research article

Does concurrent gynaecological surgery affect infectious complications rate after mastectomy with implant-based reconstruction?

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Radiol Oncol 2023; 57(1): 80-85.

Received 24 April 2022
Accepted 23 May 2022

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Disclosure: No potential conflicts of interest were disclosed.

Background. Women who undergo breast cancer surgery often have an indication for gynaecological procedure. The aim of our study was to compare infectious complications rate after mastectomy with implant-based reconstruction in patients with and without concurrent gynaecological procedure.

Patients and methods. We retrospectively reviewed clinical records of 159 consecutively operated patients after mastectomy with implant-based reconstruction. The patients were divided in 2 groups: 102 patients without (Group 1) and 57 with (Group 2) concurrent gynaecological procedure. Infectious complications rates between the groups were compared using χ^2-test. Logistic regression was performed to test for association of different variables with infectious complications.

Results. There were 240 breast reconstructions performed. Median follow-up time was 297 days (10–1061 days). Mean patient age was 47.2 years (95% CI 32.8–65.9); 48.2 years (95% CI 46.1–50.3) in Group 1 and 45.8 years (95% CI 43.2–48.3) in Group 2; p = 0.002). Infectious complications rate was 17.6% (17.6% *vs.* 17.5%, p = 0.987), implant loss occurred in 5.7% (4.9% *vs.* 7.0%, p = 0.58). Obesity (body mass index [BMI] > 30 kg/m^2), age, previous breast conserving treatment (BCT) with radiotherapy (RT) were identified as risk factors for infectious complications in univariate analysis. Obesity (adjusted odds ratio [aOR] 3.319, 95% CI 1.085–10.157, p = 0.036) and BCT with RT (aOR 7.481, 95% CI 2.230–25.101, p = 0.001) were independently associated with infectious complications in multivariate model.

Conclusions. Concurrent gynaecological procedure for patients undergoing mastectomy with implant-based reconstruction did not carry an increased risk for infectious complications.

Key words: breast cancer; infectious complications; implant-based reconstruction; concurrent surgical management; implant loss

Introduction

Combining a clean surgery that involves prosthetic material with a clean-contaminated surgery has always been controversial.[1] Women who undergo mastectomy with implant reconstruction for risk reduction or cancer often have an indication for a gynaecological procedure.[2] In premenopausal women with hormone receptor-positive tumours, ovarian suppression with surgical oophorectomy has been recognised as part of the treatment strategy for more than a century.[3] In high-risk women,

surgical intervention with prophylactic bilateral mastectomy reduces breast cancer risk by up to 95%, while bilateral salpingo-oophorectomy reduces both breast and ovarian cancer risks by around 50% and 80%, respectively.[4,5] It is also associated with improved survival.[6–8]

When immediate implant-based breast reconstruction is planned, skin-sparing mastectomy (SSM) is most commonly performed, but nipple-sparing mastectomy (NSM) can be a safe option in selected cases.[9–11]

Infectious complications in implant-based reconstructions can cause prolonged antibiotic treatment and can result in implant removal.[12,13] This may delay adjuvant treatments for breast cancer and cause scarring that can affect functional as well as aesthetic outcome. Therefore, a low infectious complications rate is important.[14] Infectious complications rate varies between centres and is around 20%.[15]

Due to increased operating time and an intraabdominal procedure, coordinated surgical management of the breast with a concurrent gynaecological procedure could increase the likelihood of infectious complications.[16] On the other hand, combining the procedures adds to patient satisfaction and optimises the time and cost management.[17] The aim of our study was to compare infectious complications rate after mastectomy with implant-based reconstruction in a group of patients with and without concurrent gynaecological procedure.

Patients and methods

Study cohort and data collection

We conducted a retrospective analysis of infectious complications in patients after implant-based reconstruction with or without concurrent gynaecological procedure and followed them until the date of complication, expander-prosthesis exchange surgery, or until last follow-up visit. We retrospectively reviewed records of 159 women (and 240 breast reconstructions) that were consecutively operated at the Institute of Oncology Ljubljana, Slovenia between February 2014 and June 2020 for a new or previously diagnosed breast cancer and/or had an increased risk for developing breast cancer, mainly due to a recognised *BRCA1/2* mutation. Unilateral or bilateral mastectomy was performed, either SSM or NSM, followed by breast reconstruction with either tissue expander or prosthesis. Fifty-seven patients had a laparoscopic gynaecological procedure (salpingectomy, oophorectomy, hysterectomy or a combination) during the same anaesthesia. Postoperative complications were tracked reviewing follow-up visits with surgical oncologist and reconstructive surgeon. We recorded infectious complications requiring the use of oral or parenteral antibiotics, infectious and wound healing complications requiring surgical treatment under general anaesthesia (necrectomy, debridement) and implant loss due to infection.

Treatment protocol

As part of standard treatment protocol at our centre immediate reconstruction is offered after prophylactic or therapeutic mastectomy, either autologous or implant-based. Patients' cases are discussed prior to surgery at a multidisciplinary team meeting between a surgical oncologist, a radiation therapist and a reconstructive surgeon. The patients are operated under general anaesthesia with perioperative antibiotic prophylaxis. Two grams of cephazolin are given for prophylaxis and the antibiotics are continued post-operatively, typically until drains are removed. If a gynaecological procedure is planned, it is performed first, followed by breast surgery. The gynaecological procedure is performed laparoscopically. Mastectomy with or without axillary lymph node surgery is performed by a surgical oncologist, followed by the reconstructive procedure that is performed by a reconstructive surgeon. A tissue implant is inserted in a pocket, which consists of pectoralis major and serratus anterior muscle. Prior to implant insertion, the area is irrigated with antibiotic solution. The drainage stays in place until less than approximately 50 ml discharge daily for two consecutive days. After the drains are removed and the wounds heal, tissue expanders are filled gradually with saline solution in an outpatient setting every two to three weeks.

Statistical analysis

Patients' characteristics were compared between the two groups (with and without gynaecological procedure) with χ^2 test or Fisher's exact test for categorical variables and Student t-test for continuous variables. Data were reported as counts and frequencies for categorical and as median with sample range or mean with 95% confidence interval (CI) for continuous variables. Univariate binary logistic regression was performed to test for association of different variables with infectious complications. Variables with a statistical significance

TABLE 1. Patients characteristics

Variable	All	Group 1	Group 2	p
	N = 159	N = 102 (64.2%)	N = 57 (35.8%)	
Age (years)	47.2 (95% CI 32.8–65,9)	48.2 (95% CI 46.1–50.3)	45.8 (95% CI 43.2–48.3)	**0.002**
BMI (kg/m^2)	24.7 (95% CI 18.9–34,8)	24.4 (95% CI 23.4–25.4)	25.8 (95% CI 24.1–27.4)	0.189
Smoking	37 (23.3%)	22 (21.6%)	15 (26.3%)	0.497
Diabetes mellitus	3 (1.9%)	3 (2.9%)	0	0.191
ASA score				0.622
1	31 (19.5%)	24 (23.5%)	7 (12.3%)	
2	80 (50.3%)	56 (54.9%)	24 (42.1%)	
3	11 (6.9%)	7 (6.9%)	4 (7.0%)	
Unknown	37 (23.3%)	15 (14.7%)	22 (38.6%)	
Previous BCT with RT	29 (18.2%)	8 (7.8%)	21 (36.8%)	**0.001**
NACT	25 (15.7%)	22 (21.6%)	3 (5.3%)	**0.007**
Adjuvant RT	35 (22.0%)	32 (31.4%)	3 (5.3%)	**0.001**
ACT	33 (20.8%)	23 (22.5%)	10 (17.5%)	0.455

Group 1: Patients without gynaecological procedure; Group 2: Patients with gynaecological procedure.

ACT = adjuvant chemotherapy; ASA = American Society of Anaesthesiology; BC = breast cancer; BCT = breast conserving therapy; BMI = body mass index; NACT = neoadjuvant chemotherapy; RT = radiotherapy

of $p < 0.1$ were included in a multivariate binary logistic regression model. Data were analysed using IBM SPSS Statistics software (Statistical package for the Social Sciences Statistical Software, IBM Corporation, Armonk, NY, USA). Statistical significance was set at $p < 0.05$.

The study was reviewed and approved by the Institutional Review Board and Ethics Committee.

Results

In 159 patients, 240 breast reconstructions were performed with 214 tissue expanders and 26 prostheses. All patients were women. Median follow-up time was 297 days (10–1061 days), 321 days (14–712 days) in Group 1 and 273 days (10–1061 days) in Group 2. Expander-prosthesis exchange surgery was mostly performed within a year from initial surgery, median 333.5 days (74 – 712 days).

Fifty-seven patients (35.8%) had a concurrent laparoscopic gynaecological procedure (Group 2). These patients were younger at the time of surgery (Group 1 48.2 years, 95% CI 46.1–50.3 *vs.* Group 2 45.8 years, 95% CI 43.2–48.3, $p = 0.002$) and more likely to have been previously treated with breast conserving therapy (BCT) including radiotherapy (RT) for breast cancer (Group 1 7.8% *vs.* Group 2 36.8%, $p = 0.001$). Patients without combined procedures (Group 1) were more likely treated with neoadjuvant chemotherapy (NACT) (21.6% *vs.* 5.3%, $p = 0.007$) and more likely received adjuvant RT (31.4% *vs.* 5.3%, $p = 0.001$). We present the patients' characteristics in Table 1.

TABLE 2. Surgical site infections after implant reconstruction

	All (%)	Group 1 (%)	Group 2 (%)	p-value
All*	28 (17.6)	18 (17.6)	10 (17.5)	0.987
Surgical intervention needed**	13 (8.2)	8 (7.8)	5 (8.8)	0.84
Implant loss***	9 (5.7)	5 (4.9)	4 (7.0)	0.58

Group 1: Patients without gynaecological procedure; Group 2: Patients with gynaecological procedure.

*all surgical site infectious complications requiring oral or i.v. antibiotic, surgical debridement under general anaesthesia or implant removal surgery**surgical intervention requiring general anaesthesia ***tissue-expander or prosthesis removal due to infection.

Overall infectious complication rate in our cohort of 159 women was 17.6% and did not significantly differ between the groups (17.6% *vs*. 17.5%, p = 0.987). Tissue implants had to be removed due to infection in 5.7% (4.9% *vs.* 7.9%, p = 0.58). We present the comparison between groups in Table 2.

Several covariates were tested for association with overall infectious complications in the entire cohort. Obesity (body mass index [BMI] > 30 kg/m^2), age and previous BCT with RT for breast cancer were identified as risk factors for infectious complications. Concurrent gynaecological procedure, smoking, diabetes, American Society of Anaesthesiology (ASA) score, neo-/adjuvant systemic therapy and adjuvant RT were not significantly associated with infectious complications (Table 3).

Age at the time of surgery, BMI and previous BCT with RT were included in the multivariate model. Obesity (BMI > 30 kg/m^2) and previous BCT with RT were independently associated with infectious complications. Women with a history of BCT and RT for breast cancer had approximately three times higher odds for infectious complications compared to those without previous BCT with RT (adjusted odd ratio [aOR] 3.319, 95% CI 1.085–10.157, p = 0.036). Obese patients (BMI > 30 kg/m^2) had about 7.5-times higher odds for infectious complications compared to women who had a BMI in the normal range between 19 and 25 kg/m^2 (aOR 7.481, 95% CI 2.230–25.101, p = 0.001) (Table3).

TABLE 3. Variables associated with infectious complications

Variable	OR	P	aOR	p
Gynaecological procedure	1.116 (0.486–2.564)	0.796	NA	NA
BMI < 25	1		1	
25–30	3.000 (0.974–9.239)	0.056	2.552 (0.777–8.382)	0.122
> 30	8.100 (2.540–25.826)	**< 0.001**	7.481 (2.230–25.101)	**0.001**
Age > 45	2.707 (1.118–6.552)	**0.027**	1.939 (0.497–3.907)	0.529
Smoking	1.061 (0.413–2.724)	0.903	NA	NA
Diabetes	2.286 (0.200-26.094)	0.506	NA	NA
ASA 1	1			
2	1.821 (0.560-5.921)	0.319	NA	NA
3	0.675 (0.067-6.789)	0.739	NA	NA
Previous BCT with RT	3.802 (1.546-9.354)	**0.004**	3.319 (1.085–10.157)	**0.036**
NACT	0.345 (0.076-1.553)	0.165	NA	NA
ACT	0.995 (0.369-2.687)	0.992	NA	NA
Adj. RT	0.909 (0.338-2.442)	0.849	NA	NA

aOR = adjusted odds ratio; ASA = American Society of Anaesthesiology; ACT = adjuvant chemotherapy; BC = breast cancer; BCT = breast conserving therapy; BMI = body mass index; NACT = neoadjuvant chemotherapy; RT = radiotherapy

Discussion

In presented retrospective single centre series of 159 women, who underwent mastectomy with implant-based reconstruction there was no association between infectious complications rate and concurrent gynaecological procedure.

The results are consistent with other studies. In a group of seventy breast cancer patients that underwent laparoscopic oophorectomy, among which 29 had a concurrent breast surgery, Willshire *et al*. have shown it is safe to carry out the gynaecological procedure in a combined setting. However, only four patients in this cohort had mastectomy with implant-based reconstruction and the focus on postoperative complications was the gynaecological procedure.[2] For 62 high-risk women that opted for breast and ovarian risk-reducing surgery, post-operative complications rate was no different between sequential *vs*. coordinated surgical management. The study included autologous reconstructions.[18] Furthermore, a new approach has been described for performing laparoscopy via a transmammary route to improve aesthetic outcome and avoid abdominal scars.[19]

In a recently published study, the rates of postoperative complications for implant-based reconstructions were comparable between 141 patients with concurrent gynaecological and 29 patients without gynaecological procedure.[20] The complications only represent the perioperative period, but the sample size is comparable to our study.

Overall, infectious complications rate in our cohort was 17.6% and implant loss occurred in 5.7%. In a recent case series of 16 patients with coordinated surgical management, a 37% 30-day postoperative complication rate was observed, but minor complications, such as seroma and excessive drainage were also included.[21] In a subgroup of 19 coordinately managed patients with implant-based reconstruction, implant loss was observed in two women (11%). In larger series, implant loss rates are comparable to our centre.[22]

In our study, patients in the two groups were different for age, history of BCT with RT, NACT and adjuvant RT. Patients that had combined procedures were younger, which is consistent with the fact that gynaecological risk reduction surgery has greater survival gain if performed earlier.[23] A higher proportion of women with a history of BCT in Group 2 is also reasonable, as they would more often have an indication for either endocrine or prophylactic gynaecological procedure.[2]

Obesity, defined as BMI > 30 kg/m^2 is an established risk factor for surgical site infection and our study results are in accordance with this.[12,24] Confidence intervals are relatively large due to low absolute number of obese patients in our study cohort. We can explain the low numbers with the fact that obese patients are more often advised against breast reconstruction at the multidisciplinary team meeting. They often have other comorbidities that can be associated with complications during and after surgery. The association with obesity in our study is statistically significant and displays more than seven times higher odds for infectious complications compared to baseline BMI. Obesity is also a risk factor for implant loss and reduces self-image after reconstructive procedure.[25] Similar is known for age; however, the effect in our cohort was small in univariate and lost in multivariate analysis. This could be because median age was below 50 years and patients in our cohort did not have many comorbidities. Smoking has also been recognised as a risk factor for complications, but in our cohort, no association was observed. The data on smoking was inconsistent due to retrospective data recollection and loose definition of smoking status.

A history of BCT with RT has been associated with an increased complication rate after tissue expander surgery in previous studies and our study shows similar results.[26,27] Postoperative RT is also often recognised as a risk factor for infection and implant loss.[15,28] In a large systematic review, Momoh *et al*. reported no difference in reconstruction failure rates between patients with a history of BCT with RT and postoperative RT.[29] In our cohort, adjuvant RT was not associated with an increased risk for infectious complications. In univariate analysis, it even displayed a protective effect, although not statistically significant, and was therefore not included in the multivariate analysis.

Neither NACT nor adjuvant chemotherapy were associated with infectious complications and the results are consistent with other studies.[30] In a large meta-analysis, NACT was shown to slightly increase implant loss rates, but no delay in starting adjuvant treatment was observed.[31]

The main limitation of our study is retrospective data collection, including quality of data and selection bias. Patients that were at higher risk for complications, were more likely advised against coordinated surgical management in the first place. Sample size was sufficient, but small numbers in subcategories resulted in large confidence intervals. The study was conducted at the only referral centre for breast cancer cases requiring reconstruction in Slovenia. Follow-up is continued in the outpatient setting and patients are seldom lost during follow-up. Other strengths of the study are recent data and a long follow-up time; most patients have been followed until expander-prosthesis exchange surgery.

Concurrent laparoscopic gynaecological procedure for patients undergoing mastectomy with implant-based reconstruction was safe and did not carry an increased risk for postoperative infectious complications. Obesity and previous BCT with RT were independent risk factors for infectious complications.

Acknowledgments

The authors acknowledge the financial support from the Slovenian Research Agency (research core funding No. P3-0352 (C).

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