

Retrospective, multicenter comparison of large-volume oncoplastic with conventional breast conserving surgery regarding oncologic outcomes in high risk breast cancer patients: the iTOP2 study

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Summary

The risk of local breast cancer recurrence after breast conservation differs by breast cancer subtype and is highest in women treated with a triple negative and lowest in women treated with luminal A breast cancer. Other risk factors independent of tumor-biology are age as well as resection margin status. Regarding resection margin the international used definition for a clear margin, which is significantly associated with a reduced local recurrence rate, is “no ink on tumor”. Most recently, a meta-analysis by Vicini suggested that a 2 mm resection free margin rather than “no tumor on ink” yielded the best local recurrence free survival rate with a 56% reduction compared with <2mm, revitalizing the debate. **We hypothesize that Clough level II oncoplastic breast conservation (OBC) reduces locoregional recurrence in high-risk breast cancer compared with conventional breast conservation (CBC) due to wider margins achieved by large-volume resections.**

Design

This will be a multicentre monitored retrospective matched pair analysis. Anonymized data of patients with primary, unilateral, high risk breast cancer of at least 1cm treated with breast conservation within a nationally or internationally certified breast unit will be collected by the study sites and transferred to a central data base for a pooled analysis. Data will be monitored every 6 months externally. Women who have been consecutively treated between 2006 and 2016 with a follow up of at least 30 months are eligible. Both surgical techniques, OBC Clough level II as well as CBC are eligible. If mastectomy had to be performed due to R1 resection, women are not eligible, mastectomy for local recurrence is eligible for data entry but follow up is stopped at that time. Women with OBC level I are not eligible.

Primary Endpoint

In breast recurrence rate

Sample size

CBC 1310 patients, OBC 440 patients

Inclusion Criteria

Women of any age at primary surgery

Histological proven unilateral invasive or non-invasive breast cancer grade 2 or 3

High risk breast cancer subtype (DCIS G3 or above 4cm size, invasive Luminal B, her2pos or triple negative)

Women have to be finally treated with breast conservation, re-excision for R1 is allowed.

For OPS, Clough level II oncoplastic techniques only should be included (resection volume of at least 20%)

Exclusion Criteria

Luminal A invasive breast cancer

Grade 1 in situ carcinoma (DIN I) and Grade 2 in situ carcinoma below 4cm in size

Metastatic disease

Level I Oncoplastic surgery (resection volume of at least 20%)

Invasive cancer size below 1cm is not allowed except there are extensive intraductal components > 4cm

Next steps:

- Application for funding (100-200Euro per case, which cannot be guaranteed at this stage): Fitzal
- Call for participation (OPBC centers) and accrual estimates: Weber
- Circulation of the protocol among participating OPBC centers (Fitzal)
- Completion of protocol (National PI's)
- Assessing the need for ethical approval at each site (Local PI's)