer patients: first oncologic outcomes of the prospective randomized phase III ABCSG 28 POSYTIVE trial

Fitzal, Bjelic, Steger, Singer, Marth, Hubalek, Balic, Knauer, Haid, Wette, Swoboda, Lusser, Fuegger, Greil, Soelkner, Fesl, Gnant on behalf of the ABCSG

Results: 90 patients (45 with surgery, 45 with primary systemic therapy without surgery). The median survival in the surgery arm was 34.6 months versus 54.8 months in the no surgery arm without statistical significance (HR 0.691 CI 0.358 – 1.333; p=0.267). Time to distant progression was insignificantly longer in the no surgery arm (surgery arm 13.9 versus no surgery arm 29.0 months).

Conclusion: This first analysis of the prospective randomized phase III trial POSYTIVE-ABCSG-28 demonstrated no benefit in overall survival for immediate surgery of the primary in de novo stage IV breast cancer patients.
Conclusions

- Surgery is suffering major de-escalation
- Broader indications for genetic testing – preventive strategies and treatment options
- DCIS - wait and see in low/intermediate grade. Baby Tam in chemoprevention.
- Breast conservation is possible in the majority of cases – less recurrences/smaller margins
- When mastectomy, NS with immediate reconstruction – except skin invasion and inflammatory cancer
- Less surgery or no surgery after PST – Trials ongoing
- Axillary clearance vs minor axillary approach or none
- Axilla after neo-adjuvant treatment – marked+sentinel nodes
- Primary tumor surgery in stage IV at presentation - only in controlled by systemic treatment and oligometastatic disease
PRINCIPLES OF BREAST SURGERY. ONCOPLASTIC SURGERY

The Breast and Best Team
Advanced Breast Cancer
Fifth International Consensus Conference
14-16 November 2019
Lisbon, Portugal
Coordinating Chair: F. Cardoso, PT

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SAVE THE DATE