Rapid Diagnosis in Breast oncology: The One Stop Clinic model

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## Disclosures

<table>
<thead>
<tr>
<th></th>
<th>Consulting/ expert</th>
<th>Conferences/ formations</th>
<th>Research grants /clinical trials</th>
<th>Stock options-patents</th>
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<tbody>
<tr>
<td>Amgen</td>
<td></td>
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<tr>
<td>Astra Zeneca</td>
<td>x</td>
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<td>GE</td>
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<td>Novartis</td>
<td>x</td>
<td>x</td>
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<td>x</td>
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<tr>
<td>Pfizer</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Puma</td>
<td>x</td>
<td>x</td>
<td>x</td>
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</tr>
<tr>
<td>Roche</td>
<td>x</td>
<td>x</td>
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</tbody>
</table>
Outline

• Background
• Organisation
• Results
Outline

- Background
- Organisation
- Results
General context

• Increasing breast cancer incidence
• International recommendations: short-term diagnosis and care in case of cancer
• « False positive » findings of mammographic screening leads to anxiety
• Increasing complexity of breast lesions
• Need for multi-disciplinary assessment already at diagnosis, before initial decision making
Why a One Stop Clinic?

Abnormal breast finding (clinical or imaging)

- Referred to GP or gynecologist
- Breast surgeon/specialist
- Image-guided sampling
- Additional tests
- Breast surgeon/specialist /Breast Oncologist
- MTM: decision
- Adequate treatment

Patients’ journey through diagnostic and therapeutic pathway may take long.
Why a One Stop Clinic?

Abnormal breast finding (clinical or imaging)

Referred to GP or gynecologist

Breast surgeon/specialist
Breast Oncologist
MTM: decision

Image-guided sampling
Pathologist
Additional tests
Trained senior radiologists
Specialized staff

Adequate diagnosis and treatment plan

One Stop Clinic: one time, one place
Diagnosis of breast lesions

- Malignant
  - Expected: Positive predictive value > 99%
- Benign
  - Expected: Negative predictive value > 97%

Outline

• Background
• Organisation
• Results
Objectives

Target population: women with abnormal/suspect breast findings

One place, one time to gather all necessary skills: surgeon + radiologist + medical oncol + pathologist + nurses + dedicated technicians

Provide an exact diagnosis in 1 day as often as possible

Provide trt decisions + individual care program/ 1 day
The One Stop Clinic

- Radiology team
- Nurse navigator
- Oncologist
- Breast surgeon
- Cytopathology team
- Volunteers
- Reception team
- Secretaries
- Psychologists
- Social workers
- Additional imaging
- Blood tests, Lab
Critical points

• Dedicated high-quality team (loving to work together)
• Detailed flowchart and organisation, shared decision trees
• Dedicated geographical organisation
• Adaptability of the system
• Regular quality controls and evaluations
One Stop Clinic: a single location

1. Welcome Desk
2. Waiting room
3. Nurse Navigator
4. Consultation
5. Guided FNA
6. FNA analysis
7. Team meeting and discussion

Breast Radiology Platform
One Stop Clinic: patients’ journey

- **PHONE CALL**
- **SHORT TERM APPOINTMENT**
  - Visit with a first clinician (surgeon or oncologist)
  - Discussion with radiologists
  - Planification of necessary images and tests
- **RESULTS** given to patients
- **CARE plan delivery**
- **Information and discussion with patient**
- **M E D I A N 6 HOURS**
  - Examinations, imaging, FNA, biopsies, blood tests, etc
Ultrasound-guided FNA is a key of the One Stop Clinic

• US-guided FNA: performed by the cytopathologist under radiologist’s guidance
  – 2 ponctions
  – 5 mn to perform, 10 mn to read
  – Immediate results in One Stop
  – No local anesthesia
  – Fast
  – Accurate with experienced pathologist

• Allows axillary exploration and FNA as needed
Results of FNA

- Non cohesive cells
- Typically malignant
- Concordant with suspicious imaging
- Carcinoma
Ex: wn with a 25 mm BI-RAD ACR4b lump UEQ, left breast Breast size 90B

42 years old, family history (mother)
- Single mass, reclassified BI-RAD ACR4a after US
- US-guided FNA: fibroadenoma
- US-guided biopsy performed
  Surveillance planned, surgery discussed

58 years old
- CSEM: 1 additional Birad 4c 7 mm mass, UIQ
- US: 1 suspect node
- US-guided FNA of both masses: adenocarcinoma
- US-guided FNA of node: +
  US-guided biopsy of main mass performed
  Left mastectomy + axillary clearance planned

37 years old
- CESM and US: single mass, N0
- US-guided FNA: carcinoma
- US-guided biopsy performed
  Lumpectomy + SN planned, patient informed that neoadjuvant chemo may be a solution according to final histology

Multidisciplinarity is crucial!
Outline

• Background
• Organisation
• Results: The One Stop Clinic Model
Methods

STARD guidelines for reporting diagnostic accuracy:

- **Population**: all pts seen for a suspect breast lesion at OSBU from April, 4th, 2004 till November, 30th, 2012 (8½ years) **N = 10 833**
## Patients’ and lesions’ characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age (years) [SD]</td>
<td>55 [13.5]</td>
</tr>
<tr>
<td>Males: n (%)</td>
<td>130 (1.2%)</td>
</tr>
<tr>
<td>Family history of cancer: n (%)</td>
<td>3,477 (32.1%)</td>
</tr>
<tr>
<td>Size of lesion: (in mm) [SD]</td>
<td>Mean 17 [14.5], Median 13 mm</td>
</tr>
<tr>
<td>Palpable abnormality: n (%)</td>
<td>3,830 (35.3%)</td>
</tr>
<tr>
<td>BI-RADS ACR classification</td>
<td></td>
</tr>
<tr>
<td>4 : n (%)</td>
<td>39.4%</td>
</tr>
<tr>
<td>5 : n (%)</td>
<td>21.8%</td>
</tr>
<tr>
<td>3 : n (%)</td>
<td>18.9%</td>
</tr>
<tr>
<td>Other: n (%)</td>
<td>19.8%</td>
</tr>
</tbody>
</table>

Patients’ and lesions’ characteristics

<table>
<thead>
<tr>
<th>Type of detection for the abnormality:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Self palpation: n (%)</td>
<td>2,072 (19.1%)</td>
</tr>
<tr>
<td>Medical palpation: n (%)</td>
<td>2,229 (2.1%)</td>
</tr>
<tr>
<td>Other symptoms: n (%)</td>
<td>468 (4.3%)</td>
</tr>
<tr>
<td>Imaging: n (%)</td>
<td>7,655 (70.7%)</td>
</tr>
<tr>
<td>Unknown: n (%)</td>
<td>409 (3.8%)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Type of imaging abnormality:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass: n (%)</td>
<td>7,441 (68.7%)</td>
</tr>
<tr>
<td>Micro-calcifications: n (%)</td>
<td>2,779 (25.7%)</td>
</tr>
<tr>
<td>Architectural distortion: n (%)</td>
<td>243 (2.2%)</td>
</tr>
<tr>
<td>None: n (%)</td>
<td>180 (1.7%)</td>
</tr>
<tr>
<td>Unknown: n (%)</td>
<td>190 (1.7%)</td>
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</table>
Evolution of procedures used at OSBU over time
### Diagnostic accuracy: benign vs malignant

Cross-tabulation of one-stop and consolidated diagnosis results (n = 10,833 visits in 10,602 patients).

<table>
<thead>
<tr>
<th>One-stop diagnosis</th>
<th>Consolidated diagnosis</th>
<th></th>
<th></th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Malignant</td>
<td>Benign</td>
<td>Atypical</td>
<td>Lost to follow-up</td>
<td></td>
</tr>
<tr>
<td>Malignant</td>
<td>3815</td>
<td>12</td>
<td>6</td>
<td>0</td>
<td>3833</td>
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<tr>
<td>Benign</td>
<td>63</td>
<td>5967</td>
<td>49</td>
<td>0</td>
<td>6079</td>
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<tr>
<td>Suspect or atypical</td>
<td>192</td>
<td>186</td>
<td>191</td>
<td>0</td>
<td>569</td>
</tr>
<tr>
<td>Undetermined</td>
<td>106</td>
<td>159</td>
<td>19</td>
<td>68</td>
<td>352</td>
</tr>
<tr>
<td>Total</td>
<td>4176</td>
<td>6324</td>
<td>265</td>
<td>68</td>
<td>10,833</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
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<tbody>
<tr>
<td></td>
<td>[95% CI]</td>
<td>[95% CI]</td>
<td>[95% CI]</td>
<td>[95% CI]</td>
</tr>
<tr>
<td></td>
<td>98.4%</td>
<td>99.8%</td>
<td>99.7%</td>
<td>99.0%</td>
</tr>
<tr>
<td></td>
<td>[98.0 – 98.8]</td>
<td>[99.7 – 99.9]</td>
<td>[99.5 – 99.9]</td>
<td>[98.7 – 99.2]</td>
</tr>
</tbody>
</table>

CI: confidence interval; PPV: positive predictive value; NPV: negative predictive value

Results: diagnostic accuracy

- All 10833: 75% exact results in a day
- 8,434 masses: 87% exact results in a day

(13% are undetermined (3-4%), or suspect/atypical)

Results: Satisfaction and anxiety
Cross sectional evaluations 2005 & 2013

<table>
<thead>
<tr>
<th>Evaluation of Doctors</th>
<th>2005</th>
<th>2013</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>M</td>
</tr>
<tr>
<td>Satisfaction SAT-35</td>
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<tr>
<td>Technical skills</td>
<td>104</td>
<td>72.6</td>
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<tr>
<td>Interpersonal skills</td>
<td>108</td>
<td>70.5</td>
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<tr>
<td>Information</td>
<td>101</td>
<td>67.7</td>
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<tr>
<td>Availability</td>
<td>112</td>
<td>56.9</td>
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## Results: Satisfaction and anxiety

**Cross sectional evaluations 2005 & 2013**

<table>
<thead>
<tr>
<th>Evaluation of Nurses</th>
<th>2005</th>
<th>2013</th>
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<tbody>
<tr>
<td></td>
<td>N</td>
<td>M</td>
</tr>
<tr>
<td>Technical skills</td>
<td>102</td>
<td>79.5</td>
</tr>
<tr>
<td>Interpersonal skills</td>
<td>107</td>
<td>79.5</td>
</tr>
<tr>
<td>Information</td>
<td>74</td>
<td>71.2</td>
</tr>
<tr>
<td>Availability</td>
<td>97</td>
<td>74.6</td>
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</table>

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## Results: Satisfaction and anxiety

Cross sectional evaluations 2005 & 2013

<table>
<thead>
<tr>
<th></th>
<th>2005</th>
<th></th>
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<th>2013</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>M</td>
<td>SD</td>
<td>Range</td>
<td>N</td>
<td>M</td>
<td>SD</td>
<td>Range</td>
</tr>
<tr>
<td><strong>Organization, physical environment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exchange of information</td>
<td>93</td>
<td>68.6</td>
<td>22.9</td>
<td>16.7-100</td>
<td>102</td>
<td>71.4</td>
<td>21.1</td>
<td>25-100</td>
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<tr>
<td>Information provided</td>
<td>97</td>
<td>72.4</td>
<td>20.9</td>
<td>8.3-100</td>
<td>99</td>
<td>78.8</td>
<td>18.5</td>
<td>25-100</td>
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<tr>
<td>Waiting time</td>
<td>93</td>
<td>63.5</td>
<td>21.5</td>
<td>8.3-100</td>
<td>99</td>
<td>69.5</td>
<td>22.9</td>
<td>8-100</td>
</tr>
<tr>
<td>Physical environment</td>
<td>102</td>
<td>59.8</td>
<td>22.6</td>
<td>16.7-100</td>
<td>105</td>
<td>71.8</td>
<td>20.5</td>
<td>25-100</td>
</tr>
<tr>
<td><strong>General satisfaction</strong></td>
<td>110</td>
<td>71.4</td>
<td>22.4</td>
<td>25-100</td>
<td>109</td>
<td>80.7</td>
<td>20.7</td>
<td>25-100</td>
</tr>
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</table>

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# Results: Full Costs

## Mean cost per patient (Euros 2012)

<table>
<thead>
<tr>
<th></th>
<th>Mean cost per patient</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staff</strong></td>
<td>€190 45</td>
<td></td>
</tr>
<tr>
<td><strong>FNA</strong></td>
<td>€102 24</td>
<td></td>
</tr>
<tr>
<td><strong>Other procedures</strong></td>
<td>€128 31</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>€420 100</td>
<td></td>
</tr>
</tbody>
</table>

Results: Full Costs according to lesions

Mean cost per patient (Euros 2012)

- Microcalcifications: 565 Euros
- Nodules: 371 Euros
- Multiple lesion: 488 Euros
- Single lesion: 415 Euros
- Cancer: 443 Euros
- Benign: 397 Euros
- Atypical: 628 Euros

Conclusions (1)

• One Stop Breast Unit allows **highly accurate diagnoses** within a very short time interval, **75%** of the women getting their results on the same day.

• **Multidisciplinarity** allows high quality in all **cases**, low amount of unnecessary surgeries and early assessments of complex cases.

• Very rapid diagnosis **does absolutely not preclude** high medical quality and limited costs.
Conclusions (2)

- The results **compare well** to all published literature in terms of **quality** of diagnoses.
- **Medical efficacy and cost data compare very favourably with that of the same patients during the same period in the same area (Paris’ south suburbs).**
- Other quality assessments showed very good results that compare favourably with published literature, namely **pain control, information recall, anxiety levels, satisfaction.** Pain control and satisfaction even slightly improved over time.
Conclusions (3)

• The One Stop Clinic is useful for all women with breast lesions but
• One-stop diagnosis is possible only for women with masses (best target)
Thank you