



Surgical complications after immediate breast reconstruction vs. mastectomy alone: impact on the time to delivery of adjuvant therapy

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Background: When mastectomy is planned in women with breast cancer who wish to have a breast reconstruction, there is a choice between immediate and delayed breast reconstruction. Mastectomy combined with immediate breast reconstruction (IBR) is, however, a more complex procedure than mastectomy alone. It is therefore of concern if adding IBR may result in a higher complication rate and thus a risk of delaying adjuvant therapy. The aim of this study was to compare the time from surgery to initiation of adjuvant therapy between women having a mastectomy and IBR with women having a simple mastectomy, and to evaluate if the postoperative complications may postpone the adjuvant therapy for women diagnosed with stage I–III breast cancer.

Methods: This retrospective cohort study included all women who underwent a mastectomy from November 2015 to March 2017 at Odense University Hospital (n=314 mastectomies). The medical records were reviewed regarding patient demographics, health characteristics, post-operative complications and time from surgery to initiation of adjuvant therapy. Women were stratified according to surgery, simple mastectomy or mastectomy with IBR.

Results: The group of women receiving IBR were younger (age 46 *vs.* 59 years, $P < 0.001$). Adjuvant chemotherapy (ACT) was administered to 20 women in the IBR group and 59 women in the simple mastectomy group. The mean time from surgery to adjuvant therapy was 33 days for the IBR group and 32 days for the simple mastectomy group ($P = 0.864$). The number of post-operative major complications were significantly higher among women having IBR compared to simple mastectomy (15% *vs.* 0%, $P = 0.014$).

Conclusions: IBR can safely be offered to selected women with stage I–III breast cancer. There was no difference between the time from surgery to adjuvant therapy, when comparing mastectomy with IBR to simple mastectomy in this study.

Keywords: Immediate breast reconstruction (IBR); adjuvant chemotherapy (ACT); post-operative complications; time to adjuvant chemotherapy (time to ACT)

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Introduction

Each year, nearly 20,000 women (1) are diagnosed with breast cancer in the Nordic countries and in 2016, approximately 4,500 of these women were Danish (2). Mastectomy is the primary surgical treatment for almost 40% of women, despite improvements in treatment (3). The surgical treatment offered depends on the characteristics of the cancer, the size of the tumor, and the preference of the individual woman. Immediate breast reconstruction (IBR) is increasingly being performed (4).

Breast reconstruction can be performed as an immediate or delayed procedure (5). Both methods attempt to reduce the negative psychological effects of a mastectomy and restore the woman's body image (6,7). While IBR may lessen the psychological stress a woman is facing, there are, however, concerns that IBR may be associated with a higher risk of post-operative complications, due to the complex procedure and longer operating time, when compared to simple mastectomy. Hence the initiation of adjuvant chemotherapy (ACT) may be postponed.

Delayed ACT has been shown to be associated with an increase in recurrence of breast cancer and worsen patient survival (8,9). Previous studies have indicated that the time from surgery to ACT may be prolonged in patients having a mastectomy with IBR compared to those having a simple mastectomy (10-13). However, the findings are inconsistent, and some studies report no significant differences (14-16).

The primary aim of this study is to compare time from surgery to initiation of ACT in women treated either with mastectomy and IBR or simple mastectomy. The secondary aim was to compare the rate of complications between groups and to define if the choice of procedure and associated complications may impact the time to initiation of ACT. We present the following article in accordance with the STROBE reporting checklist (available at <https://abs.amegroups.com/article/view/10.21037/abs-21-113/rc>).

Methods

Study design, setting and population

In this retrospective study we reviewed the charts of all women undergoing mastectomy from November 2015 to March 2017 at the Department of Plastic Surgery, Odense University Hospital (OUH). Patients were identified by 4 different ICD10 codes for mastectomy. The ICD10 codes were: KHAC20—total mastectomy, KHAC25—radical

mastectomy, KHAC10—nipple areola sparing mastectomy and KHAC15—mastectomy with excision of the nipple areola. Only women treated for breast cancer stage I–III were included. Women with stage IV metastatic cancer or women who received part of their treatment in other hospitals were excluded (*Figure 1*). Prophylactically treated patients were excluded.

Patients were divided into two groups: (I) women undergoing mastectomy with IBR and (II) simple mastectomy.

Planning of surgical procedure

The medical and surgical treatment options were outlined by the multidisciplinary team consisting of a surgeon, an oncologist, a pathologist, and a radiologist. The treatment was then based on a joint decision by the patient and the breast surgeon. If the women opted for mastectomy and IBR, a plastic surgeon was consulted prior to her final decision. All women had a sentinel node procedure prior to mastectomy to determine the status of the regional lymph nodes. Only women with tumor negative sentinel lymph nodes were candidates for mastectomy and IBR. Women with positive sentinel lymph nodes were offered a simple mastectomy due to the resulting radiotherapy. It is standard practice at our hospital not to offer immediate reconstruction to patients undergoing radiation therapy due to the higher risk of complications and risk of unsatisfying cosmetic result. The standard ACT regimes included three treatments with Epirubicin and Cyclophosphamide followed by nine treatments with Paclitaxel.

All IBR patients were reconstructed using mesh, both biologic and synthetic.

Data collection and outcomes

The primary outcome was comparison of time from surgery to initiation of ACT between the two groups. Days to ACT were defined as days between the mastectomy and the first dose of ACT.

The secondary outcomes were number and types of post-operative complications. The medical records were reviewed to identify major complications. A major complication was defined as one or more of the following complications: skin defect, necrosis, hematoma, infection and red breast syndrome. A skin defect was defined as a defect in the surgical wound that required surgical treatment. These were defined as relevant complications if they occurred

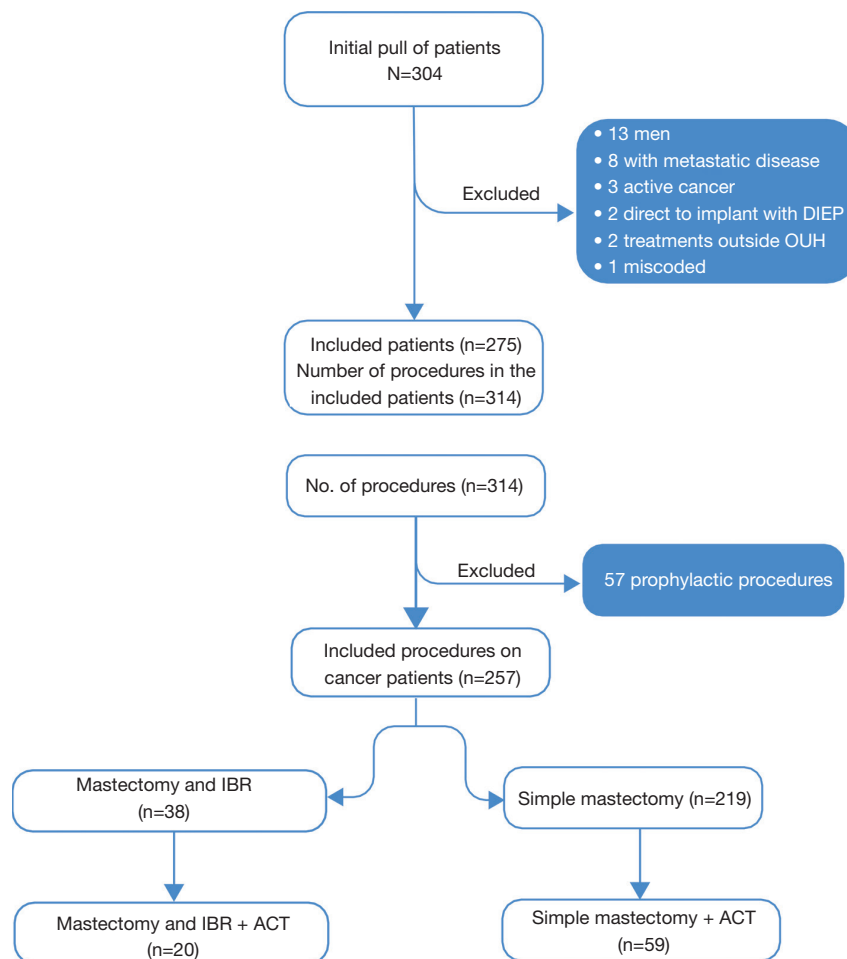


Figure 1 Flowchart of the patient selection procedure. DIEP, deep inferior epigastric perforators (flap); OUH, Odense University Hospital; ACT, adjuvant chemotherapy; IBR, immediate breast reconstruction.

within 3 months of surgery, and demanded in-hospital stay, intravenous administered medicine and/or surgical intervention. Data related to postoperative wound healing as previous radiation and neoadjuvant chemotherapy and data related to the surgery including implant type, breast specimen weight and previous breast surgery were also registered.

Study data were collected and managed using REDCap electronic data capture tools hosted at Odense University Hospital (Research Electronic Data Capture) (17).

Data management and statistical analysis

Categorical data were analyzed using Pearson chi-square test or Fisher's exact test depending on whether the count was greater or lesser than five. Continuous scale

variables were visually assessed for normality to determine whether parametric or non-parametric analysis should be performed. Normally distributed data were analyzed using independent-samples *t*-test, while Wilcoxon signed rank test was used for non-normally distributed data. Numerical data are presented as mean (SD) and categorical data are presented as count (%). All reported P values are two-sided, and the results were considered statistically significant when $P < 0.05$.

To analyze time-to-event data, a Kaplan-Meier curve was plotted and a hazard ratio (HR) was calculated using Cox regression for comparison of days to chemotherapy. Age, hypertension and tissue weight were included as a covariate in the regression. Logistic regression was used to assess risk and estimate odds ratio of complications between mastectomy only and mastectomy with IBR.

Table 1 Patient characteristics at the time of mastectomy divided by main groups: simple mastectomy and mastectomy with immediate breast reconstruction

Characteristics	Mastectomy + ACT (n=59)	Mastectomy + IBR + ACT (n=20)	P value
Age at surgery (years), mean ± SD	58.7±10.2	45.9±10.7	<0.001
BMI (kg/m ²), mean ± SD	26.1±4.5	24.9±5.2	0.346
Tobacco use, n (%)	16 (27%)	4 (20%)	0.767
Hypertension, n (%)	19 (32%)	4 (20%)	0.398
Diabetic, n (%)	5 (8%)	1 (5%)	1.000
Comorbidity*, n (%)	10 (17%)	3 (15%)	1.000
Previous radiation to breast, n (%)	1 (2%)	2 (10%)	0.156
Previous surgery to breast, n (%)			
No	50 (85%)	16 (80%)	0.729
Yes (<30 days)	3 (5%)	3 (15%)	0.167
Tissue weight (g), mean ± SD	797±408	430±196	0.0002
Implant type, n (%)			
Expander	–	1 (3%)	–
Permanent	–	37 (97%)	–

*, comorbidity: other systemic disease like hypothyroidism, bilateral salpingo-oophorectomy etc. ACT, adjuvant chemotherapy; IBR, immediate breast reconstruction; SD, standard deviation; BMI, body mass index.

If a patient was included twice because of bilateral procedure, all analyses were adjusted with clustered standard errors.

Ethics

The study was approved by the Danish Data Protection Agency (Jr 19/10793) and Danish Patient Safety Authority (Jr 3-3013-2131/1), therefore individual consent for this retrospective analysis was not required. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Results

Patient characteristics and surgical details

We identified 304 eligible patients, of these 29 were excluded (*Figure 1*). The remaining 275 women had undergone a total of 314 procedures, of which 57 were prophylactic and excluded. We performed 257 therapeutic procedures and 79 of these had ACT: 20 mastectomies with IBR, and 59 simple mastectomies.

The baseline characteristics and demographics are presented in *Table 1*. When comparing the simple mastectomy and IBR group, we found that the simple mastectomy group was significantly older (mean 59 vs. 46 years, $P < 0.001$) and had larger mastectomy specimen weight (797 vs. 430 g, $P = 0.0002$). We performed 38 breast reconstructions, 37 with permanent implants and one expander to implant.

Time to delivery of ACT

ACT was administered to 79 patients following mastectomy, 59 had a simple mastectomy and 20 mastectomy and IBR, illustrated in *Table 2*. The time to delivery of ACT was 32 and 33 days for women having simple mastectomy and mastectomy with IBR respectively ($P = 0.864$; *Figure 2*).

Complication rates

Complication rates for women receiving ACT is shown in *Table 3*. A higher rate of major complications was found among women receiving IBR and ACT 3/20 (15%), compared to simple mastectomy and ACT 0/59 (0%)

Table 2 Time to delivery of ACT for women undergoing mastectomy only and mastectomy with IBR

Data	Mastectomy	IBR	P value	HR (95% CI)
No. of patients	59	20	–	–
Time to ACT (days), mean (range)	32 (17 to 70)	33 (21 to 52)	0.864	1.06 (0.546 to 2.055)

ACT, adjuvant chemotherapy; IBR, immediate breast reconstruction.

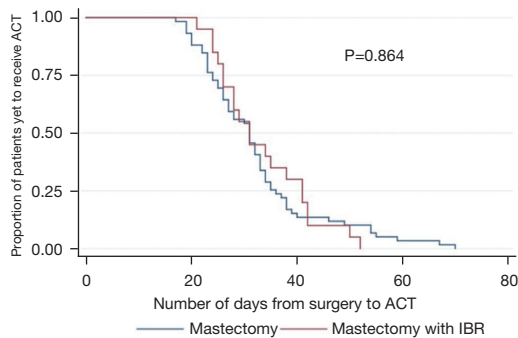


Figure 2 Time to delivery of ACT in women undergoing mastectomy only (n=59) and mastectomy with IBR (n=20). Data is presented as a Kaplan-Meier curve. ACT, adjuvant chemotherapy; IBR, immediate breast reconstruction.

($P=0.014$; Table 3).

The mean follow-up time ranged between 12 and 30 months.

Discussion

We found that women treated with mastectomy and IBR more frequently experienced postoperative complications compared to women treated with simple mastectomy. The complications did not affect the time from surgery to initiation of ACT, when comparing the two groups. Mastectomy followed by IBR is a more demanding and longer procedure than mastectomy alone and as such associated with a higher risk of complications. One would expect that major complications would be associated with a delay in initiation of ACT, which was not the case in our study. This was in line with newly published multicenter study by O'Connell *et al.* They included 409 women having mastectomy only and 147 women with mastectomy and IBR all receiving ACT. No clinically significant difference in time to delivery of adjuvant therapy was found (3). O'Connell *et al.* divided their patients into four groups of: (I) mastectomy only, (II) mastectomy and IBR with implant-only technique, (III) mastectomy and IBR with pedicled

flaps and (IV) and mastectomy IBR with free-flap technique. They found no significant difference in time to delivery of adjuvant therapy between the groups, although IBR with free-flap technique was associated with longer time to chemotherapy.

One reason and explanation for the lack of prolonged time to ACT despite higher complication rate among the mastectomy + IBR group in this study could be quick diagnosis and treatment of complications by the surgical team to avoid any delay. Similar reflections have been made by other researchers (18). Another possible reason is the small sample size and small overall number of complications in this study.

The complication rates found in this study were comparable with complication rates in previously published studies (10). Sousa *et al.* (18) had a definition of complications very similar to the definition in this study. In their study group of 315 IBR patients and 401 simple mastectomies, they found a slightly lower complication rate of 13% in the IBR group, and 3% in the mastectomy only group. Zhong *et al.* (10) looked at a group of 391 patients and found a complication rate of 15.5% for the IBR group and 3.7% for the mastectomy only group. Other studies present either higher or lower complication rates. Chang *et al.* (16) found that 25.2% of their IBR group (n=107) experienced infection, compared to 15.2% in the mastectomy only group (n=113). Furthermore, 15.9% of the IBR group had to return to surgery for various reasons, compared to only 1.8% in the mastectomy only group. Hamahata *et al.* (14) had a very low complication rate of 4% for the IBR group (n=50) and 3% for the mastectomy only group (n=66).

The differences in complication rates among studies might be due to several reasons. (I) Different definitions of complications among the different studies. (II) Variable diligence in registering complications. (III) Different approaches in handling the complications. Some use antibiotics on any suspicion (resulting in a higher registration of infections) while others have a higher threshold, resulting in lower numbers of women registered

Table 3 Number of complications in women treated for breast cancer with simple mastectomy and mastectomy with IBR and ACT

Type of complication	Mastectomy + ACT	IBR + ACT	Odds ratio (95% CI)	Log regression, P value
No. of procedures	59	20		
Total of women with complications, n (%)	26 (44%)	9 (45%)	1.04 (0.37–2.88)	0.942
Major complication	0 (0%)	3 (15%)	NA	0.014
Skin defect	4 (7%)	5 (25%)	4.58 (1.09–19.22)	0.037
Necrosis	7 (12%)	2 (10%)	0.83 (0.16–4.34)	0.821
Hematoma	12 (20%)	1 (5%)	0.21 (0.03–1.70)	0.142
Infection	7 (12%)	4 (20%)	1.86 (0.48–7.17)	0.369
Red breast syndrome	0 (0%)	1 (5%)	NA	0.203

IBR, immediate breast reconstruction; ACT, adjuvant chemotherapy; NA, not applicable.

with treatment of infection. (IV) Different methods of reconstruction—two stage reconstruction with tissue expanders *vs.* one stage with permanent implants. Many of the above mentioned studies used tissue expanders (10,12,15-19) or did not specify what kind of implants the women were reconstructed with (11,13,14). Sousa *et al.* (18) used tissue expanders as reference and found that permanent implants have a higher adjusted risk ratio of any complication, though not significant. Of the 38 mastectomies with IBR procedures in this study, only 1 was performed with an expander, the rest were permanent implants. This might explain the relatively small difference in complication rates in this study compared to other studies using expander implants only. It is standard practice at our hospital not to offer IBR to patients treated with radiation therapy, this practice differs from other hospitals and therefore limits the external validity of this study.

Patient selection may explain why no difference in time to delivery of adjuvant therapy was found between our two groups, even though the mastectomy and IBR group experienced a higher incidence of major complications (15% *vs.* 0%). Our results show that patients receiving mastectomy and IBR were younger, had fewer cases of hypertension and smaller mastectomy specimens. Surgeons are prone to select patients with fewer risk factors for IBR than mastectomy only, in order to minimize complications and prevent any delays in adjuvant therapy (3).

The majority of women with breast cancer is treated with ACT. Questions to how much of a delay in administration, that is acceptable without decreasing survival still exists. A study from 2005 by Cold *et al.* (20) could not find any survival benefit among Danish breast cancer patients due to

early start of ACT within the first 60–90 days after surgery. However, later publications have shown worse outcomes when chemotherapy was delayed for patients with stage III, triple negative or HER2 positive breast cancer (8), and an increased risk of death for patients with a delay over 4 weeks (9). Smith-Graziani *et al.* conducted a large study documenting that chemotherapy delays are associated with worse survival in older breast cancer patients. They found chemotherapy delays beyond 90 days after surgery negatively affected survival, and that delays were associated with clinical and socioeconomic factors (21).

Despite the fact that nearly all women were reconstructed with permanent implants, resulting in a relatively high rate of complications, we found similar time to delivery of ACT in the two groups. This is in accordance with some of the previous published studies, although most of these include women reconstructed with tissue expanders (3,14-16). The systematic review by Xavier Harmeling *et al.* (22) and the multicenter study by O'Connell *et al.* (3) both found that IBR does not delay time to ACT and concludes that IBR is a valid option for breast-cancer patients. However, some studies did find a significant delay among patients receiving IBR (10-13). Eck *et al.* (15) found similar time to delivery of ACT in the two groups (42 *vs.* 41 days) but great variations were present. The range of time to delivery of ACT was 8–147 in the mastectomy group and 7–175 in the IBR group. This shows that major complications can severely impact time to ACT. Our corresponding ranges were smaller and in the opposite direction: 17–70 in the mastectomy group *vs.* 21–52 in the IBR group.

This study has several weaknesses, which must be considered for future studies. Even though, the initial

population was large, the sample was small when looking at the specific outcomes. The retrospective design introduces a risk of bias regarding accurate registrations of complications. Furthermore, the higher rate of major complications in the IBR group could be caused by the more tightly controlled follow up scheme compared to the mastectomy group. One of the strengths of this study is the high data completeness. There were very few lacking data, and no recall bias, as data was obtained from medical records recorded at the present time. Patient selection was a problem in some studies where outliers were excluded. However, none of our patients were excluded because of excessively delay to ACT.

Conclusions

We found no difference in time to delivery of ACT when comparing simple mastectomy to mastectomy combined with IBR. Mastectomy combined with IBR using permanent implants seems to be a safe procedure in women with stage I–III breast cancer when treated by an experienced team of breast and plastic surgeons.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://abs.amegroups.com/article/view/10.21037/abs-21-113/rc>

Data Sharing Statement: Available at <https://abs.amegroups.com/article/view/10.21037/abs-21-113/dss>

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was approved by the Danish Data Protection Agency (Jr

19/10793) and Danish Patient Safety Authority (Jr 3-3013-2131/1), therefore individual consent for this retrospective analysis was not required. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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