Original Article

Investigating the time to adjuvant treatment following immediate breast reconstruction in breast cancer patients

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Background: Mastectomy is still recommended in up to 40% of patients with breast cancer. National Institute of Clinical Excellence (NICE) guidelines mandate that post-mastectomy immediate breast reconstruction (PMIBR) should be offered to all suitable patients. However, it is still a matter of debate if immediate breast reconstruction causes a delay in administering adjuvant therapies to patients with breast cancer. The primary aim of this study is therefore to explore any associations between immediate breast reconstruction and unacceptable delay to delivering first adjuvant treatment.

Methods: A retrospective study was undertaken during a 4-year period [2015–2018] in the Breast Surgery unit at Guy's and St Thomas' NHS Foundation Trust (GSTT). Statistical analysis, comparing time to adjuvant treatment in the immediate reconstruction and control groups, was performed. A total of 168 patients undergoing immediate reconstruction and receiving adjuvant treatment were identified through an electronic database. This group was compared with a control group of 85 age-matched patients that underwent standard breast conserving surgery or mastectomy with no reconstruction who also received adjuvant treatment, during the same time period. Regression analysis was undertaken to adjust for confounding effects.

Results: The mean time to adjuvant treatment in the immediate reconstruction group and the control group was 65.4 and 65.3 days respectively. Out of the 168 patients who underwent mastectomy with immediate reconstruction, 20 (11.9%) had a delay to their adjuvant treatment and of these in 11 (6.5%) the delay was directly related to their PMIBR surgery. Multiple regression analysis showed no significant difference.

Conclusions: There was no significant statistical difference with regards to timing to first adjuvant treatment following immediate breast reconstruction in the study group and the control group. These results support the current practice on our unit, as well as national guidelines for PMIBR. Further studies however are warranted to define what is considered as acceptable 'delay' to delivering adjuvant therapy and the adverse impact on outcome.

Keywords: Adjuvant therapy; mastectomy; deep inferior epigastric perforators (DIEP); implant; reconstruction

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Introduction

Breast cancer surgery has undergone major advances in the past two decades (1). Breast conserving surgery has become the surgery of choice instead of mastectomy for the great majority of patients. However, mastectomy remains the appropriate surgical treatment for up to 40% of breast cancer patients (2). Mastectomy can have a significant negative impact on quality of life with reduced self-esteem, poor body image and effect on sexuality and relationships all reported (3). Restoring patients' body image is a crucial component of patient care and has become an integral aspect of the holistic approach to breast cancer treatment. It is possible to carry out reconstruction at the time of mastectomy: "immediate", [post-mastectomy immediate breast reconstruction (PMIBR)] or at a later time: "delayed" (4).

The National Mastectomy and Breast Reconstruction Audit (NMBRA) (3) shows similar patient outcomes and satisfaction for immediate and delayed reconstruction for all parameters: aesthetic appearance, emotional, physical and sexual well-being.

Yet, immediate breast reconstruction is now considered as gold standard of care and all suitable patients undergoing mastectomy should be offered immediate reconstruction according to the National Institute of Clinical Excellence (NICE) guidelines (5). The two main options for performing PMIBR following a conservative mastectomy are implant-based or autologous flaps. The NMBRA has shown slightly better patient-reported satisfaction for autologous reconstructions in comparison with implants, an observation that has also been reported by others (6-8).

However, there is concern that immediate reconstruction could cause a delay in commencing adjuvant therapy as a direct consequence of an increased rate of post-operative complications caused by the added complexity of the surgical procedure (9). The optimum duration between surgery and delivery of adjuvant therapy has not yet been clearly defined. NICE guidelines suggest that subsequent or adjuvant treatment should ideally commence by 31 days following definitive surgery (5), conversely the American Society of Clinical Oncology recommends that treatment be completed within 121 days of diagnosis (10). A 2011 Cochrane review (11) reported that there was lack of evidence on either side of the debate and that local guidelines should be followed for best practice. This clearly implies that there is a paucity of data in this area and unanswered questions remain. Literatures from tertiary centres in UK are particularly lacking—making our study highly relevant to this area.

The primary aim of this study is therefore to explore the association between immediate breast reconstruction and the timing to adjuvant treatment. Immediate breast reconstruction is increasingly being offered as part of surgical treatment around the world, in line with various international guidelines. Any 'perceived' delay to delivering adjuvant treatment due to the increased complexity of surgery and possible post-operative complications, may cause anxiety to both patients and clinicians. Our study may assist in adding further support to current practice and recommendations. We present the following article in accordance with the STROBE reporting checklist (available at https://abs.amegroups.com/article/view/10.21037/abs-21-37/rc).

Methods

Patients

This is a single centre retrospective study: all patients were treated at the Guy's & St Thomas' Hospitals (GSTT) Breast Unit between January 2015 and December 2018. Suitable patients were identified using the GSTT Breast Unit's electronic theatre scheduling system. The keywords "mastectomy" and "immediate reconstruction" were used to identify patients suitable for this study. We proceeded to manually sort the records obtained into the sub-categories of: "autologous" or "implant" based immediate breast reconstruction. All patients who received adjuvant treatment (chemotherapy, radiotherapy or both) following immediate breast reconstruction, using either autologous free flaps (n=80) or implant-based (n=88) were included (total n=168). Patients undergoing risk-reducing prophylactic mastectomy or those that did not receive adjuvant treatment were excluded from this study (n=310). The control group included patients who underwent wide local excision (WLE) a common breast-conserving surgery (n=65), or mastectomy (n=20) without reconstruction—followed by adjuvant treatment as illustrated in *Figure 1*. The number of patients in the control group is matched 1:2 with the immediate reconstruction group. The decision to include patients undergoing breast conserving surgery was made due to the low number of patients undergoing mastectomy without immediate breast reconstruction at our centre. Control group patients were identified from the electronic database using keywords: "mastectomy", "simple mastectomy", "mastectomy without reconstruction" and "WLE", data was included up to January 2019. Confidential patient information was rendered anonymous without

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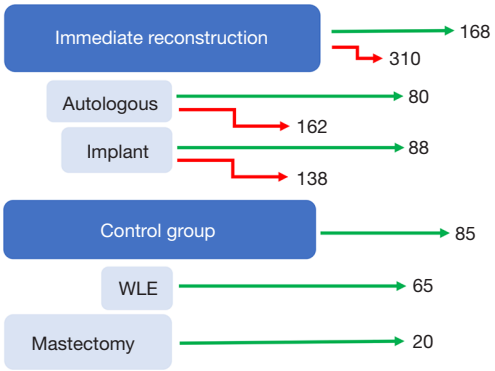

Figure 1 Flow-chart of patient selection for immediate reconstruction group and control group. Further breakdown given for each category. Green line: included; Red line: excluded. WLE, wide local excision.

breaching the duty of confidentiality—the database was independently established for clinical research purposes as per Health Research Authority guidelines. Thus, informed consent and Research Ethics Committee guidance was not necessary for this study. Demographic, tumour histology and receptor status is included in *Table 1*.

Assessment of outcomes and clinical covariates

Our primary outcome was the time between breast cancer surgery and first adjuvant treatment. In our study, we defined a delay to adjuvant treatment as patients receiving their first adjuvant intervention more than 90 days after their surgery. This is consistent with available literature (12), in particular a recent study with a large sample size (n=24,843) showing that time to adjuvant treatment exceeding 90 days is associated with adverse clinical outcomes: in particular, overall survival and patient-recorded outcomes. In our study, the 90-day definition was equivalent to the mean time between surgery and adjuvant treatment plus one standard deviation. Variables collected from the two groups include: date of birth, surgery date, radiotherapy date, chemotherapy date, complications, tumour size, histological characteristics, lymph node information, demographic information.

Statistical analysis

Regression analysis was undertaken to check for any association with other collected parameters: no confounding associations were found. *Table 2* shows the output of our regression analysis.

Statistical analysis was undertaken using unpaired *t*-tests to compare time to adjuvant treatment within the immediate reconstruction and control groups to determine if there are significant differences.

Ethical statement

This study adheres to the guidelines on medical protocols and ethics stated in the Declaration of Helsinki (as revised in 2013). The authors assert that ethical approval for publication of this manuscript was not required by their local Ethics Committee.

Results

Our results show similar mean time to adjuvant treatment between the two groups: 65.4 days (95% CI ±3.8 days) for the immediate reconstruction group and 65.3 days (95% CI ±5.1 days) for the control group (P=0.988). Furthermore, within the immediate breast reconstruction group, the time to adjuvant treatment was 65.3 days (95% CI ±6.2 days) for the implant group and 65.5 days (95% CI ±5.47 days) for the autologous group (P=0.964), as illustrated in *Figure 2*. We identified a delay to adjuvant treatment in 20 patients out of the 168 that underwent immediate breast reconstruction (11.9%); the causes for delay by type are explored in the discussion.

Table 3 shows the time to first adjuvant treatment for either chemotherapy or radiotherapy for the patients in our study cohort.

Out of the 168 patients who underwent mastectomy with immediate reconstruction, 20 out of 168 (11.9%) patients had a delay time exceeding 90 days (due to all causes of delay). These patients had a mean time to adjuvant treatment of 117 days, with a maximum delay of 179 days.

We analysed these cases by delay type: 11 out of 20 patients had delays to adjuvant treatment directly related to complications following their immediate breast reconstruction surgery (11 of 168, 6.5%). Out of these 11, 7 patients had implant based immediate breast reconstruction (7 of 168, 4.1%) and 4 patients had autologous reconstruction (4 of 168, 2.4%). As documented in *Table 2*, 9 out of these 11 patients required a return to theatre for post-operative procedures: 7 patients had implant-based reconstructions and 2 patients were autologous flaps. The remaining 2 of 11 patients (with autologous reconstructions) had minor surgical site related complications that were conservatively managed.

Nine out of the 20 patients that experienced delays, were

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Table 1 Demographic data, tumour histology and receptor status for patients included in the study

Category	DIEP (n=80)	Implant (n=88)	Total (n=168)	Control (n=85)
Age (years)				
Median	49	46	47	62
Mean (SD)	48.8 (7.8)	44.0 (10.7)	47.4 (9.5)	60.7 (11.8)
<35	3.8%	13.6%	8.9%	4.3%
36–50	51.3%	53.4%	52.4%	12.8%
51–69	45.0%	30.7%	37.5%	61.7%
>70	0.0%	2.3%	1.2%	19.1%
Smoking history				
Yes	11.70%	14.60%	13.10%	–
BMI (kg/m^2)				
Median	29.3	25.6	28	–
Mean (SD)	29.1 (3.2)	28.4 (7.8)	28.8 (5.4)	–
Tumour histology				
DCIS	3.8%	3.4%	3.6%	14.6%
Invasive ductal/NST	82.3%	86.4%	83.9%	62.5%
Invasive lobular	8.9%	5.7%	7.1%	6.3%
Mixed	1.3%	2.8%	2.4%	4.2%
Others	3.8%	2.3%	3.0%	12.5%
Receptor status				
ER+/HER2+	10%	11.4%	10.7%	11.9%
ER+/HER2–	67.5%	63.6%	65.5%	69.0%
ER–/HER2+	11.3%	5.7%	8.3%	7.1%
Triple–	11.3%	19.3%	15.5%	11.9%

DIEP, deep inferior epigastric perforators; SD, standard deviation; BMI, body mass index; DCIS, ductal carcinoma in situ; NST, no specific type; ER, oestrogen receptor; HER2, human epidermal growth factor receptor 2.

delayed due to other causes not related to post-surgical complications, as documented in *Table 3*. In 4 cases it was patients' choice for personal reasons, including seeking a second opinion, delaying the procedure until after a major festive period, and severe procedure-related anxiety. 1 patient received emergency treatment for a cardiac problem that was unrelated to their surgery and a further 4 patients needed a second stage completion axillary nodal clearance. These latter 4 patients do not qualify as delays, as their completion axillary surgery was necessary prior to deciding on and commencing adjuvant therapy.

Therefore, in our study, there was total of 11 (out of 20) their delays were directly attributed to immediate breast reconstruction surgery (6.5% of the total study population: implant reconstruction 4.1%; autologous reconstruction 2.4%) and a further 9 delays that were unrelated to the immediate breast reconstruction surgery (5.4% of the total study population). In those who had delay due to their reconstructive surgery, mean BMI was 33.8 kg/m^2 and 27.2% were smokers.

Discussion

There has been concern that post-operative complications associated with immediate reconstruction may lead to significant and unacceptable delay in delivering adjuvant

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Table 2 Regression analysis output showing no significant associations with other variables

Variables	Estimate	Standard error	t value	P value
Age	0.7735	0.4424	1.749	0.0863
BMI	1.0538	0.6673	1.579	0.1204
Preop ultrasound size	0.1041	0.1673	0.622	0.5364
ER+ve	−5.5873	15.0575	−0.371	0.713
PR+ve	−0.8083	14.1968	−0.057	0.955
HER2+ve	−7.2328	17.8692	−0.405	0.688
Smoking	−0.4115	16.8557	−0.024	0.981
Unifocal/multifocal	−10.0618	11.845	−0.849	0.401
Axillary node positive	19.2842	12.9362	1.498	0.143

ER, oestrogen receptor; PR, progesterone receptor; HER2, human epidermal growth factor receptor 2; +ve, positive.

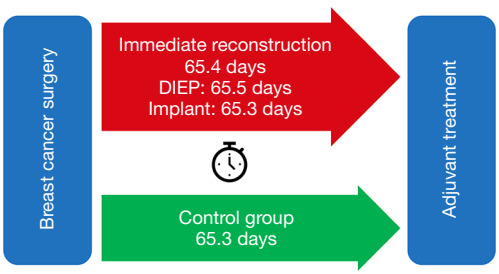

Figure 2 Summary of results in diagrammatic format, showing similar time to adjuvant treatment within the immediate reconstruction group and between the immediate reconstruction group and control group. DIEP, deep inferior epigastric perforators.

treatment. In one study, almost 39% of medical oncologists and 23% of surgical oncologists believed that immediate reconstruction can interfere with adjuvant treatments (12). Furthermore, a history of previous radiation therapy was associated with a higher rate of complications in immediate implant reconstruction, which could lead to significant delay in systemic treatment (13). The optimum duration between surgery and initiation of adjuvant therapy has not yet been clearly defined. There are wide ranging recommendations between 31 and 121 days (NICE *vs.* American Society of Clinical Oncology) to time of delivering adjuvant treatment. Furthermore, there is no clear consensus on whether undertaking immediate reconstruction delays adjuvant therapy. The evidence is contradictory: some prospective studies have found that there was no significant increase in time to adjuvant therapy after immediate reconstruction (14-18). Whereas others have reported delay (19). The effect of 'perceived' delay to adjuvant treatment has also been studied with contradictory results. Although some studies have reported that a delay may be associated with worse clinical outcomes (4,20), others found no effect (21).

Our study used the definition for delay to adjuvant treatment as patients receiving their first line of adjuvant treatment more than 90 days after their surgery, as detailed in *Table 4*. Chavez-MacGregor *et al.* (20), has shown that time to adjuvant treatment exceeding 90 days is associated with adverse poorer overall survival and patient-recorded outcomes. In our study, the 90-day definition was equivalent to the mean + one standard deviation. In our study however we cannot comment on whether such a delay had any adverse effect on patient outcomes.

In the control 10.6% experienced delay, corresponding to 9 patients having a time to commencing adjuvant treatment exceeding 90 days, as detailed in *Table 5*. Comparing the control group to the immediate reconstruction group, it was interesting to observe that a higher number in the control group experienced delay (10.6% compared to 6.5%). Although there was no statistically significant difference between the two groups, we observed that the delay rates due to complications with PMIBR in this single centre study were comparable, if not better, to those in the control group. The impact of observed delay on survival in our study groups is beyond the scope of this paper, but we aim to explore this in future study. Our results support the current practice of offering immediate reconstruction in patients with planned adjuvant therapy.

In our series, the immediate reconstruction and control group show similar times to first adjuvant treatment (65.4

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Table 3 Comparison between time to chemotherapy and radiotherapy as first adjuvant treatment

Reconstruction type	Time to first adjuvant treatment			
	Chemotherapy		Radiotherapy	
	Mean (SD)	Median	Mean (SD)	Median
DIEP	69.6 (23.5)	68	66.0 (21.1)	62
Implant	56.3 (25.4)	51	75.5 (33.1)	64
Total	62.0 (25.4)	58	70.3 (27.5)	63

All values in days. SD, standard deviation; DIEP, deep inferior epigastric perforators.

Table 4 Information on patients for which the time to adjuvant treatment is defined as delayed (≥90 days) due to complications with PMIBR

Patient	Reconstruction type	Operation year	Time to adjuvant treatment (days)	Cause for delay	Return to theatre
1	DIEP	2016	98	Skin necrosis, debridement, graft	Yes
2	DIEP	2016	91	Skin necrosis, debridement	Yes
3	DIEP	2017	104	Superficial infection	No
4	DIEP	2018	119	Skin necrosis	No
5	Implant	2017	144	Nipple necrosis, washout, revision, implant infection, implant loss	Yes
6	Implant	2017	97	Skin necrosis, revision, washout	Yes
7	Implant	2018	179	Implant rupture, wound dehiscence, washout	Yes
8	Implant	2018	121	Superficial nipple necrosis, washout	Yes
9	Implant	2018	138	Skin necrosis, revision, washout	Yes
10	Implant	2018	142	Superficial nipple necrosis	Yes
11	Implant	2018	159	Dehiscence, skin necrosis	Yes

PMIBR, post-mastectomy immediate breast reconstruction; DIEP, deep inferior epigastric perforators.

Table 5 Information on patients for which the time to adjuvant treatment is defined as delayed (≥90 days) due to factors other than their PMIBR

Patient	Reconstruction type	Operation year	Time to adjuvant treatment (days)	Cause for delay	Return to theatre
1	DIEP	2016	97	Patient decision: wanted second opinion in alternative medicine	No
2	DIEP	2017	121	ANC, declined adjuvant treatment initially	No
3	DIEP	2017	99	ANC	No
4	Implant	2016	102	Unrelated cardiac treatment	No
5	Implant	2016	101	ANC	No
6	Implant	2017	99	ANC	No
7	Implant	2017	119	Patient decision: sought out second opinion before proceeding	No
8	Implant	2018	96	Patient decision: delayed until after festive period	No
9	Implant	2018	121	Patient decision: patient anxious about starting adjuvant treatment	No

PMIBR, post-mastectomy immediate breast reconstruction; DIEP, deep inferior epigastric perforators; ANC, axillary node clearance.

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vs. 65.3 days, P=0.988). It is therefore safe to conclude that there is no significant delay to adjuvant treatment for patients undergoing immediate breast reconstruction. Furthermore, in the immediate reconstruction group, there were similar times to first adjuvant treatment: 65.3 days for the implant group *vs.* 65.5 days for the autologous group (P=0.964). It is interesting to highlight that proportion of patients in PMIBR surgery who experienced delay (6.5%) secondary to post-operative complications was lower compared with the control group (10.6%).

We acknowledge the limitations in our study of the small and retrospective population, and short follow-up which precludes of commenting on any detrimental effect of delay in delivering adjuvant treatment.

Conclusions

In conclusion, this study supports existing evidence and current clinical practice that immediate breast reconstruction in patients with breast cancer does not lead to a significant delay to the administration of first adjuvant treatment for both implant-based and autologous reconstructions. Furthermore, we have demonstrated there is no significant difference between implant reconstruction and autologous flap reconstruction in the time to adjuvant treatment. Finally, we observed a lower complication-related delay rate for immediate breast reconstruction when compared to our control group, which we believe warrants further investigation. Our results support our current clinical practice at GSTT. Larger, prospective and longer follow-up studies are needed to provide more insights into this topic—to define 'delay' and demonstrate any compromise to patients with regards to timing to adjuvant treatment.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://abs.amegroups.com/article/view/10.21037/abs-21-37/rc

Data Sharing Statement: Available at https://abs.amegroups.com/article/view/10.21037/abs-21-37/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://abs.amegroups.com/article/view/10.21037/abs-21-37/coif). AK received speaker fees from Integra. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study adheres to the guidelines on medical protocols and ethics stated in the Declaration of Helsinki (as revised in 2013). The authors assert that ethical approval for publication of this manuscript was not required by their local Ethics Committee. Confidential patient information was rendered anonymous without breaching the duty of confidentiality—the database was independently established for clinical research purposes as per Health Research Authority guidelines. Thus, informed consent and Research Ethics Committee guidance was not necessary for this study.

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