The Assessment of Early Complications and Risk Factors Affecting Their Occurrence in Breast Reconstructive Procedures

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Abstract

The presence of postoperative complications may have a significant impact on the outcome of the breast reconstruction. The aim of this study was to investigate early postoperative complications and the risk factors for their occurrence. A prospective analysis was carried out to evaluate surgical outcomes after breast reconstructive surgeries performed over a 2-year period. Procedures included expander/implant (TE/IMP), pedicle transverse rectus abdominis musculocutaneous (pTRAM), and latissimus dorsi (LD) techniques. All adverse events which occurred within 6 weeks of surgery were ranked according to severity based on the contracted Accordion grading system. Outcomes were assessed for their association with surgical, demographic, and clinical variables. Sixty-one consecutive breast reconstruction procedures were analyzed. The overall complication rate was 60.7% ($n = 37$), and 8 patients (13.1%) required reoperation. The lowest complication rate was observed in implant-based reconstructions (TE/IMP, 18.8%; pTRAM, 72.7%; LD, 78.3%; $p = 0.008$). Mild complications occurred significantly more often after LD reconstructions (LD, 60.9%; pTRAM, 22.7%; TE/IMP, 12.5%; $p = 0.031$), while severe complications were significantly more frequent after the pTRAM procedures (pTRAM, 27.3%; TE/IMP, 6.2%; LD, 8.7%; $p = 0.047$). Severe complications were associated with higher rehospitalization rate ($p = 0.010$) and longer hospital stay. Study revealed a significant impact of the operative method on the incidence and severity of early complications after breast reconstruction procedures with little effect from other demographic and clinical factors.

Keywords Breast reconstruction · Complications · Outcomes · Risk factors · Accordion Severity Grading System

Introduction

Breast reconstruction is a fundamental element of breast cancer treatment, which allows many women to recover and return to a normal life. Breast reconstructive procedures have a proven positive impact on the patients' quality of life, self-esteem, satisfaction with appearance, and sexuality [1]. However, there is a certain amount of risk of complications and failure. The overall complication rate after reconstructive

surgery is reported to be 2.3–60% [2–5] for implant-based reconstruction and 10.5–73.9% [2, 5–8] for autologous reconstruction. The risk factors for occurrence of complications mentioned in publications include obesity, older age, comorbidities, radiation therapy, or smoking [2, 6, 9–13]. Because there are inconsistent reports regarding the frequency of complications, we decided to analyze our complications and the factors which affect them. Information and thorough discussion about the risk of complications, their severity, and the benefits of choosing a specific reconstruction method should be an indispensable part of each patient's pre-operative qualification.

The aim of the study was to analyze postoperative complications associated with breast reconstruction, to compare their incidence and severity in relation to various surgical methods and assess the impact of demographic and clinical factors on their occurrence. The collected results can be used to improve the quality of patient care, improve communication between the surgeon and the patient, and support the adequate selection of the reconstruction method.

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Patients and Methods

The study was conducted in university teaching hospital as a prospective analysis of all patients who underwent breast reconstruction from 2018 to 2019. The study protocol and design were approved by the local bioethics committee. The collected data included the age of patients, body mass index, smoking status, previous radiation therapy, previous chemotherapy, comorbidities, reconstruction timing (immediate or delayed), method of reconstruction, length of hospital stay (LOS), rehospitalization rate, and all adverse events which occurred within 6 weeks of surgery. Comorbidities taken into account in the analysis included hypertension, diabetes, thyroid diseases, autoimmune diseases (systemic lupus, Sjögren's syndrome), ischemic heart disease, and multiple sclerosis. The total LOS was defined as the total time of primary hospitalization and all subsequent hospitalizations which resulted from postoperative complications. In the study we included all patients who underwent breast reconstruction due to cancer-related amputation. We excluded patients who underwent breast reconstruction for reasons other than breast cancer or the genetic burden of breast cancer (e.g., Poland's syndrome, post-traumatic reconstructions). The study included patients with unilateral and bilateral reconstruction, with immediate and delayed reconstruction, as well as secondary reconstruction after previous unsuccessful surgery (e.g., latissimus dorsi flap reconstruction after an unsuccessful expander/implant reconstruction). A single reconstruction procedure was a unit of analysis for all statistics.

The reconstructive techniques applied in the analyzed period were divided into implant-based (tissue expander/implant), autologous (pedicled transverse rectus abdominis musculocutaneous [pTRAM] flap, supercharged pTRAM), and combined methods (pedicled latissimus dorsi myocutaneous [LD] flap with implant). All expanders and implants in delayed reconstructions were placed under the pectoralis major muscle. In immediate, implant-based reconstructions, a prosthesis was placed prepectorally and covered with TIGR mesh [TIGR Matrix, Novus Scientific, Uppsala, Sweden]. Autologous reconstructions were conducted with the use of pedicled rectus abdominis flap. In selected cases, flap was supported by additional microsurgical anastomosis of the lower epigastric vessels with internal thoracic vessels (pTRAM supercharged). Combined methods involved the use of a silicone prosthesis covered with a pedicled latissimus dorsi flap. All procedures were conducted by an experienced surgical team under the supervision of the senior author.

Our main subject of interest was the occurrence of postoperative complications depending on the reconstruction method chosen and the factors affecting their occurrence. Postoperative complications were assessed with the use of the contracted version of Accordion Severity Grading System (ASGS) [14]. Following the approach adopted in the

classification, we defined complication as “an event unrelated to the purpose(s) of the procedure, an unintended result of the procedure which occurs in temporal proximity to the procedure and causes a deviation from the ideal postoperative course” [15]. The overall complication rate was expressed as the number of patients with at least one complication. If a patient had more than one complication, the highest severity complication was selected for the analysis. The study focused on the occurrence of early postoperative complications; therefore the period of 6 weeks after the surgery was used as the observation time for the onset of complications. Recorded postoperative complications meeting the definition criteria included hematoma, seroma, bleeding requiring the transfusion of blood products, marginal necrosis, partial flap necrosis, superficial wound infection, deep wound infection, donor-side (abdomen) wound dehiscence, wound dehiscence with implant exposure, and circulatory failure resulting in hospitalization within the intensive care unit.

Statistical analyses were carried out with IBM SPSS Statistics 25, TIBCO Statistica 13.3 and R 3.5.3 software. Spearman's correlation, Fisher's exact test, ordinal regression analysis, and Kruskal-Wallis variance analysis were used. The significance level was considered to be $p = 0.05$.

Results

Sixty-one consecutive breast reconstructions were performed in the years 2018–2019. Characteristics of study cohort are shown in Table 1. The mean age of patients was 54.8 years, mean BMI was 26.7, the majority of patients were non-smokers (83.6%), and more than half had at least one comorbidity (54.1%). The percentage of patients with prior chemotherapy and radiotherapy was 80.3 and 50.8%, respectively.

The group included 16 (26.2%) implant-based reconstructions, 22 (36.1%) reconstructions with autologous tissues and 23 (37.7%) combined reconstructions. Delayed reconstructions constituted 86.9% ($n = 53$), while breast amputation with immediate reconstruction 13.1% ($n = 8$) of cases. Among the procedures utilizing alloplastic materials, the final implant was used in 11 cases, and the tissue expander was used in 5 cases. The autologous tissue reconstructions were conducted with the use of a pTRAM flap in 6 cases and pTRAM supercharged in 16 cases (including 2 cancer-related amputations with immediate reconstruction). Reconstructions involving LD with implant (combined method) were conducted as delayed reconstructions in 18 cases and in 5 cases as an immediate reconstruction.

The average time of primary hospitalization in the whole group was 5.82 days. Nine patients (14.8%) required rehospitalization due to postoperative complications, which extended the total LOS in the group to an average of 7.54 days.

Table 1 Characteristics of patients, associated treatments, reconstruction procedure, and length of hospital stay ($n = 61$)

Characteristics according to		
Patients		
Mean age at surgery (years)	54.8	(32–74)
Age < 50	21	34.4%
Age $\geq$ 50	40	65.6%
Mean body mass index	26.7	(20–38)
Body mass index $\geq$ 25	25	41%
Body mass index $\geq$ 25	36	59%
Non-smokers	51	83.6%
Smokers	10	16.4%
Number of comorbidities:		
0	28	45.9%
1	21	34.4%
2–3	9	14.8%
> 3	3	4.9%
Breast reconstruction procedure		
Implant-based	16	26.2%
Autologous	22	36.1%
Combined methods	23	37.7%
Timing of the reconstruction		
Immediate	8	13.1%
Delayed	53	86.9%
Associated treatments		
Previous chemotherapy	49	80.3%
Previous radiotherapy	31	50. %
Length of hospital stay		
Primary procedure (days)	5.82	(2–14)
Re-hospitalization rate	9	14.8%
Total hospitalization time (days)	7.54	(2–33)

Forty-seven complications in 37 (60.7%) breast reconstruction procedures were recorded in the studied group. In 27 (44.7%) cases there was one complication, and in 10 (16.4%) cases there was more than one postoperative complication observed. The severity of complications assessed by contracted ASGS in relation to the reconstruction methods is presented in Table 2. A statistically significant difference was found in the complication rate versus surgical techniques. The lowest complication rate was observed in implant-based reconstructions (18.8%, 72.7%, 78.3%; $p = 0.008$). Further analysis showed that the mild (grade 1) complications occur significantly more often after combined techniques than other surgical methods (60.9%, 22.7%, 12.5%; $p = 0.031$), while severe (grade 3) complications were significantly more frequent in the autologous reconstruction group (27.3%, 6.2%, 8.7%; $p = 0.047$).

In the group of implant-based reconstruction, both cases of mild complication involved marginal necrosis, while the only

serious complication found was postoperative wound dehiscence with implant exposure.

Marginal necrosis ($n = 3$, 13.6%) was the most common reason for the classification of patients in the group of mild complications (grade 1) in the case of pTRAM, while bleeding requiring blood transfusion ($n = 5$, 22.7%) was the most common complication classifying patients to the group of moderate complications (grade 2). The most common severe complication was abdominal wound dehiscence requiring reoperation ($n = 4$, 18.2%). Partial flap necrosis was found in two cases (one of them coincided with the donor-side complication). In one case, postoperative circulatory system failure developed, which required hospitalization in the intensive care unit.

Seroma ($n = 8$, 34.8%) was the most common type of mild complication among patients who underwent LD reconstruction (in total seroma was found in 10 cases, 43.5%, but it coexisted with a more severe complication in two cases). Hematoma ($n = 1$, 4.4%) and bleeding requiring transfusion of blood products ($n = 1$, 4.4%) were the only confirmed moderate complications in this group. Two patients (8.7%) developed a severe complication—deep wound infection—which required removal of the implant.

In total, 8 patients (13.1%) required reoperation. In 4 cases the cause was abdominal wound dehiscence and in 2 cases partial flap necrosis (in one case the surgery was performed simultaneously with the donor-side surgery), and 3 patients required implant removal. No deaths were recorded in any group.

The severity as per the contracted ASGS was compared with the need for rehospitalization, and a statistically significant result ($p < 0.001$) was obtained. Patients who did not have any complications or who had grade 1 complications were never readmitted. In case of grade 2 complications, one (14.29%) patient required rehospitalization (this rate did not differ significantly from the frequency of rehospitalization in the absence of complications; $p = 0.135$), whereas, in the case of grade 3 complications, 7 (87.50%) patients needed rehospitalization (significantly more often than with grade 2 complications; $p = 0.010$). The results are shown in Table 3.

After comparing the severity of complications with the total LOS, a statistically significant, strong, positive correlation was found between the severity of postoperative complications and the total time of hospitalization ($\rho = 0.55$; $p < 0.001$). The observed statistically significant trend showed that the more severe the complication rate, the longer the total hospitalization time [$JT(3) = 4.50$; $p < 0.001$]. The results are presented in Table 4.

Of the variables considered in the study, only the type of surgery was significantly related to the severity of complications. It was observed that patients with LD reconstruction presented a 27-fold greater chance of complications and/or had more severe complications than patients with implant-

Table 2 Occurrence of postoperative complications

Complications		Reconstruction technique			<i>p</i> < 0.001
		Implant-based reconstructions	Autologous reconstructions	Combined methods	
		<i>n</i> = 16	<i>n</i> = 22	<i>n</i> = 23	
No complication	<i>n</i>	13	6	5	
	%	81.2%	27.3%	21.7%	
Total	<i>n</i>	3	16	18	
	%	18.8%	72.7%	78.3%	
Grade 1 (mild)	<i>n</i>	2	5	14	
	%	12.5%	22.7%	60.9%	
1. Grade 2 (moderate)	<i>n</i>	0	5	2	
	%	0%	22.7%	8.7%	
1. Grade 3 (severe)	<i>n</i>	1	6	2	
	%	6.2%	27.3%	8.7%	
Grade 4 (death)	<i>n</i>	0	0	0	

based methods [4504–167,838]. Furthermore, among patients who underwent reconstruction with autologous tissues, the observed rate of complications was 42 times higher than it would be for implant-based methods [5977–302,778]. Other analyzed variables, i.e., age, BMI, previous radiation therapy, previous chemotherapy, the number of comorbidities, and smoking status, were not significantly associated with the severity of postoperative complications. Results are presented in Table 5.

Discussion

The continuous assessment of treatment outcomes by analyzing postoperative complications should play an important role in the functioning of each surgical ward. To assess the severity of complications, we used the Accordion classification, which is a standardized tool for assessing postoperative complications in various surgical fields, including in general surgery [16], urology [17], and gynecology [18]. In comparison to other systems, the advantage of the Accordion scale is that it

is based on the assessment of the intervention required to correct a given complication, rather than the complication itself, which makes it more objective. This scale is available in the contracted (4 levels) and extended (6 levels) versions. In this study, we decided to use the contracted version due to the relatively small study group and narrow range in the scope of observed severe complications. The follow-up time for observing postoperative complications suggested by the authors of classification is 30–42 days; however, it can be adjusted according to the study design. The aim of the study was to assess the occurrence of early postoperative complications, which is why we adopted the follow-up period of 6 weeks.

In the study group, complications occurred in more than half of the cases (60.7%), most of which did not require reoperation. Eight patients (13.1%) required subsequent surgery. Among the risk factors analyzed, only the type of surgery showed a significant correlation with the incidence and severity of complications. Demographic and clinical variables did not affect the development of complications. Earlier studies showed varied results for risk factors of postoperative complications after breast reconstructive procedures. One multicenter

Table 3 The necessity of rehospitalization depending on the severity of complications

Complications		No rehospitalization	Rehospitalization within 6 weeks	<i>p</i> < 0.001
No complication	<i>n</i>	24	0	
	%	100%	0%	
Grade 1 (mild)	<i>n</i>	21	0	
	%	100%	0%	
1. Grade 2 (moderate)	<i>n</i>	6	1	
	%	85.7%	14.3%	
1. Grade 3 (severe)	<i>n</i>	1	7	
	%	12.5%	87.5%	

Table 4 Total length of hospital stay (days) depending on the incidence of complications

Complications	Me.	IQR	
		25c.	75c.
No complication	5,5	2.0	7.0
Grade 1 (mild)	6.0	6.0	7.0
Grade 2 (moderate)	7.0	7.0	11.0
Grade 3 (severe)	14.0	7.0	28.0

Me. median, IQR interquartile range, 25c. and 75c. lower and upper quartiles

study identified age, BMI, and radiation therapy as risk factors [6]. It also demonstrated that compared with implant/expander reconstruction, LD, pTRAM, fTRAM (free TRAM flap), and DIEP (deep inferior epigastric perforator flap) reconstructions were associated with a higher risk of developing complications. On the other hand, other studies did not show an increased risk of developing complications after autologous reconstructive surgery in women over 65 years of age [19, 20]. Obesity is a recognized risk factor for the development of postoperative complications in both implant-based and autologous reconstruction [2, 6, 9], so is smoking [10–13] and chronic comorbidities [11]. On the other hand, after analyzing the results of delayed breast reconstruction based on data collected from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP database), only BMI and previous radiotherapy were identified as risk factors for the development of complications with no association between age, smoking, hypertension, diabetes, and history of chemotherapy [2]. In contrast, in our study, none of

those factors (age, BMI, smoking, co-morbidities, radiation therapy) affected the development of complications. The study found no correlation between previous chemotherapy and postoperative complications, which coincides with published reports [6, 21].

Reconstructions with autologous tissues were related to the highest risk for complications. These results correlate with other published studies which also focused on early complications [2, 6]. This group of patients also had the highest severe complication rate (27.3%) and reoperation rate (22.7%). Due to the natural complexity of abdominal flap-based procedures which involve a more complicated operative course, these results are consistent with our expectations and clinical observations. For comparison, patients who underwent LD reconstruction showed the highest percentage of complications (78.3%), but most of these complications were mild (77.8% of all complications recorded in this group). In a large study comparing the results of 17,670 LD reconstructions with 11,405 pTRAM reconstructions, authors showed that LD reconstructions was associated with a higher risk of developing complications as compared with pTRAM (OR, 1.39 [1.24–1.57; $p < 0.001$]) [22]. LD procedures were associated with a greater risk of developing surgical site complications: wound dehiscence, wound infection, seroma, flap loss, or hematoma. pTRAM procedures were associated with a higher risk of reoperation, development of systemic complications (pulmonary embolism, pneumonia), and a longer hospital stay. Another retrospective study based on NSQIP showed a higher incidence of complications in patients who underwent pTRAM (13.4%) as compared with LD (7.1%) [23]. The significantly lower overall percentage of complications presented in this study as compared with other published results is associated with the omission of such complications

Table 5 Logistic regression coefficients explaining the severity of complications

	B	SE	p	OR	95%CI	
					LL	UL
Age	0.03	0.03	0.355	1.026	0.970	1.087
BMI	0.01	0.08	0.857	1.014	0.868	1.184
Number of comorbidities	0.52	0.29	0.073	1.687	0.952	2.992
Previous chemotherapy	0.53	0.78	0.499	1.699	0.366	7.877
Previous radiation therapy	-0.95	0.57	0.097	0.386	0.126	1.186
Smoking	0.95	0.84	0.255	2.596	0.502	13.437
Reconstruction with autologous tissues vs. implant/expander	3.75	1.00	< 0.0-01	42.564	5.977	302.778
Combined methods vs. implant/expander	3.31	0.92	< 0.0-01	27.495	4.504	167.838

B regression coefficient, SE standard error, OR odds ratio, CI confidence interval, LL lower limit, UL upper limit; p significance level

as seroma or hematoma in the comparison. According to various publications, seroma develops after LD procedures in 21–95% of cases [24, 25]. In our study, seroma was identified in almost half of the patients after LD surgery (43.5%). It seems that omitting seroma or other mild complications may significantly contribute to discrepancies in reported incidence of complications.

Patients who underwent implant-based reconstruction surgery had the lowest risk of developing complications. However, it should be noted that late complications such as implant leakage or capsular contracture were not taken into account. Compared with reconstructive procedures with autologous tissues, reconstructions with an implant are associated with a greater risk of late complications, often occurring more than a year after the surgery [26].

In our study, mild or moderate complications affected 28 (45.9%) patients and accounted for 75% of all recorded complications. The mild and moderate complications were not associated with a higher rate of rehospitalization but were associated with a slight increase in hospitalization time (the median increased by 0.5 days for mild and 1.5 days for moderate complications). That means that the corrective interventions could be conducted during the initial stay or under the supervision of the out-patient clinic. Moderate complications, the treatment of which mainly consisted in blood transfusions or the supply of antibiotics due to infection, are undeniably adverse events with some risk to the patient but usually do not cause long-term negative consequences.

Nine (14.8%) patients had severe complications, of which 8 required reoperation. The highest rehospitalization rate and significantly prolonged LOS (median increased by 8.5 days) were also observed in this group. In a study published in 2018, authors reported the frequency of major complications, defined as those that required rehospitalization or reoperation, to be 18% for implant-based reconstruction, 29.8% for pTRAM, and 17.8% for LD [6]. In another retrospective study, authors showed that the overall complications rate after implant-based procedures was close to 60% and 52% after autologous tissue reconstructions (which also included LD) [5]. They defined major complications as any complication that required reoperation, and, according to their report, their rate was 40–42% for implant-based reconstructions and 28% for autologous reconstructions.

The relatively high rate of complications observed in the studied population compared with those reported in other publications can be partly attributed to the definition of complication applied. The Accordion classification consistently includes all events requiring even the smallest intervention into the group of complications. This subsequently contributed to a larger number of complications observed. Considering any wound dehiscence or superficial infection of the wound a complication, no matter how minor they might be, reduces the subjective impact of the surgeon's opinion. It should be

noted that despite a high number of complications, the number of reoperations was relatively low, and, despite the treatment required, the majority of complications did not affect the final reconstructive effect. In many studies, the definition of a severe complication refers to patients requiring rehospitalization or reoperation [5, 6]. When such a definition was adopted, the results presented in this paper do not differ significantly from the results presented in other publications.

Our study has several limitations, including the fact that it was conducted in a single institution, it involved a relatively small study group, and there was no long-term follow-up for late complications. What is more, when we classify patients, we use only the most severe observed complication as per the Accordion scale. In our study, 16.4% of procedures had more than one complication, which means that the weight of some milder complications is neglected.

Many factors should be taken into account when making decisions about breast reconstruction, including the risk of postoperative complications. This study revealed a significant impact of the operative method on the incidence and severity of complications with little effect from other demographic and clinical factors. Despite the high overall rate of complications observed, most of them were mild to moderate, and surgery was rarely unsuccessful. Due to the nature of complications after reconstructive procedures, which may occur even many years later, studies with longer observation period are necessary as they may contribute to a more complete assessment of the risk associated with these procedures.

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Jerzy Jankau M.D., Ph.D. conceived and designed the analysis and contributed data and analysis tools.

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Data Availability The data that support the findings of this study are available on request from the corresponding author. All authors give their consent for publication of this paper upon acceptance.

Declarations

Ethics Approval All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). Study was accepted by local bioethical committee no. NKBBN/260/2019.

Consent for Publication Study was not previously presented and is not being considered for publication elsewhere.

Conflict of Interest The authors have no conflicts of interest to declare that are relevant to the content of this article.

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