High-resolution specimen PET-CT imaging for intraoperative margin assessment in early-stage breast cancer: the multicenter BrIMA study

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Introduction

Clinical Challenge



Breast-conserving surgery

Positive margin rate: 8-36%
Re-operation rate: 11-22%
[1-5]

Histopathological margin evaluation

→ IMA method to avoid reoperations?

Goal of BrIMA Study

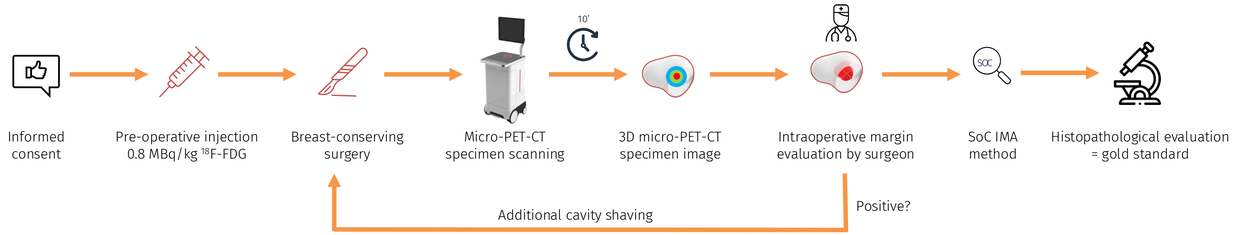
Study design
Prospective, multicenter, interventional study to evaluate clinical value of intraoperatively addressing positive margins by specimen PET-CT imaging.

Research question
What is the success rate of intraoperative micro-PET-CT specimen imaging?

- Succes = all margins of the main specimen were negative, or positive margins were adequately addressed during BCS
- Gold standard for margin assessment = histopathology

Methods

Workflow



Informed consent

Pre-operative injection 0.8 MBq/kg ^{18}F-FDG

Breast-conserving surgery

Micro-PET-CT specimen scanning

3D micro-PET-CT specimen image

Intraoperative margin evaluation by surgeon

SoC IMA method

Histopathological evaluation = gold standard

Additional cavity shaving

Positive?

Results

Data collection

148 patients

6 European breast centers

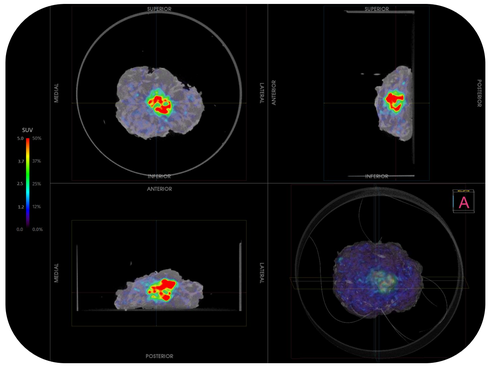


Breast cancer type	N patients
IDC (invasive ductal carcinoma)	84
IDC-AI (IDC aromatase inhibitors)	15
NAT (IDC neoadjuvant chemotherapy)	13
ILC (invasive lobular carcinoma)	16
ILC-AI (ILC aromatase inhibitors)	7
DCIS (ductal carcinoma in situ)	13

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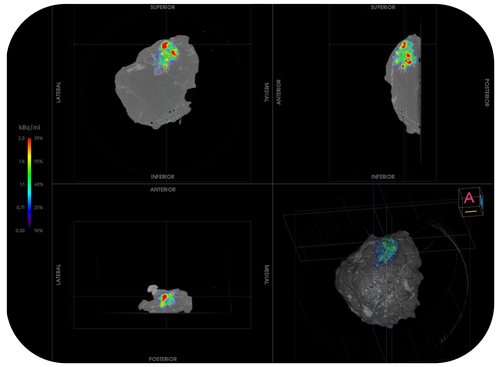
Example Cases

ILC



Surgeon: intraoperatively scored all margins negative
No further actions performed
Histopathology: confirmed negative margins

IDC



Surgeon: intraoperatively scored superior margin positive
Cavity shave was taken
Histopathology: confirmed superior positive margin

Statistical Analysis

Primary endpoint
Addressing positive margins of invasive component in IDC subgroup.

n_{IDC} = 84

negative on histopathology N = 70

positive on histopathology N = 14

n = 10 addressed

n = 3 addressed

SOC

Method	Succes rate
No IMA	70/84 = 83.3%
SoC IMA	73/84 = 86.9%
Micro-PET-CT	80/84 = 95.2%

Methods Comparison	p value
Micro-PET-CT VS No IMA	< 0.001
SoC IMA VS No IMA	0.125
Micro-PET-CT VS SoC IMA	0.065

Secondary endpoint
Addressing positive margins of invasive or in-situ components in total study population.

n_{all} = 148

negative on histopathology N = 113

positive on histopathology N = 35

n = 23 addressed

n = 8 addressed

SOC

Method	Succes rate
No IMA	113/148 = 76.4%
SoC IMA	121/148 = 81.8%
Micro-PET-CT	136/148 = 91.9%

Methods Comparison	p value
Micro-PET-CT VS No IMA	< 0.001
SoC IMA VS No IMA	0.004
Micro-PET-CT VS SoC IMA	0.003

Secondary endpoint
Number of patients that needed resurgery after primary breast-conserving surgery.

n_{all} = 148

No resurgery N = 133 (90%)

Resurgery N = 15 (10%)

Reason for resurgery	N patients
Negative main specimen	6 (4%)
Positive cavity shave	5
Positive on Postop MRI	1
Positive main specimen	9 (6%)

Conclusions

- Specimen PET-CT imaging
  - provides reliable intraoperative visualization across breast cancer subtypes
  - Outperforms SoC IMA methods in the overall population

Future Perspectives

- Can micro-PET-CT specimen imaging be used to intraoperatively detect tumor involvement in cavity shaves or lymph nodes?
- Can micro-PET-CT specimen imaging replace SoC IMA methods?

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Abbreviations

SoC = Standard of Care
PET = Positron Emission Tomography
CT = Computed Tomography
FDG = FluoroDeoxyGlucose
IMA = Intraoperative Margin Assessment

References

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