Radiation Oncology

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Ultrahypofractionated partial breast irradiation following oncoplastic surgery: secondary analysis of a phase II trial

Rachel Radigan[1,2*], Sophia L. Fu[1], Austin Barney[1], Jeffrey Pettit[1], Vani Gupta[2], Shridevi Singh[1], Marlene Mancuso[3], Vikram Soni[1], Jana Deitch[4,5], Andrew T. Wong[6] and Johnny Kao[1,2,4]

Abstract

Purpose Although partial breast irradiation (PBI) is accepted as an effective and cosmesis-preserving technique for low-risk early-stage breast cancer following standard lumpectomy, data supporting PBI following oncoplastic surgery are sparse. We report prospective data in efforts to determine whether PBI can be safely utilized after oncoplastic surgery.

Methods Patients with low-risk stage 0–1 breast cancer following successful lumpectomy with optional oncoplastic reconstruction were enrolled on a phase II trial. Patients were treated with a modified Florence regimen to 30 Gy in 5 fractions on the Varian Edge radiosurgery system using IMRT or VMAT. Presurgical MRI, post-operative seroma and surgical clips were used to assist target delineation. The effect of oncoplastic surgery on radiation dosimetry and Breast Cancer Treatment Outcome Scale scores were assessed using student's t-test for continuous variables and chi-square for categorical variables.

Results From 2018 to 2022, 50 patients with 52 tumors were enrolled with 48% undergoing oncoplastic reconstruction. Although median PTV volumes were numerically larger in the oncoplastic group (266 cc vs. 223 cc), there were no statistically significant differences in PTV volumes, ratio of PTV to whole breast or mean heart or lung doses ($p > 0.05$). Mean baseline BCTOS aesthetic scores were 1.35 for standard lumpectomy vs. 2.52 for oncoplastic ($p = 0.003$). At long-term follow-up > 2 years, mean BCTOS aesthetic scores were 1.29 for standard lumpectomy vs. 1.35 for oncoplastic ($p = 0.71$). At a median follow-up of 46 months, there were no local recurrences.

Conclusions When utilizing pre-treatment MRI, surgical clips and a relatively large PTV, PBI after oncoplastic surgery was safe and effective for appropriately selected patients. In combination with oncoplastic surgery, partial breast irradiation achieves excellent long-term cosmesis that improves over time.

Keywords Oncoplastic surgery, Partial breast irradiation, Cosmetic outcomes, Dosimetry

*Correspondence:
Rachel Radigan
rradigan@nyit.edu
[1]Good Samaritan University Hospital, West Islip, NY, USA
[2]The New York Institute of Technology College of Osteopathic Medicine, Old Westbury, NY, USA
[3]St. Joseph Hospital, Bethpage, NY, USA
[4]St. Catherine of Siena Medical Center, Smithtown, NY, USA
[5]St. Francis Hospital, Roslyn, NY, USA
[6]Summit Health, Florham Park, NJ, USA

Introduction

Compared with mastectomy, patients undergoing breast conserving surgery tend to have a more positive attitude regarding body image with superior physical and sexual function following treatment [1]. Following successful breast conserving surgery, adjuvant radiotherapy improves local control and overall survival [2]. In low-risk patients, adjuvant radiotherapy achieves 98 to 99% 10-year local control compared to 90% when radiotherapy is omitted [3, 4]. In 3 randomized trials of low-risk patients, partial breast irradiation achieves 99% 5-year local control with improved long-term cosmetic outcome compared to conventional whole breast irradiation [5–7].

Data on the safety and efficacy of partial breast irradiation following oncoplastic surgery are lacking [8]. Since a primary goal of oncoplastic surgery is to optimize cosmesis, integrating partial breast irradiation makes conceptual sense as long as efficacy remains high [9]. A recent study suggested that surgical clips following oncoplastic surgery simulated on realistic phantoms were inadequate for accurate tumor bed delineation with maximum Hausdorff distances ranging from 1.8 to 3.8 cm [10]. These data are provocative, and expert commentators have questioned the validity of partial breast irradiation following oncoplastic reconstruction [11, 12].

Confirmatory clinical data are urgently needed given the increasing popularity of both oncoplastic surgery and partial breast irradiation [13–15]. Partial breast irradiation is not new, and physicians can utilize information from pre-surgical mammography and magnetic resonance imaging (MRI), operative report, surgical clips, and post-surgical changes on computed tomography (CT) simulation to inform accurate tumor cavity delineation [10]. Therefore, we analyzed our recently completed phase II trial that included patients who underwent either standard lumpectomy or oncoplastic lumpectomy to assess patterns of failure and long-term cosmesis in treated patients.

Materials and methods

Patient selection

This phase II trial was approved by the Good Samaritan University Hospital Institutional Review board #18 – 002. Eligible patients provided written informed consent and were age ≥ 50 with unifocal stage 0 to 1 breast cancer measuring ≤ 3 cm. Patients underwent breast conserving surgery with negative invasive margins ≥ 2 mm with estrogen receptor positive and Her-2/neu negative tumor with no lymphovascular invasion. Patients with invasive breast cancer were required to have negative sentinel nodes (N0[i-]). Patients undergoing oncoplastic reconstruction were eligible. Standard lumpectomy or oncoplastic reconstruction (including tissue rearrangement) and involvement of a plastic surgeon was ascertained by reviewing the operative reports.

Accelerated partial breast irradiation performed on the edge radiosurgery system

The classic Florence accelerated PBI intensity modulated radiation therapy (IMRT) technique was modified to account for changes in presurgical imaging, surgical technique and radiation technology. Patients underwent computed tomography simulation in the supine position using a breast board with the ipsilateral arm abducted and rotated [16]. The surgical scar was marked with a radiopaque wire at simulation. The tumor cavity was contoured in Eclipse version 15.5 including visible seroma, surgical clips and pre-surgical MRI. The planning target volume (PTV) was defined as the tumor cavity + 1.5 cm cropped 5 mm off skin, cropped off chest wall and treated to 26 to 30 Gy. For patients with low and high dose PTV targets, the PTV30 was defined as tumor cavity + 5 to 10 mm using a simultaneous integrated boost technique. IMRT (typically 4 to 6 beams) or volumetric arc therapy was utilized to achieve optimal dose conformity while sparing heart, lung, uninvolved breast and skin using dose constraints used in the NSABP B39 [17]. For IMRT, beams started with tangents with other beams typically arranged 15 to 30° apart depending on anatomy to prioritize heart sparing and ensuring skin flash. When VMAT partial arcs were used, skin flash was added manually through use of a dummy structure. Target and normal tissue dosimetry were extracted from Eclipse.

Patients were treated on the Varian Edge radiosurgery system with 6 MV photons often with flattening filter free beams equipped with a 6-degree of freedom robotic couch, cone beam CT and high definition multileaf collimators. Daily cone beam CT vector transformations in the anterior posterior, superior inferior and left right directions and yaw pitch and roll vector rotations were recorded. Real-time surface imaging was accomplished using optical surface monitoring to supplement pre-treatment cone beam CT. Treatment was delivered with free breathing on non-consecutive days. Patients were assessed during treatment, at 3 months and annually thereafter.

Study endpoints and statistics

This secondary analysis evaluated the impact of oncoplastic surgery on radiation dosimetry and cosmetic outcomes. Cosmesis was assessed using the validated Breast Cancer Treatment Outcome Scale (BCTOS) following surgery and prior to radiation at baseline and at last follow-up greater than 2 years following enrollment. BCTOS subgroups were divided into functional, aesthetic and breast sensitivity subgroups [18, 19]. Student's t tests were performed to determine differences in continuous

variables between 2 groups. Chi-square tests were performed to determine differences in categorical variables.

Results

Patient characteristics

The median follow-up for surviving patients was 46 months (range 28 to 75 months). A total of 50 patients with 52 tumor cavities were enrolled with a median age at diagnosis of 75 (range 51 to 89). The median tumor size was 7 mm (range 1 to 26 mm). Patients undergoing standard or oncoplastic lumpectomy were well matched in terms of age, AJCC stage, size, margin width, race, laterality, grade and receipt of hormonal therapy (Table 1). Standard lumpectomy consisted of 27 patients with 27 tumors; oncoplastic lumpectomy included 23 patients with a total of 25 tumors (Supplemental Table 1). Oncoplastic surgery was performed by the breast surgeon alone for 18 tumors and jointly performed with plastic surgery for 7 tumors.

Supplemental Table1. Dose Distribution for Oncoplastic Cohort.

Radiation dosimetry and technique

Patients were treated with a median of 5 IMRT fields (range 4 to 8) with a median conformity index (PTV30) of 1.05 (IQR 0.96 to 1.13). With the exception of heart volume receiving 3 Gy, there were no statistically significant differences in radiation dosimetry when comparing patients treated with standard or oncoplastic lumpectomy (Table 2). The median PTV30 for standard lumpectomy was 140.9 cc (range 42.5 to 397.0 cc) whereas the median PTV30 for oncoplastic lumpectomy was 160.7 cc (range 79.7 to 407.6 cc). The median PTV26 to 28.5 for standard lumpectomy was 223.3 cc (112.8 to 709.2 cc) versus 266.1 cc (range 138.3 to 418.3 cc) for oncoplastic lumpectomy. The median mean heart dose was 0.37 Gy (range 0.08 to 1.03 Gy) for left-sided tumors vs. 0.16 Gy (range 0.05 to 0.85 Gy) for right-sided tumors. Evaluation of daily 6 degree of freedom cone beam CT couch shifts demonstrated vertical (Vrt), 0.36 ± 0.71 cm; longitudinal (Lng), 0.31 ± 0.25 cm; lateral (Lat), 0.32 ± 0.32°; couch tilt (Pitch), 1.39 ± 1.02°; couch roll (Roll). 1.17 ± 0.88; couch rotation (Rtn), 1.38 ± 1.15°.

Outcomes

All 52 tumor beds were locally controlled, and no patients died from breast cancer. In terms of treatment failures, there were 3 deaths from non-breast cancers with distant metastases, 1 lymph node recurrence (in the only patient with high grade invasive breast cancer who also declined hormonal therapy against medical advice) successfully salvaged with further surgery, whole breast and regional nodal irradiation and systemic therapy and

Table 1 Patient characteristics for patients undergoing standard vs. Oncoplastic lumpectomy

Variable	Standard *n* = 27	Oncoplastic *n* = 25	*P* value
Age, median (IQR)	75 (70 to 82)	75 (70 to 79)	0.92
Invasive	21 (78%)	20 (80%)	0.85
DCIS	6 (22%)	5 (20%)	
Tumor Size mm			0.76
≤ 20 mm	24 (89%)	24 (96%)	
> 20 mm	3 (11%)	1 (4%)	
Margin width			0.90
< 2 mm (DCIS only)	1 (4%)	1 (4%)	
≥ 2 mm	21 (78%)	19 (75%)	
Negative lumpectomy or reexcision	4 (15%)	2 (8%)	
Not specified	1 (4%)	3 (12%)	
Race			0.40
White	23 (85%)	23 (92%)	
Other	4 (15%)	2 (8%)	
Laterality			0.61
Left	17 (63%)	14 (56%)	
Right	10 (37%)	11 (44%)	
Grade			0.16
1	12 (44%)	5 (20%)	
2	14 (52%)	18 (72%)	
3	1 (4%)	2 (8%)	
Hormonal therapy			0.63
Yes	21 (78%)	18 (72%)	
No	6 (22%)	7 (28%)	

Table 2 Radiation dosimetry stratified by standard vs. Oncoplastic lumpectomy

Variable	Standard $n=27$	Oncoplastic $n=25$	*P* value
PTV30 volume cc, median (IQR)	140.9 (112.2 to 200.9)	160.7 (121.5 to 201.3)	0.79
PTV26 to 28.5 cc, median (IQR)	223.3 (173.1 to 355.4)	266.1 (201.9 to 330.7)	0.78
Ipsilateral breast volume cc, median (IQR)	917.7 (760.4 to 1217.1)	1064.9 (940.9 to 1345.4)	0.93
Ratio of PTV to whole breast % median (IQR)	25.1% (16.4 to 30.7%)	24.6% (16.2 to 27.9%)	0.70
Heart mean dose Gy, median (IQR)	0.30 (0.17 to 0.45)	0.39 (0.15 to 0.66)	0.07
Heart V3 Gy, median (IQR)	0.0% (0.0 to 0.50%)	2.2% (0.0 to 3.7%)	0.01
Contralateral breast Dmax Gy, median (IQR)	1.24 (0.23 to 3.27)	2.12 (0.48 to 3.83)	0.71
Ipslilateral lung mean cc, median (IQR)	2.5 (1.2 to 3.4)	3.0 (2.0 to 3.6)	0.12
Contralateral lung mean cc, median (IQR)	0.05 (0.02 to 0.10)	0.06 (0.03 to 0.09)	0.35
Radiation technique, IMRT fields median (IQR)	5 (5 to 6)	5 (5 to 6)	0.71
VMAT partial arcs	2 (7%)	0 (0%)	

Table 3 Standard vs. Oncoplastic mean baseline and Long-term functional, aesthetic, and sensitivity

	Standard Mean (95% CI)	Oncoplastic Mean (95% CI)	*p*-value
Baseline functional	1.16 (1.00 to 1.32)	1.44 (1.10 to 1.77)	$p=0.08$
Baseline aesthetic	1.35 (1.14 to 1.58)	2.52 (1.62 to 3.41)	$p=0.003$
Baseline sensitivity	1.33 (1.06 to 1.60)	1.50 (1.14 to 1.86)	$p=0.40$
Long-term functional	1.05 (1.00 to 1.14)	1.12 (1.00 to 1.26)	$p=0.31$
Long-term aesthetic	1.29 (1.04 to 1.55)	1.35 (1.12 to 1.58)	$p=0.71$
Long-term sensitivity	1.17 (1.09 to 1.25)	1.23 (1.10 to 1.36)	$p=0.07$

1 ipsilateral second primary triple negative breast cancer salvaged with further surgery and systemic therapy.

In terms of cosmetic outcome, BCTOS scores were generally excellent at >2-year follow-up. Mean baseline BCTOS aesthetic mean scores were 2.52 following oncoplastic surgery vs. 1.35 following standard lumpectomy ($p=0.003$). At long-term follow-up, mean BCTOS aesthetic mean scores were 1.35 following oncoplastic surgery vs. 1.29 following standard lumpectomy ($p=0.71$). All patients achieved a BCTOS aesthetic score of <2.5 with 71% scoring excellent (1 to 1.49) and 29% scoring good (1.5 to 2.3) (Table 3).

Discussion

Since a primary goal of breast conserving surgery is optimizing cosmesis, oncoplastic surgery is a highly attractive concept. This small non-randomized clinical trial provides prospective data on the safety and efficacy of partial breast irradiation in the era of oncoplastic surgery. Oncoplastic surgery clearly creates some challenges for the radiation oncologist. Fortunately, radiation oncology is rapidly moving towards higher precision image-guided techniques and technical challenges associated oncoplastic surgery can be addressed [20]. In other disease sites, extremely large elective radiation fields such as whole brain radiotherapy for brain metastases and Mantle irradiation for lymphoma have generally fallen out of favor. Therefore, partial breast irradiation should be vigorously pursued particularly for low-risk patients when there is level I evidence of high efficacy and improved cosmesis compared to whole breast radiotherapy [4–7].

In our experience, we used pre-surgical mammography, MRI and the operative report to localize the tumor in addition to wiring the scar, identifying the tumor bed on CT simulation supplemented with surgical clips. In 77% of tumor beds, we utilized a low dose subvolume (PTV26 to 28.5) with a mean PTV volume of 277.0 cc considerably larger than the mean PTV volume of 139 cc reported by the Florence group [21]. Importantly, in this study, mean breast volume was 1114 cc vs. 731 cc reported by the Florence group. Given the efficacy of the FAST FORWARD regimen, there is increasing interest in potentially deescalating radiation doses to 26 Gy in 5 fractions to further improve cosmesis [22].

While PTV volumes used in this study were relatively large, there was no detectable negative impact on long-term cosmesis with a mean long-term BCTOS aesthetic subscore of 1.32. Instead, BCTOS cosmesis improved from a baseline score of 1.85 to 1.32 ($p=0.02$). While prior data from Helsinki University Hospital suggested that oncoplastic resection resulted in worse cosmesis at 3 years compared to standard lumpectomy ($p<0.001$), there was no difference in this study [23]. A clinical trial from MD Anderson reported at 3 years 8% of women treated with hypofractionated whole breast irradiation and 14% of women treated with conventionally fractionated whole breast irradiation had suboptimal cosmesis with a BCTOS cosmesis score ≥ 2.5 [24]. The recently reported NSABP B-39 trial reported a mean BCTOS

cosmesis score at 3 years of 1.84 with whole breast irradiation and 1.96 with APBI primarily delivered via twice daily external beam radiation or catheter-based brachytherapy [25]. In this study, our rate of BCTOS cosmesis score ≥ 2.5 was 0% at ≥ 2-year follow-up for both standard lumpectomy or oncoplastic lumpectomy. Due to small sample size, non-randomized design and heterogenous surgical techniques performed by many different surgeons, this study was not designed to determine the relative merits of oncoplastic surgery vs. standard lumpectomy.

In terms of weaknesses, this is a small single institutional non-randomized phase II trial with relatively short follow-up and is therefore only hypothesis generating. This study was too small to formally classify patients into different subgroups such as level I volume displacement, level II volume displacement or volume replacement [15]. The finding that only 7 of 25 oncoplastic reconstructions involved a plastic surgeon suggests mostly level I volume displacement so these results are likely not generalizable to level II volume displacement or volume replacement procedures. Moreover, data on why surgeons chose oncoplastic surgery instead of standard lumpectomy for a given patient whether due to tumor location, morpho-volumetric characteristics, training in oncoplastic surgery or availability of a plastic surgeon was not recorded. Given the favorable risk profile of the patients (median age 75, 100% ER positive, median tumor size 7 mm), our statistical power cannot rule out a higher recurrence rate compared to whole breast irradiation. Based on a recent meta-analysis, it appears that partial breast techniques other than intraoperative irradiation have similar efficacy compared to whole breast irradiation [26]. Since catheter-based brachytherapy is considered unsuitable following oncoplastic surgery, further investigation of partial breast irradiation using IMRT is warranted.

Finally, the issue of treatment de-escalation warrants discussion. For low risk patients, a partial list of diagnostic and therapeutic interventions that could conceivably be deescalated includes breast MRI, ultrasound, adjuvant radiation, radiation fraction number, radiation volume, sentinel lymph node biopsy, oncoplastic reconstruction, genomic testing or even hormonal therapy [27–29]. Since the late 2000's, adjuvant radiation for low-risk breast cancer has already been successfully deescalated from ~ 50 Gy in 5 weeks to the whole breast followed by a tumor bed boost to ~ 60 Gy to 26 to 30 Gy in 5 fractions partial breast with a mean BCTOS cosmesis score of 1.32 in this study [16]. In 2024, there were 42,780 deaths from breast cancer in the United States and it seems appropriate to dedicate a greater portion of the research budget on improving outcomes rather than pursuing further non-inferiority radiation omission studies [30].

Conclusion

This prospective phase II study demonstrates that ABPI following oncoplastic surgery is both safe and effective for low-risk early-stage breast cancer patients. With the use of advanced imaging techniques and precise radiation planning, APBI can provide excellent long-term local control and cosmetic outcomes. This study highlights the importance of continued investigation into optimizing radiotherapy techniques to preserve both the efficacy and aesthetic outcomes for breast cancer survivors.

Abbreviations

IMRT	Intensity Modulated Radiation Therapy
VMAT	Volumetric Modulated Arc Therapy
MRI	Magnetic Resonance Imaging
PTV	Planning Target Volume
BCTOS	Breast Cancer Treatment Outcome Scale
ER	Estrogen Receptor
APBI	Accelerated Partial Breast Irradiation
CT	Computed Tomography
AJCC	American Joint Committee on Cancer

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13014-025-02630-x.

Supplementary Material 1

Acknowledgements

We acknowledge New York Institute of Technology for financial support.

Author contributions

AW and JK designed this clinical trial. SF, SS, MM, VS, KD, AW, AB, JP and JK acquired data and participated in patient care. RR, VG, AB, JP and JK gathered and analyzed data. RR and JK wrote the main manuscript text. All authors reviewed the manuscript.

Funding

Not applicable.

Data availability

Data is provided within the manuscript or supplementary information files.

Declarations

Ethics approval and consent to participate

Ethics approval and consent was attained and approved by the Good Samaritan University Hospital Institutional Review board #18 – 002 in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Consent to participate

Informed consent was obtained for all participants.

Competing interests

The authors declare no competing interests.

Received: 1 January 2025 / Accepted: 31 March 2025
Published online: 15 April 2025

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