Optimal Surgical Management of breast cancer

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EUSOMA Executive Committee
ESO Faculty member
ESMO Faculty member
The Breast Editor
Conflict of Interest Disclosure

• No financial relationships to disclose
Surgery for breast cancer

- Conservative (BCT) vs Mastectomy
- (TNM 8th edition - summary of changes)
- The role of Oncoplastic Surgery
- Delayed Reconstruction vs Immediate Reconstruction
- Total mastectomy vs Skin Sparing Mastectomy
- Sentinel Node vs Axillary dissection
- Surgery after primary systemic treatment (PST)
- The role of Surgery in ABC (Stage IV)
PRIMARY TREATMENT OF EARLY BREAST CANCER
ST. GALLEN 2017

ESCALATING AND DE-ESCALATING TREATMENT IN EARLY BREAST CANCER ACROSS SUBTYPES AND TREATMENT MODALITIES

Consensus & Controversy

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Conservative (BCT) vs Mastectomy

MRM vs BCT
Randomized trials
Meta-analysis

Comparable local control, Identical Overall survival
Better cosmetic outcome
Conservative (BCT) vs Mastectomy


.....as long as a good aesthetic outcome is obtained
Conservative (BCT) vs Mastectomy

Original Investigation

Effect of Breast Conservation Therapy vs Mastectomy on Disease-Specific Survival for Early-Stage Breast Cancer

Shallesh Agarwal, MD; Lisa Pappas, MS; Leigh Neumayer, MD; Kristine Kokeny, MD; Jayant Agarwal, MD

_JAMA Surgery_ March 2014  Volume 149, Number 3

<table>
<thead>
<tr>
<th></th>
<th>BCT</th>
<th>Mastectomy</th>
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<td>70%</td>
<td>27%</td>
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<td>5Y BCSSR</td>
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<td>94%</td>
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<td>94%</td>
<td>90%</td>
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CONCLUSIONS AND RELEVANCE  Patients who underwent BCT have a higher breast cancer-specific survival rate compared with those treated with mastectomy alone or mastectomy with radiation for early-stage invasive ductal carcinoma. Further investigation is warranted to understand what may be contributing to this effect.
Viewpoints and debate

Less is more. Breast conservation might be even better than mastectomy in early breast cancer patients

Oreste D. Gentilini a, *, Maria-Joao Cardoso b, Philip Poortmans c

* San Raffaele University and Research Hospital, Milano, Italy
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c Department of Radiation Oncology, Institut Curie, Paris, France

“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.”
<table>
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<th>Author (ref number), year</th>
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<td>10yOS</td>
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<td>5y BCSS</td>
<td>97</td>
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<tr>
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<td></td>
<td></td>
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<td>10yBCSS</td>
<td>93</td>
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<td>Chen [6], 2015</td>
<td>2004–2011</td>
<td>National Cancer Database</td>
<td>T1-2, N1-3</td>
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<td>8y OS</td>
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<td>Lagendijk, Van Maaren [9,10], 2016, 2017</td>
<td>1999–2012</td>
<td>Netherlands Cancer Registry</td>
<td>T1-2, N0-2</td>
<td>129.692</td>
<td>11.7y OS and BCSS (1999-2005 cohort)</td>
<td>OS: HR 0.74</td>
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<td></td>
<td></td>
<td>6y OS and BCSS (2006-2012 cohort)</td>
<td>BCSS: HR 0.72</td>
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<td>BCSS</td>
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</tr>
</tbody>
</table>

BCSS = Breast Cancer-Specific Survival  M = Mastectomy.
Conservative (BCT) vs Mastectomy

Margins

The association of surgical margins and local recurrence in women with early-stage invasive breast cancer treated with breast-conserving therapy: a meta-analysis.
Houssami N1, Macaskill P, Marinovich ML, Morrow M.

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.
Ann Surg Oncol. 2014 Mar;21(3):704-16
J Clin Oncol. 2014 Feb 10
Conservative (BCT) vs Mastectomy

Margins

1. Positive margins
   A positive margin, defined as ink on invasive cancer or ductal carcinoma in situ (DCIS), is associated with at least a 2-fold increase in IBTR. This increased risk in IBTR is not nullified by:
   a) Delivery of a boost dose of radiation
   b) Delivery of systemic therapy (endocrine therapy, chemotherapy, or biologic therapy), or
   c) Favorable biology

2. Negative margin widths
   Negative margins (no ink on tumor) minimize the risk of IBTR. Wider margin widths do not significantly lower this risk. The routine practice to obtain negative margin widths wider than no ink on tumor is not indicated.

3. Systemic therapy
   The rates of IBTR are reduced with the use of systemic therapy. In the uncommon circumstance of a patient not receiving adjuvant systemic therapy, there is no evidence suggesting that margins wider than no ink on tumor are needed.

4. Biologic subtypes
   Margins wider than no ink on tumor are not indicated based on biologic subtype.
Conservative (BCT) vs Mastectomy

Margins

5. Radiation therapy delivery
   The choice of WBRT delivery technique, fractionation, and boost dose should not be dependent on margin width.

6. Invasive lobular carcinoma and lobular carcinoma in situ
   Wider negative margins than no ink on tumor are not indicated for invasive lobular carcinoma (ILC). Classic lobular carcinoma in situ (LCIS) at the margin is not an indication for re-excision. The significance of pleomorphic LCIS at the margin is uncertain.

7. Young age
   Young age (≤40 years) is associated with both increased IBTR after BCT as well as increased local relapse on the chest wall after mastectomy, and is also more frequently associated with adverse biologic and pathologic features. There is no evidence that increased margin width nullifies the increased risk of IBTR in young patients.

8. Extensive Intraductal Component
   Extensive Intraductal Component (EIC) identifies patients who may have a large residual DCIS burden after lumpectomy. There is no evidence of an association between increased risk of IBTR and EIC when margins are negative.
Conservative (BCT) vs Mastectomy

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.

Very low local recurrence rates after breast-conserving therapy: analysis of 8485 patients treated over a 28-year period.
Conservative (BCT) vs Mastectomy

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 2017)
Optimal Surgical Management of Breast Cancer

Maria João Cardoso, MD, PhD

AJCC TNM classification
8th edition

Gabriel N. Hortobagyi, James L. Connolly, Carl J. D’Orsi, Stephen B. Edge, Elizabeth Mittendorf, Hope S. Rugo, Lawrence J. Solin, Donald L. Weaver, David J. Winchester and Armand Giuliano

Breast - Chapter 48
Summary of changes

• **Two stage group tables**
  1. **Anatomic Stage Group table** solely anatomic extent defined by the T, N and M
  2. **Prognostic Stage Group table** based on populations of persons with breast cancer that have been treated with appropriate endocrine and/or systemic chemotherapy, which includes anatomic T, N and M plus tumour grade and the status of biomarkers HER2, ER and PR (Genomic).
• The **Prognostic Stage Group table** is preferred for patient care and is to be used for reporting of all cancer patients in the US
• The **Anatomic Stage Group table** is provided so that it can be used in regions of the world where biomarkers can not be routinely obtained

**PRIMARY TUMOUR**

• **Lobular carcinoma in situ (LCIS)** is removed as a pTis category. LCIS is a benign condition and is removed from TNM staging
• Clear definition that **satellite tumour nodules in the skin** must be separate from the primary and macroscopically identified to categorize as T4b. Skin and dermal tumour satellite nodules identified only on microscopic examination and in the absence of epidermal ulceration or skin edema (peau d’orange) do not qualify as T4b. Such tumours must be categorized based on tumour size.
Conservative (BCT) vs Mastectomy

Still 30% of fair/poor results


Can we improve those results?
Conservative (BCT) vs Mastectomy

http://medicalresearch.inescporto.pt/breastresearch

Towards an intelligent medical system for the aesthetic evaluation of breast cancer conservative treatment. Cardoso JS1, Cardoso MJ.
Oncoplastic Surgery

When a resection of more than 20% of breast volume is planned oncoplastic techniques are recommended and can prevent major deformities.

Oncoplastic Surgery

Considered a major technical improvement
- larger scars,
- increased complications
- increasing need for contralateral breast surgery
Oncoplastic 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?
Oncoplastic Surgery

BCCT PLAN (PORTUGAL 2020)

3D tool for planning breast conserving surgery in breast cancer
• **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
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.
• **Total mastectomy vs Skin Sparing Mastectomy**
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.
Optimal Surgical Management of Breast Cancer

Maria João Cardoso, MD, PhD
- **Sentinel Node vs Axillary dissection**

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

Sentinel Node vs Axillary dissection

Axillary Dissection vs No Axillary Dissection in Women With Invasive Breast Cancer and Sentinel Node Metastasis: A Randomized Clinical Trial

Armando E. Giuliano, MD
Kelly K. Hunt, MD
Karla V. Ballman, PhD
Peter D. Beitsch, MD
Pat W. Whitworth, MD
Peter W. Blumencranz, MD
A. Marilyn Leitch, MD
Sukamal Saha, MD
Linda M. McCall, MS
Monica Morrow, MD

Context: Sentinel lymph node dissection (SLND) accurately identifies nodal metastasis of early breast cancer, but it is not clear whether further nodal dissection affects survival.

Objective: To determine the effects of complete axillary lymph node dissection (ALND) on survival of patients with sentinel lymph node (SLN) metastasis of breast cancer.

Design, Setting, and Patients: The American College of Surgeons Oncology Group Z0011 trial, a phase 3 noninferiority trial conducted at 115 sites and enrolling patients from May 1999 to December 2004. Patients were women with clinical T1-T2 invasive breast cancer, no palpable adenopathy, and 1 to 2 SLNs containing metastases identified by frozen section, touch preparation, or hematoxylin-eosin staining on permanent section. Targeted enrollment was 1,901 women with final analysis after 500 deaths, but the trial closed early because mortality rate was lower than expected.

Axillary Dissection vs No Axillary Dissection in Women With Invasive Breast Cancer and Sentinel Node Metastasis: A Randomized Clinical Trial. Giuliano A et all JAMA, February 9, 2011—Vol 305, No. 6
**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**.

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

- **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
  - Pregnancy – Done with Radioisotope only
**Sentinel Node vs Axillary dissection**

Axillary approach after primary systemic treatment (PST)

- Decreasing the Extent of Axillary Surgery With PST
- This concept is currently applicable to operable breast cancer with N0-N1 disease
- Most available data on the performance of SNB were obtained in patients with operable BC
- Feasibility and accuracy of SNB after PST is questionable in patients with LABC (T4, cN2, IBC)
• Surgery after primary systemic treatment (PST)

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

- Primary systemic treatment (PST) is responsible for a greater percentage of BCT.
- All patients proposed to PST should have their tumor marked before initiating treatment.
- Candidates to PST are those with locally advanced breast cancer (LABC) and those whose tumor breast size ratio doesn’t allow conservative treatment with a favorable cosmetic outcome.
- Triple negative and Her2 positive (T2 and or N1)
Surgery after primary systemic treatment (PST)

- Initial work-up of locorregional disease
- Monitoring response to treatment
- Axillary approach
- BCS after treatment
- New Trials after PCR
**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>
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<tr>
<td>MRI Clinical</td>
<td>11</td>
<td>0.10</td>
<td>0.89 0.83</td>
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<tr>
<td>MRI Ultrasound</td>
<td>10</td>
<td>0.15</td>
<td>0.93 0.90</td>
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<td>MRI Mammography</td>
<td>7</td>
<td>0.02</td>
<td>0.90 0.89</td>
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</table>

**Meta-analysis of Magnetic Resonance Imaging in Detecting Residual Breast Cancer After Neoadjuvant Therapy.**
- Surgery after primary systemic treatment (PST)

Tattooing
Clipping
Surgery after primary systemic treatment (PST)
• Surgery after primary systemic treatment (PST)
- **Surgery after primary systemic treatment (PST) - Axilla**
  - For patients with operable BC who are candidates for PST, ultrasound of the axilla and FNA/CB of suspicious lymph nodes should be considered as part of the staging workup.
  - SNB before PST does not offer particular clinical advantages and reduces the number of patients who could benefit from the down-staging effect of PST in the axillary nodes.
  - SNB after PST is feasible and accurate with similar performance to SNB before PST (bigger samples). Neo-adjuvant protocol.
  - By performing SNB after PST, up to 40 percent of patients who present with minimal involvement of axillary nodes may be spared from axillary dissection.
  - Caution is however required for patients who present with clinically (or pathologically) involved nodes before PST (until further results of prospective trials are obtained). **STGallen 2017 - MARI, ALLIANCE Trials**
## New Trials After PCR

<table>
<thead>
<tr>
<th>Status</th>
<th>Group/Author-PI</th>
<th>Eligibility criteria/lesion size criteria</th>
<th>Type of biopsy</th>
<th>No. of patients</th>
<th>Study unique characteristics</th>
<th>Performance results</th>
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</thead>
<tbody>
<tr>
<td>Ongoing trials</td>
<td>MD Anderson Cancer Center/Kuerer et al.18</td>
<td>TN or HER2-positive initial imaging size &lt; 5 cm and final size &lt; 2 cm and or &gt;90% of lesion sampled after NST; N0 or biopsy confirmed N1 with &lt; 4 abnormal nodes on initial ultrasound</td>
<td>Minimum of 12 9G VABC; image guidance method dependent on radiologist decision</td>
<td>50</td>
<td>No breast surgery treatment trial</td>
<td>Primary endpoint is local recurrence with continuous monitoring and early stopping rules; secondary endpoints listed in Fig. 1</td>
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<tr>
<td></td>
<td>Netherlands Cancer Institute/MICRA Trial/MACRA Trial</td>
<td>Invasive breast cancer patients; non-metastatic; with radiologic partial or complete response on CE-MRI after NST/No lesion size criteria</td>
<td>Ultrasound-guided 14G biopsies targeted around pre-NST placed marker (4 central, 4 peripheral)</td>
<td>525 (150 with partial radiologic response on CE-MRI and 375 with complete radiologic response on CE-MRI)</td>
<td>All breast cancer subtypes; Response monitoring with CE-MRI</td>
<td>Primary endpoint is specificity of &gt;92% (proportion of patients with residual disease in the surgical specimen that is also confirmed by biopsy) In addition, FNR, will be calculated</td>
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<tr>
<td></td>
<td>Vranken-Peeters et al.11</td>
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<tr>
<td>Planned trials</td>
<td>University of Heidelberg/RESPONDER Trial Heil et al.19</td>
<td>Invasive breast cancer after NST; clinical partial or complete response; target lesion visible on ultrasound or mammography/No lesion size criteria</td>
<td>Ultrasound- or mammographic-guided VABC</td>
<td>600</td>
<td>Confirmative analysis to identify a pCR using VABC</td>
<td>Primary endpoint &lt;10% FNR. Standardization of histopathological evaluation of post-NST samples</td>
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<td>University of Birmingham/Rea/NOSTRA feasibility</td>
<td>ER-negative or HER2-positive invasive breast cancer receiving NST/lesion size must be &gt; 1 cm on ultrasound or node-positive</td>
<td>Ultrasound-directed biopsy, minimum of 6</td>
<td>150</td>
<td>Microcalcifications will not be targeted; no upper limit of size criteria</td>
<td>FNR &lt; 10%</td>
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<td>NRG/B0005 Bask and De Los Santos</td>
<td>Operable focal or multifocal (T1-T3, stage II and IIIA invasive ductal carcinoma) with no size criteria (all receptor phenotypes), completed NST with a clinical complete response (by clinical examination)</td>
<td>6-8 11G VABC, stereotactic</td>
<td>175</td>
<td>Multicenter cooperative group study with trimodality imaging required</td>
<td>NPV = 90% and FNR = 10%</td>
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*Kuerer et al 2017, Ann Surg Oncol*
The role of Surgery in ABC

PROSPECTIVE TRIALS ON SURGERY IN STAGE IV BREAST CANCER AT PRESENTATION

<table>
<thead>
<tr>
<th>Country</th>
<th>Cl Tri gov ID</th>
<th>Current Name</th>
<th>Accrual Period</th>
<th>N</th>
<th>Type</th>
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<th>Radiotherapy</th>
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<td>Netherlands</td>
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<td>ST</td>
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<td>USA/Canada</td>
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<td>Surgery</td>
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<td>Surgery</td>
<td>Not addressed</td>
<td>Survival</td>
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</tbody>
</table>
The role of Surgery in ABC

Original Investigation


Alexandra Thomas, MD; Seema A. Khan, MD; Elizabeth A. Chrischilles, PhD; Mary C. Schroeder, PhD

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.

JAMA Surg MAY 2016
Optimal Surgical Management of Breast Cancer

Maria João Cardoso, MD, PhD

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 POSYITIVE trial

Fitzal, Bjelic, Steger, Singer, Marth, Hubalek, Schrenk, Balic, Knauer, Haid, Wette, Swoboda, Luisser, 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 POSYITIVE-ABCSG-28 demonstrated no benefit in overall survival for immediate surgery of the primary in de novo stage IV breast cancer patients.

Sponsored in part by the Bürgermeister Fonds der Stadt Wien 09057
- The role of Surgery in ABC

To date, the removal of the primary tumor in patients with de novo stage IV breast cancer has not been associated with prolongation of survival, with the possible exception of the subset of patients with bone only disease. However, it can be considered in selected patients, particularly to improve quality of life, always taking into account the patient’s preferences. (LoE/GoR: I/C) (70%)

Of note, some studies suggest that surgery is only valuable if performed with the same attention to detail (e.g. complete removal of the disease) as in patients with early stage disease. (LoE/GoR: II/B) (70%)

Additional prospective clinical trials evaluating the value of this approach, the best candidates and best timing are currently ongoing.
Conclusions

- Surgery is clearly suffering major de-escalation
- Breast conservation will replace mastectomy in the majority of cases
- If mastectomy, nipple sparing with immediate reconstruction in the majority of cases.
- No Surgery in case of complete response after PST – Trials ongoing
- Axillary surgery just in selected cases.
- Primary tumor surgery in stage IV - only in controlled by systemic treatment and oligometastatic disease
The Breast and Best Team
4th ESO-ESMO Breast Cancer in Young Women International Conference

6-8 October 2018
Lugano, Switzerland

Chair: O. Pagani, CH
Scientific committee: F. Cardoso, PT - N. Harbeck, DE
S. Paluch-Shimon, IL - F. Peccatori, IT - A. Partridge, US
E. Senkus, PL - Y. Wengström, SE

IMPORTANT DEADLINES

- Abstracts and travel grants: 6 May 2018
- Early registration: by 17 June 2018
- Late registration: by 23 September 2018
- Onsite registration: from 24 September 2018

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