The Clinical database of DBCG

(Danish Breast Cancer Cooperative Group)
1977-2008

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Number of patients with invasive breast cancer 1977-2007  
(n=84833)
In situ carcinoma, DCIS LCIS

1982-2006, n=3228
Hereditary Breast and Ovarian Cancer Registry (HBOC)

1999-2006, 3121 families
Restrictions of the database

- Only one record of each patient, primary key of the database is the unique civil personal registration number (CPR)
  - If bilateral breast cancer, only one side
  - If new breast cancer during follow-up or after 10 years, only the first event can be recorded

- Data reported just from clinical centers in charge of breast cancer patients.
  - If no surgery, greater risk of no registration
Completeness:
Number of patients with primary invasive breast cancer in DBCG vs CR vs Patobank
Registrations of individual patient data in DBGC

- All units involved in diagnosis and treatment contributes
  - Demographic data
  - Histo-pathological variables
  - Type of surgery
  - Systemic therapy (chemo-, endocrine- and biological-)
  - Radiation therapy
  - Follow-up until 10 years
  - Death
## Histo-pathology CRF

### A

<table>
<thead>
<tr>
<th>Biopsidato:</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Side:</td>
<td>[ ] Højre</td>
<td>[ ] Venstre</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lumpektomidato:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lokalisation (evt. flere afkrydninger):</td>
<td>[ ] Øvre lateral</td>
<td>[ ] Øvre medial</td>
<td>[ ] Nedre lateral</td>
<td>[ ] Nedre medial</td>
<td>[ ] Central</td>
</tr>
<tr>
<td>Biopsitype:</td>
<td>[ ] Excision</td>
<td>[ ] Nål-cytologi</td>
<td>[ ] Incision</td>
<td>[ ] Nål-histologi</td>
<td></td>
</tr>
<tr>
<td>Kommunikation mellem aksil- og mammakavitet</td>
<td>[ ] Ja</td>
<td>[ ] Nej</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspekte mikrokalkninger efterladt</td>
<td>[ ] Ja</td>
<td>[ ] Nej</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Papil fjernet</td>
<td>[ ] Ja</td>
<td>[ ] Nej</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bundfascie på præparat</td>
<td>[ ] Ja</td>
<td>[ ] Nej</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palpabel tumor</td>
<td>[ ] Ja</td>
<td>[ ] Nej</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nålmarkeret proces</td>
<td>[ ] Ja</td>
<td>[ ] Nej</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Klinisk Mb. Paget</td>
<td>[ ] Ja</td>
<td>[ ] Nej</td>
<td></td>
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</tr>
</tbody>
</table>
Type of surgery by year

- **biopsy only**
- **BCS**
- **mastectomy**

22. may 2008, SM
**Mamma –CRF: Definition of risk groups according to demographic and histopathological variables**

<table>
<thead>
<tr>
<th>Alder</th>
<th>Tumor størrelse</th>
<th>Positive lymfeknuder</th>
<th>Type og malign. grad</th>
<th>Receptor status</th>
<th>HER-2 status</th>
<th>TOP2A status</th>
<th>DBCG gruppe</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 35 år</td>
<td>&lt; 20 mm</td>
<td>0</td>
<td>Duktal I, ? Lobulær I-II, ? Anden type</td>
<td>Positiv/ Ukendt Medulær(neg)</td>
<td>Negativ/ ukendt</td>
<td>Normal/ukendt</td>
<td>□ I</td>
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<tr>
<td></td>
<td>&gt; 1</td>
<td></td>
<td></td>
<td>Negativ</td>
<td></td>
<td></td>
<td>□ II</td>
</tr>
<tr>
<td>&gt; 20 mm</td>
<td></td>
<td></td>
<td>Duktal II-III Lobulær III</td>
<td></td>
<td></td>
<td></td>
<td>□ II</td>
</tr>
<tr>
<td>&lt; 35 år</td>
<td></td>
<td></td>
<td></td>
<td>Negativ</td>
<td></td>
<td></td>
<td>□ II</td>
</tr>
</tbody>
</table>
**Mamma –CRF: Protocol allocation**

<table>
<thead>
<tr>
<th>DBCG gruppe</th>
<th>Alder</th>
<th>Receptor status</th>
<th>HER-2 status</th>
<th>Standard behandling *)</th>
<th>Behandlingsprogram **)</th>
<th>Protokol</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 60 år</td>
<td>Positiv / ?</td>
<td>Positiv</td>
<td>KT, ET, T</td>
<td>☐ 2007 – b,t</td>
<td>FACE(postmen.)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Negativ / ?</td>
<td>KT, ET</td>
<td>☐ 2007 – b</td>
<td>FACE(postmen.)</td>
</tr>
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<td>II</td>
<td>&gt; 60 år</td>
<td>Positiv / ?</td>
<td>ET</td>
<td>☐ 2007 – c</td>
<td>FACE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Negativ</td>
<td>Positiv</td>
<td>KT, T</td>
<td>☐ 2007 – d,t</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Negativ / ?</td>
<td>KT</td>
<td>☐ 2007 – d</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

*) KT (kemoterapi) = EC x 3 ? Doc x 3.  
** ET (endokrin terapi) = for præ (på diagnosetidspunkt): TAM i 5 år  
** for post (på diagnosetidspunkt): TAM i 2½ år ? aromatasehæmmer i 2½ år.  
T = trastuzumab.

**) Patienter med et eller flere af følgende kriterier indgår ikke i DBCG’s behandlingsprogrammer for inv. c. m. Sæt evt. flere kryds.  

- Fjernmetastaser  
- Sarkom/phyllodes  
- DCIS, LCIS, PDN (udfyld In situ skema)  
- Andet:  

Patienter med en eller flere af følgende kriterier bør følges og indberettes i henhold til DBCG’ behandlingsprogrammer. Afvigelser fra standardbehandling angives på Flow Sheet:  

- Tidl. malign. incl. c. mam. (undt. c. cutis & c. colli ut. in situ)  
- Bilateral c. mammae  
- Kontraindikation for standard behandling  
- Teknisk inoperabel  
- Ikke opereret iflg. DBCG’s kirurgiske procedure

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Definition of Patient population

- Patients with invasive breast cancer, surgery according to DBCG 95.4%
- No surgery (biopsi only) 4.2%
- Other diagnoses 0.4%
  - Sarcoma
  - Padget
  - Fibroadenoma
Patients ineligible to DBCG programmes

• Due to diagnosis 5.9%
  – Distant metastasis 1.5%
  – Previous malignancy 2.1%
  – Bilateral breast cancer 1.7%
  – Other reasons 0.6%

• Due to noneligibility for systemic therapy 24.3%
  – Contraindication due to medical condition incl. age 15.3%
  – Inflammatory breast cancer 0.2%
  – Surgery not according to DBGC guidelines 1.8%
  – Patient do not want to participate 1.1%
  – Protocol violation (misclassified or not treated according DBCG) 2.2%
  – Unknown 3.8%
Protocol allocation in DBG C programmes

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Follow-up of enrolled patients during treatment and after treatment for 10 years (currently 30,000 patients)

- Systemic therapy
  - Chemotherapy (type, dose, number of series, 18-48 weeks)
  - Endocrine therapy (type, dose, 1-5 years, + extended)
  - Trastuzumab (1 year)

- Radiotherapy (target, dose, number of fractions)

- Adverse events, targeted dependent on treatment

- Recurrence
  - loco-regional, distant, contralateral breast, other malignancy
  - death as first event

- Death for all patients (by linkage to CPR)
Events in DBGC programmes
Reasons for withdrawal without event in DBGC programmes

- 10 years follow up completed
- Programme violation (excl. Crit.)
- Not treated according to allocation
- Lost to follow up
- Lack of capacity
- Patients condition
- Voluntary withdrawal

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IT systems

• Oracle database, many tables
• Programming language: SQL
• Data entry
  – in the secretariate: Forms6
  – From the clinical units: on-line system
• Statistical analyses language: SAS and R
• Mirror of the database in SAS-files
  – Historic samples
Data validation

• At data entry:
  – validating values of individual variables
  – consistency of data from the same CRF
  – check of protocol allocation

• Daily validation of
  – double entry
  – consistency of data between CRFs

• Regular check for missing CRFs
  – Gap in the flow of CRFs
  – Too long time since last follow-up
Clinical quality database

- 11 indicators of clinical quality are defined for breast cancer treatment (June 2005).
- Yearly reports: mean values by units and time trend
- Example: Indicator no 4
  - Rate of node negative patients,
  - suitable for SN methods,
  - whose nodal status is determined by SN.
  - Reference value was 95%
  - 2005-6 the numbers were: 1659 / 1975, rate=84 %
Rate of node negative patients, suitable for SN methods, whose nodal status is determined by SN for each unit.
Rate of node negative patients, suitable for SN methods, whose nodal status is determined by SN for a single unit vs. total mean for the same units according to time.
Rate of node negative patients, suitable for SN methods, whose nodal status is determined by SN for a single unit vs. nationwide means according to time.
Achievements from the DBCG database

The establishment of the multidisciplinary breast cancer group with its associated database has provided the opportunity to

• improve the quality of the diagnostic and therapeutic aspects of breast cancer (guidelines)

• run trials, national or in international collaboration.

• the clinical data combined with the availability of tumour tissue has provided the ideal conditions for translational research.
Achievements from the DBCG database

- Clinical trials, nationwide, international.
- Translational research, connection to tumor tissue.
- Supply data as well as statistical expertise for specific research.
- Epidemiological research.
- Guidelines.
- Quality control, nationwide, international (EBCTCG)
- International collaboration- early warning
- Tools for information and education, professional- and public-
SLUT