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CLINICAL TRIALS (JE LANG, SECTION EDITOR)

Preoperative Radiotherapy Trials to Facilitate Immediate Breast Reconstruction after Mastectomy

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Abstract

Purpose of Review Postmastectomy radiotherapy (PMRT) is often a component of treatment algorithms for locally advanced or node-positive breast cancer. Breast reconstruction may be delayed or not performed due to negative effects of PMRT on the reconstruction. Administering radiotherapy in the preoperative setting allows for immediate breast reconstruction (IBR) to be performed in patients who have indications for PMRT and desire IBR. This review summarizes the current literature on this new concept.

Recent Findings Most prospective treatment protocols included neoadjuvant systemic therapy followed by radiotherapy (RT) dose of 50–50.4 Gy conventionally fractionated and mastectomy with immediate autologous reconstruction after 6–8 weeks. There were no cases of IBR being aborted due to technical complications and overall postoperative complications ranged from 3 to 36%. These were typically non-operatively managed, and cosmetic results when evaluated were favorable. Initial oncologic outcomes indicate low locoregional recurrence rates (≤ 10%) and high 5-year overall survival rates of 87–98%.

Summary Although published studies are heterogeneous in nature, they suggest that preoperative RT followed by mastectomy with IBR is technically feasible and safe. Larger prospective studies with longer follow-up times may establish this as a new standard in the multidisciplinary treatment of high-risk breast cancer.

Keywords Post-mastectomy radiotherapy · Mastectomy · Immediate breast reconstruction · Preoperative radiotherapy · Breast cancer

Introduction

Postmastectomy radiotherapy (PMRT) is typically indicated in cases of locally advanced, large, or node-positive breast cancers as these have a high risk of locoregional failure [1–3]. Immediate breast reconstruction (IBR) after mastectomy has significant benefits including a single operation, decreased overall costs, superior cosmetic results, and improved psychosocial outcomes [4•]. However, PMRT can have detrimental effects on both implant-based and autologous reconstruction. Negative effects of PMRT on implant-based reconstructions include higher rates of capsular contracture, infection, pain, impaired wound healing, and suboptimal cosmesis. Autologous reconstructions that are irradiated may experience flap contracture, volume loss, impaired cosmesis, and greater fat necrosis [1, 4•]. Thus, the multidisciplinary team and patient must weigh advantages and disadvantages of IBR when PMRT is indicated, and often, breast reconstruction is completely delayed or staged such that a tissue expander (TE) is placed after mastectomy (delayed-immediate reconstruction). Placement of a TE as part of the delayed-immediate method also is associated with increased complications including explantation and prolongs the entire reconstructive process [5, 6]. Integrating breast reconstruction into a therapeutic sequence involving PMRT remains a challenge.

Other radiosensitive cancers such as esophageal and rectal cancer are routinely treated with preoperative radiotherapy (RT). For rectal cancer, preoperative RT can result in decreased tumor size and potential sphincter-preserving operation [7, 8]. Historically, inoperable breast cancers were treated with RT and older chemotherapy regimens with some patients proceeding to surgery. For the modern patient in whom PMRT

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is recommended, there has been interest in whether preoperative RT, following neoadjuvant systemic therapy (NST), can be administered prior to mastectomy with IBR. This review summarizes the literature on preoperative RT to facilitate IBR with respect to RT regimens, complications, cosmetic outcomes, and oncologic outcomes.

Treatment Regimen

Individual studies standardized preoperative RT regimens however across studies, the regimens varied by dose, fractionation, additional boost, and regional nodal fields. Most studies administered RT doses of 50–50.4 Gy conventionally fractionated [9••, 10••, 11–15, 16••, 17•, 18–20]. In one retrospective study of 30 patients by Ho et al., patients received 50–50.4 Gy conventionally fractionated or 42.5 Gy hypofractionated over 3.5 weeks [15]. The PRADA trial described treatment with hypofractionated RT, either 42.72 Gy in 16 fractions or 40 Gy in 15 fractions [21]. A boost dose was administered in two studies, ranging from 6 to 11 Gy [10••, 14]. Regional nodal fields being irradiated differed significantly with many groups stating RT was delivered to supraclavicular, internal mammary, and axillary basins on an individual case basis [9••, 11, 12, 14, 17–21]. Ho et al. reported that RT was delivered to both supraclavicular and axillary nodes [15].

A significant consideration of any preoperative RT plan is the time interval between completion of RT and surgery. One of the oldest published studies had a median interval of 16 weeks, and the authors stated this was to allow complete resolution of acute radiation effects [14]. Conversely, the shortest interval was a mean 4.4 weeks in the PRADA study [21]. The majority of studies waited 6–8 weeks before surgery [9••, 10••, 11–13, 15, 16••, 17•, 18–20, 22, 23]. Grinsell et al. based the 6-week interval on experience with other oncologic reconstructions such as after sarcoma resections [23].

Patients recommended PMRT often have indications to receive systemic therapy. Retrospective studies consisted of NST or adjuvant systemic therapy [9••, 10••, 11–15, 24, 25]. More recent prospective studies described protocols of NST followed by preoperative RT. [16••, 17•, 18–23]

Reconstructive methods differed in the literature. Both implant-based and autologous reconstructions were performed in retrospective studies [9••10••, 11–15, 24–26]. In contrast, published prospective trials described autologous reconstructions including latissimus dorsi (LD) flaps with or without implant, transverse rectus abdominis myocutaneous (TRAM) flaps or deep inferior epigastric perforator (DIEP) flaps [16••, 17•, 18–23]. Autologous tissue is commonly used in previously irradiated fields such as after rectal cancer and sarcoma resections. This and other factors such as elimination of capsular contracture are the rationale for autologous reconstruction in prospective protocols.

Complications

No studies in the literature reported intraoperative complications after preoperative RT. Furthermore, there were no instances of IBR being aborted which supports the technical feasibility of IBR after radiotherapy.

Surgical complications were an outcome measure in many studies and are especially important when determining the safety of this therapeutic sequence (Table 1). Overall complication rates were 3–36% which included complications such as seroma, hematoma, infection, skin necrosis, capsular contracture, and reconstruction failure (loss of flap or implant) [11–13, 20–22]. A prospective trial by O' Halloran and colleagues found no difference in complications ($p = 0.117$) between 14 patients undergoing preoperative RT and 15 undergoing PMRT [20].

Complications were also divided into early (≤ 1 month) and late (> 1 month). Early complication rates ranged from 22 to 67%, and these included seromas, hematomas, infection, skin necrosis, and flap necrosis. Seromas are a common minor complication, and exclusion of this decreased the rates of early complications to 11–46% [9••, 10••, 15, 16••]. Pinsolle et al. retrospectively compared 34 patients receiving preoperative RT and implant-based IBR with 11 patients who had PMRT and implant-based IBR, and found no difference in rates of capsular contracture or hematoma. They also compared the preoperative RT group with another group not receiving any RT and found no difference in skin necrosis rates [24]. Another study reported that all cases of skin necrosis were bilateral including the contralateral, non-radiated prophylactic mastectomy side, and thus, preoperative RT was not the cause of the skin necrosis [12]. A large ACS-NSQIP database study using predefined morbidity variables found no difference in complication rates (surgical site infections, organ space surgical site infection, wound dehiscence, and prosthesis/flap failure) between the preoperative RT and no RT groups (adjusted OR = 1.05; 95% CI 0.37–2.76, $p = 0.934$) [26].

Late complications such as capsular contracture, implant loss, partial or total flap loss,, and lymphedema occurred in 26–43% of cases [9••, 10••, 16••]. Capsular contracture, with or without an autologous flap, occurred in 15–24% [16••, 24]. Partial autologous flap loss ranged from 3 to 5% [12, 15], and one study reported a case of total flap loss [10••]. Lee and colleagues investigated lymphedema rates and observed no association with preoperative RT ($p = 0.683$) [25]. Although many of the studies were single arm without a prospectively matched control, the complication rates are similar to those seen in the literature with PMRT and provide preliminary data of the safety of this therapeutic sequence.

Table 1 Complications and cosmetic outcomes of published studies on preoperative radiotherapy and immediate breast reconstruction

Author	Year	Type of study	Sample	RT protocol size (*n*)	Interval between preoperative RT and surgery	Type of reconstruction	Summary of complication rates and cosmetic outcomes
Pinsolle et al. [24]	2006	Retrospective, single institution	42	NR	NR	Autologous (LD flap) and/or implant	Increased capsular contracture with preop RT; no difference in skin necrosis with or without RT
Giacalone et al. [16••]	2010	Prospective, single institution	26	50 Gy	8.5 weeks (mean)	Autologous (LD flap) with implant	No difference in early or late complications compared to PMRT with delayed reconstruction group
Monrigal et al. [10••]	2011	Retrospective, single-institution	210	50 Gy ± boost 10 Gy	6–8 weeks	Autologous (LD or TRAM flaps) and/or implant	21.9% rate of early complications, 26.2% rate of late complications
Ho et al. [15]	2012	Retrospective, single institution	30	50.4 Gy or 42.5Gy (hypofractionated)	6.9 weeks (median)	Autologous (TRAM or LD flaps)	37% local complications, 66% rated as good or excellent esthetic outcome
Paillocher et al. [9••]	2016	Retrospective, single institution	111	50 Gy	5.9 weeks (median)	Autologous (LD flap) +/implant	66.6% rate of early complications, 43.2% rate of late complications. High patient satisfaction
Zinzindohoue et al. [17•]	2016	Prospective, multicenter	83	50 Gy (median)	6–8 weeks	Autologous (LD flap) +/implant	6% rate of skin necrosis, no associated factors
Baker et al. [18] (abstract)	2017	Prospective, multicenter	59	50.4 Gy (median)	Approximately 6 weeks	Autologous	13.6% rate of grade 3 complications, no grade 4 or 5 complications. Cosmesis rated good to excellent
Baltodano et al. [26]	2017	Retrospective, database	75	NR	NR	Autologous or implant	No differences in postoperative surgical site morbidity, systemic morbidity, and overall morbidity with preop RT versus no RT
Barrou et al. [13]	2017	Retrospective, multicenter	103	50 Gy + 46 Gy to regional nodes	6–8 weeks	Autologous (LD flap)	Overall complication rate of 9.7%. Reconstruction with implant associated with higher complication rate
Lee et al. [25]	2017	Retrospective, single institution	18	NR	NR	Autologous or implant	No increased risk of lymphedema with preop RT compared to no RT
Pazos et al. [11]	2017	Retrospective, single institution	22	50.4 Gy	6.7 weeks (median)	Autologous (DIEP, TRAM or LD flaps) or implant	Cosmetic result excellent or good in 66% of upfront mastectomy patients. 25% implant loss rate for wound-healing problems
Thiruchelvam et al. [21] (abstract)	2017	Prospective, multicenter	19	40–42.72 Gy	4.4 weeks (mean)	Autologous (DIEP flap)	21.1% complication rate requiring reoperation; no skin necrosis or flap loss
Chao et al [22]. (abstract)	2018	Prospective, multicenter	82	NR	6–7 weeks	Autologous (DIEP flap)	25% rate of any complications, 7.2% rate grade 3 complications. 1 flap necrosis and 1 skin necrosis, no flap loss
Grinsell et al [23].	2018	Prospective, single institution	29	NR	6 weeks	Autologous (DIEP or LD flaps)	3% skin necrosis and no flap loss
Hughes et al. [12]	2018	Retrospective, single institution	40	50.4 Gy	6.4 weeks (mean)	Autologous (DIEP or free flaps)	12.5% major complication rate and 15% minor complication rate
O' Halloran et al. [20]	2018	Prospective, single institution	14	50.4 Gy	7 weeks (mean)	Autologous (DIEP or LD flaps) and/or implant	No difference in complication rate compared to PMRT group

RT radiotherapy, *NR* not reported, *PMRT* postmastectomy radiotherapy

Cosmetic Outcomes

Esthetic outcomes have not been well studied in the published literature and have been evaluated with short surveys of patients and physicians. Giacalone et al. had two independent physicians evaluate cosmesis on a 4-point scale. Physicians rated the results to be excellent or good in 78% of cases. Patients similarly rated their results as excellent or good in 89% of cases. They also found no difference in physician or patient evaluations when compared with a delayed breast reconstruction group ($p = 0.723$) [16••]. Two other studies noted excellent to good outcomes assessed by physicians in 66% of patients [11, 15]. Favorable outcomes were seen in those undergoing autologous breast reconstruction. Conversely, only 37% of patients who had prior attempts at breast conservation had excellent or good results [11]. A survey of patient satisfaction demonstrated high satisfaction on average, and 70% stated they would elect to have the same treatment again [9••]. These are promising data since cosmetic outcomes are an important consideration for patients, and IBR can have a positive psychological impact.

Oncologic Outcomes

Whether preoperative RT improves oncologic outcomes remains unclear. Published prospective trials have all described protocols that include modern NST regimens [16••, 17•, 18–23], and therefore, it is challenging to know if there is an added benefit of preoperative RT in achieving pathologic complete response (pCR), decreasing locoregional recurrences, or improving survival. Rates of pCR were 17–55%; however, there were variable or unspecified definitions of pCR [11–14, 16••, 17•, 18–20, 23]. Gerlach et al. showed a greater pCR rate of 42% with preoperative RT compared with 3% with PMRT ($p < 0.0001$); however, patients received older neoadjuvant systemic therapy regimens which may account for differences [14]. O' Halloran and colleagues found no difference in pCR rates between the preoperative RT and PMRT groups ($p = 0.335$) [20]. While locoregional recurrence rates were less than or equal to 10% with a follow-up of 16–96 months, distant recurrence rates ranged from 0 to 26% [9••, 10••, 11, 12, 15, 16••, 18, 20, 21, 23] which is consistent with the high risk biology of these breast cancers. Five-year overall survival rates were 87–98%, and 5-year disease-free survival rates were 72–93% in two studies [9••, 10••]. These data indicate that this therapeutic sequence may be oncologically safe though prospective trials with longer follow-up are needed.

Conclusions

Multimodality therapy for locally advanced and node-positive breast cancers is essential to decreasing recurrence and improving survival. The current sequence of treatment is historical, and the key may be to ensure that all therapies are administered in some order. Recognizing the importance of IBR and challenges associated with integrating breast reconstruction into the overall treatment strategy, several trials investigating preoperative radiotherapy and immediate breast reconstruction have been published over the last decade. Although most studies have small numbers of patients and short follow-up, they demonstrate that IBR is technically feasible and safe after preoperative RT. The multidisciplinary group at MD Anderson is conducting the first U.S. prospective trial (NCT02912312) of safety and feasibility with a planned accrual of 30 patients [27]. Females ≥ 18 years of age with pathologically confirmed invasive breast cancer, staged cT0-T3 cN0-N3a who have a multidisciplinary recommendation for mastectomy, axillary staging, and radiotherapy and desire immediate breast reconstruction are eligible for the trial. Exclusion criteria are bilateral, recurrent, metastatic, inflammatory breast cancer, those who have received RT previously, or those who do not have an indication for RT. This prospective trial is embedded within a larger randomized controlled trial comparing hypofractionated and conventionally fractionated RT. Primary outcome of the RCT is rate of lymphedema, and secondary outcomes for the preoperative RT cohort are intraoperative/technical complications, postoperative complications, and oncologic outcomes. Larger prospective studies with longer follow-up times are necessary to establish preoperative RT and IBR as standard of care in high-risk breast cancer.

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Compliance with Ethical Standards

Conflict of Interest Henry Kuerer reports personal fees and other from Genomic Health, Inc.; other from Physicians' Education Resource, LLC; personal fees from TME, Inc.; personal fees from McGraw-Hill Professional, UpToDate, Inc.; grants from National Cancer Institute; other from Annals of Surgical Oncology; other from NRG Oncology (Institutional PI and Breast Committee); other from American Society of Breast Surgeons (Chair, Publications Committee); and personal fees from NEJM Group, Inc. outside the submitted work. Puneet Singh declares no conflicts of interest relevant to this manuscript.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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