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Original article

Reducing implant loss rates in immediate breast reconstructions

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ABSTRACT

UK best practice guidelines for oncoplastic breast reconstruction were published in 2012. Implant-based reconstruction quality indicator (QI) targets for readmission, return to theatre and implant loss rates were set at 5% by 3 months, along with guidance to achieve these targets. The aims of this study were to quantify complication rates following implant-based reconstruction before and after the implementation of the guidelines. A retrospective audit of 86 patients with 106 implants in the 12 months to June 2013 was performed, C1. Following institutional changes including reducing antibiotic usage, a prospective audit was performed on 89 patients with 105 implants to June 2014, C2. Extended follow-up of salvaged implants was also performed. Demographics were not significantly different between the two cohorts apart from smoking. Implant loss rates fell from 7.5%(C1) to 1.9%(C2), $p = 0.054$ but at the cost of an increase in the return to theatre rate (14.2%–18%, $p > 0.05$). The implant salvage rate increased from 47% in C1 to 89.5% in C2, however, 3 of the implants that were salvaged were lost in the long term giving an overall salvage rate of 82.4% in C2. While an implant loss rate of <5% at 3 months appears achievable with less antibiotic use, this was made possible by the institution of an aggressive readmission and salvage policy. We would question the QI standards for readmission and return to theatre for immediate implant-based breast reconstruction, given that our implant loss rate of 1.9% was achieved with a return to theatre rate of 18%.

1. Introduction

Immediate implant-based reconstruction following mastectomy is accepted practice throughout the world and rates are increasing [1]. Currently 1 in 5 women in the UK requiring mastectomy opt for immediate reconstruction [2]. Complications rates of up to 52% have been quoted [3]. This can have a significant impact on patients, both physically and emotionally [4,5], as well potentially delaying adjuvant treatment and increasing costs. Factors such as obesity, smoking, lower socioeconomic status, and the use of Acellular Dermal Matrices (ADMs) are known to increase the risk of complications [6–9]. However, it is not always possible to avoid these risk factors in breast cancer patients undergoing immediate reconstruction. Following publication of the UK National Mastectomy and Breast Reconstruction Audits (NMBRA) [10–13], best practice guidelines for oncoplastic breast reconstruction were published jointly by ABS and BAPRAS, in 2012 [14]. Implant-based reconstruction quality indicator targets for readmission rates, return to theatre and implant loss rates were published (5% at 3 months), along with guidance on ways to achieve these targets. The aims of this study were to quantify complication rates following implant-based reconstruction, before and after the implementation of the guidelines and to benchmark practice to the quality indicators.

2. Patients and methods

A retrospective audit of patients in the 12 months to June 2013 was performed (first cohort, C1). Patients undergoing one stage procedures with fixed volume implants and those undergoing 2 stage procedures using expanders were included. Delayed reconstructions were excluded. Overall complication rates, readmission rates, return to theatre rates and implant loss rates at one and three months were recorded, along with patient demographics and risk factors (age, BMI, diabetes, smoking, previous

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radiotherapy), the type of surgery performed both to breast and axilla at the time of implant insertion, method of lower pole implant coverage, use of antibiotics and any organisms cultured.

Following this review, changes in practice were adopted in line with the 2012 published guidelines [14]. Amendments were made to both antibiotic prophylaxis and treatment. For prophylaxis, gram negative cover was added, with patients receiving cefuroxime preoperatively instead of flucloxacillin and gentamicin instead of clindamycin for those with a known penicillin allergy. Active screening for Meticillin Susceptible *Staphylococcus aureus* (MSSA) colonisation in addition to screening for Meticillin Resistant *Staphylococcus aureus* (MRSA) was introduced. Proven colonisation was managed with five days of topical decolonisation therapy prior to surgery. For treatment of established infections, specific guidance was included in the Trust Guide to Antimicrobial Therapy. Additional anaerobic cover was included for infections occurring after procedures involving the nipple areolar complex. Changes to the Trust's Antibiotic guidance was agreed across the Surgical Services and Plastic Surgery Directorates, and ratified by the Trust's Antimicrobial Steering Group, a subcommittee of the Medicines Management Committee.

Protocols for managing implant-based cases were reviewed and updated, with agreement between general and plastic surgeons. Entry into theatre was restricted during implant cases, with a requirement for all those present to wear surgical masks. Any ADM's used were carefully prepared according to manufacturer instructions. All drains were tunnelled at least 15 cm from the surgical site and any patient discharged with a drain in situ had a clearly documented plan and daily telephone review. Patients were reviewed early following discharge and had contact information to facilitate review and potential early intervention if any complications arose. Any patients presenting with symptoms after discharge from hospital were seen and assessed by an experienced member of the breast team. Immediate access to ultrasound guided aspiration was available while a low index of clinical suspicion was instituted for readmission and return to theatre for implant salvage. Salvage procedures included washout with saline and/or betadine, with replacement of original implant, or insertion of a smaller implant or tissue expander at the surgeons discretion.

In the 12 months to June 2014 a prospective audit of patients (second cohort, C2) undergoing mastectomy and implant-based reconstruction was carried out following institutional changes, using the same methodology as before, enabling comparison to C1. Long-term follow up of any patients undergoing salvage procedures was also carried out prospectively for both cohorts to April 2016. Categorical variables were compared using a chi-squared test and continuous variables were compared using a *t*-test and significance was taken at the 5% level.

3. Results

106 implants were placed in 86 patients in the first cohort, C1 (66 unilateral, 20 bilateral) and 105 implants were placed in 89 patients in the second cohort, C2 (73 unilateral, 16 bilateral). There were no significant differences in age (C1: 49.8(15–73); C2: 50.6(19–79) $p = 0.656$), BMI (C1: 25.4(19–44); C2: 26.3(18–37) $p = 0.211$), exposure to previous radiotherapy($p = 0.15$), use of fixed volume implants versus tissue expanders ($p = 0.8$), bilateral or unilateral placement ($p = 0.455$) or type of axillary surgery ($p = 0.08$), between the two cohorts (see Table 1). The proportion of cases carried out by general surgeons and plastic surgeons also did not differ significantly between the two cohorts ($p = 0.12$). 6 surgeons were represented in C1, whilst 8 were represented in C2. A majority of patients in C1 (79.2%) and C2 (70.4%) had procedures carried out by surgeons represented in both cohorts. There were significantly fewer active smokers in C2, as compared to C1 ($p = 0.011$). Significantly more skin and nipple sparing mastectomies, as opposed to skin sparing mastectomies, were performed in C2 ($p = 0.002$), however the proportion of skin reducing procedures was the same. Significantly less STRATTICE™ (LifeCell, USA) ADM was used for lower pole coverage in the second cohort but there was a concomitant increase in the use of TiLOOP® (pfmmedical, Germany), titanium coated polypropelene mesh and VERITAS collagen matrix (Baxter, USA) ADM.

In C1 the overall rate of any complication at 3 months was 27.3% (29/106). In C2 this rate did not differ significantly (33.3%, 35/105;

Table 1
Patient characteristics.

		Cohort 1	Cohort 2	P Score
Number of implants		106	105	
Age mean (range)		49.8 (15–73)	50.6 (19–79)	0.656
BMI mean (range)		25.4 (19–44)	26.3 (18–37)	0.211
Number of patients	Unilateral implant	66	73	0.455
	Bilateral implants	20	16	
Smoking status (number of patients)	Non smoker	54	71	**0.011**
	Current smoker	17	5	
	Ex-smoker	15	13	
Previous radiotherapy		4	9	0.15
Surgery	Skin sparing mastectomy	45	23	**0.002**
	Skin and nipple sparing mastectomy	31	52	
	Skin reducing mastectomy	30	30	
Implant used	Fixed volume implant	98	98	0.80
	Tissue expander	8	7	
Lower pole coverage	None	34	38	**0.000023**
	Dermal sling	30	30	
	Strattice	29	6	
	Veritas	13	22	
	TiLoop	0	9	
Axillary surgery	None	47	43	0.08
	SLNB	51	61	
	ANC	5	1	
	Completion ANC	3	0	
Speciality	General surgery	55	57	0.12
	Plastic surgery	51	48	

The bold represents highlight statistical significance.