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Outcome and Impact on Adjuvant Treatment Processing Time after Mastectomy with or without Immediate Breast Reconstruction on a Large Cohort and Determination of a Postoperative Complications Predictive Score

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Abstract

Background: Mastectomies are indicated in 12 to 40% of patients with an increase of immediate breast reconstruction (IBR) rate during the last years and complication rates between 5% to 61%.

We analyzed data collected from 2016 to 2020 to assess the rate of IBR and complications, interval-time to adjuvant therapy and to establish a predictive score of postoperative complications.

Methods: We included all mastectomies performed from January 2016 to July 2020, in a retrospective analysis with prospective data collection of age, body mass index (BMI), ASA-status, diabetes, tobacco use, adjuvant treatments, year of treatment, type of mastectomy, modalities of IBR, complications and postoperative hospitalization length (POHL). We calculated a predictive score for complications.

Results: Among 2,112 mastectomies, IBR rate was 40.5%. Complication rate was 31.9% without difference between IBR and no-IBR groups. Grade 2-3 complications were significantly more frequent only for a BMI >30 (OR=1.8, p=0.002). Implant loss rate was 7.2% (44/609).

A predictive score was determined with a significant increase of complications and Grade 2-3 breast complications rates (p<0.0001). The median POHL was 1 and 2 days in no-IBR and IBR groups. Interval-time >60-days was associated only with age >75 years for adjuvant chemotherapy and age >75 years, Grade 2-3 complications and IBR for post-mastectomy radiotherapy.

Conclusions: Performing IBR was not significantly associated with complications and higher rate of interval-time >60-days for adjuvant chemotherapy. The complication predictive score can be a tool to inform patients at risks of complications and to compare results with others studies and techniques.

Keywords: Breast Cancer; Reconstruction; Complications; Chemotherapy; Radiotherapy

Introduction

Since the 1990s, there has been a steady increase in breast-conserving surgeries associated with the development of oncoplasty. Nevertheless, total mastectomies for breast cancer (BC) are still indicated for 12 to 30% of patients

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and up to 40% [1-4]. It was 12.2% in a large French cohort of invasive BC [5]. The complication rates varies between 5% and 61% in the literature [6]. However, it is difficult to compare results between the different studies because of the large disparities in immediate breast reconstruction (IBR) rates and techniques, the complications reported, the indications for mastectomies and the monitoring time. However, increased body mass index (BMI) and smoking were reported factors to increase the risk of complications as well as previous radiotherapy and operative time [7]. IBR rate increase during the last years [8] in order to improve quality of life [9] and implant-based reconstruction was the most commonly performed procedure [10-12]. Several new procedures are been developed, as robotic procedures [13-16], pre-pectoral implant-IBR with or without mesh [7, 17-20]. Moreover, in recent year's nipple sparing mastectomy (NSM) increase for prophylactic mastectomies [21], for local recurrence [22] and for primary BC [23, 24]. Generally, the NSM studies reported better aesthetic results than skin sparing mastectomy (SSM) and better quality of life [25-27]. NSM with IBR is consider today as a valid procedure for prophylactic mastectomy [21, 28-31] and an acceptable option for breast cancer (BC) therapeutic mastectomy [32-34]. The time to delivery adjuvant therapy after mastectomy is a key point to optimized oncologic treatments and has been few analyzed specifically for mastectomies with or without IBR [35]. In this study, we report our experience at the Paoli Calmettes Institute, by analyzing the data collected over 55 months from 2016 to 2020 to assess IBR rate, complication rate, interval-time to adjuvant therapy and to establish a predictive score for postoperative complications.

Materials and Methods

We included all mastectomies performed from January 2016 to July 2020, with or without IBR from institutional database (study: MAST-C-IPC 2021-024). A retrospective analysis with a prospective data collection was perform in order to determine the immediate surgical results and interval-time to adjuvant treatments.

Patients

Data were collected regarding patients: age, BMI, ASA (American Society of Anesthesiologists) status, diabetes, tobacco use, treatments received (neo-adjuvant or adjuvant chemotherapy, radiotherapy, endocrine therapy), year of treatment, type of mastectomy (nipple-sparing mastectomy (NSM), skin-sparing mastectomy (SSM), or classic if no reconstruction), modalities of IBR, and complications appeared in 90 days following the operation. Thirteen surgeons performed mastectomies.

Complications were analyzed according to the Clavien-Dindo classification [36]. The operative time was recorded from skin incision to skin closure collected on the anesthetic data. The length of postoperative stay was reported from the surgery day to the discharge day from hospital. A loco regional anesthesia with pectoralis block was systematically perform. Interval-times between surgery and adjuvant chemotherapy (AC) or post-mastectomy radiotherapy (PMRT) were analyze.

Statistics

Quantitative criteria were analyze with median, mean, 95% CI. Comparisons were determined using the Chi-2 test for qualitative criteria and t-test for quantitative criteria. Factors significantly associated with criteria analyzed were determine by a binary logistic regression adjusted for all significant variables identified by the univariate analysis. We calculated a predictive score for complications using the odds ratio derived from logistic regression. The performance of this score was analyze by calculating the AUC (Area under the Curve) value. Statistical significance was set as $p \leq 0.05$. Analyses were perform with SPSS version 16.0 (SPSS Inc., Chicago, Illinois).

Results

Population

During a period of 55 months, 2,112 mastectomies were perform for 1,983 patients: 1,748 mastectomies for primary BC, 219 for local recurrence and 145 for prophylactic mastectomies. Mastectomies were realized after ipsilateral surgery for first non-in-sano conservative surgery in 430 patients (430/1748: 25%). Bilateral mastectomies (258 mastectomies) were perform for 129 patients (12.2%): for primary BC in 56.6%, for local recurrence in 8.9% and for prophylactic mastectomy in 34.5%.

Previous radiotherapy was perform for 287 mastectomies (13.6%): 219 for local recurrences after conservative treatment, 57 for reversals therapeutic sequence (neo-adjuvant chemotherapy [NAC] and neo-adjuvant radiotherapy [N-RTH]) and 11 for a history of irradiation as treatment of Hodgkin's disease. For patients with IBR, a high rate of NSM was achieved (399/851: 46.9%).

IBR

The IBR rate was 40.5%: 35.4% (618/1,748) for primary BC, 47.9% (105/219) for local recurrences and 91% (132/145) for prophylactic mastectomies. The annual IBR rates according to years of surgery were not significantly different. Number of mastectomies with or without IBR for each surgeon is report in Supplementary Figure 1. Characteristics of patients according to IBR status are report in Table 1. In univariate analysis, several criteria were significantly associated with or without IBR (Tables 1, 2). Tobacco use did not appear as a significant factor to perform an IBR.

In binary logistic regression, IBR were significantly

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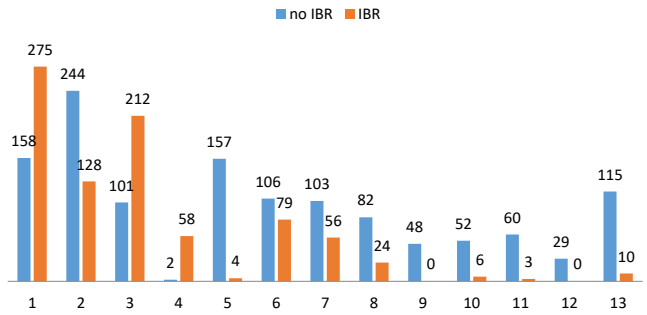

Legend: IBR: immediate breast reconstruction

Supplementary Figure 1: Number of mastectomies with or without IBR for each surgeon.

associated with age (less IBR for patients >50 years), ASA status (less IBR for ASA 2-3 versus ASA 1), diabetes (less IBR for diabetic patients), BMI (less IBR for BMI >25), mastectomy weight (less IBR for weight >300gr), neo-adjuvant treatment (less IBR for neo-adjuvant treatment), histological status (more IBR for preoperative diagnosis of in situ carcinomas and prophylaxis, and less IBR for local recurrence), and history of radiotherapy (Table 3).

Complications

The complication rate was 31.90% (n=675): 29.9% for IBR group and 33.3% for no-IBR group, including 23.2% of grade 3 complications requiring revision surgery. The different grades of 599 breast complications were distributed as 59.6% grade 1 (n=357), 11.0% grade 2 (n=66), 29.2% grade 3 (n=175) and 0.0017% grade 4 (n=1). Others complications were in relation with dorsal complication for latissimus dorsi-flap reconstruction.

Criteria significantly associated with complications in univariate analysis are reported in Table 4, with a significantly higher rate of grade 2 and 3 complications for ASA score

Table 1: Characteristics of all patients and according to immediate breast reconstruction (IBR) or no-IBR.

		All patients		no IBR		IBR		Chi 2
		Nb	%	Nb	%	Nb	%	p
	All patients	2112		1257	59.5	855	40.5	
years	2016	407	19.3	242	19.3	165	19.3	0.076
	2017	402	19.0	231	18.4	171	20.0	
	2018	503	23.8	279	22.2	224	26.2	
	2019	529	25.0	335	26.7	194	22.7	
	2020	271	12.8	170	13.5	101	11.8	
age	<= 40	288	13.6	113	9.0	175	20.5	<0.0001
	41-50	504	23.9	215	17.1	289	33.8	
	51-74	991	46.9	626	49.8	365	42.7	
	>= 75	329	15.6	303	24.1	26	3.0	
ASA	1	616	29.2	235	18.7	381	44.6	<0.0001
	2	1246	59.0	788	62.7	458	53.6	
	3	243	11.5	227	18.0	16	1.9	
	4	7	0.3	7	0.6	0	0	
Smoker	No	1699	80.4	1017	80.9	682	79.8	0.539
	Yes	413	19.6	240	19.1	173	20.2	
Diabetes	No	2002	94.8	1156	92.0	846	98.9	<0.0001
	Yes	110	5.2	101	8.0	9	1.1	
BMI	<= 24.9	1302	61.6	640	50.9	662	77.4	<0.0001
	25-29.9	500	23.7	359	28.6	141	16.5	
	>= 30	310	14.7	258	20.5	52	6.1	
Mastectomy	NSM	399	18.9	2	0.2	397	46.4	<0.0001
type	SSM	452	21.4	1	0.1	451	52.7	
	standard	1261	59.7	1254	99.8	7	0.8	
Indication	Primary BC	1748	82.8	1130	89.9	618	72.3	<0.0001
	Local recurrence	219	10.4	114	9.1	105	12.3	
	Prophylactic	145	6.9	13	1.0	132	15.4	

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POLHS	<= 3 days	1865	88.3	1199	95.4	666	77.9	<0.0001
	> 3 days	247	11.7	58	4.6	189	22.1	
Mastectomy	<= 300	721	34.1	293	23.3	428	50.1	<0.0001
weight	> 300	1391	65.9	964	76.7	427	49.9	
previous ipsilateral	No	1432	67.8	900	71.6	532	62.2	<0.0001
breast surgery	Yes	680	32.2	357	28.4	323	37.8	
NAC	No	1631	77.2	900	71.6	731	85.5	<0.0001
	Yes	481	22.8	357	28.4	124	14.5	
previous ipsilateral	No	1825	86.4	1142	90.9	683	79.9	<0.0001
radiotherapy	Yes	287	13.6	115	9.1	172	20.1	
NAC and N-RTH	No	2055	97.3	1256	99.9	799	93.5	<0.0001
	Yes	57	2.7	1	0.1	56	6.5	
axillary surgery	No	605	28.6	232	18.5	373	43.6	<0.0001
	SLNB	794	37.6	410	32.6	384	44.9	
	ALND	713	33.8	615	48.9	98	11.5	
Radiotherapy	No	986	46.7	416	33.1	570	66.7	<0.0001
	PMRT	848	40.2	726	57.8	122	14.3	
	previous RTH	221	10.5	114	9.1	107	12.5	
	NAC + N-RTH	57	2.7	1	0.1	56	6.5	
Adjuvant	No	1467	69.5	778	61.9	689	80.6	<0.0001
chemotherapy	Yes	645	30.5	479	38.1	166	19.4	
Endocrine	No	782	37.0	372	29.6	410	48.0	<0.0001
therapy	Yes	1330	63.0	885	70.4	445	52.0	
Histology	DCIS	258	12.2	84	6.7	174	20.4	<0.0001
	NST	1349	63.9	920	73.2	429	50.2	
	Lobular	332	15.7	218	17.3	114	13.3	
	Others	26	1.2	21	1.7	5	0.6	
	Begnin	147	7.0	14	1.1	133	15.6	
Bilateral	No	1854	87.8	1155	91.9	699	81.8	<0.0001
mastectomy	Yes	258	12.2	102	8.1	156	18.2	

Legend: IBR: immediate breast reconstruction, ASA: American Society of Anesthesiologists, BMI: Body mass index, POHLS: Post-operative hospitalization length, NAC: neo-adjuvant chemotherapy, N-RTH: neo-adjuvant radiotherapy, DCIS: ductal carcinoma in-situ, NST: non-specific invasive carcinoma, BC: breast cancer, SLNB: sentinel lymph node biopsy, ALND: axillary lymph node dissection.

≥2, BMI>= 30, mastectomy weight >300g. In binary logistic regression, complications were significantly associated with year of treatment (fewer complications during the last 2 years), smokers (more complications for smoker patients), age (more complications for patients >50 years), radiotherapy (more complications for patients with a previous radiotherapy), axillary lymph-node dissection associated with mastectomy +/- IBR (more complications than SLNB or no axillary surgery) and mastectomy weight (more complications for weight >300g) (Table 5). In binary logistic regression, grade 2 and 3 complications were significantly more frequent only for a BMI >30 (OR=1.8, p=0.002). When adjusting the regression analysis for IBR or no IBR, there was no significant difference between IBR group and no-IBR group.

Breast complications according to grading is report in Table 6: Seroma was the most frequent complication with 86.9% of grade 1, while there was 66.7% of grade 3 hematomas. There were 68.8% of grade 1 cutaneous complications. Cutaneous complications and infections were more frequent for IBR-patients and seromas were more frequent for no-IBR patients. Implant loss rate was 7.2% (44/609): 6.1% (34/560) for implant-based IBR and 20.4% (10/49) for latissimus dorsi-flap (LDF) IBR with implant (p <0.001).

Complication score

The following equation to calculate a complication risk score was: smoker + age + previous radiotherapy + axillary surgery + mastectomy weight. Odds ratios described above

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Table 2: Results (median, mean and 95% confidence interval) of quantitative variables.

		median	mean	95%CI	t-test: p
age	all patients	56	57.74	57.1-58.4	
	no IBR	64.0	62.5	61.7-63.4	<0.0001
	IBR	49	50.7	49.9-51.5	
BMI	all patients	23.38	24.54	24.3-24.8	
	no IBR	24.86	25.74	25.4-26.1	<0.0001
	IBR	22.0	22.77	22.5-23.0	
Weight of	all patients	410	512	494-529	
mastectomy	no IBR	525	622	597-648	<0.0001
	IBR	300	350	335-365	
POLHS	all patients	1	1.87	1.80-1.93	
	no IBR	1	1.4	1.33-1.47	<0.0001
	IBR	2	2.55	2.45-2.65	
anesthesia	all patients	142	169.1	165-173	
duration	no IBR	123	128.4	126-131	<0.0001
	IBR	200	228.9	222-235	
surgery	all patients	92	115.8	113-119	
duration	no IBR	74	80.3	79-82	<0.0001
	IBR	141	168	162-174	
implant size	IBR	280	289	282-296	

Legend: IBR: immediate breast reconstruction, BMI: Body mass index, POHLS: Post-operative hospitalization length.

Table 3: Binary logistic regression analysis: Factors associated with immediate breast reconstruction (IBR) in comparison with patients with no-IBR.

IBR verus		**p**	**OR**	**95% CI**	
no IBR				**Inferior**	**Superior**
age	<= 40		1		
	41-50	0.924	0.982	0.686	1.407
	51-74	<0.0001	0.530	0.374	0.755
	>= 75	<0.0001	0.108	0.063	0.187
ASA	1		1		
	2	<0.0001	0.572	0.445	0.736
	3	<0.0001	0.160	0.087	0.295
	4	0,999	NE	NE	NE
Diabetes	Yes vs No	0.020	0.388	0.175	0.859
BMI	<= 24,9		1		
	25-29,99	0.001	0.606	0.455	0.807
	>= 30	<0.0001	0.418	0.283	0.617
Indication	Primary		1		
	Local recurrence	<0.0001	0.212	0.115	0.391
	Prophylactic	0.002	4.540	1.709	12.061
Mast weight	> vs <=300	<0.0001	0.595	0.464	0.763
NAC	Yes vs No	<0.0001	0.361	0.264	0.493
previous RTH	Yes vs No	<0.0001	12.996	7.619	22.166
Histology	DCIS		1		
	NST	<0.0001	0.276	0.197	0.385
	Lobular	<0.0001	0.312	0.210	0.464
	Others	<0.0001	0.088	0.028	0.273
	Begnin	0.692	0.819	0.306	2.196

Legend: IBR: immediate breast reconstruction, ASA: American Society of Anesthesiologists status, NAC: neo-adjuvant chemotherapy, RTH: radiotherapy.

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Table 4: Significant criteria associated with complications in univariate analysis.

		All complications					Grade 2-3 breast complications				
	Complication	**No**		**Yes**		**Chi 2**	**No**		**Yes**		**Chi 2**
		Nb	%	Nb	%	p	Nb	%	Nb	%	p
all patients		1437	68.0	675	32.0		1870	88.5	242	11.5	
years	2016	269	18.7	138	20.4	<0.0001	352	18.8	55	22.7	0.094
	2017	259	18.0	143	21.2		363	19.4	39	16.1	
	2018	316	22.0	187	27.7		445	23.8	58	24.0	
	2019	381	26.5	148	21.9		479	25.6	50	20.7	
	2020	212	14.8	59	8.7		231	12.4	40	16.5	
age	<= 40	220	15.3	68	10.1	<0.0001	262	14.0	26	10.7	0.101
	41-50	362	25.2	142	21.0		454	24.3	50	20.7	
	51-74	653	45.4	338	50.1		873	46.7	118	48.8	
	>= 75	202	14.1	127	18.8		281	15.0	48	19.8	
ASA	1	454	31.6	162	24.0	<0.0001	560	29.9	56	23.1	0.050
	2	834	58.0	412	61.0		1097	58.7	149	61.6	
	3	146	10.2	97	14.4		208	11.1	35	14.5	
	4	3	0.2	4	0.6		5	0.3	2	0.8	
Smoker	No	1188	82.7	511	75.7	<0.0001	1513	80.9	186	76.9	0.143
	Yes	249	17.3	164	24.3		357	19.1	56	23.1	
Diabetes	No	1376	95.8	626	92.7	0.005	1779	95.1	223	92.1	0.063
	Yes	61	4.2	49	7.3		91	4.9	19	7.9	
BMI	<= 24.9	926	64.4	376	55.7	<0.0001	1176	62.9	126	52.1	<0.0001
	25-29.9	320	22.3	180	26.7		443	23.7	57	23.6	
	>= 30	191	13.3	119	17.6		251	13.4	59	24.4	
Mastectomy type	NSM	270	18.8	129	19.1	0.131	344	18.4	55	22.7	0.096
	SSM	325	22.6	127	18.8		411	22.0	41	16.9	
	standard	842	58.6	419	62.1		1115	59.6	146	60.3	
Indication	Primary BC	1181	82.2	567	84.0	0.160	1547	82.7	201	83.1	0.967
	Local recurrence	147	10.2	72	10.7		195	10.4	24	9.9	
	Prophylactic	109	7.6	36	5.3		128	6.8	17	7.0	
Histology	DCIS	178	12.4	80	11.9	0.117	234	12.5	24	9.9	0.564
	NST	910	63.3	439	65.0		1190	63.6	159	65.7	
	Lobular	218	15.2	114	16.9		289	15.5	43	17.8	
	Others	17	1.2	9	1.3		24	1.3	2	0.8	
	Begnin	114	7.9	33	4.9		133	7.1	14	5.8	
Bilateral	No	1260	87.7	594	88.0	0.887	1649	88.2	205	84.7	0.143
mastectomy	Yes	177	12.3	81	12.0		221	11.8	37	15.3	
IBR	No	838	58.3	419	33.3	0.106	1110	59.4	147	60.7	0.728
	Yes	599	41.7	256	29.9		760	40.6	95	39.3	
Surgeon						0.002					0.137
NAC	No	1123	78.1	508	75.3	0.148	1446	77.3	185	76.4	0.745
	Yes	314	21.9	167	24.7		424	22.7	57	23.6	
previous ipsilateral	No	965	67.2	467	69.2	0.369	1262	67.5	170	70.2	0.421
surgery	Yes	472	32.8	208	30.8		608	32.5	72	29.8	
previous ipsilateral	No	1261	87.8	564	83.6	0.010	1616	86.4	209	86.4	1.000

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radiotherapy	Yes	176	12.2	111	16.4		254	13.6	33	13.6	
NAC + N-RTH	No	1411	98.2	644	95.4	<0.0001	1819	97.3	236	97.5	1.000
	Yes	26	1.8	31	4.6		51	2.7	6	2.5	
axillary surgery	No	433	30.1	172	25.5	0.006	545	29.1	60	24.8	0.164
	SLNB	550	38.3	244	36.1		706	37.8	88	36.4	
	ALND	454	31.6	259	38.4		619	33.1	94	38.8	
Mastectomy weight	<= 300	542	37.7	179	26.5	<0.0001	658	35.2	63	26.0	0.005
	> 300	895	62.3	496	73.5		1212	64.8	179	74.0	

Legend: IBR: immediate breast reconstruction, ASA: American Society of Anesthesiologists, BMI: Body mass index, NSM: Nipple-sparing mastectomy, SSM: Skin-sparing mastectomy, BC: breast cancer, DCIS: ductal carcinoma in-situ, NST: non-specific invasive carcinoma NAC: neo-adjuvant chemotherapy, N-RTH: neo-adjuvant radiotherapy, SLNB: sentinel lymph node biopsy, ALND: axillary lymph node dissection.

Table 5: Factors associated to complications and grade 2-3 breast complications in binary logistic regression.

Complication: Yes vs No		**p**	**OR**	**95% CI**	
				Inferior	**Superior**
Years	2016		1		
	2017	0.823	1.034	0.769	1.392
	2018	0.667	1.064	0.802	1.410
	2019	0.027	0.723	0.541	0.964
	2020	<0.0001	0.495	0.343	0.714
ASA	1		1		
	2	0.517	1.082	0.853	1.373
	3	0.492	1.140	0.785	1.655
	4	0.157	3.051	0.650	14.322
Smoker	Yes vs No	<0.0001	1.707	1.348	2.163
Diabetes	Yes vs No	0.333	1.230	0.809	1.869
Age	<= 40		1		
	41-50	0.211	1.245	0.883	1.754
	51-74	0.015	1.493	1.080	2.064
	>= 75	0.002	1.849	1.244	2.749
BMI	<= 24,9		1		
	25-29,99	0.504	1.087	0.852	1.386
	>= 30	0.339	1.156	0.859	1.556
previous RTH	Yes vs No	<0.0001	1.6660	1.248	2.207
axillary surgery	No		1		
	SLNB	0.262	1.157	0.897	1.492
	ALND	0.028	1.334	1.032	1.724
Mastect weight	> vs <= 300	0.001	1.496	1.185	1.888
Surgeon		0.978	1.000	0.980	1.021
Grade 2-3 breast		p	OR	95% CI	
complication				Inferior	Superior
ASA	1		1		
	2	0.243	1.218	0.874	1.697
	3	0.295	1.289	0.802	2.072
	4	0.216	2.903	0.536	15.736
BMI	<= 24,9		1		
	25-29,99	0.789	1.050	0.734	1.502
	>= 30	0.002	1.836	1.255	2.686
Mast weight	> vs <= 300	0.168	1.270	0.904	1.784

Legend: ASA: American Society of Anesthesiologists, BMI: Body mass index, POHLS: Post-operative hospitalization length, RTH: radiotherapy.

Citation: Léa Morante, Sandrine Rua, Monique Cohen, Laura Sabiani, Marc Martino, Max Buttarelli, Aurore Van Troy, Anthony Gonçalves, Agnès Tallet, Aurélie Jalaguier Coudray, Marie Bannier, Gilles Houvenaeghel. Outcome and Impact on Adjuvant Treatment Processing Time after Mastectomy with or without Immediate Breast Reconstruction on a Large Cohort and Determination of a Postoperative Complications Predictive Score. Archives of Clinical and Medical Case Reports. 7 (2023): 390-408.

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Table 6: Breast complications according to grading for all patients and for patients with or without IBR.

	Type of complication	Grade 1	Grade 2	Grade 3	Grade 4	Total	%
All	cutaneous	108	20	29	0	157	26.2
patients	hemetoma	37	7	88	0	132	22.0
	infection	3	19	45	1	68	11.4
	seroma	152	11	12	0	175	29.2
	others	57	9	1	0	67	11.2
	Total (%)	357 (59.6)	66 (11.0)	175 (29.2)	1 (0.2)	599	100
no-IBR	cutaneous	39	9	13	0	61	14.9
	hematoma	29	6	55	0	90	21.9
	infection	3	17	18	0	38	9.3
	seroma	152	10	12	0	174	42.4
	others	40	6	1	0	47	11.5
	Total (%)	263 (64.1)	48 (11.7)	99 (24.1)	0	410	
IBR	cutaneous	69	11	16	0	96	50.8
	hematoma	8	1	33	0	42	22.2
	infection	0	2	27	1	30	15.9
	seroma	0	1	0	0	1	0.5
	others	17	3	0	0	20	10.6
	Total (%)	94 (49.7)	18 (9.5)	76 (40.2)	1 (0.5)	189	100

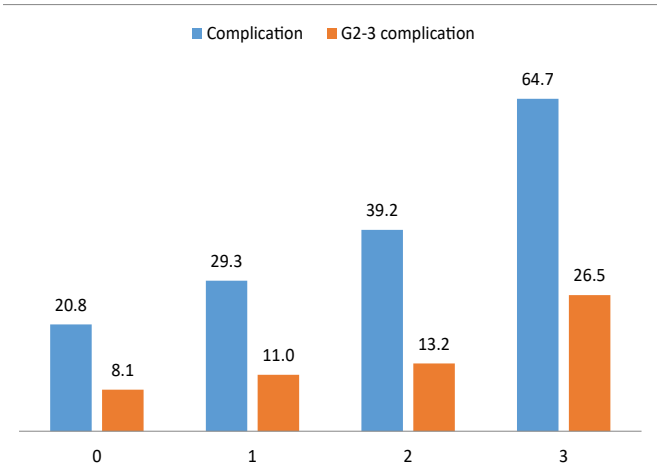
Legend: IBR: immediate breast reconstruction.

were used to determine the value of each criterion: smoker (0 or 2), age (0 for age ≤50 years, 1.5 for age between 61 and 74, 2 for age ≥75 years), previous radiotherapy (0 or 2), axillary surgery (0 for SLNB or no axillary surgery and 1 for axillary lymph-node dissection), mastectomy weight (0 if ≤ 300g or 1.5 if > 300g). A simplified score (C-score-G1-2-3) was determined according to the result of the equation: 0 for values ≤ 1.5, 1 for values between 2 and 3, 2 for values between 3.5 and 6 and 3 for values ≥6.5. A significantly increasing rate of complications ($p<0.0001$) and grade 2-3 complications was observe for higher values of this simplified score (Figure 1) with 0.603 AUC value (95% CI: 0.577-0.628) for all complications.

A simplified score for Grade 2-3 breast complications (C-score-G2-3) was determined [simplified C-score-G1-2-3 value (0 to 3) + BMI (>=30=2, <30=0)]. A significant increase of Grade 2-3 breast complications rates was observed ($p<0.0001$) with 0.591 AUC value (95%CI: 0.552-0.630) (Figure 2).

IBR types

Implant-based IBR were performed on 649 patients (76%), excluding one patient with exclusive lipofilling IBR. LDF-IBR was performing for 205 patients (24%) and was associated with an implant-based for 52 patients (22.2%). Factors significantly associated with IBR-LDF in univariate analysis are report in Supplementary Table 1. In binary logistic regression, higher rate of IBR by LDF was significantly associated with BMI ≥25, neo-adjuvant treatments, diabetes, radiotherapy, lobular histology, age between 51-74 years old, and lesser rate was significantly associated with SSM, bilateral mastectomies and prophylactic mastectomies (Supplementary Table 2).



Legend: 543 patients score 0 (25.7%), 621 score 1 (29.4%), 914 score 2 (43.3%) and 34 score 3 (1.6%).

For example, for a simplified C-score G1-2-3 value of 3, the postoperative complication rate was 64.7% with 26.5% of grade 2-3 complications versus 20.8% of complications for a simplified score of 0 with only 8.1% of grade 2 and 3 complications.

Figure 1: Complication rate and grade 2-3 complications according to the simplified score (C-score G1-2-3).

Citation: Léa Morante, Sandrine Rua, Monique Cohen, Laura Sabiani, Marc Martino, Max Buttarelli, Aurore Van Troy, Anthony Gonçalves, Agnès Tallet, Aurélie Jalaguier Coudray, Marie Bannier, Gilles Houvenaeghel. Outcome and Impact on Adjuvant Treatment Processing Time after Mastectomy with or without Immediate Breast Reconstruction on a Large Cohort and Determination of a Postoperative Complications Predictive Score. Archives of Clinical and Medical Case Reports. 7 (2023): 390-408.

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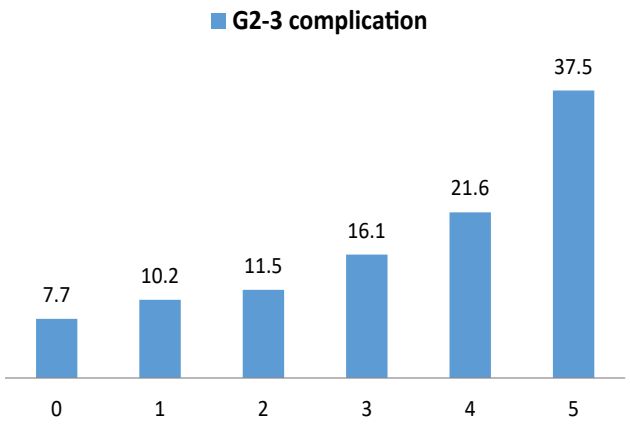

Legend: 519 patients score 0 (24.6%), 510 score 1 (24.1%), 771 score 2 (36.5%), 137 score 3 (6.5%), 167 score 4 (7.9%) and 8 score 5 (0.4%).

Figure 2: Grade 2-3 complications rates according to the simplified score.

Post-operative hospitalization length (POHL)

The median POHL was 1 day (mean 1.87): 1 day without IBR and 2 days with IBR (Table 2) and 247 patients (11.7%) were hospitalize more than 3 days. The POHL was ≤1 day for 54.3% of mastectomies (1,146/2,112): 73.5% (924/1,257) in the no-IBR group and 25.96% (222/855) in the IBR-group (222/650: 34.2% of IBR-implants).

The POHL rate ≤1 day has increased over the past 2 years compared to 2016-2018 for patients without IBR (69.9% vs. 78.8%) and for patients with IBR (19.8% vs. 37.6%). In univariate analysis, factors significantly associated with a POHL >3 days were the year of treatment, age, type of mastectomy, indication for mastectomy, histology, bilateral mastectomy, IBR or no-IBR, axillary surgery, previous ipsilateral surgery, previous ipsilateral radiotherapy and the surgeon (Table 7). In binary logistic regression, POHL >3 days was significantly increased by NST or lobular histological status, bilateral mastectomies, IBR, previous radiotherapy,

Supplementary Table 1: Factors associated with LDF-IBR versus implant-IBR.

	IBR	Implant		LDF		Chi 2
(1 patient: lipofilling-IBR excluded)		**Nb**	**%**	**Nb**	**%**	**p**
	All patients	649	76.0	205	24.0	
NAC	No	597	92.0	133	64.9	<0.0001
	Yes	52	8.0	72	35.1	
years	2016	124	19.1	41	20.0	<0.0001
	2017	112	17.3	59	28.8	
	2018	153	23.6	71	34.6	
	2019	167	825.7	26	12.7	
	2020	93	14.3	8	3.9	
Indication	Primary	459	70.7	159	77.6	<0.0001
	Local recurrence	60	9.2	44	21.5	
	Prophylactic	130	20.0	2	1.0	
Mast type	NSM	315	48.5	81	39.5	0.013
	SSM	331	51.0	120	58.5	
	standard	3	0.5	4	2.0	
Bilateral	No	494	76.1	204	99.5	<0.0001
mastectomy	Yes	155	23.9	1	0.5	
ASA	1	311	47.9	70	34.1	0.002
	2	327	50.4	131	63.9	
	3	11	1.7	4	2.0	
Smoker	No	524	80.7	157	76.6	0.197
	Yes	125	19.3	48	23.4	
Diabetes	No	646	99.5	199	97.1	0.008
	Yes	3	0.5	6	2.9	
Previous	No	428	65.9	104	50.7	<0.0001
breast surgery	Yes	221	34.1	101	49.3	
Previous	No	581	89.5	102	49.8	<0.0001

Citation: Léa Morante, Sandrine Rua, Monique Cohen, Laura Sabiani, Marc Martino, Max Buttarelli, Aurore Van Troy, Anthony Gonçalves, Agnès Tallet, Aurélie Jalaguier Coudray, Marie Bannier, Gilles Houvenaeghel. Outcome and Impact on Adjuvant Treatment Processing Time after Mastectomy with or without Immediate Breast Reconstruction on a Large Cohort and Determination of a Postoperative Complications Predictive Score. Archives of Clinical and Medical Case Reports. 7 (2023): 390-408.

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radiotherapy	Yes	68	10.5	103	50.2	
NAC+N-RTH	No	648	99.8	150	73.2	<0.0001
	Yes	1	0.2	55	26.8	
Cup size	A-B	377	58.1	92	44.9	0.002
	C	182	28.0	68	33.2	
	> C	90	13.9	45	22.0	
Axillary	No	277	42.7	95	46.3	<0.0001
surgery	SLNB	329	50.7	55	26.8	
	ALND	43	6.6	55	26.8	
Histology	DCIS	140	21.6	34	16.6	<0.0001
	NST	303	46.7	126	61.5	
	Lobular	76	11.7	37	18.0	
	Others	1	0.2	4	2.0	
	Begnin	129	19.9	4	2.0	
Age	<= 40	143	22.0	32	15.6	0.002
	41-50	233	35.9	56	27.3	
	51-74	254	39.1	110	53.7	
	>= 75	19	2.9	7	3.4	
BMI	<= 24.9	529	81.5	132	64.4	<0.0001
	25-29.9	90	13.9	51	24.9	
	>= 30	30	4.6	22	10.7	
Mastectomy	<= 300	347	53.5	80	39.0	<0.0001
weight	> 300	302	46.5	125	61.0	

Legend: IBR: immediate breast reconstruction, LDF: latissimus dorsi-flap, ASA: American Society of Anesthesiologists, BMI: Body mass index, RTH: radiotherapy, NSM: Nipple-sparing mastectomy, SSM: Skin-sparing mastectomy, BC: breast cancer, DCIS: ductal carcinoma in-situ, NST: non-specific invasive carcinoma NAC: neo-adjuvant chemotherapy, N-RTH: neo-adjuvant radiotherapy, SLNB: sentinel lymph node biopsy, ALND: axillary lymph node dissection.

Supplementary Table 2: Factors associated with LDF-IBR versus implant IBR in binary logistic regression.

LDF-IBR versus implant-IBR		**p**	**OR**	**95% CI**	
				Inferior	**Superior**
ASA	1		1		
	2	0.115	0.696	0.443	1.093
	3	0.231	0.380	0.078	1.855
BMI	<= 24.9		1		
	25-29.9	<0.0001	3.002	1.758	5.125
	>= 30	<0.0001	2.867	1.272	6.462
Mastectomy	<= 300		1		
weight	> 300	0.381	0.791	0.468	1.336
Mast type	NSM		1		
	SSM	0.043	0.643	0.420	0.985
	standard	0.163	4.005	0.571	28.078
Indication	Primary		1		
	Local recurrence	<0.0001	0.025	0.005	0.128
	Prophylactic	0.036	0.040	0.002	0.806
NAC	No		1		

Citation: Léa Morante, Sandrine Rua, Monique Cohen, Laura Sabiani, Marc Martino, Max Buttarelli, Aurore Van Troy, Anthony Gonçalves, Agnès Tallet, Aurélie Jalaguier Coudray, Marie Bannier, Gilles Houvenaeghel. Outcome and Impact on Adjuvant Treatment Processing Time after Mastectomy with or without Immediate Breast Reconstruction on a Large Cohort and Determination of a Postoperative Complications Predictive Score. Archives of Clinical and Medical Case Reports. 7 (2023): 390-408.

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	Yes	0.035	2.214	1.057	4.637
Bilateral	No		1		
mastectomy	Yes	<0.0001	0.003	0.000	0.046
Diabetes	No		1		
	Yes	0.035	5.446	1.122	26.431
Previous	No		1		
radiotherapy	Yes	<0.0001	140.95	29.33	677.5
Cup size	A-B		1		
	C	0.164	1.443	0.860	2.422
	> C	0.439	1.308	0.662	2.585
Histology	DCIS		1		
	NST	0.678	1.119	0.659	1.900
	Lobular	0.030	1.991	1.068	3.710
	Others	0.187	5.359	0.444	64.70
	Begnin	0.170	6.712	0.442	101.86
Age	<= 40		1		
	41-50	0.261	1.545	0.724	3.297
	51-74	0.012	2.603	1.236	5.485
	>= 75	0.322	1.899	0.533	6.763

Legend: IBR: immediate breast reconstruction, LDF: latissimus dorsi-flap, ASA: American Society of Anesthesiologists, BMI: Body mass index, NAC: neo-adjuvant chemotherapy, NSM: Nipple-sparing mastectomy, SSM: Skin-sparing mastectomy, DCIS: ductal carcinoma in-situ, NST: non-specific invasive carcinoma NAC: neo-adjuvant chemotherapy.

and decreased during the last 2 years of treatment, and by age between 41-50 years (Table 8).

Operative time and anesthesia time

The median operative time was 92 minutes (mean 115.8). The median duration of anesthesia was 142 minutes (mean 169.1) with a significant longer duration for IBR versus no-IBR (Table 2).

Adjuvant treatments

AC was administered in 28.6% of mastectomies (603/2112): 35.5% (463/1306) for primary invasive BC without neo-adjuvant chemotherapy (NAC) [25.6% (127/497) and 41.5% (336/809) for mastectomies with and without IBR, respectively] and 17.0% (31/182) of patients for invasive ipsilateral breast local recurrence [14.6% (15/103) and 20.3% (16/79) for mastectomies with and without IBR, respectively]. NAC was administered in 482 patients (22.8%: 482/2112): 21.5% (95/442) for primary invasive BC [15.7% (19/121) and 23.7% (76/321) for mastectomies with and without IBR, respectively] and 24.3% (9/37) of patients for invasive ipsilateral breast local recurrence (2 patients with IBR and 35 without IBR). PMRT was delivered in 38.2% of mastectomies (806/2112): 48.3% (802/1661) for primary invasive BC without previous radiotherapy: 21.7% (120/553) and 61.6% (682/1108) for mastectomies with and without IBR, respectively.

Endocrine therapy was delivered in 76.9% (1166/1517) of mastectomies for primary invasive BC [79.7% (372/467) and 75.6% (794/1050) for mastectomies with and without IBR, respectively] and 70.9% (127/179) of patients with invasive ipsilateral breast local recurrence [76.3% (58/76) and 67% (69/103) for mastectomies with and without IBR, respectively]. Median interval-time between surgery and adjuvant therapy was 46 days: 42 days for AC and 51 days for PMRT (Table 9). Median interval-times between surgery and adjuvant therapy were not significantly different for mastectomies with and without IBR (p=0.536), for mastectomies with and without complications (p=0.057) and significant (50 and 45 days) for mastectomies with and without Grade 2-3 complications (p<0.0001), and for patients 51-74 years old (p=0.048) and >=75 years old (p=0.033). Interval-times were >60-days in 20.5% of patients (184/896) (712 patients <= 60-days): in 16.1% for AC and 26.8% for PMRT (p<0.0001). Results were non-significant according to IBR or no-IBR (p=0.294), according to complications or not (p=0.138). Higher rates of interval-times >60-days were observed for mastectomies with Grade 2-3 complications (p=0.026) and according to age groups (p<0.0001).

In binary logistic regression, significant factor associated with interval-time >60-days for AC was age >=75-years old (OR=3.718, p=0.008, CI95%=1.42-9.74) in comparison with patients <=40-years old. Others age groups (41-50 and

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Table 7: Factors associated with a POHL >3 days in univariate analysis.

POHL		<= 3 days		> 3 days		Chi2
		Nb	%	Nb	%	p
all patients		1865	88.3	247	11.7	
years	2016	345	18.5	62	25.1	<0.0001
	2017	352	18.9	50	20.2	
	2018	423	22.7	80	32.4	
	2019	485	26.0	44	17.8	
	2020	260	13.9	11	4.5	
age	<= 40	242	13.0	46	18.6	0.019
	41-50	453	24.3	51	20.6	
	51-74	869	46.6	122	49.4	
	>= 75	301	16.1	28	11.3	
ASA	1	529	28.4	87	35.2	0.060
	2	1120	60.1	126	51.0	
	3	210	11.3	33	13.4	
	4	6	0.3	1	0.4	
Smoker	No	1507	80.8	192	77.7	0.267
	Yes	358	19.2	55	22.3	
Diabetes	No	1769	94.9	233	94.3	0.760
	Yes	96	5.1	14	5.7	
BMI	<= 24.9	1143	61.3	159	64.4	0.285
	25-29.9	440	23.6	60	24.3	
	>= 30	282	15.1	28	11.3	
Mastectomy type	NSM	306	16.4	93	37.7	<0.0001
	SSM	358	19.2	94	38.1	
	standard	1201	64.4	60	24.3	
Indication	Primary BC	1573	84.3	175	70.9	<0.0001
	Local recurrence	173	9.3	46	18.6	
	Prophylactic	119	6.4	26	10.5	
Histology	DCIS	229	12.3	29	11.7	0.024
	NST	1208	64.8	141	57.1	
	Lobular	287	15.4	45	18.2	
	Others	22	1.2	4	1.6	
	Begnin	119	6.4	28	11.3	
Bilateral mastectomy	No	1657	88.8	197	79.8	<0.0001
	Yes	208	11.2	50	20.2	
IBR	No	1199	64.3	58	23.5	<0.0001
	Yes	666	35.7	189	76.5	
Surgeon						<0.0001
NAC	No	1443	77.4	188	76.1	0.686
	Yes	422	22.6	59	23.9	
previous ipsilateral	No	1290	69.2	142	57.5	<0.0001
surgery	Yes	575	30.8	105	42.5	
previous ipsilateral	No	1657	88.8	168	68.0	<0.0001
radiotherapy	Yes	208	11.2	79	32.0	

Citation: Léa Morante, Sandrine Rua, Monique Cohen, Laura Sabiani, Marc Martino, Max Buttarelli, Aurore Van Troy, Anthony Gonçalves, Agnès Tallet, Aurélie Jalaguier Coudray, Marie Bannier, Gilles Houvenaeghel. Outcome and Impact on Adjuvant Treatment Processing Time after Mastectomy with or without Immediate Breast Reconstruction on a Large Cohort and Determination of a Postoperative Complications Predictive Score. Archives of Clinical and Medical Case Reports. 7 (2023): 390-408.

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NAC + N-RTH	No	1836	98.4	219	88.7	<0.0001
	Yes	29	1.6	28	11.3	
axillary surgery	No	500	26.8	105	42.5	<0.0001
	SLNB	713	38.2	81	32.8	
	ALND	652	35.0	61	24.7	
Mastectomy weight	<= 300	626	33.6	95	38.5	0.134
	> 300	1239	66.4	152	61.5	

Legend: POHL: postoperative hospitalization length, IBR: immediate breast reconstruction, ASA: American Society of Anesthesiologists, BMI: Body mass index, NAC: neo-adjuvant chemotherapy, N-RTH: neo-adjuvant radiotherapy, NSM: Nipple-sparing mastectomy, SSM: Skin-sparing mastectomy, BC: breast cancer, DCIS: ductal carcinoma in situ, NST: non-specific tumor (invasive ductal carcinoma), SLNB: sentinel lymph node biopsy, ALND: axillary lymph node dissection.

Table 8: Factors associated with a POHL >3 days in binary logistic regression

POHL > 3 days versus		**p**	**OR**	**95% CI**	
< 3 days				**Inferior**	**Superior**
Years	2016		1		
	2017	0.214	0.755	0.485	1.176
	2018	0.764	0.941	0.633	1.399
	2019	0.001	0.454	0.290	0.711
	2020	<0.0001	0.194	0.096	0.391
Age	<= 40		1		
	41-50	0.033	0.598	0.373	0.960
	51-74	0.929	1.020	0.662	1.570
	>= 75	0.202	1.487	0.809	2.732
Mast type	NSM		1		
	SSM	0.120	0.743	0.511	1.080
	standard	0.403	2.182	0.351	13.575
Indication	Primary		1		
	Local recurrence	0.209	0.654	0.337	1.269
	Prophylactic	0.334	0.572	0.184	1.777
Histology	DCIS		1		
	NST	0.044	1.629	1.013	2.619
	Lobular	0.002	2.391	1.378	4.147
	Others	0.140	2.893	0.705	11.878
	Begnin	0.278	1.940	0.586	6.421
Bilateral Mast	Yes vs No	0.003	1.895	1.242	2.890
IBR	Yes vs No	0.002	17.643	2.829	110.022
previous surgery	Yes vs No	0.257	1.262	0.844	1.887
previous RTH	Yes vs No	<0.0001	3.481	2.050	5.909
axillary surgery	No		1		
	SLNB	0.580	0.884	0.571	1.369
	ALND	0.439	1.210	0.746	1.964

Legend: POHL: postoperative hospitalization length, IBR: immediate breast reconstruction, RTH: radiotherapy, NSM: Nipple-sparing mastectomy, SSM: Skin-sparing mastectomy, DCIS: ductal carcinoma in situ, NST: non-specific tumor (invasive ductal carcinoma), SLNB: sentinel lymph node biopsy, ALND: axillary lymph node dissection.

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Table 9: Interval time between surgery and adjuvant therapy.

	median	mean	95%CI	t-test: p
interval-time before adjuvant therapy				
all patients	46	50	48.6-51.5	
no IBR	45	49.8	48.1-51.5	0.536
IBR	47	50.9	47.8-54.1	
AC	42	46.2	44.3-48.0	<0.0001
PMRT	51	55.6	53.2-58.0	
Complication	48	52.8	49.9-55.6	0.057
no complication	44	48.7	47.0-50.4	
G 2-3 complication	50	57.9	52.3-63.5	<0.0001
no G 2-3 complication	45	48.9	47.4-50.4	
<= 40-years	41	43.6	40.6-46.7	
41-50	44	46.6	44.0-49.2	0.727
51-74	46	51.7	49.3-54.1	0.048
>= 75-years	54	57.0	53.3-60.7	0.033
interval-time >60 days	**Nb**	**%**		
all patients (n=896)	184	20.5		
AC (n=527)	85	16.1		<0.0001
PMRT (n=369)	99	26.8		
no IBR (702)	141	20.1		0.294
IBR (n=194)	43	22.2		
Complication (n=289)	66	22.8		0.138
no complication (n=607)	118	19.4		
G 2-3 complication (n=110)	31	28.2		0.026
no G 2-3 complication (n=786)	153	19.5		
<= 40-years (n=130)	17	13.1		<0.0001
41-50 years (n=219)	36	16.4		
51-74 years (n=422)	86	20.4		
>= 75-years (n=125)	45	36.0		

Legend: IBR: immediate breast reconstruction, AC: adjuvant chemotherapy, PMRT: post-mastectomy radiotherapy.

51-74), grade 2-3 complications and IBR versus no IBR were non-significant. Significant factors associated with interval-time >60-days for PMRT were age >=75-years old (OR=4.146, p=0.002, CI95%=1.66-10.34) in comparison with patients <=40-years old, Grade 2-3 complications (OR=2.059, p=0.040, CI95%=1.03-4.10) in comparison with no-Grade 2-3 complications and IBR (OR=3.000, p=0.002, CI95%=1.49-6.02) versus no-IBR. Others age groups (41-50 and 51-74) were non-significant.

Discussion

We reported a large cohort of patients treated by mastectomy in recent years with a high rate of IBR. IBR was significantly associated with several factors in multivariate analysis corresponding to a selection of patients in whom an IBR was perform. Consequently, complication rate was analyze in regression analysis adjusted on confounding factors and there was no significant impact of IBR or no-IBR. High BMI (> 30) was the only independent factor associated with Grade 2-3 complications. A predictive score of complication risk was calculate in order to evaluate for each patient the level of complication rate for all grades and grade 2-3. Performing IBR was not significantly associated with higher rate of interval time >60-days for AC but interval time >60-days rate for PMRT was increased by IBR and complications Grade 2-3.

IBR

IBR rate from 2016 to 2020 was estimate at 40.5%, which is relatively high and much higher than reported in the literature. It also marks a significant increase compared to 2014. Indeed, Negre et al. [5] carried out an observational

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study in France using the database of the Information Systems Medicalization Program (PMSI) between 2008 and 2014 making it possible to identify 140,904 women who had undergone a total mastectomy for BC. The IBR rate in France was therefore assess at 16.1%. In England, the number or implant-IBR have increased since 2009: 10.0% until 2005 and 23.3% by 2013-2014 [10]. In Chinese, IBR rate was 9.6% (1,554/16,187) in year 2018, with implant or expander in 76.6% of these IBR [12]. However, the average rate of reconstruction in the United States in 2010 was 45%, surging to 54% in 2015 [37].

There is a great disparity in IBR rates among surgeons in the same center, linked to surgical habits, their training, and the average age of their patient. However, some of the surgeons not performing IBR either referred their patients to other surgeons on the team, or performed the procedure in collaboration with another surgeon on the team. In the UK multicenter prospective cohort study [7], 2108 patients had 2655 mastectomies with implant-IBR in 81 units during 28 months: 11 patients' per-year per unit in comparison with 144 implant-IBR patients per-year in our unit. We reported a high rate of NSM, 46.9% among patients with IBR. NSM rate was 17.7% (287/1625) for implant reconstructions in the MROC study [6] and 23% (486/2108) in the UK multicenter prospective cohort study [7].

Complications

There was no significant difference of complication rate between the IBR group and the no-IBR group: 29.9% for the IBR group vs. 33.3% for the no-IBR group. The surgical revision rate was 23.2%. However, we have shown patient's selection for IBR in comparison with no-IBR in regression analysis. Consequently, factors associated with complications were analyze with adjustment on these confounding factors and IBR was not associated with complications or Grade 2-3 complications. Only BMI >=30 was significantly associated with more Grade 2-3 complications (OR=1.836).

In a prospective multicenter American study, the surgical revision rate was 19.3% (453/2343) [38] and in the NMBRA cohort, which included 3,389 patients with IBR, this rate was 15.8%. [39]. Although the comparison of complication rates between different studies is difficult due to a large disparity of IBR types, reported complications, indications for mastectomies, and monitoring time, we reported a complication rate similar to those reported in other studies [6, 40-45]. However, complications rates reported in recent studies of NSM were lower (5.1% to 20%) with 20.5% average overall complication rate in a recent review of 3716 NSM-IBR only for prophylactic indications [34].

We reported a 6.1% rate of implant loss for 560 implant-based IBR, which is lesser than rates reported by others [6, 40, 41], mainly in relation with infectious and cutaneous complications, but with use of pre-operative antimicrobial therapy for patients with nasal germs and per-operative antimicrobial prophylaxis that is not performed systematically by others. However, implant loss rate was higher for LDF-IBR associated with breast implant, 20.4% in our study, frequently realized for patients with previous ipsilateral radiotherapy.

Different types of complications were observe for patients with IBR in comparison with patients without IBR in our study: a small difference of infection rate (30/855: 3.5%) was observe for IBR in comparison with patients without IBR (38/1257: 3.0%) and higher cutaneous complication rate was observe after IBR (96/855: 11.2%) in comparison with patients without IBR (61/1257: 4.9%). In literature studies, the more frequent complication for mastectomy with implant-IBR was infection, 0% to 17.8%, and obesity was associated with more complications [7, 46] as we reported. In contrast, hematomas and seromas were more frequent for patients without IBR: 90/1257: 7.2% versus 42/855: 4.9% hematomas, 174/1257: 13.8% versus 1/855: 0.1% seromas for no-IBR-group versus IBR-group, respectively. However, hematomas were more severe complications for IBR versus no-IBR, 78.6% (33/42) grade 3 for IBR and 61.1% (55/90) for no-IBR. The most frequent complication that we reported was seromas (29.2%), with 87.4% (152/174) of grade 1 seromas and then, cutaneous complications (26.2%), with 18.5% of grade 3 as extensive necrosis requiring surgical revision. The 3rd most frequent complication is hematoma (22%), of which 67% were grade 3.

We reported an implant loss rate of 7.2%, concordant with literature rates from 1 to 9.9%. Potter et al [7] reported an implant loss rate of 8.75% (182/2081: 95%CI=8-10), infection rate of 25% (522 patients, 95%CI=23-27) and 370 patients (18%, 95%CI=16-20) required return to theatre for complications within 3 months of their initial surgery. Bennet et al. reported a skin infection rate of 9.8% and a reconstruction failure rate of 7.1% [38]. In addition, as our results show, obesity is significantly associated with a high complication risk rate, as reported in a recent study by Srinivasa et al. with an increased high-grade complication rate for implant-IBR: (OR 1.71) and for autologous flap (OR 2.72) in the BMI > 30 group [46]. This significant BMI impact was also reported by Potter et al [7] for implant loss, infection and reoperation. The Simplified Predictive Complication Score is a decision aid to inform patients of complications risk, especially for high scores. It can be use very simply during the preoperative consultation, the main goal being to avoid delaying adjuvant treatments and to more precisely identify patients eligible for IBR, and the risk of failure. Moreover, this Score can help to compare complications rates between several studies, several techniques of IBR and several periods of treatment. For example, implant-IBR with or without meshes, and pre-

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pectoral or retro-pectoral implant-IBR. Predictive score of complication include several factors known before surgery but also mastectomy weight that is not known before surgery. Breast cup size was not recorded in our database for patients without IBR. However, a strong correlation is well established between mastectomy weight >300 gr and breast cup size >=C. An external validation of this score is necessary with, if possible, optimized accuracy.

NSM

We reported 46.4% NSM that is particularly high. In the MROC study, the NSM rate was 17.7% (287/1,625) for IBR by implants [6]. The limits to performing NSM were the risk of local recurrence linked to a retro-areolar glandular residue [24] or, conversely, the management of the skin casing (and therefore the risk of nipple areola complex (NACx) necrosis) [47]. Nevertheless, in the literature, there are many data contradicting, since the reported local recurrence rate on NAC is very low and the rate of NAC necrosis was less than 11% [21, 24, 48, 49, 50]. NSM can therefore be proposed safely and after information on the risk of NACx necrosis when it's indicated. The remaining question, which still generates considerable questioning and requires validating prospective series, is regarding the limits of the therapeutic indication of NSM, particularly tumor-nipple distance of 2 centimeters or 1 centimeter [51].

Treatment

Regarding radiotherapy, a recent review by Ho et al [52] evaluated the possibility of IBR in combination with radiotherapy without increasing the risk of complications, and without compromising the oncological or esthetic outcome. It seems that PMRT and IBR are compatible, but PMRT may adversely affect patient-reported outcome [53].

POHL

54.3% of mastectomies had a POHL ≤1 day. The mean POHL was 1.8 days with a median of 1 day for mastectomies without IBR, and 2 days for mastectomies with IBR. Ambulatory or semi-ambulatory hospitalization is tending to increase, since studies have shown that it allows, on the one hand, reducing postoperative complications and, on the other hand, to help socio-professional reintegration. In addition, in a study carried out by the American College of Surgeons [54] including 40,000 patients, 8,365 (20.6%) were operated in ambulatory surgery, 23,252 (57.2%) spent one night in hospital and 8,958 (22.2%) stayed more than one night in hospital. Patients operated in ambulatory had a morbidity of 2.4% vs. 3.9% after 1 night hospitalization vs. 8.8% for prolonged hospitalization (p <0.0001).

This is the largest study on the safety of ambulatory surgery for breast cancer, showing a significantly higher complication rate in hospitalized patients. These data suggest that mastectomy for breast cancer can be perform safely as ambulatory surgery with patients who have been well informed.

Interval time between mastectomy and adjuvant treatment

Interval time >60-days between mastectomy and AC was not impacted by IBR and complications. However, interval time >60-days between mastectomy and PMRT was significantly impacted by IBR and complications Grade 2-3. Age >=75-years was also significantly associated with interval time >60-days between mastectomy and AC or PMRT. These results suggest that IBR is not a contra-indication in order to start adequately AC. However, O'Connell et al reported that major complications were significantly associated with treatment delays [35].

Bilateral mastectomies

A study of the American College of Surgeons [55] between 2007 and 2010 compared the morbidity of unilateral (n=3,722) versus bilateral mastectomies (n=497).

The surgical complication rate was significantly higher in the bilateral versus unilateral group: 5.8% versus 2.9% [unadjusted odds ratio (OR) 2.1, 95% confidence interval (CI) 1.3–3.3, p <0.01]. The data observed in our series differ from those observed by the American College of Surgeons. Indeed, we have observed a complication rate similar in the bilateral mastectomies group and the unilateral mastectomies group: 31% vs 32% with p = 0.143.

Limitations

The main limitation is the retrospective design of this study but with a prospective data collection.

Conclusion

Treatment by mastectomy with or without IBR is a technique with an acceptable overall complication rate. Performing IBR was not significantly associated with complications and higher rate of interval time >60-days for AC but rate of interval time >60-days for PMRT was increased by IBR and complications Grade 2-3. The preoperative complication predictive score can be a tool to orient the therapeutic strategy by informing patients at risks of complications. The aim of this score is also to not delay adjuvant treatments and to compared results with others studies and or with more recent techniques like pre-pectoral implant-IBR with or without use of acellular or synthetic matrices and tumescent or non-tumescent techniques.

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Conflict of Interest Statement

The authors have no conflict of interest to declare.

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