

Mastectomie pour récidive locale avec ou sans reconstruction immédiate

Pauline Simon

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2019

FACULTE DE MEDECINE
HYACINTHE BASTARAUD
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MASTECTOMIE POUR RECIDIVE LOCALE AVEC OU SANS RECONSTRUCTION IMMEDIATE

Types of mastectomies and immediate reconstructions for ipsilateral breast local recurrences

THÈSE

Soutenue à la Faculté de Médecine de Aix-Marseille et examinée par les enseignants de la dite Faculté pour le compte de la Faculté de Médecine Hyacinthe Bastaraud des Antilles.

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Pour obtenir le grade de

DOCTEUR EN MEDECINE

Par

SIMON Pauline

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LISTE DES ABREVIATIONS

ALND	:	Axillary Lymph Node Dissection
ASA	:	American Society of Anesthesiology score
BMI	:	Body Mass Index
CI :		Confidence Interval
DCIS	:	Ductal Carcinoma In Situ
IBR	:	Immediate Breast Reconstruction
ILBLR	:	Ipsilateral BreastLocal Recurrence
ILR	:	Ipsilateral Recurrence
LDF	:	Latissimus Dorsi-muscle Flap
LDFR	:	Latissimus Dorsi-Flap Reconstruction
MFS	:	Metastases Free Survival
NAC	:	NippleArea Complex
NSM	:	Nipple-Sparing Mastectomy
NST	:	NonSpecific Tumor
OR	:	Odds Ratios
OS	:	Overall Survival
PNSM	:	Prophylacti cNipple-Sparing Mastectomy
POHL	:	Post-Operative Hospitalization Lengths
SLNB	:	Sentinel Lymph Node Biopsy
SSM	:	Skin-Sparing Mastectomy
VS	:	Versus

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Abstract

Purpose

Ipsilateral breast local recurrence (ILBLR) is a rare event, with an annual incidence rate of 0.6% for which there is very little data on the performance of mastectomy with immediate breast reconstruction (IBR).The objective was to report post-operative results of different types of mastectomy with or without IBR for ILBLR.

Patients and methods

Two hundred and seven patients who get a mastectomy with or without IBR after breast conservative treatment were identified from January 2016 to April 2019.The characteristics of patients, surgery, complication rate, duration of surgery and anesthesia, postoperative hospitalization have been determined.

Results

Of the 207 mastectomies for ILBLR, 32.8% had an IBR (68/207).

Less reconstruction was performed for patients with body mass index ≥30 (OR 0.214), infiltrating ductal carcinomas (OR 0.272) and ASA-3 patients (OR 0.254).

Types of mastectomy were 31 nipple-sparing mastectomy (NSM) (45.6%) and 37 skin-sparing mastectomy (SSM) (54.4%).

IBR rates was 32.85% (68/207) for ILBLR.

Reconstruction was performed by dorsal muscle flap(LDF) in 37 patients (54.4%) and with implants in 31 patients (45.6%). Twenty percent of NSM with implants and 71.4% of IBR by LDFwere performed by robotic surgery (15/21). More IBR with dorsal muscle flap was performed when the mastectomy was of the NSM type (p=0.037).

The overall complication rate was 37.4% (77/206), respectively 45.6% and 33.1% with and withoutIBR (p=0.056). Only dorsal muscle flap reconstruction compared to implant-IBR was associated with complications (OR 8.275, p=0.009, CI95% 1.7-40). No difference was found between robotic and open surgery (p=0.263).

The only factor associated with a postoperative hospitalization >3dayswas dorsal muscle flap reconstruction (OR 6.283 p=0,009).

Conclusion

Salvage mastectomy with IBR is a good choice for local recurrence after BCT and did not contribute to higher surgical complications. NSM can be considered as a good treatment option in highly selected patients for ILBLR.

Résumé

Contexte

La récidive locale (RL) homolatérale du sein est un événement rare, avec un taux d'incidence annuel de 0,6 % pour lequel il existe très peu de données sur les résultats post-opératoires des mastectomies avec reconstruction mammaire immédiate (RMI).

Les principaux objectifs de notre étude étaient de présenter les résultats chirurgicaux des patientes opérées dans notre centre d'une RL et de déterminer ainsi les effets de la radiothérapie antérieure ainsi que de fournir des données pertinentes sur les taux de complications et les facteurs de risque de celles-ci.

Matériels et Méthodes

Deux cent sept patientes traitées par mastectomie avec ou sans reconstruction immédiate après un traitement conservateur du sein ont été identifiées entre janvier 2016 et avril 2019.

Les données cliniques, letype de chirurgie, le taux de complications, la durée de la chirurgie et de l'anesthésie, la durée du séjour ont été déterminés.

Résultats

Sur les 207 mastectomies pour récidive locale, 32,8 % avaient uneRMI (68/207).

Moins de reconstructions ont été effectuées chez les patientes présentant un indice de masse corporelle ≥30 (Odds Ratio (OR) 0,214), des carcinomes canalaires infiltrants (OR 0,272) et des scores ASA-3 (OR 0,254).

Les types de mastectomie étaient 31 mastectomies avec conservation de l'étui cutané et de la plaque aréolo-mamelonnaire (NSM) (45,6 %) et 37 mastectomies avec conservation de l'étui cutané seul(SSM) (54,4 %). 32,85% des patientes ont bénéficiées d'une RMI (68/207).

La reconstruction mammaire a été réalisée par lambeau du muscle grand dorsal (LGD) chez 37 patientes (54,4%) et avec implants chez 31 patientes (45,6%). Vingt pour cent des mastectomies type NSM avec implants et 71,4 % des RMI par LGD ont été réalisées par chirurgie robotique (15/21). Le taux global de complications était de 37,4% (77/206), respectivement 45,6% et 33,1% avec et sans RMI (p=0,056). Seule la reconstruction par LGD par rapport à l'implant était associée à des complications (OR 8,275, p=0,009,

CI95% 1,7-40). Aucune différence n'a été observée entre la chirurgie robotique et la chirurgie ouverte (p=0,263).

Le seul facteur associé à une hospitalisation postopératoire supérieure à 3 jours était la reconstruction par LGD (OR 6,283 p=0,009).

Conclusion

L'antécédent de cancer du sein n'a pas contribué à des complications chirurgicales plus importantes chez les patientes opérées d'une RL. La mastectomie avec RMI est un bon choix pour ces patientes. La mastectomie de type NSM peut être considérée comme une bonne option thérapeutique chez des patientes sélectionnées pour le traitement d'une récidive locale homolatérale avec ou sans chirurgie robotique.

Introduction

The ipsilateral breast local recurrence (ILBLR)appears after breast conserving treatment (BCT), defined as breast-conserving surgery followed by whole-breast radiation therapy. Metastatic disease in the internal mammary, supraclavicular, infraclavicular, or ipsilateral axillary nodes was classified as a regional recurrence. In 2017,the rate of locoregional recurrences was 8.2% after BCT in very young woman (women<35-years old) with 11-year median follow-up(1). About 10% of patients of all ages will subsequently develop ILBLR (2). The annual incidence rate of isolated ILBLR in women diagnosed with an early invasive breast cancer (BC) was 0.6%(3).Incidence of isolated ILBLR (1.1 to 4.4% at 5-years) and interval between initial treatment and local recurrence vary significantly according to tumor subtypes (4).

ILBLR represents a challenge for clinicians because the management is not standardized. Very few studies have been dedicated to mastectomy with conservation of nipple area complex (NAC) for the treatment of ILBLR. The main objectives of our study were to present the surgical results of patients operated in our center for ILBLR and thereby determine the effects of previous radiotherapy on surgical outcomes in nipple sparing mastectomy (NSM) and immediate breast reconstruction (IBR) patients. The last objective was to provide relevant data on complication rates and risk factors for complications.

Material Methods

Study design

This study was approved byinstitutional committee.

A retrospective, monocentric, cohort study was performed with the prospective data from patients who required a total mastectomy on a period of 40 months from January 2016 to April 2019. Among these patients, we analyzed mastectomies performed for ILBLRafter initial BCT.

Patients and outcomes

The patients' anthropometric (body mass index (BMI)) and clinical data such as age, ASA status(American Society of Anesthesiology score), medical history (hypertension, diabetes), and tobacco use were recorded.Previous treatment for BC: sentinel lymph node biopsy(SLNB), axillary lymph node dissection (ALND), neoadjuvant chemotherapy, previous breast radiotherapy were also collected for risk factors analysis. Reconstruction methods and delay procedures were reviewed. ILBLRhistologies were recorded with distinction in ductal and lobular invasive carcinoma, ductal carcinoma in situ(DCIS) and others (tubular, mucinous, medullary breast carcinoma). Post-operative acute complications were defined as complications that occurred until the third post-operative month. The rest were considered as chronic complications.

The acute complications were classified according to their nature: infectious (infection, fever), cutaneous (skin blistering, skin necrosis), hemorrhagic (hematoma, anemia) and complications related to lymph production (seroma, lymphedema).

The chronic ones were classified according to those related to the implant (fibrosis, ruptures, malposition), those linked to adjuvant treatment (inflammation, radiodermitis). Each type of complications was graded according to the Dindo classification (Annexe) (5).

For patients with breast implant we realized a nasal research of staphylococcus germ and pre-operative antimicrobial therapy for patients with nasal-germs. Then, per-operative antimicrobial-prophylaxis was systematically performed for all patients with IBR.

Surgical technique

Mastectomy and reconstructions were performed by a team of seven dedicated surgeons for breast and two plastic surgeons. The reconstruction method was determined by patient anatomy and preferences, and a variety of methods were used: latissimus dorsi-muscle flap

(LDF) with traditional open technique or robotic technique (6) with or without implant, subpectoral implant, expander tissue, as judged appropriate.
The incision placements for NSM were preoperatively discussed and determined by breast and reconstructive surgeons together. NSMwere conducted by breast surgeons using a standard procedure.

All patients were operated by total mastectomy with conservation of NACwhen the tumor-to-NAC distance was at least 2cm on preoperative radiological examinations. A retro-mammary biopsy was systematically performed, without extemporaneous analysis.

Periods

Two periods were established: P1 (years 2016-2017), P2 (years 2018-April 2019).

Statistics

For descriptive statistics, Mann-Whitney test was used to investigate continuous variables. The Fisher exact and the Pearsontests were used to investigate associations between two categorical variables. Multivariate analyses were performed using binary logistic regression in order to determined Odds Ratios (OR) with confidence interval(CI) 95% and p-values. A p-value ≤ 0.05 was considered statistically significant. All statistical analyses were performed using software SPSS 16.0.

Results

Patients: 1433 total mastectomies were performed, including 104 prophylactics, 1122 for primary BCand207for ILBLR (13.4%) for 72, 1077 and 207 patients respectively. IBR rates were 95.2% (99/104 mastectomies), 37.3% (419/1122) and 32.85% (68/207) for prophylactic, primary BC andILBLRrespectively.

ILBLRmastectomy with or without IBR:

Characteristics of patients with total mastectomy for ILBLRwith or without IBR were reported on Table 1. Patients without IBR were older than patients with IBR, with higher BMI, higher ASA status, higher mastectomy weight, higher breast cup size and with more ductal invasive tumors (Table 1). In multivariate analysis lesser IBR were performed for patients with BMI ≥30 (OR=0.214, p=0.025, CI95% 0.055-0.824), for ductal invasive carcinomas (OR=0.272, p=0.002, CI95% 0.119-0.624) and for ASA 3 status (OR=0.254, p=0.057, CI95% 0.062-1.044).

Duration of surgery and anesthesia: A longer duration of surgery and anesthesia were observed for patients with IBR and during the first period in univariate analysis. In multivariate analysis only IBR was correlated with higher duration of surgery in comparison with no IBR (OR 94.5, p<0.0001, CI95% 21-418).

There were no significant differences of endocrine therapy rate and adjuvant chemotherapy rate and no significant difference of interval time between surgery and adjuvant chemotherapy between patients with or without IBR (median 42.5 versus 43 days, mean 43.9 versus 51.9 days, respectively) (Table 1).

Characteristics	Patients with IBR (n = 68)	Patients without IBR (n = 139)	*p*
Age, n (%)			**.003**
<= 40	2 (2.9)	0 (0)	
41-50	12 (17.6)	12 (8.6)	
51-74	47 (69.1)	88 (63.3)	
>= 75	7 (10.3)	39 (28.1)	
BMI, n (%)			**.002**
< 25	51 (75.0)	74 (53.2)	
25 - 29.9	14 (20.6)	35 (25.2)	
>= 30	3 (4.4)	30 (21.6)	
Tobacco, n (%)			.086
No	54 (79.4)	122 (87.8)	
Yes	14 (20.6)	17 (12.2)	
Diabetes, n (%)			.238
No	66 (97.1)	130 (93.5)	
Yes	2 (2.9)	9 (6.5)	
ASA, n (%)			**<.0001**
1	20 (29.4)	17 (12.2)	
2	44 (64.7)	90 (64.7)	
3	4 (5.9)	32 (23.0)	
Mastectomy, n (%)			<.0001
NSM	31 (45.6)	1 (0.7)	
SSM	37 (54.4)	0 (0)	
Radical	0 (0)	138 (99.3)	
IBR type, n (%)			
Implant alone	31 (45.6)	-	
LDF	37 (54.4)	-	
Complication, n (%)			**.056**
No	37 (54.4)	93 (66.9)	
Yes	31 (45.6)	46 (33.1)	
Reoperation, n (%)			.151
No	60 (88.2)	130 (93.5)	
Yes	8 (11.8)	9 (6.5)	
Grade complication, n (%)			.310
0	37 (54.4)	93 (66.9)	
1	21 (30.9)	33 (23.7)	
2	2 (2.9)	4 (2.9)	
3	8 (11.8)	9 (6.5)	
Grade Breast complication, n (%)			.460
0	49 (72.1)	94 (67.6)	
1	10 (14.7)	32 (23.0)	
2	2 (2.9)	4 (2.9)	
3	7 (10.3)	9 (6.5)	
Years, n (%)			.478
2016	20 (29.4)	39 (28.1)	
2017	25 (36.8)	42 (30.2)	

2018	19 (27.9)	41 (29.5)	
2019	4 (5.9)	17 (12.2)	
Bilateralmastectomy, n (%)			.516
No	64 (94.1)	132 (95.0)	
Yes	4 (5.9)	7 (5.0)	
Mastectomyweight, n (%)			**<.0001**
≤300	40 (58.8)	36 (25.9)	
> 300	28 (41.2)	103 (74.1)	
Axillary, n (%)			
No	49 (72.1)	101 (72.7)	
SLNB	16 (23.5)	11 (7.9)	.002
ALND	3 (4.4)	26 (18.7)	.003
Missing	-	1 (0.7)	
Chemotherapy, n (%)			.104
No	56 (82.4)	102 (73.4)	
Yes	12 (17.6)	37 (26.6)	
Endocrine therapy, n (%)			.057
No	32 (47.1)	48 (34.5)	
Yes	36 (52.9)	91 (65.5)	
Cup size, n (%)			**.047**
A-B	36 (52.9)	55 (39.6)	
≥C	32 (47.1)	84 (60.4)	
POHL, n (%)			**<.0001**
≤3	35 (51.5)	126 (90.6)	
>3	33 (48.5)	13 (9.4)	
Histologies types, n (%)			**<.0001**
DCIS	23 (33.8)	14 (10.1)	
NST	35 (51.5)	103 (74.1)	
Lobular	7 (10.3)	16 (11.5)	
Others*	3 (4.4)	6 (4.3)	
Intervalchemotherapy, n (%)			.601
≤60 days	10 (83.3)	29 (80.6)	
> 60 days	2 (16.7)	7 (19.4)	

Legend
ALND axillary lymph node dissection, BMI body mass index, DCIS ductal carcinoma in situ,IBR immediate breast reconstruction, LDF latissimus dorsi-muscle flap,Others*: tubular, mucinous, medullary breast carcinoma POHL post-operative hospitalization lengths, NST nonspecific tumor, NSM nipple sparing mastectomy, % percentage,SLNB sentinel lymph node biopsy, SSM skin sparing mastectomy

Table 1: Characteristics of patients diagnosed with ipsilateral breast local recurrence after conservative treatment of breast cancer (n=207).

Patients with IBR forILBLR mastectomy:

Types of mastectomy were 31 NSM (45.6%) and 37 SSM (54.4%). Any significant difference was observed between NSM and SSM for all analyzed criteria, except for histology of ILBLRwith lesser rates of NSM for ductal and lobular invasive carcinomas in comparison withDCIS and others (Table 2).

Characteristics	Total IBR (n = 68)	NSM (n = 31, 45.6)	SSM (n = 37, 54.4%)	*p*
IBR type, n (%)				.063
Implant	20 (29.4)	9 (29.0)	11 (29.7)	
Expander	11 (16.2)	1 (3.2)	10 (27.0)	
LDF non autologous	4 (5.9)	3 (9.7)	1 (2.7)	
Autologous LDF	25 (36.8)	14 (45.2)	11 (29.7)	
LDF non autologous + Implant	4 (5.9)	3 (9.7)	1 (2.7)	
Autologous LDF + implant	4 (5.9)	1 (3.2)	3 (8.1)	
Age, n (%)				.153
≤ 40	2 (2.9)	2 (6.5)	0 (0)	
41-50	12 (17.6)	6 (19.4)	6 (16.2)	
51-74	47 (69.1)	22 (71.0)	25 (67.6)	
≥75	7 (10.3)	1 (3.2)	6 (16.2)	
BMI, n (%)				.299
< 25	51 (75.0)	26 (83.9)	25 (67.6)	
25 - 29.9	14 (20.6)	4 (12.9)	10 (27.0)	
≥30	3 (4.4)	1 (3.2)	2 (5.4)	
Tobacco, n (%)				.101
No	54 (79.4)	22 (71.0)	32 (86.5)	
Yes	14 (20.6)	9 (29.0)	5 (13.5)	
Diabetes, n (%)				.708
No	66 (97.1)	30 (96.8)	36 (97.3)	
Yes	2 (2.9)	1 (3.2)	1 (2.7)	
ASA, n (%)				.131
1	20 (29.4)	11 (35.5)	9 (24.3)	
2	44 (64.7)	20 (64.5)	24 (64.9)	
3	4 (5.9)	0 (0)	4 (10.8)	
Cup size, n (%)				.734
A-B	36 (52.9)	18 (58.1)	18 (48.6)	
C	25 (36.8)	10 (32.3)	15 (40.5)	
≥ C	7 (10.3)	3 (9.7)	4 (10.8)	
Complication				.252
No	37 (54.4)	15 (48.4)	22 (59.5)	
Yes	31 (45.6)	16 (51.6)	15 (40.5)	
Reoperation				.259
No	60 (88.2)	26 (83.9)	34 (91.9)	
Yes	8 (11.8)	5 (16.1)	3 (8.1)	
Grade complication				.717
0	37 (54.4)	15 (48.4)	22 (59.5)	

1	21 (30.9)	10 (32.3)	11 (29.7)	
2	2 (2.9)	1 (3.2)	1 (2.7)	
3	8 (11.8)	5 (16.1)	3 (8.1)	
Grade 2-3, n (%)				.258
No	58 (85.3)	25 (80.6)	33 (89.2)	
Yes	10 (14.7)	6 (19.4)	4 (10.8)	
Mastectomyweight, n (%)				.131
≤300g	40 (58.8)	21 (67.7)	19 (51.4)	
> 300g	28 (41.2)	10 (32.3)	18 (48.6)	
Axillary, n (%)				
No	49 (72.1)	25 (80.6)	24 (64.9)	
SLNB	16 (23.5)	5 (16.1)	11 (29.7)	
ALND	3 (4.4)	1 (3.2)	2 (5.4)	
Years, n (%)				.115
2016	20 (29.4)	5 (16.1)	15 (40.5)	
2017	25 (36.8)	14 (45.2)	11 (29.7)	
2018	19 (27.9)	9 (29.0)	10 (27.0)	
2019	4 (5.9)	3 (9.7)	1 (2.7)	
Chemotherapy, n (%)				.270
No	56 (82.4)	27 (87.1)	29 (78.4)	
Yes	12 (17.6)	4 (12.9)	8 (21.6)	
Endocrine therapy, n (%)				.176
No	32 (47.1)	17 (54.8)	15 (40.5)	
Yes	36 (52.9)	14 (45.2)	22 (61.1)	
Histologies types, n (%)				**.023**
DCIS	23 (33.8)	16 (51.6)	7 (18.9)	
NST	35 (51.5)	11 (35.5)	24 (64.9)	
Lobular	7 (10.3)	2 (6.5)	5 (13.5)	
Others*	3 (4.4)	2 (6.5)	1 (2.7)	
POHL, n (%)				.412
≤3	35 (51.5)	15 (48.4)	20 (54.1)	
>3	33 (48.5)	16 (51.6)	17 (45.9)	

Table 2:Characteristics of patients with immediate breast reconstruction after mastectomy for ipsilateral breast cancer local recurrence (n=68).

Trends Over Time: We further looked at the proportion of NSMs that were performed for recurrent disease. We doubled our NSM rate forILBLRfrom 16% in 2016 to 29% in 2018.

A strong correlation between BMI, cup size and mastectomy weight were observed ($p<0.01$).
Type of reconstruction:Reconstruction was realized with LDF in 37 patients (54.4%) and with implant in 31 patients (45.6%), 20 definitive breast implants and 11 expanders.For 8 patients, LDFR (latissimus dorsi-flap reconstruction) was associated with breast implant (8/37: 21.6%). In univariate analysis, the first period and NSM versus SSM were significantly associated with LDF reconstructions. More LDFRs were performed for patients with cup size ≥ C, but without significant difference. In multivariate analysis, LDFRs were more often realized during the first period, for NSM and for patients with BMI≥25 (near significant result) (Table 3).

LDF vs Implant	*p*	Odd Ratio	CI 95%	
			Inferior	Superior
BMI ≥25 vs <25	.053	3.717	.98	14.0
P1 vs P2	**.005**	5.968	1.70	20.9
NSM vs SSM	**.009**	4.752	1.48	15.3

Table 3: Multivariate analysis of the factors that influence the choice of LDF reconstruction.

Other factors could determine the choice of LDF reconstructions: physic and professional activities, predominant side of activity, skin thickness and skin trophicity in relation with previous breast radiotherapy and patient's wishes.
Robotic surgery: 43 robotic procedures for 28 patients were performed among 68 mastectomies with IBR: 2 NSM with breast implant among 10 NSM with breast implant, 5 R-LDF reconstructions with SSM among 16 patients, 6 non robotic NSM with R-LDF reconstruction and 15 R-NSM with R-LDF reconstruction among 21 NSM with LDF reconstruction.
Duration of surgery and anesthesia: In univariate analysis, significant longer durations of surgery were reported for NSM versus SSM, breast implant versus LDF reconstruction, LDF with implant versus without implant, first period P1 versus P2 and robotic surgery versus no robotic surgery (Supplementary data 1). In multivariate analysis, only LDF reconstructions in comparison with implant reconstructions were significantly associated with durations of surgery > 180min(OR 94, $p<0.0001$, CI95% 21-418).

Surgery time*(min)* **Patients with IBR**	Mean	Median	CI 95%	*p*
Type of Mastectomy				
NSM	253	252.5	212-294	**.029**
SSM	189	148	148-230	
Type of Reconstruction				
Breast implant	112	93	95-130	**<.0001**
LDF	303	285	274-332	
RLDF				
LDF without implant	283	266	257-309	**.005**
LDF with implant	377	365	287-466	
Period				
P1	250	257	213-287	**.001**
P2	152	143	119-184	
RoboticSurgery				
Yes	311	300	274-349	**<.0001**
No	155	139	126-183	

Supplementary data 1: Univariate analysis of factors associated with longer duration of surgery for patients with immediate breast reconstruction.

Interval time before chemotherapy:Median interval-time between surgery and chemotherapy when it was required was 43 days for patients with IBR (CI95%35-54) and 43 days for patients without IBR (CI95%41-62) without significant difference (p=0.417). IBR seems not to be a reason for delayed adjuvant treatment.

Post-operative outcome:

Complications:

All patients: Complication rate was 37.4% (77/206 patients) including all complications, 45.6% and 33.1% for IBR and no IBR respectively (p=0.056). Reoperation rate was 8.2% (17/207 mastectomies), 11.8% and 6.5% for IBR and no IBR respectively (p=0.151). There was no significant difference between IBR and no IBR for different grade of complications, with 14.7% (10/68) and 9.3% (13/139) Grade 2-3 complications for IBR and no IBR, respectively.

In univariate analysis significant factors known before surgery correlated with any complication were BMI (≥25), tobacco, IBR, mastectomy weight ((>300g), surgery time

(>180 min) and anesthesia time (>260 min).In multivariate analysis, BMI ≥25 (OR 2.02 p=0.023, CI95% 1.1-3.7), IBR (OR 1.9, p=0.046, CI95% 1.0-3.6) and tobacco (OR 2.17, p=0.055, CI95% 0.98-4.80) were correlated with higher risk of complications.

For patients without IBR: 33 grade 1 complication (71.7% of all complications) were observed (28 seromas, 4 small skin necrosis and 1 hematoma), 4 grade 2 complication (2 skin blistering, 1 skin necrosis and 1 hematoma) and 9 grade 3 complication (5 hematoma, 2 infections and 2 skin necrosis).

Patients with IBR: Complication rate was 45.6% including all complications (31/68) and reoperation rate was 11.8% (8/68) (Table 1). Twenty-one patients had grade 1 complication (67.7% of all complications), including 14grade 1 dorsal complications corresponding to dorsal seromas which needed one or several punctures, 7 small breast skin blistering and 1 breast hematoma without reoperation. Two grade 2 breast complications were observed: 1 infection with medical treatment and 1 partial skin necrosis without reoperation. Eight reoperations (Grade 3) were required for 2 breast hematomas, 2 breast infections, 3 reoperations with implant loss and 1 dorsal bleeding. The implant loss rate was 7.7% (3/39), 6.4% (2/31) and 12.5% (1/8) for breast implant or expander alone and implant associated with LDF, respectively.

In univariate analysis, more complications were observed with significant results for patients with tobacco use, cup size ≥C versus A-B, LDF reconstructions versus implant, duration of surgery >180mn (supplementary data 2). In multivariate analysis, only LDF reconstructions in comparison with implant reconstructions were significantly associated with complications (OR 8.275, p=0.009, CI95% 1.7-40). Robotic surgery was not significant in comparison with non-robotic surgery (Table 3).

Complication rate Grade 2-3 was 14.7% (10/68). Any factor was significantly associated with Grade2-3 complications.

Characteristics	Complications		*p*
	No (n = 37)	Yes (n = 31)	
Tobacco, n (%)			**.030**
no	33 (89.2)	21 (67.7)	
yes	4 (10.8)	10 (32.3)	
BMI, n (%)			.061
< 25	31 (83.8)	20 (64.5)	

≥25	6 (16.2)	11 (35.5)	
Cup size, n (%)			**.028**
A-B	24 (64.9)	12 (38.7)	
≥C	13 (35.1)	19 (61.3)	
Mastectomy, n (%)			.252
NSM	15 (40.5)	16 (51.6)	
SSM	22 (59.5)	15 (48.4)	
Reconstruction, n (%)			**.011**
Implant	23 (62.2)	8 (25.8)	
LDF	11 (29.7)	18 (58.1)	
LDF + Implant	3 (8.1)	5 (16.1)	
Surgery time, n (%)			**.006**
≤180 m	21 (56.8)	7 (23.3)	
> 180 m	16 (43.2)	23 (76.7)	

Supplementary data 2: Univariate analysis of factors associated with complications for patients with immediate breast reconstruction.

Post-operative hospitalization length:

All patients: Post-operative hospitalization lengths (POHL) were higher for patients with IBR (medians 3.0 and 1.0) without any other significant factor.

Patients with IBR: In univariate analysis, significant higher POHL were observed for LDF reconstruction versus implant (p<0,0001), for BMI ≥25 (near significant p=0.054) and for robotic surgery (p<0.0001) without significant difference between NSM and SSM (p=0.288). In multivariate analysis, only LDF reconstructions without implant and with implant were significantly associated with POHL >3 days (Table 4).

Table 4: Multivariate analysis of factors associated with surgery time, complications and POHL for patients with immediate breast reconstruction.

Lipofillingswere realized in 12 patients at time of follow-up with 1 procedure for 10 patients and 2 and 3 procedures for 2 patients (median 188cc, mean 278cc, CI95% 132-423cc): in 3 patients after breast implant reconstruction and 9 patients after autologous LDF reconstruction.

Surgery time ≤vs > 180mn Patients with IBR	*P*	Odd Ratio	CI 95%	
			Inferior	Superior
Robotic surgery versus no robotic	.460	4.711	.077	286.7
NSM versus SSM	.574	.465	.032	6.704
P2 versus P1	.163	.166	.013	2.074
LDF versus Implant	**<.0001**	193.4	12.14	3080
All Complications Patients with IBR	*p*	Odd Ratio	CI 95%	
			Inferior	Superior
Tobacco yes versus no	.058	3.833	.956	15.365
Cup size ≥C versus A-B	.087	2.689	.867	8.337
LDF versus Implant	**.009**	8.275	1.711	4.014
Robotic surgery versus no Robotic	.263	.413	.088	1.946
POHL ≤3 versus >3 days	*p*	Odd Ratio	CI 95%	
			Inferior	Superior
BMI >= 25 versus <25	.599	1.446	.365	5.725
Robotic surgery versus no robotic	.327	2.080	.481	8.984
Implant / Expander		1		
LDF	**.009**	6.283	1.567	25.19
LDF and Implant	.058	13.49	.918	198.2

Discussion

ILBLR remains a significant problem: The management of a breast cancer recurrence is not standardized. A salvage mastectomy is recommended and a level I/II axillary dissection. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. (Version 2. 2019)(7). The use of repeat BCT to treat ILBLR has been investigate with mixed results. Chen and Martinez evaluated 179 patients who underwent lumpectomy for treatment of ILBLR. Only 21 % of repeat BCT patients were documented to have re-irradiation (8). These patients had significantly worse 5 years overall survival (67%) than the patients who underwent mastectomy (78%). In a recent study, patients treated by lumpectomy alone had shorter overall survival (OS) and metastases free survival (MFS) than those with lumpectomy and re-irradiation (9). Lumpectomy alone seems therefore inappropriate for ILBLR (10). A new conservative treatment combined with brachytherapy or intraoperative radiotherapy has been proposed to patients with tumors carrying good prognosis (9,11). A clinical trial has evaluated partial breast radiation after BCT for recurrent disease, and data at the 1-year follow-up interval indicates to be safe and feasible (12).
ILBLR is a rare event with an estimated rate of 0,5-1,5% per year after BCT for invasive carcinoma and an overall incidence ranging from 5 to 10 % after 10 years(13,14)

Local recurrence enhances mortality: The 5-year survival rate after treatment for ILBLR by mastectomy has been around 60 to 86% (2,15). Survivals after ipsilateral recurrence (ILR)-events were significantly different with ILR-free interval < 2-years or between 2 and 5 years in comparison with patients with ILR-free interval >5-years and for different tumor subtypes(9,16).

We report 32.8% of mastectomy with IBRfor ILBLR. In the study by Frederick et al, 2015 (17), the IBR rate after mastectomy for ILBLRwas 60%. Our rate of 32.8% reflects careful patient selection to achieve a high success rate and reasonably low complications.The satisfaction with the cosmetic outcome strongly influenced quality of life and an unsatisfactory outcome after IBR was still considered a better condition than simple mastectomy (18).

Type of IBR. For patients with previous radiotherapy for ILBLR, the latissimus dorsi-muscle nourishes and protects the thin skin. Robotic latissimus dorsi-muscle flap reconstruction (RLDFR) was indicated in selected cases according to patient’s choice and particularly for

patients who don't want reconstruction with breast implant. In the most important experience of RLDFR published by Houvenaeghel& al, the rate of RLDFR after previous radiotherapy was 44,4 % (included mastectomy for ILBLR and mastectomy performed for primary BC after neo-adjuvant chemotherapy and radiotherapy) (19). In our study the majority of IBR after previous radiotherapy was performed by RLDFR with a rate of 54.4%.

Type of mastectomy with IBR. NSM is preferred over SSM in patients when the tumor is at a distance to the NAC. NSM has got an equal prognosis (recurrence or survival) relative to that of SSM and total mastectomy but with better cosmesis and quality of life after treatment. NSM can be proposed in selected cases of ILBLR(20).We reported a high rate of NSM forILBLRduring this recent period, 23.8% of NSM for ILBLR (20/84). NSM has become increasingly common for therapeutic indications because of the their cosmetic advantage (18) associated with better woman's body image and quality of life (21,22), improved patient satisfaction and psychosexual benefits (23). However, the potential disadvantage includes an increased risk of necrosis of the skin flaps and/or the NAC. Complications rates are difficult to compare with other studies in reason with the lack of consensus as to how to define the outcomes. In 2011, a systematic review of the published breast reconstruction literature revealed that the complications of necrosis, hematoma, seroma, and infection were defined in fewer than 20% of the 134 studies reviewed (24). This lack of consistency with respect to outcomes definitions makes it difficult to determine accurate complication rates for procedure.

NSM and outcomes: for recurrent, primary and prophylactic surgery

A little is known about the suitability and outcomes of NSM with IBR in the treatment of recurrent breast cancer. The largest prospective one includes 982 NSM with immediate reconstruction, and 49 for ILBLR(25). Overall complications were significantly more frequent in NSM with prior radiotherapy (21.7%) compared to those with no radiotherapy (10.2%). Prior radiotherapy increases the overall rates of skin necrosis (11.5% vs 4.5 %) and nipple loss (11.6% vs 0.9%). Complications that required surgical intervention were seen in 18.8 % in the cohort with prior radiotherapy vs 7.1% in the cohort with no prior radiotherapy. In a recent study of Lee and al. (26), prior BCT did not contribute to higher surgical complications rate in patients who received NSM and IBR after ILBLR except for the total

nipple loss with a higher rate in the group with prior radiotherapy when compared with the group with NSM for primary breast cancer (0.8% vs 11.1%, P = 0.041).
In our study, there was no significant difference between NSM and SSM for different grade of complications or for the rate of complications, but we identified 2others additionalindependent risk factors correlated with higher risk of complications: Tobacco and body mass index. These factors are all available before surgery, which may allow surgeons modify the reconstruction plans to reduce the complication rate. Thermal-injury is also a determining factor of complication (27), our group use plasma blade instead of traditional electrocauterization to reduce thermal injury during NSM(28).This report of NSM in patients with ILBLRshows that NSM may be considered as a treatment option for these patients. NSM in this setting is associated with an acceptably low rate of complications and satisfactory short-term outcomes for appropriately selected patients.

Recently, NSM has become a favorable option for primary BC surgery when performed in highly selected patients(29). In a recent systemic review study of the oncological safety of primary NSM,the overall complication rate was 22.3% and the nipple necrosis rate was 5.9%(30). Importantly, they found that the rates of complications, including nipple necrosis, decreased over time which was attributed to improving surgeon expertise. NACnecrosis is a particular issue when patients have risk factors such as smoking, young age, high body mass index, peri-areolar skin incision for mastectomy(31–35).The identification of such risk factors could help clarify patient selection criteria.

About complications of prophylactic NSM (PNSM), the largest series of 3716 PNSM was published by Muller and all(36). They reported an average overall complication rate at 20.5%, 8.1 % NAC necrosis and 7.1% necrosis of the cutaneous skin flaps.
A recent retrospective review by Yao et al(37) is one of the largest studies to date on genetic carriers undergoing NSM. This study examined outcomes of 397 NSMs BRCA1/2 carriers.
Flap necrosis occurred in 10 (2.5%) and NAC loss occurred in 7 (1.8%) breasts, three dues to cancer involvement (5.8%) and four from necrosis. In our study the rate of cutaneous necrosis after IBR for ILBLR was 1.4 % (1/68), quite similar with these studies on prophylactic NSM.
Overall complication rates were low and comparable to non-carrier populations(32).
The use of robotic minimally invasive surgery has also shown a low complication rate. In the study of Sarfaty(38), a total of 33 women underwent 63 robotic prophylactic NSM with IBR by pre-pectoral implant. In a short term (21 days), there were no cases of major/minor

mastectomy skin flap or NAC necrosis, three postoperative infections and one prothesis exclusion.

In our study, there were no significant difference between the rate of overall complications (p=0,056), complication grade (0,310) and reoperation rate (p=0,151) with or without IBR. Previous studies have shown that the complication rate are still higher in radiated breasts, even with autologous tissue (39,40). Our results can be explained by a rigorous selection of patients with IBR. This may be also attributed to differences in technique, newer implants or differences in radiotherapy protocols. Our results are in agreement with a recent publication by Lee et al showing that prior BCdid not contribute to higher surgical complications in patients who received NSM and IBR as a salvage procedure after ILBLR(26). However, it is difficult to conclude on the implication of IBR on the complications of a mastectomy for ILBLR because there is no study comparing the complications of a mastectomy for recurrence with and without reconstruction.

About the type of breast reconstruction, only LDF reconstructions in comparison with implant reconstructions were significantly associated with complications because of the time of surgery (>180 minutes). LDF is first line for patients who have high-risk comorbidities such as diabetes, obesity, or tobacco use and for patients whose breasts have been radiated(41).

Complications, time of surgery, anesthesia and robotic surgery:

We reported our experience of 43 robotic procedures for 28 patients among 68 mastectomies with IBR. It was a robotic NSM /SSM with or without LDF for ILBLR with a standardized surgical procedure: dissection with non-robotic scissors after subcutaneous infiltration and then robotic dissection(6). This surgical procedure with incision in anterior axillary line allowed good cosmetic results without scar on breast and without dorsal scar with RLDF and the endoscopic incisions had the lowest rate of NAC necrosis at 4.9 percent on the recent study of Daar et all(31). We reported a stronger selection of patients. Even if we have patients with previous radiotherapy, patients with IBR were significantly younger (86.7% were between 41 and 74 years old), with a BMI < 25 (75%), small breast volume with a weight of specimen less than 300g (58.8%) and classified as low risk for anesthesia (ASA 1 & 2) for 94%. In multivariate analysis, robotic surgery was not significant in terms of complications compared to non-robotic surgery (p=0, 263) andnot significant for duration of surgery > 180mincompared to a conventional surgery (p=0,460). It's probably the increase experience

of robotic breast-surgery in our center which allowed non-significant times of procedures as described in a recently published article (6).

Strengths of the present study include the relatively important number of cases compared to other series on ILBLR. We proposed a variety methods of reconstruction : LDF with traditional open technique or robotic technique (6) with or without implant, subpectoral implant, expander tissue with a relatively low rate of complications. There is no confounding issue with the radiation treatment protocols because only one radiation therapy center was used to treat the patients.Some limitations of the present study can be underline: our cohort was not prospective, and we did not include a non-irradiated control group for comparison.

Conclusion

Prior BCT did not contribute to higher surgical complications in patients who received mastectomy and IBR. Salvage mastectomy and IBRis a good choice for local recurrence after BCT. NSM can be considered as a good treatment option in highly selected patients for ILBLR with or without robotic surgery for NSM and/or LDFR.

Annexe

Classification of surgical complications

Grade	Definition
1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Acceptable therapeutic regiments are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
2	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions, antibiotics and total parenteral nutrition are also included.
3	Requiring surgical, endoscopic or radiological intervention
3a	Intervention under regional/local anaesthesia
3b	Intervention under general anaesthesia
4	Life-threatening complication requiring intensive care/intensive care unit management
4a	Single organ dysfunction
4b	Multi-organ dysfunction
5	Patient demise

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UFR SCIENCES MEDICALES HYACINTHE BASTARAUD

SERMENT D'HIPPOCRATE

Au moment d'être admis à exercer la médecine, en présence des maîtres de cette école et de mes condisciples, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité qui la régissent.

Mon premier souci sera, de rétablir, de préserver ou de promouvoir la santé dans tous les éléments physiques et mentaux, individuels collectifs et sociaux. Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions.
J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou dignité.
Même sous la contrainte, je ne ferai usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients de décisions envisagées, de leurs raisons et de leurs conséquences.
Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer leurs consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera.
Je ne me laisserai influencer ni par la recherche du gain ni par la recherche de la gloire.

Admis dans l'intimité des personnes, je tairai les secrets qui me sont confiés.
Reçu à l'intérieur des maisons, je respecterai les secrets des foyers.
Et ma conduite ne servira pas à corrompre les mœurs.

Je ferai tout pour soulager les souffrances, sans acharnement.
Je ne provoquerai jamais la mort délibérément.
Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission.
Que je sois modéré en tout, mais insatiable de mon amour de la science.
Je n'entreprendrai rien qui ne dépasse mes compétences ; je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité.
Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses,
Que je sois déshonoré et méprisé si j'y manque.

NOM ET PRENOM : SIMON Pauline

SUJET DE LA THÈSE :
MASTECTOMIE POUR RECIDIVE LOCALE AVEC OU SANS RECONSTRUCTION IMMEDIATE

THÈSE : MEDECINE
Qualification : Médecine Spécialisée **ANNÉE :**2019

NUMERO D'IDENTIFICATION : 2019ANTI0446

MOTS CLEFS : Récidive locale de cancer du sein, mastectomie, reconstruction mammaire, implants mammaires, chirurgie robot-assistée

RESUME

Les principaux objectifs de notre étude étaient de présenter les résultats chirurgicaux des patientes opérées dans notre centre d'une récidive locale(RL) de cancer du sein et de déterminer ainsi les effets de la radiothérapie antérieure ainsi que de fournir des données pertinentes sur les taux de complications et les facteurs de risque de celles-ci.

Matériels et Méthodes : Deux cent sept patientes traitées par mastectomie avec ou sans reconstruction immédiate (RMI) après un traitement conservateur du sein ont été identifiées entre janvier 2016 et avril 2019.
Les données cliniques, le type de chirurgie, le taux de complications, la durée de la chirurgie et de l'anesthésie, la durée du séjour ont été déterminés.

Résultats : Sur les 207 mastectomies pour récidive locale, 32,8 % avaient une RMI(68/207).
Moins de reconstructions ont été effectuées chez les patientes présentant un indice de masse corporelle ≥30 (OR 0,214), des carcinomes canalaires infiltrants (OR 0,272) et des scores ASA-3 (OR 0,254).
Les types de mastectomie étaient 31 mastectomies avec conservation de l'étui cutané et de la paque aréolo-mamelonnaire (NSM) (45,6 %) et 37 mastectomies avec conservation de l'étui cutané seul (SSM) (54,4 %). 32,85% des patientes ont bénéficiées d'une reconstruction mammaire immédiate (68/207). Elle a été réalisée par lambeau du muscle grand dorsal (LGD) chez 37 patientes (54,4%) et avec implants chez 31 patientes (45,6%). Vingt pour cent des mastectomies type NSM avec implants et 71,4 % des reconstructions par LGD ont été réalisées par chirurgie robotique (15/21). Le taux global de complications était de 37,4% (77/206), respectivement 45,6% et 33,1% avec et sans RMI (p=0,056). Seule la reconstruction par LGD par rapport à l'implant était associée à des complications (OR 8,275, p=0,009, CI95% 1,7-40). Aucune différence n'a été observée entre la chirurgie robotique et la chirurgie ouverte (p=0,263).
Le seul facteur associé à une hospitalisation postopératoire > 3 jours était la reconstruction par LGD (OR 6,283 p=0,009).

Conclusion : L'antécédent de cancer du sein n'a pas contribué à des complications chirurgicales plus importantes chez les patientes opérées d'une RL. La mastectomie avec RMI est un bon choix pour ces patientes. La mastectomie de type NSM peut être considérée comme une bonne option thérapeutique chez des patientes sélectionnées pour le traitement d'une récidive locale homolatérale avec ou sans chirurgie robotique.

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